

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**AMENDMENT NO. 2  
TO  
FORM S-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

**GOSSAMER BIO, INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

2834  
(Primary Standard Industrial  
Classification Code Number)  
3013 Science Park Road, Suite 200  
San Diego, California 92121  
(858) 684-1300

47-5461709  
(I.R.S. Employer  
Identification No.)

(Address, including zip code, and telephone number, including  
area code, of registrant's principal executive offices)

Sheila Gujrathi, M.D.  
President and Chief Executive Officer  
Gossamer Bio, Inc.  
3013 Science Park Road, Suite 200  
San Diego, California 92121  
(858) 684-1300

(Name, address, including zip code, and telephone number, including  
area code, of agent for service)

*Copies to:*

Matthew T. Bush  
Cheston J. Larson  
Kevin C. Reyes  
Latham & Watkins LLP  
12670 High Bluff Drive  
San Diego, California 92130  
(858) 523-5400

Christian Waage  
Executive Vice President  
and General Counsel  
Gossamer Bio, Inc.  
3013 Science Park Road, Suite 200  
San Diego, California 92121  
(858) 684-1300

Charles S. Kim  
Sean Clayton  
David Peinsipp  
Kristin VanderPas  
Cooley LLP  
4401 Eastgate Mall  
San Diego, California 92121  
(858) 550-6000

**Approximate date of commencement of proposed sale to the public:  
As soon as practicable after this Registration Statement is declared effective.**

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

**CALCULATION OF REGISTRATION FEE**

Title of Each Class of Securities To Be Registered	Amount to be Registered (1)	Proposed Maximum Offering Price Per Share	Proposed Maximum Aggregate Offering Price (2)	Amount of Registration Fee (3)
Common Stock, \$0.0001 par value per share	16,531,250 shares	\$16.00	\$264,500,000	\$32,057.40

(1) Includes 2,156,250 shares of common stock that the underwriters have the option to purchase.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(a) under the Securities Act of 1933, as amended.

(3) All of this registration fee was previously paid by the Registrant in connection with the filing of its Registration Statement on Form S-1 on December 21, 2018.

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

Subject to Completion  
Preliminary Prospectus dated January 30, 2019

**14,375,000 Shares**



## Common Stock

This is an initial public offering of shares of common stock of Gossamer Bio, Inc. We are selling 14,375,000 shares of our common stock.

Prior to this offering, there has been no public market for our common stock. It is currently estimated that the initial public offering price will be \$16.00 per share. Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol “GOSS.”

We are an “emerging growth company” as defined under the federal securities laws and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and may elect to do so in future filings.

**Investing in our common stock involves risks that are described in the “[Risk Factors](#)” section beginning on page 11 of this prospectus.**

	<u>Per Share</u>	<u>Total</u>
Initial public offering price	\$	\$
Underwriting discounts and commissions <sup>(1)</sup>	\$	\$
Proceeds, before expenses, to us	\$	\$

(1) See the section titled “Underwriting” for additional information regarding compensation payable to the underwriters.

To the extent that the underwriters sell more than 14,375,000 shares of common stock, the underwriters have the option to purchase up to an additional 2,156,250 shares of common stock from us at the initial public offering price less the underwriting discount.

**Neither the Securities and Exchange Commission nor any other state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

Certain of our existing stockholders, including entities affiliated with certain of our directors, have indicated an interest in purchasing an aggregate of approximately \$100.0 million in shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because these indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any or all of these stockholders, or any or all of these stockholders may determine to purchase more, less or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these stockholders as they will on any other shares sold to the public in this offering.

The underwriters expect to deliver the shares of common stock to purchasers on or about \_\_\_\_\_, 2019.

**BofA Merrill Lynch**

**SVB Leerink**

**Barclays**

**Evercore ISI**

Prospectus dated \_\_\_\_\_, 2019

## TABLE OF CONTENTS

	<u>Page</u>
<a href="#">PROSPECTUS SUMMARY</a>	1
<a href="#">RISK FACTORS</a>	11
<a href="#">SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</a>	66
<a href="#">MARKET AND INDUSTRY DATA</a>	67
<a href="#">USE OF PROCEEDS</a>	68
<a href="#">DIVIDEND POLICY</a>	69
<a href="#">CAPITALIZATION</a>	70
<a href="#">DILUTION</a>	72
<a href="#">SELECTED FINANCIAL DATA</a>	74
<a href="#">MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</a>	76
<a href="#">BUSINESS</a>	89
<a href="#">MANAGEMENT</a>	130
<a href="#">EXECUTIVE AND DIRECTOR COMPENSATION</a>	139
<a href="#">CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS</a>	161
<a href="#">PRINCIPAL STOCKHOLDERS</a>	165
<a href="#">DESCRIPTION OF CAPITAL STOCK</a>	168
<a href="#">SHARES ELIGIBLE FOR FUTURE SALE</a>	173
<a href="#">MATERIAL UNITED STATES FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS</a>	176
<a href="#">UNDERWRITING</a>	180
<a href="#">LEGAL MATTERS</a>	188
<a href="#">EXPERTS</a>	188
<a href="#">WHERE YOU CAN FIND MORE INFORMATION</a>	188
<a href="#">INDEX TO CONSOLIDATED FINANCIAL STATEMENTS</a>	F-1

---

Neither we nor the underwriters have authorized anyone to provide you with information other than that contained in this prospectus or any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell, and seeking offers to buy, common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus or any free writing prospectus is accurate only as of its date, regardless of its time of delivery or of any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

**PROSPECTUS SUMMARY**

*This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, especially the section in this prospectus titled “Risk Factors” and our financial statements and the related notes thereto included at the end of this prospectus, before making an investment decision. As used in this prospectus, unless the context otherwise requires, references to “we,” “us,” “our,” “the Company” and “Gossamer Bio” refer to Gossamer Bio, Inc. and its subsidiaries on a consolidated basis.*

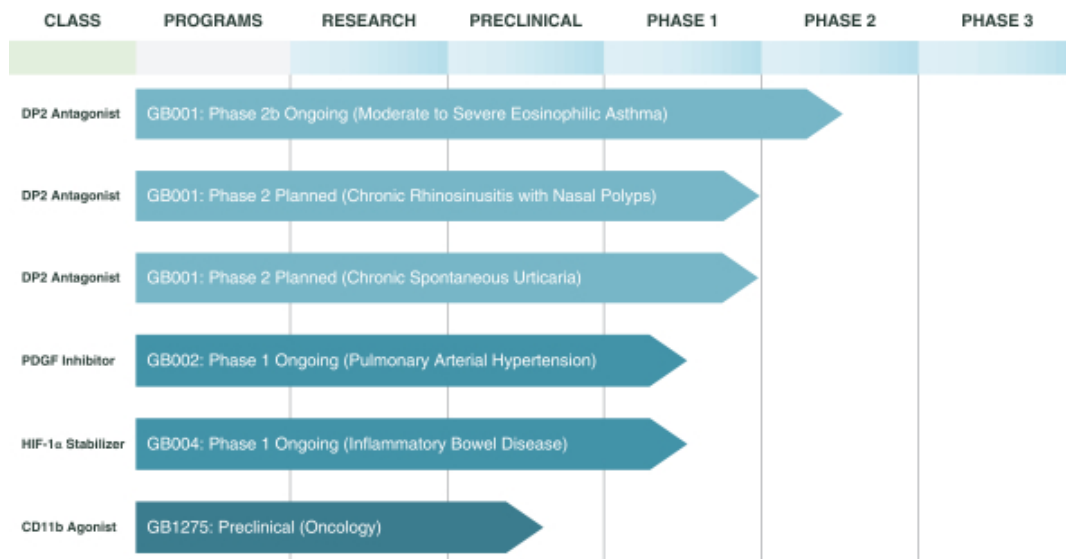
**Overview**

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.

**Our Development Programs**

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 six programs: three clinical-stage product candidates and three preclinical programs. We commenced a Phase 2b clinical trial for our most advanced product candidate, GB001, in October 2018.

The following table summarizes our current programs:



***GB001 (DP2 Antagonist)***

GB001 is an oral antagonist of prostaglandin D<sub>2</sub> receptor 2, or DP2, in development for the treatment of moderate-to-severe eosinophilic asthma and other allergic conditions. Eosinophilic asthma is caused by high levels of white blood cells known as eosinophils and is associated with more severe symptoms, late-onset disease and resistance to steroid treatment. We estimate that approximately 50% of severe asthma patients in the United States have eosinophilic asthma. Despite the availability of new biologic therapies for these patients, asthma exacerbations remain a significant healthcare problem and unmet medical need. As of December 31, 2018, GB001 had been studied in 409 subjects in total and was generally well tolerated. In a Phase 2 clinical trial conducted in Japan, GB001 showed a statistically significant improvement in time-to-first asthma exacerbation compared to placebo. In a separate 248 subject Phase 2 clinical trial, neither treatment group, GB001 nor montelukast, achieved the primary endpoint of improvement in forced expiratory volume in one second, or FEV<sub>1</sub>, as compared to placebo, which we believe was primarily related to study design and execution issues related to patient selection, including adherence to inhaled corticosteroid therapy, eosinophilic phenotype thresholds and disease severity. A single serious adverse event, 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 levels approximately three to five times higher than the other patients receiving the 160 mg dose, and the dose was significantly higher than the highest dose of 60 mg currently being evaluated in our ongoing Phase 2b clinical trial. We commenced a Phase 2b clinical trial in moderate-to-severe eosinophilic asthma in October 2018.

Furthermore, we believe that there are a number of indications along the allergic spectrum for which GB001 may provide benefit. Accordingly, we plan to pursue the parallel development of GB001 in chronic rhinosinusitis with nasal polyps, or CRSwNP, and chronic spontaneous urticaria, or CSU. We expect to initiate proof-of-concept Phase 2 clinical trials for these indications in 2019. We retain worldwide rights to GB001, excluding Japan.

***GB002 (PDGF Receptor Kinase Inhibitor)***

GB002 is an orally inhaled, small molecule, selective platelet-derived growth factor, or PDGF, receptor kinase inhibitor in development for the treatment of pulmonary arterial hypertension, or PAH, an orphan disease with high unmet medical need. PAH is characterized by abnormally high pressure in the blood vessels transporting blood from the right side of the heart to the lungs and is a progressive and often fatal disease. In contrast to the three classes of marketed vasodilatory therapies for PAH, GB002 has the potential to be the first treatment with disease-modifying effects. Modulation of the PDGF pathway has been shown to be therapeutically relevant in PAH. In 2013, Novartis Pharmaceutical Corporation announced results from a Phase 3 clinical trial in PAH of imatinib (Gleevec), a tyrosine kinase inhibitor with known activity against PDGF and marketed for oncology indications. These results were notable for not only achievement of statistically significant improvement in the study's primary efficacy endpoint, but also for systemic toxicities. To our knowledge, no further development of the drug has occurred in PAH. To date, these toxicities have not been observed with GB002 in our ongoing Phase 1 studies in healthy volunteers. We plan to commence a Phase 1b clinical trial in PAH in the first half of 2019 and a Phase 2/3 clinical trial in PAH in the second half of 2019. We retain worldwide rights to GB002. The U.S. Food and Drug Administration, or FDA, has granted GB002 orphan drug designation for the treatment of patients with PAH.

***GB004 (HIF-1a Stabilizer)***

GB004 is a novel, gut-targeted, oral small molecule in development 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-1a, or HIF-1a, through the inhibition of prolyl hydroxylase domain proteins, or PHDs, key enzymes involved in HIF degradation. Preclinical data from animal models of IBD demonstrated that HIF-1a

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 a Phase 1 single-ascending-dose, or SAD, study in healthy volunteers and are dosing healthy volunteers in a Phase 1 multiple-ascending-dose, or MAD, study. We plan to pursue clinical development in both UC and CD patients and, following submission of an Investigational New Drug, or IND, application with the FDA, initiate a Phase 1b clinical trial in UC in the first half of 2019. We also plan to initiate a Phase 2 clinical trial in UC in the first half of 2020. We retain worldwide rights to GB004.

#### ***Our Research Capabilities and Preclinical Programs***

We currently have three programs in preclinical development. GB1275 is an oral small molecule, CD11b agonist in preclinical development for the treatment of oncology indications for which we plan to submit an IND application and, after acceptance, initiate a Phase 1 clinical trial in 2019. We are also currently evaluating a portfolio of novel BTK inhibitors for the treatment of autoimmune indications and small molecule cancer metabolism modulators for the treatment of solid tumors. 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.

#### **Our Team**

Our founders and management team have held senior positions at leading biopharmaceutical companies, including Receptos, Inc., Genentech USA, Inc. (Roche), or Genentech, Bristol-Myers Squibb Company, GlaxoSmithKline LLC and Celgene Corporation, among others, and possess substantial experience and expertise across the spectrum of drug discovery, development and commercialization.

Sheila Gujrathi, M.D., our Co-Founder and President and Chief Executive Officer, was previously Chief Medical Officer of Receptos until its acquisition by Celgene in 2015, and has also served in senior leadership roles at Bristol-Myers Squibb and Genentech. Faheem Hasnain, our Co-Founder and Executive Chairman and former Chief Executive Officer, previously served as Chief Executive Officer at Receptos, and has over 30 years of senior leadership experience at both large and small biopharmaceutical companies. Jakob Dupont, M.D., our Chief Medical Officer, has experience across the spectrum of clinical development, having most recently served as Vice President and Global Head of Breast and Gynecologic Cancer Development at Genentech. 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.

The development and operational expertise of our executive and senior scientific team will be essential as we execute on our strategy of building a large, diversified biopharmaceutical company to deliver significant value to both patients and shareholders.

#### **Our Strategy**

Our goal is to be an industry leader in the disease areas of immunology, inflammation and oncology 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.
- Maximize the impact of our product candidates by expanding development across multiple indications.

- Exeditiously generate proof-of-concept data from our preclinical programs to facilitate value creation and efficient capital deployment.
- Leverage the drug discovery, development and commercialization expertise of our world-class team.

#### **Risks Related to Our Business**

Our ability to execute our business strategy is subject to numerous risks, as more fully described in the section titled “Risk Factors” immediately following this Prospectus Summary. These risks include, among others:

- 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.
- 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.
- We depend heavily on the success of GB001, GB002 and GB004, 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.
- 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, our assumptions about why our product candidates are worthy of future development and potential approval are based on data primarily 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, or at all.
- 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.
- 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.
- We rely on third parties to conduct many of our preclinical studies and clinical trials and to manufacture our product candidates, and these third parties may not perform satisfactorily.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies.
- We have recently substantially increased the size of our organization, and we may encounter difficulties in managing our growth and expanding our operations successfully.
- If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties, including for GB002 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 GB002 and GB004, and we must rely on the direct licensor's compliance with its obligations under its original license agreement.

- After this offering, our executive officers, directors and principal stockholders, if they choose to act together, will continue to 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.

### **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. Our website address is [www.gossamerbio.com](http://www.gossamerbio.com). The information contained in, or accessible through, our website does not constitute part of this prospectus. We have included our website address as an inactive textual reference only.

This prospectus includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this prospectus 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.

### **Implications of Being an Emerging Growth Company**

As a company with less than \$1.07 billion in revenue during our last fiscal year, we qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012. An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and only two years of related Management's Discussion & Analysis of Financial Condition and Results of Operations in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley;
- reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended, or the Securities Act, which such fifth anniversary will



[Table of Contents](#)

occur in 2024. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, or the Exchange Act, our annual gross revenues exceed \$1.07 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

### The Offering

Common stock offered by us	14,375,000 shares
Common stock to be outstanding immediately after this offering	60,401,910 shares (62,558,160 shares if the underwriters exercise their option to purchase additional shares of common stock in full)
Option to purchase additional shares	We have granted the underwriters an option exercisable for a period of 30 days to purchase up to 2,156,250 additional shares of our common stock.
Use of proceeds	We intend to use the net proceeds of this offering to fund research and development of our product candidates and development programs and for working capital and general corporate purposes. See “Use of Proceeds” for a more complete description of the intended use of proceeds from this offering.
Risk factors	You should read the “Risk Factors” section of this prospectus and the other information in this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Directed shares	At our request, the underwriters have reserved for sale, at the initial public offering price, up to 5% of the shares offered hereby for our directors, officers, employees, business associates and related persons who have expressed an interest in purchasing common stock in the offering. See “Underwriting” for more information.
Nasdaq Global Select Market Symbol	“GOSS”

The number of shares of our common stock to be outstanding after this offering set forth above is based on 46,026,910 shares of our common stock outstanding as of September 30, 2018, including 7,799,605 shares subject to forfeiture, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 30,493,460 shares of our common stock immediately prior to the closing of this offering, and excludes:

- 2,104,311 shares of common stock issuable upon exercise of stock options outstanding as of September 30, 2018, at a weighted-average exercise price of \$2.94 per share;
- 3,013,036 shares of common stock issuable upon exercise of stock options granted after September 30, 2018, at a weighted-average exercise price of \$10.71 per share;
- 5,754,525 shares of our common stock reserved for future issuance under our 2019 equity incentive plan, or the 2019 Plan, which will become effective in connection with this offering (which number includes 4,525 shares remaining available for issuance under our 2017 equity incentive plan, or the 2017 Plan, as of December 31, 2018, which will become available for issuance under the 2019 Plan upon its effectiveness, but does not include any potential evergreen increases pursuant to the terms of the 2019 Plan); and

- 700,000 shares of common stock reserved for future issuance under our 2019 employee stock purchase plan, or the ESPP, which will become effective in connection with this offering (which number does not include any potential evergreen increases pursuant to the terms of the ESPP).

Unless otherwise indicated, this prospectus assumes or gives effect to the following:

- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, each of which will occur immediately prior to the closing of this offering;
- the automatic conversion of all outstanding shares of our convertible preferred stock into 30,493,460 shares of our common stock immediately prior to the closing of this offering;
- a 20,612-for-one stock split of our common stock effected in January 2018;
- a one-for-4.5 reverse stock split of our common stock, which we effected on January 23, 2019;
- no exercise of the outstanding options described above; and
- no exercise by the underwriters of their option to purchase 2,156,250 additional shares of our common stock.

Certain of our existing stockholders, including entities affiliated with certain of our directors, have indicated an interest in purchasing an aggregate of approximately \$100.0 million in shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because these indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any or all of these stockholders, or any or all of these stockholders may determine to purchase more, less or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these stockholders as they will on any other shares sold to the public in this offering.

### Summary Consolidated Financial Data

The following tables set forth a summary of our historical consolidated financial data as of, and for the periods ended on, the dates indicated. We have derived the summary consolidated statements of operations data for the years ended December 31, 2016 and 2017 from our audited consolidated financial statements included elsewhere in this prospectus. We have derived the summary consolidated statements of operations data for the nine months ended September 30, 2017 and 2018 and the summary consolidated balance sheet data as of September 30, 2018 from our unaudited consolidated financial statements included elsewhere in this prospectus. The unaudited consolidated financial statements have been prepared on a basis consistent with our audited consolidated financial statements included in this prospectus and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, necessary to fairly state our financial position as of September 30, 2018 and results of operations for the nine months ended September 30, 2017 and 2018. You should read this data together with our consolidated financial statements and related notes included elsewhere in this prospectus and the sections titled “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our historical results for any prior period are not necessarily indicative of our future results.

	<u>Year Ended December 31,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2016</u>	<u>2017</u>	<u>2017</u>	<u>2018</u>
	(unaudited)			
	(in thousands, except share and per share data)			
<b>Consolidated Statements of Operations Data:</b>				
Operating expenses:				
Research and development	\$ —	\$ 891	\$ 216	\$ 29,411
In process research and development	—	5,500	—	49,659
General and administrative	83	262	105	30,116
Total operating expenses	83	6,653	321	109,186
Loss from operations	(83)	(6,653)	(321)	(109,186)
Other income (expense):				
Interest income	—	—	—	1,022
Interest expense	—	(118)	—	(8)
Other expense	—	—	—	(3)
Total other income (expense)	—	(118)	—	1,011
Net loss	\$ (83)	\$ (6,771)	\$ (321)	\$ (108,175)
Net loss per share, basic and diluted <sup>(1)</sup>	\$ (0.01)	\$ (0.74)	\$ (0.04)	\$ (17.64)
Weighted-average shares of common stock outstanding, basic and diluted <sup>(1)(2)</sup>	9,160,888	9,160,888	9,160,888	6,133,911
Pro forma net loss per share, basic and diluted (unaudited) <sup>(1)</sup>		\$ (0.74)		\$ (4.36)
Pro forma weighted-average shares of common stock outstanding, basic and diluted (unaudited) <sup>(1)</sup>		9,160,888		24,831,306

(1) See Note 2 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the historical and pro forma net loss per share, basic and diluted, and the number of shares used in the computation of the per share amounts.

(2) In connection with the issuance of the Series A convertible preferred stock in January 2018, certain of our founders entered into stock restriction agreements, whereby 4,580,444 of previously unrestricted shares of common stock became subject to forfeiture to us upon the founders’ termination of employment or service, which obligation lapses as the shares vest.

	As of September 30, 2018		
	Actual	Pro Forma(1) (unaudited) (in thousands)	Pro Forma As Adjusted(1)(2)
<b>Consolidated Balance Sheet Data:</b>			
Cash, cash equivalents and marketable securities	\$ 256,443	\$ 256,443	\$ 466,678
Working capital(3)	243,412	243,412	453,647
Total assets	262,181	262,181	472,416
Convertible preferred stock	338,367	—	—
Accumulated deficit	(115,069)	(115,069)	(115,069)
Total stockholders' equity	(91,778)	246,589	456,824
<p>(1) Gives effect to the automatic conversion of all of our outstanding shares of convertible preferred stock into an aggregate of 30,493,460 shares of common stock and the related reclassification of the carrying value of the convertible preferred stock to permanent equity immediately prior to the closing of this offering.</p> <p>(2) Gives effect to (i) the pro forma adjustments set forth in footnote (1) above and (ii) the issuance and sale of 14,375,000 shares of our common stock in this offering at the assumed initial public offering price of \$16.00 per share, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each \$1.00 increase (decrease) in the assumed initial public offering price of \$16.00 per share would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents and marketable securities, working capital, total assets and total stockholders' equity by approximately \$13.4 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price of \$16.00 per share would increase (decrease) the pro forma as adjusted amounts of each of cash, cash equivalents and marketable securities, working capital, total assets and total stockholders' equity by approximately \$14.9 million, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of our initial public offering determined at pricing.</p> <p>(3) We define working capital as current assets less current liabilities. See our consolidated financial statements included elsewhere in this prospectus for further details regarding our current assets and current liabilities.</p>			

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this prospectus, including our consolidated financial statements and related notes included elsewhere in this prospectus and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” before making an investment decision. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline and you could lose part or all of your investment.*

### **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 early clinical trials. GB001, GB002 and GB004 are in clinical development, while our other development programs remain in the preclinical or research stage. We have not yet demonstrated an ability to successfully complete any clinical trials, 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 \$6.8 million and \$108.2 million for the year ended December 31, 2017 and the nine months ended September 30, 2018, respectively. As of September 30, 2018, we had an accumulated deficit of \$115.1 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 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

## [Table of Contents](#)

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 GB001, GB002 and GB004, continue research and development and initiate clinical trials of our 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 GB002 and GB004. 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. Furthermore, following the completion of this offering, we expect to incur additional costs associated with operating as a public company. 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 the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, will enable us to fund our operations for at least the next 12 months. In particular, we expect that the net proceeds from this offering and our existing cash, cash equivalents and marketable securities will allow us to complete our ongoing Phase 2b clinical trial for GB001, our planned Phase 1b clinical trial in PAH for GB002 and our planned Phase 1b clinical trial in UC for GB004. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop 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;

## Table of Contents

- 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.

***Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, 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, 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, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. 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**

***We depend heavily on the success of GB001, GB002 and GB004, 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 three clinical-stage product candidates are in Phase 1 or Phase 2 clinical development. We commenced a Phase 2b clinical trial of GB001 in moderate-to-severe eosinophilic asthma in October 2018.



## [Table of Contents](#)

GB002 is currently undergoing Phase 1 clinical studies in healthy volunteers, and we plan to commence a Phase 1b clinical trial in PAH in the first half of 2019 and a Phase 2/3 clinical trial in PAH in the second half of 2019. Our third clinical-stage product candidate, GB004, is currently undergoing a Phase 1 clinical trial in healthy volunteers, and, following submission of an IND with the FDA, we expect to initiate a Phase 1b clinical trial in UC in the first half of 2019. 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 GB004 and 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 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.

## [Table of Contents](#)

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, our assumptions about why our product candidates are worthy of future development and potential approval are based on data primarily 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 may not predict the results of later clinical trials of the product candidate, 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, while two Phase 2 clinical trials of GB001 have been conducted prior to our acquisition of GB001, we do not know how GB001 will perform in future clinical trials, including as a result of any differences from targeting a population of more severe asthma subjects with elevated eosinophil counts, as well as other differences in our planned trial design. Further, GB001 did not meet its primary efficacy endpoint of improvement in FEV<sub>1</sub> 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. While we have designed our ongoing Phase 2b trial in a manner intended to address what we believe to be the shortcomings of the first Pulmagen Phase 2 clinical trial, we cannot be certain that such failure was not due to GB001 itself or that the results of our ongoing Phase 2b trial will otherwise be successful in a broader patient population. 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 GB002 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 Pharmaceutical Corporation, or Novartis, in a Phase 3 clinical trial; however, we may not observe similar efficacy in our clinical trials of GB002. 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, Teijin, a third party over which we have no control, has the right to develop and commercialize GB001 in Japan. If serious adverse events or other problems occur during any clinical trials of GB001 conducted by Teijin, the FDA or other regulatory authorities may delay, limit or deny approval of GB001 or require us to conduct additional clinical trials as a condition to marketing approval, which would increase our costs. If we receive FDA approval for GB001 and a new and serious safety issue is identified in clinical trials conducted by Teijin, regulatory authorities may withdraw their approval of the product or otherwise restrict our ability to market and sell GB001. In addition, treating physicians may be less willing to prescribe our product due to concerns over such adverse events, which would limit our ability to commercialize GB001.

## [Table of Contents](#)

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 2b clinical trial of GB001 in moderate-to-severe eosinophilic asthma, and we plan to commence a Phase 1b clinical trial of GB002 in PAH patients in the first half of 2019 and a Phase 2/3 clinical trial of GB002 in PAH in the second half of 2019, among other planned trials. In addition, before we can initiate our planned Phase 1b clinical trial of GB004 in UC patients, currently planned for the first half of 2019, 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. We will have to follow the same procedure for our other preclinical product candidates which we plan to advance to clinical development, 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 the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the 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 trial at the rate we expect, or failing to return for post-treatment follow-up;
- subjects choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;

## [Table of Contents](#)

- lack of adequate funding to continue the 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 GB002, 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;
- 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 may 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 GB002. 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 GB002, 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 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, operating results 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. GB001 was generally well tolerated with a treatment-emergent adverse event rate similar to placebo in completed Phase 2 clinical trials. 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 160mg dose. The patient experienced intrahepatic cholestasis, which resolved after treatment discontinuation. We are also currently conducting Phase 1a SAD and MAD double-blind, placebo-controlled, randomized trials of orally inhaled GB002 in healthy adult volunteers, and no treatment related safety issues have been reported to date. However, further analysis may reveal adverse events inconsistent with the safety profile observed to date. Additionally, while we have not yet completed clinical trials for GB002 and have only completed a Phase 1 SAD study in healthy volunteers for GB004, and it is likely that there may be side effects associated with their use. 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 GB002 will not exhibit similar toxicities. 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.

## [Table of Contents](#)

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.

***As an organization, we are in the process of completing our first Phase 1 clinical trials, have never conducted later-stage clinical trials or submitted an NDA, and 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 GB001, GB002, GB004 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 are in the process of completing Phase 1 clinical trials for GB001, GB002 and GB004 and conducting a Phase 2b clinical trial for GB001. We have not yet conducted any clinical trials for our other product candidates. We have not previously conducted any later stage or pivotal clinical trials, have limited experience as a company in preparing, submitting and prosecuting regulatory filings and have not previously submitted an IND or 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 GB001, GB002, GB004 or any other product candidates 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;



## Table of Contents

- 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. 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 for GB002 for patients with PAH, and we may seek orphan drug designation in the European Union for GB002 for patients with PAH, as well as 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.

***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.***

From time to time, we may publicly disclose preliminary or topline or data from our clinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the 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, we commenced a Phase 2b clinical trial in moderate-to-severe eosinophilic asthma in October 2018 and expect to conduct an interim analysis in the first half of 2020. If the interim analysis is positive, we plan on initiating a Phase 3 clinical trial thereafter. However, if the final data from the Phase 2b

clinical trial materially differs in an adverse manner from the interim analysis, we may have unnecessarily expended or committed substantial resources to the Phase 3 clinical trial, which costs we may never be able to recover.

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 you or 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, operating results, prospects or financial condition.

#### **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 clinical trials for GB001, GB002 and GB004 and preclinical studies for our other 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, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical 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 GB001, GB002, GB004 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

## Table of Contents

- 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. 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. We may not be successful in our efforts to establish 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

## [Table of Contents](#)

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, certain policies of the current U.S. administration may impact our business and industry. Namely, the current U.S. administration has taken 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 how these executive actions, including the Executive Orders, will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. 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.



## [Table of Contents](#)

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, 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 our 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. GB001, currently 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 Novartis, Chiesi Farmaceutici S.p.A., Merck & Company, Inc. and

## [Table of Contents](#)

Sunshine Lake Pharma Co., Ltd. If approved, we will also face branded competition from existing biologics, including Xolair (omalizumab/anti-immunoglobulin E, or anti-IgE, marketed by Genentech and Novartis) and Dupixent (dupilumab/anti-IL-4/IL-13, marketed by Regeneron Pharmaceuticals, Inc., or Regeneron, 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-5, 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 asthma, including tezepelumab (anti-TSLP; Amgen/AstraZeneca), REGN3500 (anti-IL-33; Regeneron), etokimab (anti-IL-33; AnaptysBio, Inc.), GSK3772847 (anti-IL-33; GlaxoSmithKline) and RG6149 (anti-ST2; Genentech).

Additionally, while there are no agents currently approved beyond corticosteroids for CRSwNP, several agents approved for or in development for asthma are currently in development for CRSwNP, including Xolair, Fasenra, Dupixent and etokimab.

Xolair is currently FDA-approved for the treatment of CSU. We may also face competition from agents currently in development for the indication, including ligelizumab (anti-IgE; Novartis) and AK002 (anti-Siglec-8; Allakos Inc.).

GB002 is a potentially first-in-class PDGF receptor kinase inhibitor initially targeted for intermediate and high-risk PAH patients. While potentially unique in our class, we expect our primary competition in this patient set will include prostanoids, available in oral form as Orenitram (United Therapeutics Corporation, or United Therapeutics) and Uptravi (Janssen Pharmaceuticals, Inc., or Janssen), by inhalation as Tyvaso (United Therapeutics), and by infusion as Remodulin (United Therapeutics). While we 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, GB002 would be used along with these background therapies. PAH is also an active indication for investigational drugs, and we may face competition in the future from ralinepag (Arena Pharmaceuticals, Inc.), sotatercept (Acceleron Pharma, Inc.) and bardoxolone methyl (Reata Pharmaceuticals, Inc.).

GB004 is potentially a first-in-class HIF-1a 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-aminosalicylic acid, or 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 Janus kinase, or JAK, inhibitors. Further disruption is expected in the coming years through the introduction of oral S1P1 inhibitors and additional oral JAK inhibitors.

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

## [Table of Contents](#)

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, or natural disasters including earthquakes, typhoons, floods and fires.

### **Risks Related to Our Business Operations and Industry**

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

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. 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;

## Table of Contents

- 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 operating results. As a result, comparing our operating results 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 operating results 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 and our Executive Chairman, 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. 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, except for our Chief Executive Officer and Executive Chairman. 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 104 full-time employees and 1 part-time employee as of December 31, 2018. As we continue development and pursue the

potential commercialization of our product candidates, as well as function as a public company, we will 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 and privacy 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 and privacy 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. 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 false claims and civil monetary penalties 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;
- 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;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, also impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;



## Table of Contents

- 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) 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; state and local laws that require the registration of pharmaceutical sales representatives; state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA; state and foreign governments that have enacted or proposed requirements regarding the collection, distribution, use, security, and storage of personally identifiable information and other data relating to individuals (including the EU General Data Protection Regulation 2016/679, or GDPR, and the California Consumer Protection Act, or CCPA), and federal and state consumer protection laws are being applied to enforce regulations related to the online collection, use, and dissemination of data, thus complicating compliance efforts.

As of May 25, 2018, the GDPR replaced the Data Protection Directive with respect to the processing of personal data in the European Union. The GDPR imposes many requirements for controllers and processors of personal data, 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 pseudonymised (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 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.

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 received 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.

***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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the Affordable Care Act, was enacted in the United States. Among the provisions of the Affordable Care Act of importance to our potential product candidates, the Affordable Care Act: establishes an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extends manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expands eligibility criteria for Medicaid programs; expands the entities eligible for discounts under the Public Health program; increases the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; creates a new Medicare Part D coverage gap discount program; establishes 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 establishes a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

At this time, we are unsure of the full impact that the Affordable Care Act will have on our business. There have been judicial and political challenges to certain aspects of the Affordable Care Act. For example, since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements of the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act 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 January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share. The Bipartisan Budget Act of 2018, or the BBA, among other things, amends the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole," by increasing from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. In July 2018, CMS published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. 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

## [Table of Contents](#)

mandate is a critical and inseparable 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. While the Texas District Court Judge, as well as the Trump Administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act 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, including the BBA, will remain in effect through 2027 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.

At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices through proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services has begun the process of soliciting feedback on some of these measures and, at the same time, is implementing others under its existing authority. Although some of these, and other, proposals will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

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.

## [Table of Contents](#)

We expect that the Affordable Care Act, these 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.

***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.

***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 product liability insurance coverage in the aggregate. 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 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. 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, medical epidemics 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.

***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 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 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;



## Table of Contents

- 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 our GB002 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 GB002 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 GB002. 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.

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

## [Table of Contents](#)

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 GB002 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

## [Table of Contents](#)

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 GB002 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 prospectus, 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 operating results.

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 and This Offering**

***An active, liquid and orderly market for our common stock may not develop, and you may not be able to resell your common stock at or above the public offering price.***

Prior to this offering, there has been no public market for our common stock. Although we expect to list our common stock on the Nasdaq Global Select Market, or Nasdaq, an active trading market for our common stock may never develop or be sustained following this offering. We and the representatives of the underwriters will determine the initial public offering price of our common stock through negotiation. This price will not necessarily reflect the price at which investors in the market will be willing to buy and sell our shares following this offering. In addition, an active trading market may not develop following the consummation of this offering or, if it is developed, may not be sustained. 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. 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 initial public offering price. 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;

## Table of Contents

- 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;
- 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, after listing, 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.

### ***We may allocate the net proceeds from this offering in ways that you and other stockholders may not approve.***

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section titled "Use of Proceeds." Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment, and the failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected results, which could cause our stock price to decline.

***You will suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase.***

The initial public offering price of our common stock is substantially higher than the pro forma as adjusted net tangible book value per share of our outstanding common stock immediately after the completion of this offering. Purchasers of common stock in this offering will experience immediate dilution of approximately \$8.44 per share, assuming an initial public offering price of \$16.00 per share. In the past, we issued options to acquire common stock at prices significantly below the initial public offering price. To the extent these outstanding options are ultimately exercised, investors purchasing common stock in this offering will sustain further dilution. For a further description of the dilution that you will experience immediately after this offering, see “Dilution.”

***After this offering, our executive officers, directors and principal stockholders, if they choose to act together, will continue to 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.***

Following the completion of this offering, our executive officers, directors and greater than 5% stockholders, in the aggregate, will own approximately 56.6% of our outstanding common stock (assuming no exercise of the underwriters’ option to purchase additional shares and no exercise of outstanding options). Furthermore, many of our current directors were appointed by our principal stockholders. As a result, such persons or their appointees to our board of directors, acting together, will 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. Moreover, certain of our existing stockholders, including certain affiliates of our directors, have indicated an interest in purchasing shares of our common stock in this offering at the initial public offering price. Based on an assumed initial public offering price of \$16.00 per share, if our greater than 5% stockholders purchase all of the shares they have indicated an interest in purchasing in this offering, the number of shares of our common stock beneficially owned by our executive officers, directors and greater than 5% stockholders will, in the aggregate, increase to approximately 63.9% of our outstanding common stock (assuming no exercise of the underwriters’ option to purchase additional shares and no exercise of our outstanding options). However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these stockholders, or any of these stockholders may determine to purchase more, less or no shares in this offering.

***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 any future debt agreements may preclude us from paying dividends. 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.

Based on shares of common stock outstanding as of September 30, 2018, upon the closing of this offering, we will have outstanding a total of 60,401,910 shares of common stock after this offering, assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options. Of these shares, only the 14,375,000 shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable, without restriction, in the public market immediately following this offering, unless they are purchased by one of our affiliates.

Our directors and executive officers and holders of substantially all of our outstanding securities have entered into lock-up agreements with the underwriters pursuant to which they may not, with limited exceptions, for a period of 180 days from the date of this prospectus, offer, sell or otherwise transfer or dispose of any of our securities, without the prior written consent of Merrill Lynch, Pierce, Fenner & Smith Incorporated, SVB Leerink LLC and Barclays Capital Inc. Such exceptions include the ability of certain of our executive officers to sell up to \$8.0 million of shares of common stock to satisfy certain tax liabilities related to their previous acquisition of shares. The underwriters may permit our officers, directors and other stockholders and the holders of our outstanding options who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements, subject to limitations. See "Underwriting." Sales of these shares, or perceptions that they will be sold, could cause the trading price of our common stock to decline. After the lock-up agreements expire, up to an additional 46,026,910 shares of common stock will be eligible for sale in the public market of which 34,213,634 shares are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act.

In addition, as of September 30, 2018, up to 3,804,716 shares of common stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After this offering, the holders of 30,493,460 shares of our outstanding common stock, or approximately 66.3% of our total outstanding common stock as of September 30, 2018, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting and the 180-day lock-up agreements described above. See "Description of capital stock—Registration rights." 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 could have a material adverse effect on the trading price of our common stock.

***We are an emerging growth company, and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.***

We are an emerging growth company, as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed \$1.07 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to

## [Table of Contents](#)

rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in this prospectus. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

***We will incur significant increased 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 will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Exchange Act, which will require, among other things, that we file with the U.S. Securities and Exchange Commission, or 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 will apply to us when we cease to be an emerging growth company. 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.

We expect the rules and regulations applicable to public companies to substantially 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



## [Table of Contents](#)

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, we expect these rules and regulations to make it more difficult and 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. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, 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 will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2019. When we lose our status as an “emerging growth company” and reach an accelerated filer threshold, our independent registered public accounting firm will be 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. To comply with the requirements of being a reporting company under the Exchange Act, we will need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. 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.

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.

***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 that will be in effect immediately prior to the consummation of this offering will contain provisions that could significantly

## [Table of Contents](#)

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 will 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 and amended and restated bylaws will 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, 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 and amended and restated bylaws will provide 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 provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, our amended and restated certificate of incorporation will 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 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 in connection with this offering or other ownership changes.***

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we 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, 2017, we had federal and state net operating loss, or NOL, carryforwards of approximately \$1.1 million and \$1.1 million, respectively. Such federal and state NOL carryforwards will begin to expire in 2036, unless previously utilized.

Under recently enacted U.S. tax legislation, 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 annually. Our NOL 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 federal NOL 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 this offering. Similar rules may apply under state tax laws. We have not yet determined the amount of the cumulative change in our ownership resulting from this offering or other transactions, or any resulting limitations on our ability to utilize our NOL carryforwards and other tax attributes. 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.

***Recent U.S. tax legislation may materially adversely affect our financial condition, results of operations and cash flows.***

The Tax Act has significantly changed the U.S. federal income taxation of U.S. corporations, including by reducing the U.S. corporate income tax rate and revising the rules governing NOLs. Many of these changes became effective beginning in 2018, without any transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the U.S. Treasury Department and the IRS, any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities. As a result of the rate reduction from the Tax Act, we have reduced our deferred tax asset balance as of December 31, 2017 by \$0.8 million. However, due to our full valuation allowance position, there was no net impact on our income tax provision at December 31, 2017, as the reduction in the deferred tax asset balance was fully offset by a corresponding decrease in the valuation allowance.

There may be other material adverse effects resulting from the legislation that we have not yet identified. While some of the changes made by the tax legislation may adversely affect us in one or more reporting periods and prospectively, other changes may be beneficial on a going forward basis. We continue to work with our tax advisors to determine the full impact that the recent tax legislation as a whole will have on us. We urge our investors to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

***We could be subject 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. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, research and development, the anticipated timing, costs, design and conduct of our planned clinical trials for our product candidates and preclinical studies and clinical trials for our other development programs, the timing and likelihood of regulatory filings and approvals for our product candidates, our ability to commercialize our other product candidates, if approved, the pricing and reimbursement of our product candidates, if approved, the potential benefits of strategic collaborations and our ability to enter into strategic arrangements, 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.

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 prospectus 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 prospectus and are subject to a number of risks, uncertainties and assumptions described under the sections in this prospectus entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. 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 undertake no obligation 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. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this prospectus. See “Where You Can Find More Information.”

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to rely unduly upon these statements.

## **MARKET AND INDUSTRY DATA**

We obtained the industry, market and competitive position data used throughout this prospectus from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies and publicly available information in addition to research, surveys and studies conducted by third parties. References in this prospectus to data provided by Datamonitor refer to Datamonitor Healthcare | Informa Pharma Intelligence. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires. In addition, while we believe the industry, market and competitive position data included in this prospectus is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed in “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

## USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the common stock that we are offering will be approximately \$210.2 million (or \$242.3 million if the underwriters exercise their option to purchase additional shares in full), assuming an initial public offering price of \$16.00 per share, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$16.00 per share would increase (decrease) the net proceeds to us from this offering by approximately \$13.4 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, by approximately \$14.9 million, assuming the assumed initial public offering price stays the same.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for our common stock and to facilitate our future access to the public equity markets.

We intend to use the net proceeds from the offering as follows:

- approximately \$70.0 million to fund the research and development of GB001;
- approximately \$40.0 million to fund the research and development of GB002;
- approximately \$35.0 million to fund the research and development of GB004;
- approximately \$40.0 million to fund research and development of our other development programs; and
- the remainder for working capital and general corporate purposes.

We may also use a portion of the remaining net proceeds and our existing cash, cash equivalents and marketable securities to in-license, acquire, or invest in complementary businesses, technologies, products or assets. However, we have no current commitments or obligations to do so.

We believe, based on our current operating plan, that the net proceeds from this offering and our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operations for at least the next 12 months, although there can be no assurance in that regard. In particular, we expect that the net proceeds from this offering and our existing cash, cash equivalents and marketable securities will allow us to complete our ongoing Phase 2b clinical trial for GB001, our planned Phase 1b clinical trial in PAH for GB002 and our planned Phase 1b clinical trial in UC for GB004. However, our expected use of proceeds from this offering described above represents our current intentions based on our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the proceeds to be received upon the completion of this offering or the actual amounts that we will spend on the uses set forth above. The net proceeds from this offering, together with our cash, cash equivalents and marketable securities, will not be sufficient for us to fund all of our product candidates through regulatory approval, and we will need to raise additional capital to complete the development and commercialization of all of our product candidates.

The amounts and timing of our actual expenditures will depend on numerous factors, including the time and cost necessary to conduct our planned clinical trials and preclinical studies and the results of such trials and studies, and other factors described under “Risk Factors” in this prospectus, as well as the amount of cash used in our operations and any unforeseen cash needs. Therefore, our actual expenditures may differ materially from the estimates described above. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds.

Pending the uses described above, we plan to invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

## **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.



## CAPITALIZATION

The following table sets forth our cash, cash equivalents and marketable securities and capitalization as of September 30, 2018:

- on an actual basis;
- on a pro forma basis to reflect (1) the automatic conversion of all outstanding shares of our convertible preferred stock into 30,493,460 shares of common stock and the related reclassification of the carrying value of the convertible preferred stock to permanent equity immediately prior to the closing of this offering, and (2) the filing and effectiveness of our amended and restated certificate of incorporation immediately prior to the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 14,375,000 shares of our common stock in this offering at an assumed initial public offering price of \$16.00 per share, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information below is illustrative only, and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this information in conjunction with our consolidated financial statements and the related notes included in this prospectus and the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and other financial information contained in this prospectus.

	As of September 30, 2018		
	Actual	Pro Forma (unaudited) (in thousands, except share and per share data)	Pro Forma As Adjusted(1)
Cash, cash equivalents and marketable securities	\$ 256,443	\$ 256,443	\$ 466,678
Convertible preferred stock, \$0.0001 par value per share; 137,220,799 shares authorized, issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	338,367	—	—
<b>Stockholders’ equity (deficit):</b>			
Preferred stock, \$0.0001 par value per share; no shares authorized, issued or outstanding, actual; 70,000,000 shares authorized and no shares issued and outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, \$0.0001 par value per share; 49,160,177 shares authorized; 15,533,450 shares issued and 7,733,845 shares outstanding, actual, excluding 7,799,605 shares subject to forfeiture; 700,000,000 shares authorized, pro forma and pro forma as adjusted; 46,026,910 shares issued and 38,227,305 shares outstanding, pro forma, excluding 7,799,605 shares subject to forfeiture; 60,401,910 shares issued and 52,602,305 shares outstanding, excluding 7,799,605 shares subject to forfeiture, pro forma as adjusted	2	5	6
Additional paid in capital	23,054	361,418	571,652
Accumulated deficit	(115,069)	(115,069)	(115,069)
Accumulated other comprehensive income	235	235	235
<b>Total stockholders’ equity (deficit)</b>	<b>(91,778)</b>	<b>246,589</b>	<b>456,824</b>
<b>Total capitalization</b>	<b>\$ 246,589</b>	<b>\$ 246,589</b>	<b>\$ 456,824</b>

## [Table of Contents](#)

- (1) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$16.00 per share would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents and marketable securities, total stockholders' equity and total capitalization by approximately \$13.4 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price of \$16.00 per share would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents and marketable securities, total stockholders' equity and total capitalization by approximately \$14.9 million, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of common stock in the table above is based on 46,026,910 shares of our common stock outstanding as of September 30, 2018, including 7,799,605 shares subject to forfeiture, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 30,493,460 shares of our common stock immediately prior to the closing of this offering, and excludes:

- 2,104,311 shares of common stock issuable upon exercise of stock options outstanding as of September 30, 2018, at a weighted-average exercise price of \$2.94 per share;
- 3,013,036 shares of common stock issuable upon exercise of stock options granted after September 30, 2018, at a weighted-average exercise price of \$10.71 per share;
- 5,754,525 shares of our common stock reserved for future issuance under our 2019 Plan, which will become effective in connection with this offering (which number includes 4,525 shares remaining available for issuance under our 2017 Plan as of December 31, 2018, which will become available for issuance under the 2019 Plan upon its effectiveness, but does not include any potential evergreen increases pursuant to the terms of the 2019 Plan); and
- 700,000 shares of common stock reserved for future issuance under our ESPP, which will become effective in connection with this offering (which number does not include any potential evergreen increases pursuant to the terms of the ESPP).

## DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

As of September 30, 2018, we had a historical net tangible book deficit of \$91.8 million, or \$(5.91) per share of common stock based on 15,533,450 shares of common stock outstanding, including 7,799,605 shares subject to forfeiture, as of such date. Our historical net tangible book value per share represents total tangible assets less total liabilities and convertible preferred stock, divided by the number of shares of common stock outstanding (including shares subject to forfeiture) at September 30, 2018.

On a pro forma basis, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 30,493,460 shares of our common stock and the related reclassification of the carrying value of the convertible preferred stock to permanent equity immediately prior to the closing of this offering stock, our pro forma net tangible book value as of September 30, 2018 would have been approximately \$246.6 million, or approximately \$5.36 per share of our common stock.

After giving further effect to the sale of 14,375,000 shares of common stock that we are offering at an assumed initial public offering price of \$16.00 per share, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2018 would have been approximately \$457.4 million, or approximately \$7.56 per share. This amount represents an immediate increase in pro forma net tangible book value of approximately \$2.20 per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately \$8.44 per share to new investors purchasing shares of common stock in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution (without giving effect to any exercise by the underwriters of their option to purchase additional shares):

Assumed initial public offering price per share	\$16.00
Historical net tangible book deficit per share as of September 30, 2018	\$(5.91)
Pro forma increase in historical net tangible book deficit per share as of September 30, 2018 attributable to the conversion of convertible preferred stock	11.27
Pro forma net tangible book value per share as of September 30, 2018	5.36
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering	2.20
Pro forma as adjusted net tangible book value per share after this offering	7.56
Dilution per share to new investors participating in this offering	\$ 8.44

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$16.00 per share would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by approximately \$0.22, and dilution in pro forma net tangible book value per share to new investors by approximately \$0.22, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us would increase (decrease) our pro forma as adjusted net tangible book value per share after this offering by approximately \$0.12 per share and decrease (increase) the dilution to investors participating in this offering by approximately \$0.12 per share, assuming that the assumed initial public offering price of \$16.00 per share remains the same, and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us.

## [Table of Contents](#)

If the underwriters exercise their option to purchase additional shares of our common stock in full in this offering, the pro forma as adjusted net tangible book value after the offering would be approximately \$7.82 per share, the increase in pro forma net tangible book value per share to existing stockholders would be approximately \$2.46 per share and the dilution per share to new investors would be \$8.18 per share, in each case assuming an initial public offering price of \$16.00 per share.

The following table summarizes on the pro forma as adjusted basis described above, as of September 30, 2018, the differences between the number of shares purchased from us, the total consideration paid to us in cash and the average price per share paid by existing stockholders for shares issued prior to this offering and the price to be paid by new investors in this offering. The calculations below are based on an assumed initial public offering price of \$16.00 per share, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	<u>Shares Purchased</u>		<u>Total Consideration</u>		<u>Average Price</u>
	<u>Number</u>	<u>Percent</u>	<u>Amount</u>	<u>Percent</u>	<u>Per Share</u>
Existing stockholders before this offering <sup>(1)</sup>	46,026,910	76.2%	\$322,814,842	58.4%	\$ 7.01
New investors participating in this offering	14,375,000	23.8	230,000,000	41.6	\$ 16.00
<b>Total</b>	<b>60,401,910</b>	<b>100%</b>	<b>552,914,842</b>	<b>100%</b>	

(1) Certain of our existing stockholders, including entities affiliated with certain of our directors, have indicated an interest in purchasing an aggregate of approximately \$100.0 million in shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because these indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any or all of these stockholders, or any or all of these stockholders may determine to purchase more, less or no shares in this offering.

If the underwriters exercise their option to purchase additional shares of our common stock in full:

- the percentage of shares of common stock held by existing stockholders will decrease to approximately 73.6% of the total number of shares of our common stock outstanding after this offering; and
- the number of shares held by new investors will increase to 16,531,250, or approximately 26.4% of the total number of shares of our common stock outstanding after this offering.

The foregoing tables and calculations (other than the historical net tangible book value calculation) are based on 46,026,910 shares of our common stock outstanding as of September 30, 2018, including 7,799,605 shares subject to forfeiture, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 30,493,460 shares of our common stock immediately prior to the closing of this offering, and exclude:

- 2,104,311 shares of common stock issuable upon exercise of stock options outstanding as of September 30, 2018, at a weighted-average exercise price of \$2.94 per share;
- 3,013,036 shares of common stock issuable upon exercise of stock options granted after September 30, 2018, at a weighted-average exercise price of \$10.71 per share;
- 5,754,525 shares of our common stock reserved for future issuance under our 2019 Plan, which will become effective in connection with this offering (which number includes 4,525 shares remaining available for issuance under our 2017 Plan as of December 31, 2018, which will become available for issuance under the 2019 Plan upon its effectiveness, but does not include any potential evergreen increases pursuant to the terms of the 2019 Plan); and
- 700,000 shares of common stock reserved for future issuance under our ESPP, which will become effective in connection with this offering (which number does not include any potential evergreen increases pursuant to the terms of the ESPP).

To the extent any outstanding options are exercised, or we issue additional equity or convertible debt securities in the future, there will be further dilution to new investors.

## SELECTED CONSOLIDATED FINANCIAL DATA

The following tables set forth selected historical consolidated financial data as of, and for the periods ended on, the dates indicated. We have derived the selected consolidated statements of operations data for the years ended December 31, 2016 and 2017 and the selected consolidated balance sheet data as of December 31, 2016 and 2017 from our audited consolidated financial statements included elsewhere in this prospectus. We have derived the selected consolidated statements of operations data for the nine months ended September 30, 2017 and 2018 and the selected consolidated balance sheet data as of September 30, 2018 from our unaudited consolidated financial statements included elsewhere in this prospectus. The unaudited consolidated financial statements have been prepared on a basis consistent with our audited consolidated financial statements included in this prospectus and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, necessary to fairly state our financial position as of September 30, 2018 and results of operations for the nine months ended September 30, 2017 and 2018. You should read this data together with our consolidated financial statements and related notes included elsewhere in this prospectus and the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our historical results for any prior period are not necessarily indicative of our future results.

	<u>Year Ended December 31,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2016</u>	<u>2017</u>	<u>2017</u>	<u>2018</u>
			(unaudited)	
	(in thousands, except share and per share data)			
<b>Consolidated Statements of Operations Data:</b>				
Operating expenses:				
Research and development	\$ —	\$ 891	\$ 216	\$ 29,411
In process research and development	—	5,500	—	49,659
General and administrative	83	262	105	30,116
Total operating expenses	<u>83</u>	<u>6,653</u>	<u>321</u>	<u>109,186</u>
Loss from operations	(83)	(6,653)	(321)	(109,186)
Other income (expense):				
Interest income	—	—	—	1,022
Interest expense	—	(118)	—	(8)
Other Income	—	—	—	(3)
Total other income (expense)	<u>—</u>	<u>(118)</u>	<u>—</u>	<u>1,011</u>
Net loss	<u>\$ (83)</u>	<u>\$ (6,771)</u>	<u>\$ (321)</u>	<u>\$ (108,175)</u>
Net loss per share, basic and diluted <sup>(1)</sup>	<u>\$ (0.01)</u>	<u>\$ (0.74)</u>	<u>\$ (0.04)</u>	<u>\$ (17.64)</u>
Weighted-average shares of common stock outstanding, basic and diluted <sup>(1)(2)</sup>	<u>9,160,888</u>	<u>9,160,888</u>	<u>9,160,888</u>	<u>6,133,911</u>
Pro forma net loss per share, basic and diluted (unaudited) <sup>(1)</sup>		<u>\$ (0.74)</u>		<u>\$ (4.36)</u>
Pro forma weighted-average shares of common stock outstanding, basic and diluted (unaudited) <sup>(1)</sup>		<u>9,160,888</u>		<u>24,831,306</u>

(1) See Note 2 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the historical and pro forma net loss per share, basic and diluted, and the number of shares used in the computation of the per share amounts.

(2) In connection with the issuance of the Series A convertible preferred stock in January 2018, certain of our founders entered into stock restriction agreements, whereby 4,580,444 of previously unrestricted shares of common stock became subject to forfeiture to us upon the founders’ termination of employment or service, which obligation lapses as the shares vest.

[Table of Contents](#)

	As of December 31,		As of September 30,
	<u>2016</u>	<u>2017</u>	<u>2018</u>
	(in thousands)		(unaudited)
<b>Consolidated Balance Sheet Data:</b>			
Cash, cash equivalents and marketable securities	\$ 60	\$ 315	\$ 256,443
Working capital <sup>(1)</sup>	(83)	(821)	243,412
Total assets	60	445	262,181
Convertible preferred stock	—	—	338,367
Accumulated deficit	(123)	(6,894)	(115,069)
Total stockholders' deficit	(123)	(6,862)	(91,778)

(1) We define working capital as current assets less current liabilities. See our consolidated financial statements included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

## 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 appearing in this prospectus. Some of the information contained in this discussion and analysis is set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

### 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. 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 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 programs. We currently have six programs: three clinical-stage product candidates and three preclinical programs. We commenced a Phase 2b clinical trial for our most advanced product candidate, GB001, in moderate-to-severe eosinophilic asthma in October 2018 and expect to conduct an interim analysis in the first half of 2020. If the interim analysis is positive, we plan on initiating a Phase 3 clinical trial thereafter. We also expect to initiate proof-of-concept Phase 2 clinical trials of GB001 in CRSwNP and CSU in 2019. We are developing GB002 for the treatment of PAH, and plan to commence a Phase 1b clinical trial in PAH in the first half of 2019 and a Phase 2/3 clinical trial in PAH in the second half of 2019. We are developing GB004 for the treatment of IBD, including UC and CD, and, following submission of an IND application with the FDA, expect to initiate a Phase 1b clinical trial in UC in the first half of 2019. We also plan to initiate a Phase 2 clinical trial in UC in the first half of 2020. We currently have three programs in preclinical development. GB1275 is an oral small molecule, CD11b agonist in preclinical development for the treatment of oncology indications for which we plan to submit an IND application and, after acceptance, initiate a Phase 1 clinical trial in 2019. We are also currently evaluating a portfolio of novel BTK inhibitors for the treatment of autoimmune indications and small molecule cancer metabolism modulators for the treatment of solid tumors.

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 trials. We have funded our operations primarily through equity financings. We raised \$310.0 million from October 2017 through July 2018 through Series A and B convertible preferred stock financings and a convertible note financing. 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 September 30, 2018, we had \$256.4 million in cash, cash equivalents and marketable securities.

We have incurred significant operating losses since our inception, and expect to continue to incur significant operating losses for the foreseeable future. For the year ended December 31, 2017 and for the nine months ended September 30, 2018, our net loss was \$6.8 million and \$108.2 million, respectively. As of September 30, 2018, we had an accumulated deficit of \$115.1 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 GB002 and GB004. 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.

## **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



## [Table of Contents](#)

- 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. For the nine months ended September 30, 2018, the majority of our third-party expenses related to the research and development of GB001 and GB002. 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:

- 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.

## [Table of Contents](#)

### *In process research and development*

In process research and development, or IPR&D, expenses include in-process research and development 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 payments made to Pulmokit, Inc., in connection with the in-license of GB002, the value of our stock issued to former AA Biopharma Inc. shareholders, in connection with the acquisition of GB001, and our upfront payments made to Aerpio Pharmaceuticals, Inc., or Aerpio, in connection with the in-license of GB004, our upfront payments made to Adhaere Pharmaceuticals, Inc., or Adhaere, in connection with the acquisition of GB1275, and upfront payments made in connection with the acquisition of our other 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 and (2) interest expense related to the convertible promissory note issued in October 2017. The note converted into shares of our Series A convertible preferred stock in January 2018. See Note 5 to our consolidated financial statements included elsewhere in this prospectus for a description of the note.

## **Results of Operations for the Nine Months Ended September 30, 2017 and 2018**

The following table sets forth our selected statements of operations data for the nine months ended September 30, 2017 and 2018:

	<u>Nine Months Ended September 30,</u>		<u>Change</u>
	<u>2017</u>	<u>2018</u>	<u>\$</u>
	<u>(in thousands)</u>		
	<u>(unaudited)</u>		
<b>Operating expenses:</b>			
Research and development	\$ 216	\$ 29,411	\$ 29,195
IPR&D	—	49,659	49,659
General and administrative	105	30,116	30,011
<b>Total operating expenses</b>	<b>321</b>	<b>109,186</b>	<b>108,865</b>
<b>Loss from operations</b>	<b>(321)</b>	<b>(109,186)</b>	<b>(108,865)</b>
<b>Other income (expenses)</b>			
Interest income	—	1,022	1,022
Interest expense	—	(8)	(8)
Other expense	—	(3)	(3)
<b>Total other income, net</b>	<b>—</b>	<b>1,011</b>	<b>1,011</b>
<b>Net loss</b>	<b>\$ (321)</b>	<b>\$ (108,175)</b>	<b>\$ (107,854)</b>

## Operating expenses

### Research and development

Research and development expenses were \$29.4 million for the nine months ended September 30, 2018, compared to \$216,000 for the nine months ended September 30, 2017. The \$29.4 million for the nine months ended September 30, 2018 was primarily attributable to \$7.6 million of costs associated with preclinical studies and clinical trials for GB001, \$7.2 million of cost associated with preclinical studies and clinical trials for GB002, \$6.1 million of personnel-related costs and \$4.6 million of external consultants costs.

The following table shows our research and development expenses by program for the nine months ended September 30, 2017 and 2018:

	Nine Months Ended September 30,		Change \$
	2017	2018 (in thousands) (unaudited)	
GB001	\$ —	\$ 11,523	11,523
GB002	216	\$ 10,931	10,715
GB004	—	\$ 2,713	2,713
Other programs	—	\$ 1,287	1,287
Unallocated expenses	—	\$ 2,957	2,957
Total research and development	<u>216</u>	<u>\$ 29,411</u>	<u>29,195</u>

### IPR&D

IPR&D expenses were \$49.7 million for the nine months ended September 30, 2018, compared to \$0 for the nine months ended September 30, 2017. The \$49.7 million for the nine months ended September 30, 2018 was primarily attributable to our \$20.0 million upfront payment made to Aerpio in connection with the in-license of GB004, \$19.3 million of costs associated with the issuance of our stock in connection with our acquisition of GB001 and AA Biopharma and our \$7.5 million upfront payment in connection with our acquisition of GB1275 and Adhaere.

### General and administrative

General and administrative expenses were \$30.1 million for the nine months ended September 30, 2018, compared to approximately \$105,000 for the nine months ended September 30, 2017. The \$30.1 million for the nine months ended September 30, 2018 was primarily attributable to \$20.0 million in stock-based compensation costs, \$3.6 million in personnel-related costs, \$2.2 million in professional fees, \$1.6 million in facility-related costs and \$1.1 million in legal fees.

### Other income (expense), net

Other income (expense), net was \$1.0 million for the nine months ended September 30, 2018, compared to \$0 for the nine months ended September 30, 2017. The \$1.0 million was attributable to \$1.0 million interest income earned on our cash, cash equivalents and marketable securities during the period.

**Results of Operations for the Years Ended December 31, 2016 and 2017**

The following table sets forth our selected statements of operations data for the years ended December 31, 2016 and 2017:

	<b>Year Ended December 31,</b>		<b>Change</b>
	<b>2016</b>	<b>2017</b>	<b>\$</b>
	(in thousands)		
<b>Operating expenses:</b>			
Research and development	\$ —	\$ 891	\$ 891
IPR&D	—	5,500	5,500
General and administrative	83	262	179
<b>Total operating expenses</b>	<b>83</b>	<b>6,653</b>	<b>6,570</b>
<b>Loss from operations</b>	<b>(83)</b>	<b>(6,653)</b>	<b>(6,570)</b>
Other expense	—	(118)	(118)
<b>Net loss</b>	<b>\$ (83)</b>	<b>\$ (6,771)</b>	<b>\$ (6,688)</b>

**Operating expenses***Research and development*

Research and development expenses were approximately \$0.9 million for the year ended December 31, 2017, compared to \$0 for the year ended December 31, 2016. The \$0.9 million was primarily attributable to \$0.6 million in legal fees, \$0.2 million in external consultant costs and salaries and \$0.1 million of employee-related costs for research and development staff. All research and development expenses for the year ended December 31, 2017 were attributable to GB002.

*IPR&D*

IPR&D expenses were approximately \$5.5 million for the year ended December 31, 2017, compared to \$0 for the year ended December 31, 2016. The \$5.5 million was attributable to our upfront payment for the in-license of GB002 from Pulmokine.

*General and administrative*

General and administrative expenses were approximately \$0.3 million for the year ended December 31, 2017, compared to approximately \$0.1 million for the year ended December 31, 2016. The \$0.3 million for the year ended December 31, 2017 was primarily related to legal fees.

**Other income (expense), net**

Other income (expense), net was \$0.1 million for the year ended December 31, 2017, compared to \$0 for the year ended December 31, 2016. The \$0.1 million was primarily related to interest expense on the convertible promissory note.

**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, 2017 and September 30, 2018, we had an accumulated deficit of \$6.9 million and \$115.1 million, respectively.

## Table of Contents

Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Since our inception, our operations have been financed primarily by gross proceeds of \$310.0 million from the sale of our convertible preferred stock and a convertible promissory note. In January and March 2018, we issued and sold an aggregate of 45,714,286 shares of Series A convertible preferred stock at \$1.75 per share, for approximately \$73.9 million in gross proceeds and the cancellation of a \$6.1 million convertible promissory note. In January 2018, we acquired GB001 pursuant to a merger agreement with AA Biopharma under which we issued to former AA Biopharma shareholders an aggregate of 20,000,000 shares of our Series Seed convertible preferred stock and 1,101,278 shares of our common stock. In connection with this acquisition, we received \$12.8 million in cash. In July 2018, we raised approximately \$230.0 million in gross proceeds from the sale of 71,506,513 shares of Series B convertible preferred stock. As of September 30, 2018, we had cash, cash equivalents and marketable securities of \$256.4 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to capital preservation and liquidity.

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

	Year Ended December 31,		Nine Months Ended September 30,	
	2016	2017	2017	2018
			(in thousands)	
Net cash provided by (used in) operating activities	\$ 20	\$ (5,745)	\$ (24)	\$ (26,021)
Net cash used in investing activities	—	—	—	(136,030)
Net cash provided by financing activities	40	6,000	4	303,003
Net increase in cash, cash equivalents and restricted cash	<u>\$ 60</u>	<u>\$ 255</u>	<u>\$ (20)</u>	<u>\$ 140,952</u>

### Operating activities

During the nine months ended September 30, 2018, operating activities used approximately \$26.0 million of cash, primarily resulting from a net loss of \$108.2 million, partially reduced by in process research and development expenses of \$49.7 million, changes in operating assets and liabilities of \$12.2 million and stock-based compensation expense of \$20.1 million. Net cash provided by changes in operating assets and liabilities consisted primarily of increases in accounts payable and accrued expenses of \$14.6 million, partially offset by an increase in prepaid expenses due to prepayments for clinical development activities and security deposits.

During the nine months ended September 30, 2017, operating activities were nominal.

During the year ended December 31, 2017, operating activities used approximately \$5.7 million of cash, primarily resulting from a net loss of \$6.8 million, partially reduced by increases in accounts payable of \$1.0 million.

During the year ended December 31, 2016, operating activities were nominal.

### Investing activities

During the nine months ended September 30, 2018, investing activities used approximately \$136.0 million of cash, primarily resulting from the upfront payment made to Aerpio of \$20.0 million in connection with the in-license of GB004, the purchase of marketable securities of \$115.1 million, upfront

## [Table of Contents](#)

payments of \$10.6 million in connection with the acquisition of our preclinical programs and the purchase of property and equipment of \$3.2 million, partially offset by \$12.8 million of cash proceeds received from AA Biopharma in connection with our acquisition.

There were no investing activities for the nine months ended September 30, 2017.

There were no investing activities for the years ended December 31, 2016 and 2017, respectively.

### *Financing activities*

During the nine months ended September 30, 2018, financing activities provided \$303.0 million of cash, primarily resulting from the net proceeds from issuance of our Series A and B convertible preferred stock of \$303.0 million.

There were no financing activities for the nine months ended September 30, 2017.

During the year ended December 31, 2017, financing activities provided \$6.0 million of cash, primarily resulting from the proceeds from issuance of a convertible promissory note.

During the year ended December 31, 2016, financing activities were nominal.

### *Funding requirements*

Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities, together with the estimated net proceeds from this offering, will be sufficient to fund our operations through at least the next 12 months from the date of this offering. 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;

## [Table of Contents](#)

- 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.

Until such time as we can generate substantial product revenues to support our cost structure, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, licenses and other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. Our failure to raise capital or enter into such other arrangements when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise additional capital when needed, we could be forced to delay, limit, reduce or terminate 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.

### Contractual Obligations and Commitments

The following table summarizes our contractual obligations at September 30, 2018:

	Payments Due By Period				More than 5 Years
	Total	Less than 1 Year	1 - 3 Years	3 - 5 Years	
Operating lease obligations <sup>(1)</sup>	\$15,854	\$ 341	\$ 5,905	\$ 6,260	\$ 3,348
Purchase obligations <sup>(2)</sup>	—	—	—	—	—
<b>Total contractual obligations</b>	<b>\$15,854</b>	<b>\$ 341</b>	<b>\$ 5,905</b>	<b>\$ 6,260</b>	<b>\$ 3,348</b>

(1) Operating leases include our continuing rent obligations through December 2024.

(2) At September 30, 2018, we had \$3.6 million of open purchase orders. All of our purchase orders may be cancelled without significant penalty.

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 September 30, 2018, we were unable to estimate the timing or likelihood of achieving the milestones or making future product sales and, therefore, any related payments are not included in the table above. For additional information regarding these license agreements, including our payment obligations thereunder, see “Business—License Agreements” and Note 6 to our consolidated financial statements included elsewhere in this prospectus.

## [Table of Contents](#)

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. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts and not included in the table above.

### **Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under the rules and regulations of the SEC.

### **Critical Accounting Policies and Significant Judgments 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. Our most critical accounting policies are summarized below. See Note 2 to our consolidated financial statements included elsewhere in this prospectus for a description of our other significant accounting policies.

#### ***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.



### ***Stock-based compensation***

We measure and recognize compensation expense for all options based on the estimated fair value of the award on the grant date. We use the Black-Scholes option-pricing model to estimate the fair value of option awards. The fair value is recognized as expense on a straight-line basis over the requisite service period. We account for forfeitures as they occur. We record expense for awards subject to performance-based milestone vesting over the remaining 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 determination of the grant date fair value of options using an option pricing model is affected principally by our estimated fair value of shares of our common stock and requires management to make a number of other assumptions, including the expected life of the option, the volatility of the underlying shares, the risk-free interest rate and expected dividends. The assumptions used in our Black-Scholes option-pricing model represent management's best estimates at the time of measurement. These estimates are complex, involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective. If any assumptions change, our stock-based compensation expense could be materially different in the future. See Note 9 to our consolidated financial statements included elsewhere in this prospectus for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted in the nine months ended September 30, 2018.

As of September 30, 2018, the unrecognized stock-based compensation expense related to employee stock options and unvested restricted stock was \$3.7 million and \$28.2 million, respectively, and is expected to be recognized as expense over a weighted-average period of approximately 4.0 years. The intrinsic value of all outstanding stock options as of September 30, 2018 was approximately \$27.5 million, based upon the assumed initial public offering price of \$16.00 per share, of which approximately \$0.5 million related to vested options and approximately \$27.0 million related to unvested options.

#### *Fair value of common stock*

We are required to estimate the fair value of the common stock underlying our stock-based awards when performing fair value calculations, which is the most subjective input into the Black-Scholes option pricing model. The fair value of the common stock underlying our stock-based awards was determined on each grant date by our board of directors, taking into account input from management and independent third-party valuation analyses. All options to purchase shares of our common stock are intended to be granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant. In the absence of a public trading market for our common stock, on each grant date we develop an estimate of the fair value of our common stock in order to determine an exercise price for the option grants. Our determinations of the fair value of our common stock were made using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants Audit and Accounting Practice Aid Series: *Valuation of Privately Held Company Equity Securities Issued as Compensation*, or the Practice Aid.

Our board of directors considered various objective and subjective factors, along with input from management, to determine the fair value of our common stock, including:

- valuations of our common stock performed by independent third-party valuation specialists;
- our stage of development and business strategy, including the status of research and development efforts of our product candidates, and the material risks related to our business and industry;

## Table of Contents

- our results of operations and financial position, including our levels of available capital resources;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- the lack of marketability of our common stock as a private company;
- the prices of our convertible preferred stock sold to investors in arm's length transactions and the rights, preferences, and privileges of our convertible preferred stock relative to those of our common stock;
- the likelihood of achieving a liquidity event for the holders of our common stock, such as an initial public offering or a sale of our company, given prevailing market conditions;
- trends and developments in our industry; and
- external market conditions affecting the life sciences and biotechnology industry sectors.

Our valuations were prepared in accordance with the guidelines in the Practice Aid, which prescribes several valuation approaches for setting the value of an enterprise, such as the cost, income and market approaches, and various methodologies for allocating the value of an enterprise to its common stock. The cost approach establishes the value of an enterprise based on the cost of reproducing or replacing the property less depreciation and functional or economic obsolescence, if present. The income approach establishes the value of an enterprise based on the present value of future cash flows that are reasonably reflective of our company's future operations, discounting to the present value with an appropriate risk adjusted discount rate or capitalization rate. The market approach is based on the assumption that the value of an asset is equal to the value of a substitute asset with the same characteristics. Each valuation methodology was considered in our valuations. In determining a fair value for our common stock, we estimated the enterprise value of our business using either the market approach or the back-solve method. The back-solve method assigns an implied enterprise value based on the most recent round of funding or investment and allows for the incorporation of the implied future benefits and risks of the investment decision assigned by an outside investor. In accordance with the Practice Aid, we considered the various methods for allocating the enterprise value across our classes and series of capital stock to determine the fair value of our common stock at each valuation date. We only granted restricted stock awards prior to January 2018. From January 2018 to July 2018, we concluded that a hybrid of the Option Pricing Method, or OPM, and the guideline transaction method with current value method allocation, or CVM, was the most appropriate for each of the valuations of our common stock performed by our independent third-party valuation specialist. Under the OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The values of the preferred and common stock are inferred by analyzing these options. Under the CVM, the enterprise value is calculated based on an assumed forced asset sale at a future date and the corresponding allocation of proceeds based on the rights and preferences of each class of equity. The valuations assigned a relative weighting to each of the OPM back-solve and asset sale scenarios, based on the likelihood that the Company would be able to successfully advance its development programs to the next development stage with its current capital resources. We believed this hybrid method was the most appropriate given the expectation of various potential liquidity outcomes and the difficulty of selecting appropriate enterprise values given our early stage of development, while allowing us to accurately capture the potential downside risk of our clinical-stage assets. In November 2018, we changed to a hybrid of the OPM and Probability-Weighted Expected Return Method, or PWERM. The PWERM is a scenario-based analysis that estimates the value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class. Under this hybrid method, we considered the expected initial public offering liquidity scenario, but also used the OPM to capture all other scenarios in the event a near-term initial public offering does not occur.

## [Table of Contents](#)

Following the completion of this offering, our board of directors will determine the fair value of our common stock based on its closing price as reported on the date of grant on the primary stock exchange on which our common stock is traded.

### ***Recent accounting pronouncements***

See Note 2 to our consolidated financial statements included elsewhere in this prospectus for a description of recent accounting pronouncements applicable to our consolidated financial statements.

### ***Qualitative and quantitative 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, particularly because our investments, including cash equivalents, are in the form of U.S. Treasury securities and a money market fund that is invested in U.S. Treasury securities.

We are also exposed to market risk related to changes in foreign currency exchange rates. We 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 September 30, 2018 and December 31, 2017, we had minimal or no liabilities denominated in foreign currencies.

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 year ended December 31, 2017 or nine months ended September 30, 2018.

### ***JOBS Act***

As an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of Sarbanes-Oxley.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the consummation of this offering, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.07 billion, (iii) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded \$700.0 million as of the last business day of the second fiscal quarter of such year, or (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

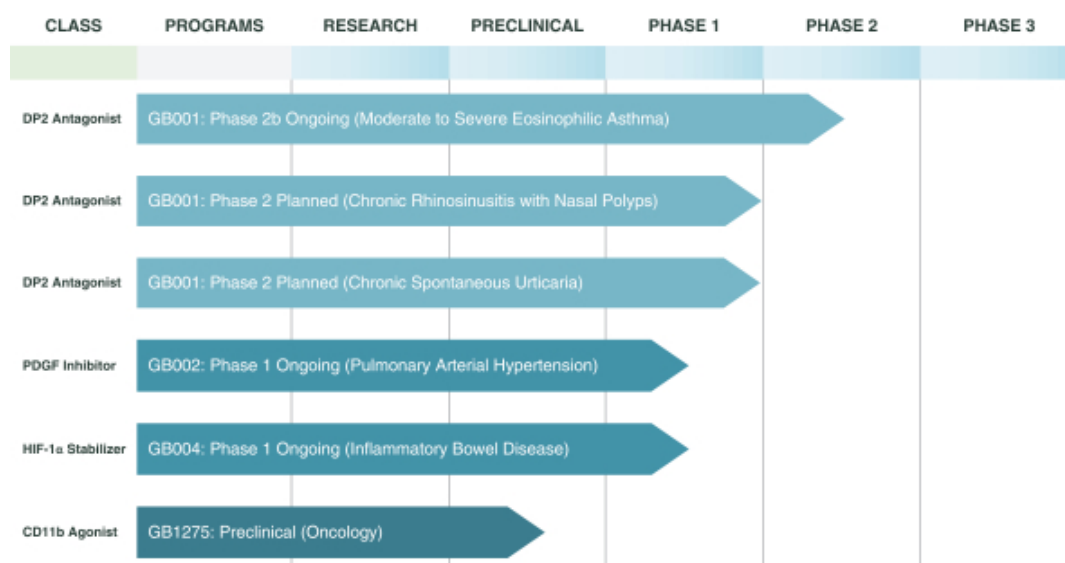
**BUSINESS**

**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 six programs: three clinical-stage product candidates and three preclinical programs. We commenced a Phase 2b clinical trial for our most advanced product candidate, GB001, in October 2018.

The following table summarizes our current programs:



**GB001 (DP2 Antagonist)**

GB001 is an oral antagonist of prostaglandin D<sub>2</sub> receptor 2, or DP2, in development for the treatment of moderate-to-severe eosinophilic asthma and other allergic conditions. Eosinophilic asthma is caused by high levels of white blood cells known as eosinophils and is associated with more severe symptoms, late-onset disease and resistance to steroid treatment. We estimate that approximately 50% of severe asthma patients in the United States have eosinophilic asthma. Despite the availability of new biologic therapies for these patients, asthma exacerbations remain a significant healthcare problem and unmet medical need. As of December 31, 2018, GB001 had been studied in 409 subjects in total and was generally well tolerated. In a Phase 2 clinical trial conducted in Japan, GB001 showed a statistically significant improvement in time-to-first asthma exacerbation compared to placebo. In a separate 248 subject Phase 2 clinical trial, neither treatment group, GB001 nor

montelukast, achieved the primary endpoint of improvement in forced expiratory volume in one second, or FEV<sub>1</sub>, as compared to placebo, which we believe was primarily related to study design and execution issues related to patient selection, including adherence to inhaled corticosteroid, or ICS, therapy eosinophilic phenotype thresholds and disease severity. A single serious adverse event, 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 levels approximately three to five times higher than the other patients receiving the 160 mg dose, and the dose was significantly higher than the highest dose of 60 mg currently being evaluated in our ongoing Phase 2b clinical trial. We commenced a Phase 2b clinical trial in moderate-to-severe eosinophilic asthma in October 2018.

Furthermore, we believe that there are a number of indications along the allergic spectrum for which GB001 may provide benefit. Accordingly, we plan to pursue the parallel development of GB001 in chronic rhinosinusitis with nasal polyps, or CRSwNP, and chronic spontaneous urticaria, or CSU. We expect to initiate proof-of-concept Phase 2 clinical trials for these indications in 2019. We retain worldwide rights to GB001, excluding Japan.

#### ***GB002 (PDGF Receptor Kinase Inhibitor)***

GB002 is an orally inhaled, small molecule, selective platelet-derived growth factor, or PDGF, receptor kinase inhibitor in development for the treatment of pulmonary arterial hypertension, or PAH, an orphan disease with high unmet medical need. PAH is characterized by abnormally high pressure in the blood vessels transporting blood from the right side of the heart to the lungs and is a progressive and often fatal disease. In contrast to the three classes of marketed vasodilatory therapies for PAH, GB002 has the potential to be the first treatment with disease-modifying effects. Modulation of the PDGF pathway has been shown to be therapeutically relevant in PAH. In 2013, Novartis Pharmaceutical Corporation, or Novartis, announced results from a Phase 3 clinical trial in PAH of imatinib (Gleevec), a tyrosine kinase inhibitor with known activity against PDGF and marketed for oncology indications. These results were notable for not only achievement of statistically significant improvement in the study's primary efficacy endpoint, but also for systemic toxicities. To our knowledge, no further development of the drug has occurred in PAH. To date, these toxicities have not been observed with GB002 in our ongoing Phase 1 studies in healthy volunteers. We plan to commence a Phase 1b clinical trial in PAH in the first half of 2019 and a Phase 2/3 clinical trial in PAH in the second half of 2019. We retain worldwide rights to GB002. The U.S. Food and Drug Administration, or FDA, has granted GB002 orphan drug designation for the treatment of patients with PAH.

#### ***GB004 (HIF-1a Stabilizer)***

GB004 is a novel, gut-targeted, oral small molecule in development 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-1a, or HIF-1a, through the inhibition of prolyl hydroxylase domain proteins, or PHDs, key enzymes involved in HIF degradation. Preclinical data from animal models of IBD demonstrated that HIF-1a 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 a Phase 1 single-ascending-dose, or SAD, study in healthy volunteers and are dosing healthy volunteers in a Phase 1 multiple-ascending-dose, or MAD, study. We plan to pursue clinical development in both UC and CD patients and, following submission of an Investigational New Drug, or IND, application with the FDA, initiate a Phase 1b clinical trial in UC in the first half of 2019. We also plan to initiate a Phase 2 clinical trial in UC in the first half of 2020. We retain worldwide rights to GB004.

#### ***Our Research Capabilities and Preclinical Programs***

We currently have three programs in preclinical development. GB1275 is an oral small molecule, CD11b agonist in preclinical development for the treatment of oncology indications for which we plan to submit

an IND application and, after acceptance, initiate a Phase 1 clinical trial in 2019. We are also currently evaluating a portfolio of novel BTK inhibitors for the treatment of autoimmune indications and small molecule cancer metabolism modulators for the treatment of solid tumors. 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.

## Our Team

Our founders and management team have held senior positions at leading biopharmaceutical companies, including Receptos, Inc., Genentech USA, Inc. (Roche), or Genentech, Bristol-Myers Squibb Company, GlaxoSmithKline LLC and Celgene Corporation, among others, and possess substantial experience and expertise across the spectrum of drug discovery, development and commercialization.

Sheila Gujrathi, M.D., our Co-Founder and President and Chief Executive Officer, was previously Chief Medical Officer of Receptos until its acquisition by Celgene in 2015, and has also served in senior leadership roles at Bristol-Myers Squibb and Genentech. Faheem Hasnain, our Co-Founder and Executive Chairman and former Chief Executive Officer, previously served as Chief Executive Officer at Receptos, and has over 30 years of senior leadership experience at both large and small biopharmaceutical companies. Jakob Dupont, M.D., our Chief Medical Officer, has experience across the spectrum of clinical development, having most recently served as Vice President and Global Head of Breast and Gynecologic Cancer Development at Genentech. 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.

The development and operational expertise of our executive and senior scientific team will be essential as we execute on our strategy of building a large, diversified biopharmaceutical company to deliver significant value to both patients and shareholders.

## 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 six 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 believe GB001 has the potential to be effective in a variety of allergic and inflammatory diseases beyond moderate-to-severe eosinophilic asthma, and we expect to initiate proof-of-concept Phase 2 clinical trials in CRSwNP and CSU in 2019. We also plan to develop GB004 in both UC and CD.
- **Expediently 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**

### ***GB001 (DP2 Antagonist)***

GB001 is an oral DP2 antagonist in development for the treatment of moderate-to-severe eosinophilic asthma and other allergic conditions. As of December 31, 2018, GB001 had been studied in 409 subjects in total and was generally well tolerated. In a Phase 2 clinical trial conducted in Japan, GB001 showed a statistically significant improvement in time-to-first asthma exacerbation compared to placebo. We commenced a Phase 2b clinical trial in moderate-to-severe eosinophilic asthma in October 2018 and expect to conduct an interim analysis in the first half of 2020. If the interim analysis is positive, we plan on initiating a Phase 3 clinical trial thereafter. We have held a Type C meeting with the FDA to inform our Phase 2b and Phase 3 clinical trial design and endpoints. In addition, we plan to pursue the parallel development of GB001 in CRSwNP and CSU by initiating proof-of-concept Phase 2 clinical trials for these indications in 2019. We retain worldwide rights to GB001, excluding Japan.

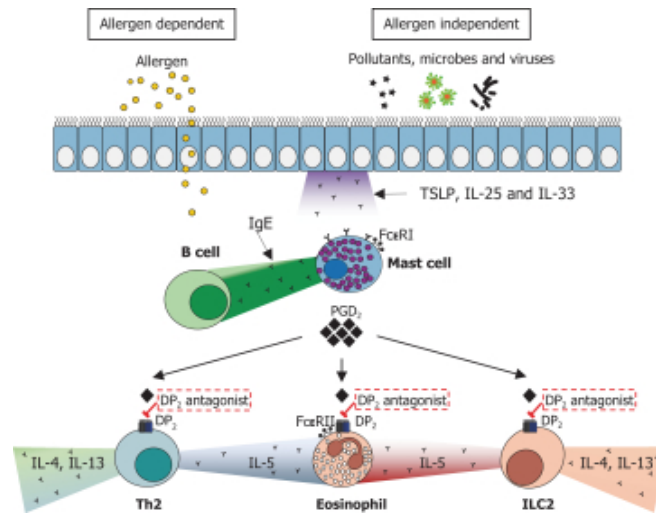
### **Mechanism of Action**

DP2, also known as CRTh2, is a receptor for prostaglandin D<sub>2</sub>, or PGD<sub>2</sub>, a lipid mediator produced mainly by mast cells. DP2 is primarily responsible for mediating the pro-inflammatory effects of PGD<sub>2</sub>, as depicted below in Figure 1, including:

- the activation of T helper 2, or Th2, cells, mast 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.

**Figure 1. Mechanism of DP2 in Allergic Airway 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 CRSwNP, CSU, eosinophilic esophagitis and atopic dermatitis.

DP2 antagonism has been clinically validated by Novartis' oral DP2 antagonist, fevipiprant, in a Phase 2 clinical trial. In this trial, both the 150 mg once-daily and 75 mg twice-daily doses demonstrated statistically significant improvements in FEV<sub>1</sub> compared to placebo in adult patients with asthma inadequately controlled with ICS. In addition, post hoc analyses of Phase 2 safety data related to asthma worsening, including exacerbations, appeared to demonstrate a reduction in the number of subjects experiencing an asthma event on fevipiprant compared to placebo. As of December 31, 2018, fevipiprant, at 150 mg once-daily and 450 mg once-daily doses, is being investigated by Novartis in six Phase 3 clinical trials in asthma patients.

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 K<sub>i</sub>, of 1 to 2 nanomolar, significantly greater than its affinity for the other PGD<sub>2</sub> receptors. No significant activity was demonstrated in a standard selectivity panel of 90 other receptors and enzymes. GB001 has also shown a slow rate of disassociation from DP2, with a receptor residence time of 19.8 minutes, as measured by half-life. Additionally, in an *in vitro* assay, GB001 inhibited PGD<sub>2</sub> induced internalization of DP2. 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 resistance to steroid treatment.

*Overview of the Asthma Market*

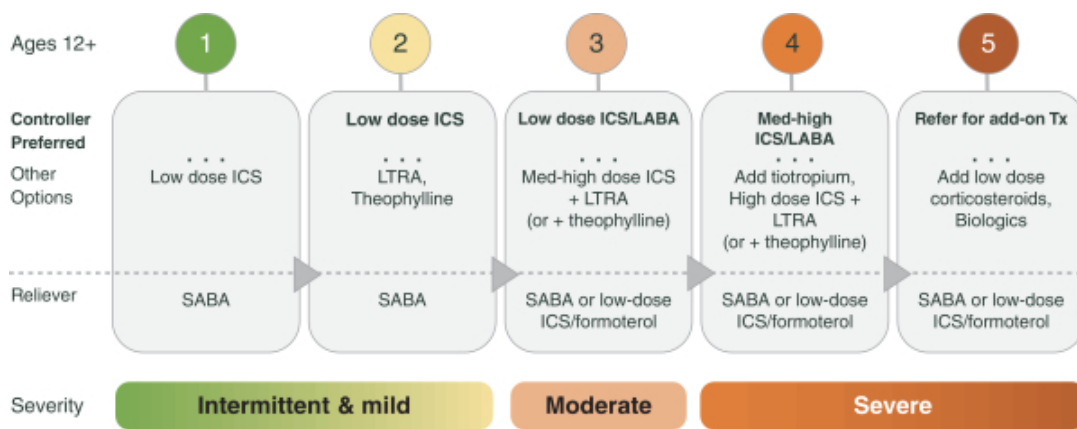
Asthma is a substantial, widespread condition afflicting more than 330 million patients worldwide and about 25 million patients in the United States. Approximately 25% and 12% of patients in the United States have moderate and severe disease, respectively, according to Datamonitor. The disease is responsible for more than \$50 billion in annual direct healthcare costs in the United States and results in an estimated 420,000 and 3,500 deaths per year worldwide and in the United States, respectively.

Total asthma drug sales in the U.S. market were approximately \$7.9 billion in 2017 and are projected to reach \$13.9 billion by 2026, according to Datamonitor. Nearly \$5.6 billion of the estimated \$13.9 billion in sales is attributable to biologic therapies. In the future, we believe asthma market growth may be driven by increasing disease diagnosis and new biologic and small molecule agents entering the market.

*Treatment Paradigm in Asthma*

The treatment guidelines for asthma, depicted below for adolescents and adults in Figure 2, is a step-up paradigm.

**Figure 2. Treatment Guidelines for Asthma**



LABA = long-acting beta agonist; LTRA = leukotriene receptor antagonist; SABA = short-acting beta agonist

The goals of the step-up treatment paradigm are to achieve long-term control of asthma symptoms, minimize the use of SABAs and maintain near-normal lung function and activity levels. Reduction in asthma exacerbations is the primary endpoint predominantly used in new product development in asthma, while surrogate endpoints for improvements in lung function are commonly used as supportive secondary endpoints. Biologics, including the recently approved IL-5 and IL-4/IL-13 antibodies, are typically used only in the most refractory, severe patients. We believe this is because of their route of administration through either subcutaneous (omalizumab, mepolizumab, benralizumab and dupilumab) or intravenous (reslizumab) injection, high cost and concerns about potential adverse events.

While the recent introduction of biologic agents has altered the course of treatment for refractory, severe patients, the last major change in the treatment paradigm for mild or moderate asthma came with the 1998 FDA approval of Singulair (montelukast), an LTRA, which became the top controller therapy for asthma. Worldwide

sales for Singulair peaked at approximately \$5.5 billion in 2011, prior to the entry of generic competition. Singulair's profile as an effective oral drug with a well-understood safety profile made it an attractive option for patients across the severity spectrum despite inferior efficacy, as measured by asthma exacerbations rate reduction, compared to that of the biologic agents. The success of Singulair highlights the unmet need and opportunity in the asthma market for safe and effective, orally-administered therapies.

#### *GB001 Product Differentiation*

We believe there is a significant market opportunity for improved and effective oral therapies in moderate-to-severe asthma with consistent safety and tolerability profiles that can be used prior to biologics. Published Phase 2 clinical trial results for fevipiprant appear to be comparable to the anti-inflammatory effects demonstrated by certain biologics in clinical studies. We believe oral options are generally preferred to biologics due to their route of administration, which leads to improved patient adherence. Furthermore, oral administration is especially important as children and adolescents are frequent sufferers of asthma. We believe GB001 as an oral agent has the potential to reduce asthma exacerbations and improve lung function, and thereby could be positioned as a pre-biologic treatment alternative.

#### *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 rights outside of Japan to all of the data from the two Phase 2 clinical trials conducted by Pulmagen and Teijin described below. As of December 31, 2018, 409 subjects have received at least one dose of 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 FEV<sub>1</sub> 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 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 treatment emergent adverse event, or TEAE, rate 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 FEV<sub>1</sub> 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.

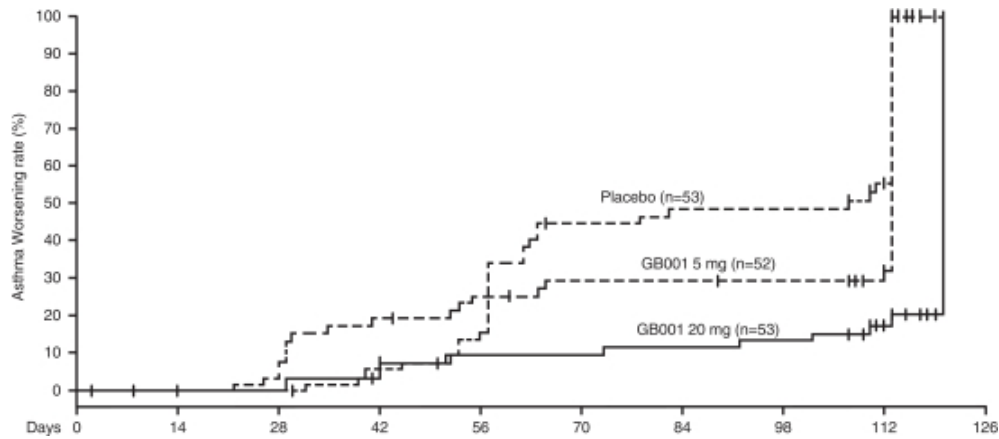
##### *Summary of Completed Teijin Phase 2 Clinical Trial*

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 eosinophilic 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.

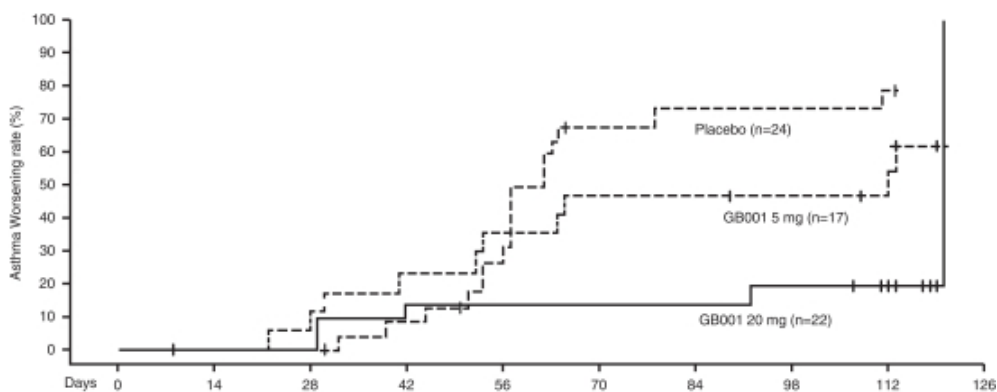
A total of 91 patients completed the trial, with the dropout rate higher in the placebo arm (62%), as compared to the GB001 arms (40%, 5 mg; 25%, 20 mg). A statistically significant difference was seen in the AM PEF between placebo and both arms of GB001 ( $p = 0.015$ , 5 mg;  $p = 0.027$ , 20 mg). The 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 statistically significant. The FDA's evidentiary standard of efficacy generally relies on a p-value of less than or equal to 0.05. In addition, time-to-first asthma worsening, a key secondary endpoint, 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 asthma exacerbations. Figure 3 below presents the improvement in time-to-first asthma worsening of patients as measured by the asthma worsening rate.

**Figure 3. Improvement in Time-To-First Asthma Worsening of Patients with Mild to Moderate Eosinophilic Asthma**



The dose response in the time-to-first exacerbation was even more pronounced in the subgroup of patients with high blood eosinophils, defined as those with greater than 300 cells per microliter ( $\mu\text{L}$ ), as shown below in Figure 4.

**Figure 4. Pronounced Improvement in Time-To-First Asthma Worsening of Patients with High Blood Eosinophils**



Subgroup analyses demonstrated patients with high blood eosinophils at baseline treated with the 20 mg dose of GB001 also had statistically significant improvement in FEV<sub>1</sub> compared with placebo ( $p = 0.016$ ). GB001 was well tolerated in this trial, with an adverse event profile consistent with placebo, including nasopharyngitis, gastrointestinal disorders and measures of blood and liver markers. No serious adverse events, or SAEs, were observed in the GB001 treatment arms.

These results showed a clear, dose-dependent response to treatment with GB001, both in measures of lung function and asthma exacerbation reduction.

*Summary of Pulmagen and Teijin Phase 1 Clinical Trials*

In Phase 1 studies conducted by Pulmagen and Teijin, GB001 demonstrated safety and pharmacodynamic, or PD, parameters consistent with the DP2 drug class.

Most 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 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.

*Ongoing Phase 2b Eosinophilic Asthma Clinical Trial*

We commenced a Phase 2b clinical trial of GB001 in moderate-to-severe eosinophilic asthma in October 2018, and we expect to conduct an interim analysis of the results of this trial in the first half of 2020. We have designed this trial to efficiently assess proof-of-principle and help enable rapid transition to Phase 3 clinical trials, and we have held a Type C meeting with the FDA to inform our trial design and endpoints. We plan on enrolling 480 patients in the study in a 1:1:1:1 randomized to three GB001 dose arms of 20 mg, 40 mg and 60 mg per day and one placebo arm with once-daily dosing.

We believe that we have designed our trial in a manner to address the potential shortcomings of the Pulmagen Phase 2 clinical trial, in that:

- the study population will consist of more severe patients than those enrolled in the Pulmagen Phase 2 clinical trial;

## [Table of Contents](#)

- enrollment inclusion criteria will be based on a history of asthma exacerbations within the last year;
- enrolled patients will be required to have moderate-to-severe asthma with eosinophil counts greater than or equal to 250 cells/ $\mu$ L; and
- enrolled patients will be closely monitored during the run-in period to help ensure that the lack of adherence to background therapy is not a contributing factor for their poorly controlled asthma.

The primary endpoint is reduction in asthma worsening from baseline, assessed at week 24, with an additional four weeks of follow-up. The parameters included in the asthma worsening composite primary endpoint include changes in FEV<sub>1</sub>, AM PEF, rescue medication use and asthma control and severe asthma exacerbations. We will also assess FEV<sub>1</sub> independently as a secondary efficacy measure.

We plan to conduct an interim analysis after approximately 320 patients complete the 24-week treatment period, and we expect the results of this interim analysis to be available in the first half of 2020. If the results obtained in the interim analysis support further development, we plan on initiating our first Phase 3 clinical trial thereafter. We expect to report full data from the Phase 2b clinical trial in the second half of 2020. If the full data support further development, we will initiate a second Phase 3 clinical trial.

### *Clinical Development Plan in Additional Indications*

Because DP2 plays a central role in the activation of Th2 cells, we believe GB001 could be effective in the treatment of other Th2-associated allergic and inflammatory disorders, such as CRSwNP, CSU, eosinophilic esophagitis and atopic dermatitis. Based on unmet medical need and a review of the mechanistic rationale and market opportunities, we have decided to initially pursue further development in CRSwNP and CSU in parallel with our eosinophilic asthma program.

#### *Chronic Rhinosinusitis with Nasal Polyps*

CRS is a debilitating disorder marked by persistent symptoms including congestion, stuffiness, nasal discharge, pain or facial pressure, impairment or loss of the sense of smell (anosmia), cough and fatigue. Mast cells and eosinophils are involved in allergic forms of chronic nasal inflammation, including CRS. Nasal polyps are a type 2 cytokine driven inflammatory process, and in Caucasians, eosinophils are the predominant inflammatory cell. Approximately 80% of patients in Western countries with CRSwNP have eosinophilic upper airway inflammation.

CRS is associated with an increased risk for late-onset asthma, suggesting significant overlap in the underlying pathology of the diseases. PGD<sub>2</sub> has been correlated with the recruitment and activation of Th2 cells in nasal polyps, and type 2 cytokines, such as IL-4, IL-5 and IL-13, have been shown to play a pivotal role in nasal polyp formation. Among others, clinical studies of anti-IL-5 and anti-IL-4 receptor antibodies and an anti-immunoglobulin E, or anti-IgE, antibody are currently being studied in CRSwNP by other biopharmaceutical companies.

According to a 2014 study, annual direct costs related to CRS were estimated to be \$6.9 to \$9.9 billion worldwide. The prevalence of CRS is estimated to be 4% of the U.S. population, or approximately 13 million individuals. CRSwNP patients represent 25 to 30% of total CRS patients. CRSwNP patients are initially treated with intranasal corticosteroids. When patients fail intranasal corticosteroids, oral corticosteroids typically serve as the next line of therapy, although this treatment provides only two to four weeks of benefit while causing systemic side effects such as reduced glucose tolerance, osteoporosis and weight gain. Failure to control symptoms with corticosteroids presents the need for potential surgical intervention. A long-term study of post-surgical patients showed that nearly 80% of patients had polyps recur at least once, and 36% of patients required an additional surgery. We believe a significant number of patients in the United States are inadequately controlled with standard-of-care steroid treatment.

We plan to commence a Phase 2 proof-of-concept trial in adult patients with CRSwNP in 2019 and expect data to read out in 2020.

#### *Chronic Spontaneous Urticaria*

Chronic urticaria, or CU, is characterized by the recurring eruption of transient, itchy, red welts on the skin. Patients with CU are often severely impaired in their quality of life, including negative effects on sleep, daily activities, school/work life and social interactions. Urticaria symptoms are caused by degranulation of dermal mast cells, and an allergic-mediated response is believed to contribute to mast cell activation in many cases. One of the most common forms of CU is CSU, previously known as the idiopathic form, or chronic idiopathic urticaria. In CSU patients, an underlying trigger for the skin lesions cannot be identified, thus making it impractical to employ a therapeutic strategy that relies on avoidance of causative environmental exposures. A published estimate of the U.S. prevalence of CSU ranged from 0.5% to 1.0% of the population, and approximately 20% of patients, or approximately 300,000 to 600,000 patients, have symptoms for more than five years.

The current treatment guidelines for the management of all forms of urticaria recommend the use of non-sedating oral H1-antihistamines as first-line therapy. For patients that do not respond to standard doses of H1-antihistamines, doses are increased by as much as four times. Though this can increase the response rates, side effects may also increase. Patients that do not respond to or are unable to tolerate high dose antihistamines have few remaining options. For antihistamine refractory patients with CSU, the only currently approved treatment is the biologic agent, omalizumab.

We plan to commence a Phase 2 proof-of-concept trial in adult patients with CSU in 2019 and expect data to read out in 2020.

#### ***GB002 (PDGF Receptor Kinase Inhibitor)***

GB002 is an orally inhaled, small molecule, PDGF receptor kinase inhibitor in development for the treatment of PAH. In contrast to the three classes of marketed vasodilatory therapies for PAH, GB002 has the potential to be the first treatment with disease-modifying effects. Inhaled GB002, which is designed to act on both isoforms of the PDGF receptor, a and b, has inhibited and reversed cell overgrowth in lung blood vessels in PAH animal 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 marketed for oncology indications, showed statistically significant improvement in its primary efficacy endpoint, thus providing mechanistic validation, but systemic toxicities were also observed. To date, these toxicities have not been observed with GB002 in our ongoing Phase 1 studies in healthy volunteers. We have received FDA feedback through Type C meeting interactions to inform our Phase 2/3 clinical trial design and endpoints. We plan to commence a Phase 1b clinical trial in PAH in the first half of 2019 and a Phase 2/3 clinical trial in PAH in the second half of 2019. We in-licensed GB002 from Pulmokine, Inc. in 2017 and retain worldwide rights. The FDA has granted GB002 orphan drug designation for the treatment of patients with PAH.

#### *Mechanism of Action*

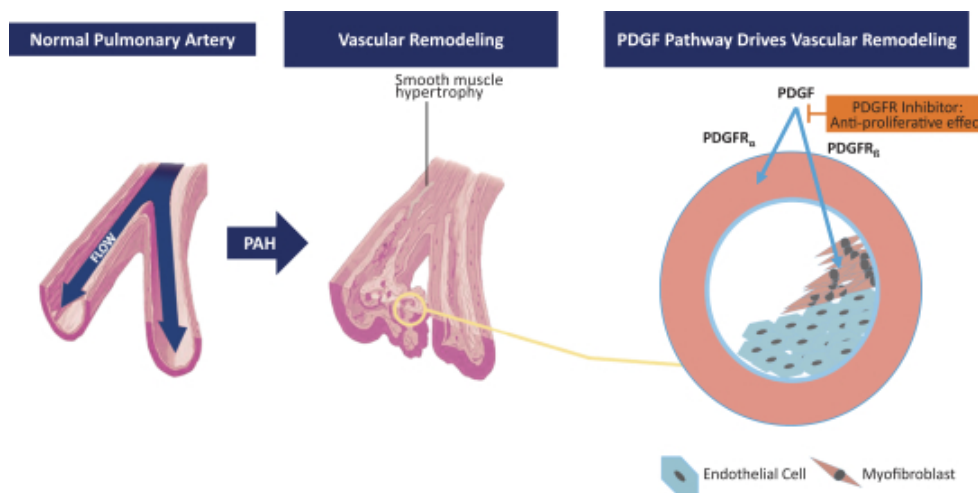
PAH is driven by abnormal cellular proliferation within and around the small blood vessels of the lung that carry blood from the right side of the heart to the lungs. Functional and structural changes in the pulmonary vasculature, known as vascular remodeling, can lead to smooth muscle cell proliferation 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.

The PDGF receptor 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. Further supporting this mechanism, PDGF receptors 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 GB002 is designed to act on both isoforms of the PDGF receptor, a and b. 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. PDGF receptor a is highly expressed in pulmonary arteriole vascular smooth muscle cells, or PAVSMCs. Inhibiting PDGF receptor a may help reduce the abnormal cell proliferation of PAVSMCs that results in blood vessel thickening. PDGF receptor b 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 PDGF receptor b is therefore important in decreasing the abnormal cell proliferation of these cell types.

Figure 5 below shows the key role of the PDGF pathway in pulmonary vascular remodeling and the disease pathogenesis of PAH.

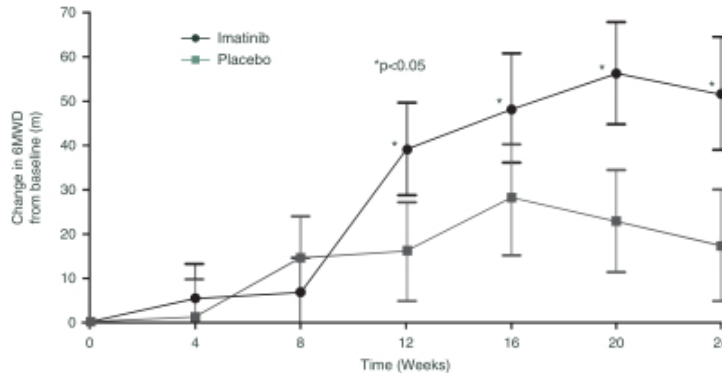
**Figure 5. PDGF Pathway in Pulmonary Vascular Remodeling**



Mechanistic validation of a PDGF receptor kinase inhibitor has been observed in studies of imatinib (Gleevec), an oral tyrosine kinase inhibitor with known activity against the PDGF receptor kinase, that demonstrated proof-of-concept in humans in a Phase 3 clinical trial in PAH.

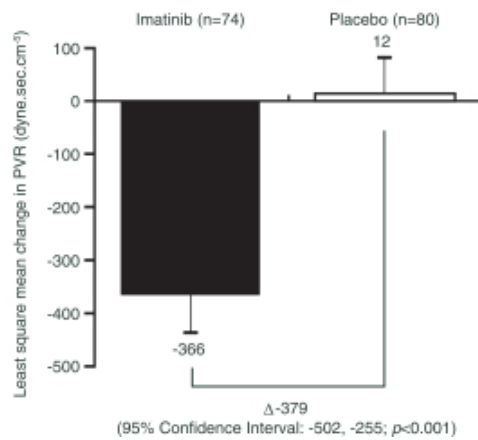
The IMPRES trial was a Phase 3 clinical trial conducted by Novartis of imatinib (Gleevec) in PAH. Gleevec is currently approved in certain oncology indications. Imatinib has known activity against multiple tyrosine kinases, including the PDGF and c-KIT receptors and c-ABL. 202 patients were enrolled in the IMPRES trial, of which 41% had been treated with prostanoids, oral phosphodiesterase type 5, or PDE5, inhibitors and oral endothelin receptor agonists, or ERAs. As shown in Figure 6 below, the study met its primary endpoint, improvement in six-minute walk distance, or 6MWD, versus placebo at week 24 from baseline, with statistical significance ( $p = 0.002$ ).

**Figure 6. Improvement in Six-Minute Walk Distance of PAH Patients Treated with Imatinib**



As shown in Figure 7 below, 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.

**Figure 7. Improvement in Pulmonary Vascular Resistance of PAH Patients Treated with Imatinib**



However, systemic adverse events such as bleeding and poor tolerability 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 an orphan 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**

<b>Functional Class</b>	<b>Description</b>
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, NTproBNP, 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, 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 2016 were estimated at approximately \$5.6 billion and are expected to exceed \$6.0 billion by 2019.

#### *Treatment Paradigm in PAH*

Current 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, 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 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.

### *GB002 Product Differentiation*

GB002 is an orally inhaled PDGF receptor kinase inhibitor designed to build on the evidence of efficacy seen in trials of imatinib while overcoming imatinib's observed systemic safety issues. GB002 was designed with a higher degree of selectivity as compared to imatinib. GB002 has increased potency against the PDGF receptor-b isoform, similar potency against the PDGF-a isoform, and less activity against c-ABL. We believe GB002 has the potential to be a differentiated PDGF-targeted therapeutic that is designed to potentially provide:

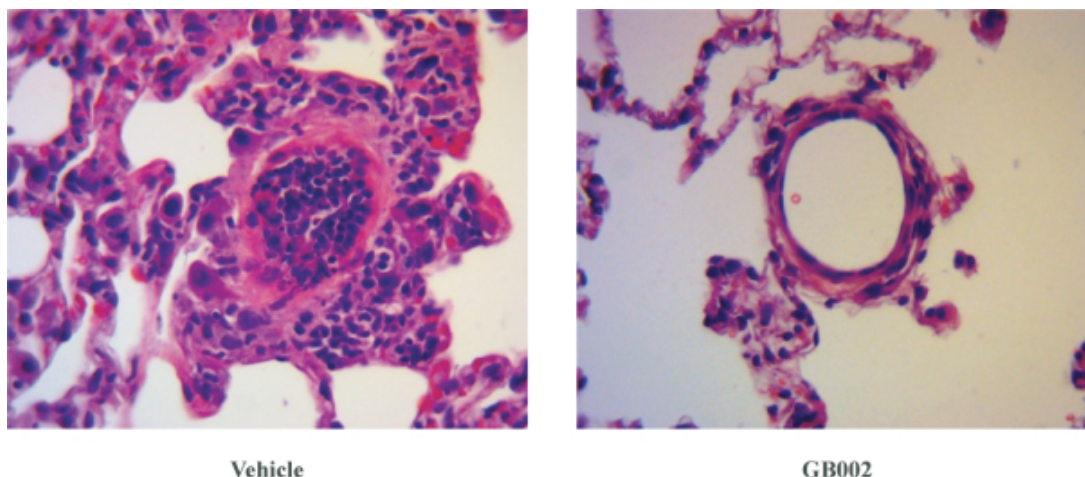
- an improved response to PDGF-driven abnormal cell proliferation in pulmonary arteries by addressing the underlying mechanism that leads to arterial wall thickening, rather than resultant vasodilation;
- a more tolerable safety profile than imatinib due to the direct delivery to the lungs, as supported by the absence adverse bleeding observed to date in toxicology programs or Phase 1 studies; and
- a convenient, simple and portable inhalation methodology and delivery system.

### *Clinical Development History of GB002*

#### *Summary of Preclinical Program*

GB002 inhibits both PDGF a and b, and inhibited and reversed cell overgrowth in lung blood vessels in PAH in a rat model, as shown below in Figure 8. This rat model replicates many features of human PAH, including the abnormal cell proliferation that can block the small vessels of the lung. GB002 substantially reduced the occlusive lesions in the small lung blood vessels in this model. Additionally, in this model, GB002 demonstrated a statistically significant reduction in right ventricular systolic pressure as compared to placebo.

**Figure 8. Reversed Vascular Remodeling by GB002 Through Inhibition of PDGF**



#### *Summary of Ongoing Phase 1 Study*

We are currently conducting Phase 1a SAD and MAD double-blind, placebo-controlled, randomized studies of orally inhaled GB002 in healthy adult volunteers. In the SAD portion of the study, we have completed five dosing cohorts, each consisting of six volunteers on active drug and two on placebo. We have assessed pharmacokinetics, or PK, parameters and safety. No treatment-related safety issues have been reported during the

study to date. We have completed dosing for the three cohorts in the MAD portion of the study, in which healthy volunteers receive doses of GB002 or placebo for seven days. As of December 31, 2018, no treatment-related safety issues have arisen during the study.

#### *Summary of Planned Phase 1b Clinical Trial*

We expect to commence a Phase 1b ascending dose, single-blind, placebo-controlled, randomized trial of GB002 in functional class II and III PAH patients in the first half of 2019. We plan to enroll two to three cohorts of approximately eight patients each and follow patients for two weeks of dosing. The primary goal of the trial is to assess safety, and we also intend to assess certain PK/PD measurements in patients. We anticipate reporting data from our Phase 1b clinical trial in PAH in the first half of 2020.

#### *Planned Phase 2/3 PAH Clinical Trial*

We plan to commence a randomized, double-blind, placebo-controlled Phase 2/3 clinical trial in functional class III and IV PAH patients in the second half of 2019. We have received FDA feedback through Type C meeting interactions to inform our Phase 2/3 clinical trial design and endpoints. Our planned primary endpoint is the change from baseline in pulmonary vascular resistance at week 24. Key planned secondary endpoints include change from baseline to week 24 in 6MWD and NTproBNP. If we meet the primary endpoint and observe a favorable trend in the key secondary endpoints with a tolerable safety profile, we plan to discuss the possibility of expedited pathways for review and approval with the FDA. We anticipate reporting topline data from our Phase 2/3 clinical trial in PAH in the second half of 2021.

#### **GB004 (HIF-1a Stabilizer)**

GB004 is a novel, gut-targeted, oral small molecule being developed for the treatment of IBD including UC and CD. GB004 stabilizes HIF through the inhibition of HIF PHDs, key enzymes involved in HIF degradation. Preclinical data from animal models of IBD demonstrated that HIF-1a 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 a Phase 1 SAD study in healthy volunteers and are currently dosing healthy volunteers in a Phase 1 MAD study. We plan to pursue clinical development in both UC and CD patients and, following an IND submission with the FDA, initiate a Phase 1b clinical trial in UC in the first half of 2019. We also plan to initiate a Phase 2 clinical trial in UC in the first half of 2020. We in-licensed GB004 from Aerpio Pharmaceuticals, Inc., or Aerpio, in June 2018 and retain worldwide rights.

#### *Mechanism of Action*

HIFs have an important role in protecting cells from low oxygen levels. PHDs are enzymes that hydroxylate HIFs when oxygen levels are normal. At low oxygen levels, the activity of PHDs are inhibited, and HIFs are stabilized. Stabilized HIFs subsequently activate the expression of genes that protect cells and promote the healing of tissue that has been injured. Pharmacological inhibition of PHDs can replicate the effects of low oxygen levels on HIF stabilization.

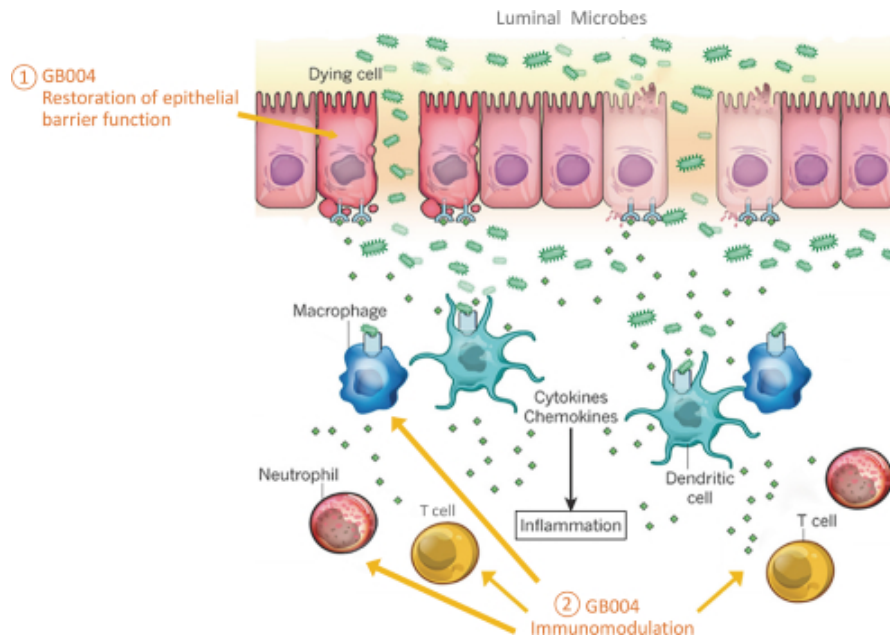
IBD represents a state of chronic tissue injury. In IBD animal models, stabilizing HIF through the inhibition of PHD promoted the restoration of intestinal epithelial barrier function and reduction of inflammation. GB004 is a PHD inhibitor designed to be gut-targeted with higher intestinal exposure than systemic exposure. GB004 has also demonstrated greater accumulation of HIF-1a than HIF-2a in IBD animal models. Systemically active PHD inhibitors, which stabilize HIF-2a thereby increasing systemic erythropoietin, or EPO, production by the liver and kidney, are under development for the treatment of anemia in chronic kidney disease. By contrast, the use of orally administered GB004, which stabilized HIF-1a in an IBD animal model, did not result in higher red blood cell counts or a clinically significant increase in plasma EPO levels. We believe this is likely a consequence of both the limited systemic exposure of oral GB004 and its predominately selective inhibition of PHDs that stabilize HIF-1a.

*Gut-targeting*

In animal models of IBD, the reduction in inflammation was similar between oral and intravenously- administered GB004. Oral administration resulted in lower systemic exposure and greater accumulation of HIF-1a than HIF-2a without an increase in EPO, blood count or HIF-mediated effects outside of the gastrointestinal, or GI, tract, including in the heart, kidney, and liver. Other data in non-diseased animals have also shown that orally delivered GB004 preferentially concentrated in the GI tract at a rate many times higher than in other organs, such as the heart, kidney or liver.

Figure 9 below depicts the proposed mechanism of action of GB004.

**Figure 9. Mechanism of PHD Inhibitor to Restore Epithelial Barrier Function**



GB004's potential beneficial effects in IBD can be broken into two categories: restoration of epithelial barrier function and immunomodulation.

*Restoration of Epithelial Barrier Function*

HIF-1a expression leads to increases in genes known to promote epithelial integrity and mucosal barrier function. GB004 stabilizes HIF-1a, promoting healing of the intestinal epithelial barrier. The treatment of 2,4,6-trinitrobenzenesulfonic acid (TNBS) colitis mouse models with 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. While current therapies target the inflammatory response in IBD, GB004 represents a novel mechanism designed to directly enhance the repair of the epithelial barrier. We believe that repairing damage to epithelium and the associated reduction of inflammation would lead to a significant improvement in the symptoms experienced by IBD patients.

*Immunomodulation*

HIF-1a is an important modulator of the innate and adaptive immune response. HIF-1a increases antimicrobial peptides, factors that protect the host from infection. In addition, HIF-1a may be critical for

regulatory immune cell function and these cells are important cells for reducing inflammation in IBD. Taken together, HIF-1a mediated effects on innate and adaptive immune responses in the gut contribute to resolution of inflammation and complement the epithelial barrier protective effects of HIF-1a stabilization.

#### *Overview of IBD*

IBD refers to two conditions, UC and CD, that are characterized by chronic inflammation of the GI tract.

##### *Ulcerative Colitis*

UC is a chronic GI inflammatory disorder that involves the mucosal lining of the colon. Patients with UC suffer from a multitude of GI symptoms, such as diarrhea, rectal bleeding and weight loss. UC is characterized by a chronic course of remissions and exacerbations. Within 10 years of diagnosis, it is estimated that 20% of adults with UC will have undergone colectomy.

##### *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 U.S. market for IBD biologics reached an estimated \$7 billion in 2016 and is projected to grow to over \$10 billion by 2025, according to Datamonitor. The current biologic market is dominated by the anti-TNF inhibitors Humira, marketed by AbbVie Inc., and Remicade, marketed by Janssen Pharmaceuticals, Inc., or Janssen, and the growing share of the anti-integrin 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 which 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. Additionally, approximately 38% of patients who initially respond to corticosteroids either become steroid-dependent or require surgery within a year of initiating corticosteroids for UC.

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 moderately to severely active inflammation is dominated by anti-TNF biologics given their better efficacy and side effect profile than immunomodulators. This paradigm is shifting because of the approval of agents in other classes,

## [Table of Contents](#)

such as an anti-integrin, an anti-IL-12 / IL-23 and a JAK inhibitor. 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.

Furthermore, current treatments and those in development focus on immunosuppression, interference in immune cell migration and inflammatory pathways.

### *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-1a than HIF-2a which may lead to restoration of epithelial barrier function and resolution of inflammation, while avoiding the potential adverse effects of increased EPO.

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 inflammation and potentially restoring intestinal epithelial barrier function and restitution through GB004's gut-targeted nature and preferential stabilization of HIF-1a, 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 Plan in IBD and Other Indications*

#### *Summary of Ongoing Phase 1 SAD and MAD Trial*

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 the single-dose PK profiles after escalating GB004 doses. 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. All GB004 doses evaluated in this study were determined to be safe and well tolerated. No deaths or SAEs occurred. There were no significant differences in systemic levels of vascular endothelial growth factor, or VEGF, and EPO between GB004 and placebo patients.

We are currently evaluating GB004 in a randomized, double-blind, placebo-controlled, MAD study to assess the safety, tolerability, PK and PD effects in healthy male and female volunteers. A total of 40 subjects are planned to be randomized into five cohorts with eight subjects each. Dose levels to be evaluated in the five cohorts are 60 mg and 120 mg per day in male volunteers, 240 mg per day in four male volunteers and four female volunteers, 120 mg per day in female volunteers and, if required, 60 mg per day in female volunteers. Volunteers unable to complete seven days of dosing may be replaced.

#### *Summary of Planned Phase 1b Clinical Trial in UC*

We plan to submit an IND for GB004 in IBD and, after acceptance, initiate a Phase 1b trial of GB004 in approximately 30 symptomatic adult UC patients in the first half of 2019. Dose selection for this trial will be informed by the results of the MAD study. The goals of the study are to assess safety, tolerability, PK/PD and target engagement of GB004 in patients with UC. We expect to report topline data from this trial in the first half of 2020. We expect to initiate a Phase 2 clinical trial in UC in the first half of 2020 and anticipate reporting topline data from the trial by the first half of 2022.

### ***Our Research Capabilities and Preclinical Programs***

We currently have three programs in preclinical development and expect to file an IND application with the FDA for one of these programs, GB1275, in 2019. We are continuing to build our research capabilities,

## [Table of Contents](#)

specifically focusing on our areas of expertise within immunology, inflammation and oncology, in order to advance new programs into the clinic, as well as optimize our existing programs.

### *GB1275 (CD11b Agonist)*

GB1275 is an oral small molecule, CD11b agonist in preclinical 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 immune system cells including tumor-associated macrophages, or TAMs, and myeloid derived suppressor cells, or MDSCs, which play a significant role in tumor growth, immune evasion and metastases. CD11b is also upregulated in many tumor types, and the presence of CD11b+ cells is associated with poor prognosis in multiple cancer types. We acquired GB1275 through our acquisition of Adhaere Pharmaceuticals, Inc. in September 2018 for an upfront payment of \$7.5 million in cash, up to \$62.0 million in regulatory, development and sales milestones and tiered royalties on worldwide net sales at percentages ranging from low to mid-single digits, subject to customary reductions.

Innate immune cells modulate the tumor microenvironment, or TME, and fuel cancer cell growth and survival. We believe that validation for targeting the immunosuppressive TME in pancreatic cancer has been supported by evidence of durable clinical benefit in trials with an anti- colony-stimulating factor 1 receptor, or anti-CSF1R, antibody plus nivolumab, an agent approved for oncology indications, as well as C-C chemokine receptor type 2, or CCR2, inhibition in combination with chemotherapy. Our novel approach to integrin modulation, using small molecule CD11b agonists, targets innate immune cells, which enhances immune-mediated tumor killing. Preclinical data for GB1275 suggest our approach to integrin modulation transiently increases the myeloid cell adhesion to the blood vessel wall and reduces influx of TAMs and MDSCs in tumors, thereby increasing density of CD8+ T-cells in the TME and decreasing tumor growth.

Preclinical studies have demonstrated reduced tumor burden and improved survival with GB1275 as a single agent and in combination with chemotherapy and immuno-oncology therapies across multiple tumor models, including pancreatic, breast and colon cancers in mice. Preclinical data also suggest differentiation from other approaches targeting immunosuppressive mechanisms, including anti-CSF1R antibodies and CCR2 inhibition, and we therefore plan to advance GB1275 in development for the treatment of immuno-oncology resistant tumors, such as pancreatic and triple negative breast cancer.

Preclinical studies and profile characterization of GB1275 support daily oral dosing with no significant toxicology findings. We plan to submit an IND for GB1275 and, after acceptance, initiate a Phase 1 clinical trial of GB1275 in 2019. We anticipate reporting data from this trial in 2021.

### *Autoimmune Program*

We have a portfolio of novel BTK inhibitors with differentiated selectivity profiles with and without central nervous system penetration. We are currently evaluating these molecules with the goal of advancing an optimized compound into clinical development for the treatment of autoimmune indications.

### *Oncology Program*

We are developing small molecule cancer metabolism modulators that have the potential to treat solid tumors that are refractory to currently available checkpoint inhibitors. We are currently evaluating these molecules with the goal of advancing an optimized compound into clinical development for the treatment of solid tumors.

## **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. GB001, currently 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 Novartis, Chiesi Farmaceutici S.p.A., Merck & Company, Inc. and Sunshine Lake Pharma 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-5, 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 asthma, including tezepelumab, REGN3500 (anti-IL-33; Regeneron), etokimab (anti-IL-33; AnaptysBio, Inc.), GSK3772847 (anti-IL-33; GlaxoSmithKline) and RG6149 (anti-ST2; Genentech).

Additionally, while there are no agents currently approved beyond corticosteroids for CRSwNP, several agents approved for or in development for asthma are currently in development for CRSwNP, including Xolair, Fasenra, Dupixent and etokimab.

Xolair is currently FDA-approved for the treatment of CSU. We may also face competition from agents currently in development for the indication, including ligelizumab (anti-IgE; Novartis) and AK002 (anti-Siglec-8; Allakos Inc.).

GB002 is a potentially first-in-class PDGF receptor kinase inhibitor initially targeted for intermediate and high-risk PAH patients. While potentially unique in our class, we expect our primary competition in this patient set will include prostanoids, available in oral form as Orenitram (United Therapeutics Corporation, or United Therapeutics) and Upravi (Janssen), by inhalation as Tyvaso (United Therapeutics), and by infusion as Remodulin (United Therapeutics). While we 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, GB002 would be used along with these background therapies. PAH is also an active indication for investigational drugs, and we may face competition in the future from ralinepag (Arena Pharmaceuticals, Inc.), sotatercept (Acceleron Pharma, Inc.) and bardoxolone methyl (Reata Pharmaceuticals, Inc.).

GB004 is potentially a first-in-class HIF-1a 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. Further disruption is expected in the coming years through the introduction of oral S1P1 inhibitors and additional oral JAK inhibitors.



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 GB002 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 to Pulmokine and are obligated to make future development and regulatory milestone payments of up to \$63 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 GB002 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

## [Table of Contents](#)

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 and are obligated to make future development and regulatory milestone payments of up to \$55 million, commercial milestone payments of up to \$85 million and sales milestone payments of up to \$260 million. We are also obligated to pay tiered royalties on sales for each licensed product, at percentages ranging from a high-single-digit to mid-teens, 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. We believe 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.

### ***GB001***

As of December 31, 2018, 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 adjustment or extension, and a number of patents and pending patent applications in other jurisdictions, including issued patents in Australia, Canada, China, the European Patent Convention, India, Mexico, New Zealand and Russia, and a pending application in Brazil directed to compound and pharmaceutical composition claims. As of December 31, 2018, we owned one pending U.S. patent application directed to compound claims, which, if issued, 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.

### ***GB002***

As of December 31, 2018, with respect to GB002, we have exclusively licensed one pending U.S. patent application and one pending PCT application owned by Pulmokine directed to method of use claims, which, if issued, is not due to expire before 2037, excluding any additional term for patent term adjustment or extension. We also have exclusively licensed two 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 adjustment or extension; two pending U.S. patent applications, which, if issued, are not due to expire before 2034, excluding any additional term for patent term adjustment or extension; and a number of patents and pending patent applications in other jurisdictions, including issued patents in Australia, 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 GB002 compound, formulation and method of use claims.

### ***GB004***

As of December 31, 2018, with respect to GB004, we have exclusively licensed from Aerpio nine 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 adjustment or extension; one pending U.S. patent application directed to compound and method of use claims, which, if issued, is not due to expire before 2030, excluding any additional term for patent term adjustment or 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.

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;

## [Table of Contents](#)

- 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](http://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. GB002 has received orphan drug designation for the treatment of patients with PAH.

### ***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

## [Table of Contents](#)

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% (and 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.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and political challenges to certain aspects of the ACA. For example, since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes 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 January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. 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 inseparable 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. While the Texas

District Court Judge, as well as the Trump Administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact 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, including the BBA, will remain in effect through 2027 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. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services has begun the process of soliciting feedback on some of these measures and, at the same time, is implementing others under its existing authority. Although some of these, and other proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. 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, data privacy and security, 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. 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 civil and criminal false claims laws and civil monetary penalties 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.

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. In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, imposes certain requirements relating to the privacy, security and transmission of protected health information on HIPAA covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates who conduct certain activities for or on their behalf involving protected health information on their behalf.

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 and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians 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; state and local laws that require the registration of pharmaceutical sales representatives; and state and local laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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.

### ***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.

## [Table of Contents](#)

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 information. 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 information 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.

As of May 25, 2018, Regulation 2016/676, known as the General Data Protection Regulation, or GDPR, replaced the Data Protection Directive with respect to the processing of personal data in the European Union. The GDPR imposes many requirements for controllers and processors of personal data, 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 pseudonymised (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 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.

### **Employees**

As of December 31, 2018, we had 104 full-time employees and 1 part-time employee, 33 of whom have a Ph.D. or M.D. 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.

### **Research and Development**

We have invested \$6.4 million, \$0.2 million and \$79.1 million in research and development, including IPR&D, for the year ended December 31, 2017 and the nine months ended September 30, 2017 and 2018, respectively.

### **Facilities**

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

---

[Table of Contents](#)

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 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.

**Legal Proceedings**

We are not currently subject to any material legal proceedings. From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

## MANAGEMENT

### Executive Officers and Directors

The following table sets forth the name, age and position of each of our executive officers and directors as of December 31, 2018.

<u>Name</u>	<u>Age</u>	<u>Position</u>
<b>Executive Officers</b>		
Sheila Gujrathi, M.D.	48	President, Chief Executive Officer and Director
Faheem Hasnain	60	Executive Chairman of the Board of Directors
Bryan Giraud	43	Chief Financial Officer
Christian Waage	51	Executive Vice President and General Counsel
Jakob Dupont, M.D.	53	Chief Medical Officer
Luisa Salter-Cid, Ph.D.	59	Chief Scientific Officer
<b>Non-Employee Directors</b>		
Joshua H. Bilenker, M.D.(1)(2)	47	Director
Kristina Burow(3)	45	Director
Russell Cox(1)(3)	55	Director
Thomas Daniel, M.D.(3)	64	Director
Renée Galá(1)	46	Director
Otello Stampacchia, Ph.D.(2)	49	Director

(1) Member of the audit committee

(2) Member of the nominating and corporate governance committee

(3) Member of the compensation committee

### Executive Officers

*Sheila Gujrathi, M.D.* is our Co-Founder and has served as our President and Chief Executive Officer since July 2018 and as a member of our board of directors since our inception in October 2015. She previously served as our President and Chief Operating Officer from our inception until July 2018. Prior to joining us, Dr. Gujrathi served as Chief Medical Officer of Receptos, Inc. from June 2011 until the company's acquisition by Celgene Corporation in August 2015. Prior to joining Receptos, she was Vice President of the Global Clinical Research Group in Immunology at Bristol-Myers Squibb from 2008 to 2011. Dr. Gujrathi also worked at Genentech, Inc. from 2002 to 2008 where she held roles of increasing responsibility in the Immunology, Tissue Growth and Repair clinical development group, and served as the Avastin Franchise Team Leader. From 1999 to 2002, Dr. Gujrathi was a management consultant at McKinsey & Company in the healthcare practice where she provided strategic advice on a variety of projects in the healthcare and pharmaceutical industry. Dr. Gujrathi serves as a member of the board of directors of Five Prime Therapeutics, Inc. and TP Therapeutics, Inc. and previously served as a member of the board of directors of Ambrx Inc. Dr. Gujrathi received her B.S. with highest distinction in Biomedical Engineering and her M.D. from Northwestern University in their accelerated Honors Program in Medical Education. She completed her Internal Medicine Internship and Residency at Brigham and Women's Hospital, Harvard Medical School. She received additional training at University of California, San Francisco and Stanford University in their Allergy and Immunology Fellowship Program. Dr. Gujrathi's knowledge of our business, as well as her extensive development, clinical and executive management experience, contributed to our board of directors' conclusion that she should serve as a director of our company.

*Faheem Hasnain* is our Co-Founder and served as our Chairman and Chief Executive Officer from our inception through July 2018, at which time he became our Executive Chairman. Prior to joining us, Mr. Hasnain served as President, Chief Executive Officer and as a director of Receptos from November 2010 until the company's acquisition by Celgene in August 2015. Prior to joining Receptos, Mr. Hasnain was the President and Chief Executive Officer and a director of Facet Biotech Corporation. He held that position from December 2008

until the company's acquisition by Abbott Laboratories in April 2010. Previously, Mr. Hasnain was President, Chief Executive Officer and a director of PDL BioPharma, Inc. from October 2008 until Facet Biotech was spun off from PDL BioPharma in December 2008. From October 2004 to September 2008, Mr. Hasnain served at Biogen Inc., most recently as Executive Vice President in charge of the oncology/rheumatology strategic business unit. Prior to Biogen, Mr. Hasnain held roles with Bristol-Myers Squibb, where he was President of Oncology Therapeutics Network, and for 14 years at GlaxoSmithKline and its predecessor organizations. He serves as Chairman of the board of directors of SENTE, Inc., Tocagen, Inc. and Vital Therapies, Inc., and as a member of the board of directors of Kura Oncology, Inc. He previously served as Chairman of the board of directors of Ambit Biosciences Corporation and served as a member of the board of directors of Aragon Pharmaceuticals, Seragon Pharmaceuticals, Inc., Pernix Sleep, Inc., Somaxon Pharmaceuticals, Inc. and Tercica, Inc. Mr. Hasnain received a B.H.K. and B.Ed. from the University of Windsor Ontario in Canada. Mr. Hasnain's knowledge of our business, as well as his years of experience in drug discovery and development and as a biopharmaceutical executive and board member, contributed to our board of directors' conclusion that he should serve as Executive Chairman of our company.

*Bryan Giraudo* has served as our Chief Financial Officer since May 2018. Prior to joining us, Mr. Giraudo was a Senior Managing Director at Leerink Partners (now known as SVB Leerink) from 2009 to April 2018, where he was responsible for their western North America and Asia Pacific biotechnology and medical technology banking practice. Before joining Leerink, Mr. Giraudo was a Managing Director in Merrill Lynch, Pierce, Fenner & Smith Incorporated's Global Healthcare Investment Banking Group. He has been a member of the board of directors of Protagonist Therapeutics, Inc. since May 2018. Mr. Giraudo received his B.A. from Georgetown University.

*Christian Waage* has served as our Executive Vice President and General Counsel since August 2017. Previously, Mr. Waage held various positions from November 2013 to August 2016 at Receptos, most recently serving as Managing Director after its acquisition by Celgene, previously serving as Senior Vice President and General Counsel. From 2012 through its acquisition by Vista Equity Partners LLC in 2013, he served as Vice President, General Counsel and Corporate Secretary at Websense, Inc. From 2008 through its acquisition by AstraZeneca PLC in 2012, Mr. Waage served as Vice President, General Counsel and Corporate Secretary of Ardea Biosciences, Inc. Prior to 2008, Mr. Waage served as a partner at DLA Piper LLP. He has been a member of the board of directors of Heron Therapeutics, Inc. since June 2016. Mr. Waage received his J.D. from the University of San Diego, School of Law and a B.A. degree in economics from the University of California, San Diego.

*Jakob Dupont, M.D.* has served as our Chief Medical Officer since December 2018. He previously served as the Vice President and Global Head of Breast and Gynecologic Cancer Development for Genentech from January 2017 to December 2018. Before that, Mr. Dupont served as the Senior Vice President and Chief Medical Officer of OncoMed Pharmaceuticals, Inc. from January 2012 to December 2016 and as the Vice President, Clinical Research from October 2011 to January 2012. From September 2006 to October 2011, Dr. Dupont held roles of increasing responsibility in early to late-stage clinical development at Genentech Inc., most recently as its Global Medical Director, Avastin from January 2011, in which capacity he oversaw the global medical strategy and late-stage medical program for Avastin. Since February 2009, Dr. Dupont has also served as an adjunct clinical assistant professor at the Stanford University School of Medicine. Prior to joining Genentech in 2006, Dr. Dupont was a faculty member at Memorial Sloan-Kettering Cancer Center from January 2002 to September 2006. Dr. Dupont received an A.B. in Philosophy from Vassar College, received an M.A. in Philosophy from New York University, studied pre-medical sciences at Columbia University and received an M.D. from the Joan & Sanford I. Weill Medical College of Cornell University. Dr. Dupont completed his Medical Oncology Fellowship at Memorial Sloan-Kettering Cancer Center, his Internal Medicine Residency at the New York Presbyterian Hospital—Cornell Campus, and his Internal Medicine Internship at The University of Michigan Medical Center in Ann Arbor, Michigan.

*Luisa Salter-Cid, Ph.D.* has served as our Chief Scientific Officer since August 2018. Prior to joining us, Dr. Salter-Cid worked at Bristol-Myers Squibb in increasing positions of responsibility from 2005 to August

2018, most recently as Vice President and Head of Immunology, small molecule Immuno-Oncology and Genomics Discovery where she focused on target validation and development of innovative biologic and small-molecule therapeutics to address significant unmet needs in autoimmune diseases and cancer. During her time at Bristol-Myers Squibb, Dr. Salter-Cid led teams that advanced more than 20 compounds into clinical development, and is an author on over 70 publications and patents. Previously, from 2002 to 2005, Dr. Salter-Cid was a Senior Project Leader at La Jolla Pharmaceuticals, Inc. Dr. Salter-Cid also held positions at Genset Corporation and Johnson & Johnson. She was a member of the Scientific Advisory Board of Enterome SA until July 2018. Dr. Salter-Cid holds a B.S. in Biology from University of Lisbon and a Ph.D. in Immunology from the University of Miami School of Medicine.

#### **Non-Employee Directors**

*Joshua H. Bilenker, M.D.* has served as a member of our board of directors since December 2018. He has served as Chief Executive Officer of Loxo Oncology, Inc. since July 2013. Dr. Bilenker joined Aisling Capital LLC in April 2006 and has served as an Operating Partner since November 2013. Previously, Dr. Bilenker served as a Medical Officer in the Office of Oncology Drug Products at the FDA from August 2004 to April 2006. Dr. Bilenker has served on the board of directors of Loxo Oncology, Inc. since July 2013 as well as on the boards of directors of several private companies. Dr. Bilenker previously served on the board of directors of ViewRay, Inc. from January 2008 to June 2017, T2 Biosystems, Inc. from August 2011 to January 2017 and Roka Bioscience, Inc. from January 2012 to March 2015. Dr. Bilenker formerly served as a board member of the NCCN Foundation and BioEnterprise. Dr. Bilenker holds an A.B. in English from Princeton University and an M.D. from the Johns Hopkins School of Medicine. Dr. Bilenker's experience at the FDA and his extensive service as a director or officer of, and as an investor in, other healthcare companies contributed to our board of directors' conclusion that he should serve as a director of our company.

*Kristina Burow* has served on our board of directors since January 2018. She has served as a Managing Director with ARCH Venture Partners, or ARCH, since November 2011 and previously held roles of increasing responsibility at ARCH from August 2002 to November 2011. Ms. Burow also currently serves on the boards of directors of Vividion Therapeutics, Inc., Beam Therapeutics Inc., Sienna Biopharmaceuticals, Inc., Lycera Corp., BlackThorn Therapeutics, Inc., Metacrine, Inc., Scholar Rock, Inc., Unity Biotechnology Inc., AgBiome Inc., Borgen, Inc., AgTech Accelerator and Vir Biotechnology Inc. Ms. Burow previously was a co-founder and director of Receptos prior to its acquisition and of Sapphire Energy, Inc. Prior to ARCH, Ms. Burow was an Associate with the Novartis BioVenture Fund in San Diego and an early employee at the Genomics Institute of the Novartis Research Foundation. Ms. Burow holds a B.A. in Chemistry from the University of California, Berkeley, an M.A. in Chemistry from Columbia University and an M.B.A. from the University of Chicago. Ms. Burow's extensive experience serving on the board of directors of clinical-stage biotechnology companies and her investment experience in the life sciences industry contributed to our board of directors' conclusion that she should serve as a director of our company.

*Russell Cox* has served on our board of directors since December 2018. He has served as a member of the board of directors and as Chief Executive Officer of Vital Therapies, Inc., a biotechnology company, since January 2018. Between May 2014 and January 2018, he served as the Executive Vice President and Chief Operating Officer of Jazz Pharmaceutical plc, or Jazz, with responsibility for global commercial activities, research and development, manufacturing and technical operations, new product planning and global molecule leadership. Prior to that, Mr. Cox served as Jazz's Executive Vice President and Chief Commercial Officer from March 2012 until May 2014. Earlier, he served in a variety of senior management roles at Jazz, which he joined in 2010. Previously, Mr. Cox served as Senior Vice President and Chief Commercial Officer of Ipsen Group, a pharmaceutical company, from January 2009 to January 2010. From 2007 until December 2008, he was Vice President of Marketing at Tercica, Inc. prior to its acquisition by Ipsen Group. From 2003 to 2007, he served as Vice President, Marketing with Scios Inc., which was acquired by Johnson & Johnson in 2003. Before 2003, Mr. Cox spent 12 years with Genentech, where he was a Product Team Leader responsible for the growth hormone franchise and led numerous product launches as a Group Product Manager. Mr. Cox has served on the board of

directors of Aeglea BioTherapeutics, Inc., a biotechnology company, since 2015. Mr. Cox received a B.S. in biomedical science from Texas A&M University. Mr. Cox's extensive industry experience with life sciences companies contributed to our board of directors' conclusion that he should serve as a director of our company.

*Thomas Daniel, M.D.* has served on our board of directors since January 2018. Dr. Daniel has served as a venture partner with ARCH Venture Partners since October 2016. Dr. Daniel has been the Executive Chairman of Vividion Therapeutics, Inc. since February 2017. Dr. Daniel was previously Celgene's Chairman of Research from January 2016 until June 2016, President of Research and Early Development from December 2006 to January 2016, and Executive Vice President and President of Research and Early Development from February 2012 until January 2016. Prior to joining Celgene, Dr. Daniel served as the Chief Scientific Officer and director at Ambrx Inc. Prior to Ambrx, Dr. Daniel served as Vice President of Research at Amgen Inc., where he was research site head of Amgen Washington and therapeutic area head of inflammation. Dr. Daniel also served as the Senior Vice President of Discovery Research at Immunex Corporation until its acquisition by Amgen. Dr. Daniel is a director of publicly held companies, Zafgen, Inc., Magenta Therapeutics, Inc., and privately-held biotechnology companies, Vir Biotechnology Inc., ImmusanT, Inc., Locana, Inc. and Sana Biotechnology. He was previously a director at Epizyme, Inc. and Juno Therapeutics. Dr. Daniel serves as a member of the Biomedical Science Advisory Board of Vanderbilt University Medical Center, the Scientific Advisory Board of the Parker Institute for Cancer Immunotherapy and the Board of Overseers for The Scripps Research Institute. A nephrologist and former academic investigator, Dr. Daniel was previously the K.M. Hakim Professor of Medicine and Cell Biology at Vanderbilt University, and Director of the Vanderbilt Center for Vascular Biology. Dr. Daniel received a B.A. from the Southern Methodist University in Texas in 1974 and an M.D. from the University of Texas, Southwestern, in 1978, and completed medical residency at Massachusetts General Hospital. Dr. Daniel's significant academic and research experience and his experience serving on numerous boards contributed to our board of directors' conclusion that he should serve as a director of our company.

*Renée Galá* has served on our board of directors since December 2018. Since January 2019, Ms. Galá has served as the Chief Financial Officer of Grail, Inc., a healthcare company. Previously, Ms. Galá served as the Senior Vice President and Chief Financial Officer of Theravance Biopharma from December 2014, following the company's spinout from Theravance, Inc., until January 2019. Ms. Galá joined Theravance (now Innoviva, Inc.) in June 2006 and held various roles in the finance organization before leading the company's spin-out transaction. Before Theravance, Ms. Galá worked at Eli Lilly and Company from 2001 to 2006, where she held positions of increasing responsibility in global treasury, pharmaceutical sales, and corporate strategy/business development. Prior to joining Eli Lilly, Ms. Galá spent seven years in the energy industry in the United States and internationally in positions focused on corporate finance, project finance, and mergers and acquisitions. Ms. Galá has been a member of the board of directors of Corcept Therapeutics Inc. since June 2016. Ms. Galá holds a bachelor's degree in mathematics from Vanderbilt University and an MBA from Columbia Business School. Ms. Galá's experience as a Chief Financial Officer in the life science industry, her leadership and management experience and her financial expertise contributed to our board of directors' conclusion that she should serve as a director of our company.

*Otello Stampacchia, Ph.D.* has served on our board of directors since January 2018. He has served as founder and Managing Director of Omega Funds since 2004. Previously, Dr. Stampacchia was in charge of life sciences direct investments at AlpInvest Partners B.V. from 2001 to 2003, and from 2000 to 2001, Dr. Stampacchia was the portfolio manager of the Lombard Odier Immunology Fund. Previously, Dr. Stampacchia was a member of the healthcare corporate finance and mergers and acquisitions team at Goldman Sachs Group, Inc. from 1997 to 2000. Before joining Goldman Sachs, Dr. Stampacchia helped co-found the healthcare investment activities at Index Securities, now Index Ventures, Inc. Dr. Stampacchia is currently a member of the boards of directors of Replimune Group, Inc., Kronos Bio, Inc., Morphic Therapeutic and ESSA Pharma, Inc. Previously, Dr. Stampacchia served on the boards of directors of Paratek Pharmaceuticals, Micromet, CropDesign NV and DeveloGen AG. He has a Ph.D. degree in Molecular Biology from the University of Geneva and a European Ph.D. in Biotechnology (EDBT) from the European Association for Higher Education in Biotechnology. He has an M.S. in Genetics from Università degli Studi di Pavia.



Dr. Stampacchia's extensive experience investing in and serving on the boards of life science companies contributed to our board of directors' conclusion that he should serve as a director of our company.

## **Board Composition and Election of Directors**

### ***Director Independence***

Our board of directors currently consists of eight members. Our board of directors has determined that all of our directors, other than Sheila Gujrathi, M.D. and Faheem Hasnain, are independent directors in accordance with the listing requirements of the Nasdaq Global Select Market. The Nasdaq independence definition includes a series of objective tests, including that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his or her family members has engaged in various types of business dealings with us. In addition, as required by Nasdaq rules, our board of directors has made a subjective determination as to each independent director that no relationships exist, which, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of the director. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management. There are no family relationships among any of our directors or executive officers.

### ***Classified Board of Directors***

In accordance with the terms of our amended and restated certificate of incorporation that will go into effect immediately prior to the closing of this offering, our board of directors will be divided into three classes with staggered, three-year terms. At each annual meeting of stockholders, the directors whose terms then expire will be eligible for reelection until the third annual meeting following reelection. Effective upon the closing of this offering, our directors will be divided among the three classes as follows:

- the Class I directors will be Ms. Burow, Dr. Daniel and Dr. Gujrathi, and their terms will expire at our first annual meeting of stockholders following this offering;
- the Class II directors will be Dr. Bilenker, Mr. Hasnain and Dr. Stampacchia, and their terms will expire at our second annual meeting of stockholders following this offering; and
- the Class III directors will be Mr. Cox and Ms. Galá, and their terms will expire at our third annual meeting of stockholders following this offering.

Our amended and restated certificate of incorporation that will go into effect immediately prior to the closing of this offering will provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our board of directors or a change in control of our company. Our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of our outstanding voting stock then entitled to vote in an election of directors.

## **Board Leadership Structure**

Our board of directors is currently led by our Executive Chairman, Faheem Hasnain. Our board of directors recognizes that it is important to determine an optimal board leadership structure to ensure the independent oversight of management as the company continues to grow. We separate the roles of chief executive officer and chairman of the board in recognition of the differences between the two roles. The chief

## [Table of Contents](#)

executive officer is responsible for setting the strategic direction for our company and the day-to-day leadership and performance of our company, while the chairman of the board of directors provides guidance to the chief executive officer and presides over meetings of the full board of directors. We believe that this separation of responsibilities provides a balanced approach to managing the board of directors and overseeing our company.

Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

### **Role of Board in Risk Oversight Process**

Our board of directors has responsibility for the oversight of our risk management processes and, either as a whole or through its committees, regularly discusses with management our major risk exposures, their potential impact on our business and the steps we take to manage them. The risk oversight process includes receiving regular reports from board committees and members of senior management to enable our board to understand our risk identification, risk management and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, strategic and reputational risk.

The audit committee reviews information regarding liquidity and operations, and oversees our management of financial risks. Periodically, the audit committee reviews our policies with respect to risk assessment, risk management, loss prevention and regulatory compliance. Oversight by the audit committee includes direct communication with our external auditors, and discussions with management regarding significant risk exposures and the actions management has taken to limit, monitor or control such exposures. The compensation committee is responsible for assessing whether any of our compensation policies or programs has the potential to encourage excessive risk-taking. The nominating and corporate governance committee manages risks associated with the independence of the board, corporate disclosure practices and potential conflicts of interest. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board is regularly informed through committee reports about such risks. Matters of significant strategic risk are considered by our board as a whole.

### **Board Committees and Independence**

Our board of directors has established three standing committees—audit, compensation and nominating and corporate governance—each of which operates under a charter that has been approved by our board.

#### ***Audit Committee***

The audit committee's main function is to oversee our accounting and financial reporting processes and the audits of our consolidated financial statements. This committee's responsibilities include, among other things:

- appointing our independent registered public accounting firm;
- evaluating the qualifications, independence and performance of our independent registered public accounting firm;
- approving the audit and non-audit services to be performed by our independent registered public accounting firm;
- reviewing the design, implementation, adequacy and effectiveness of our internal accounting controls and our critical accounting policies;
- discussing with management and the independent registered public accounting firm the results of our annual audit and the review of our quarterly unaudited financial statements;

## Table of Contents

- reviewing, overseeing and monitoring the integrity of our consolidated financial statements and our compliance with legal and regulatory requirements as they relate to financial statements or accounting matters;
- reviewing on a periodic basis, or as appropriate, any investment policy and recommending to our board any changes to such investment policy;
- reviewing with management and our auditors any earnings announcements and other public announcements regarding our results of operations;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and approving any related party transactions and reviewing and monitoring compliance with our code of conduct and ethics; and
- reviewing and evaluating, at least annually, the performance of the audit committee and its members including compliance of the audit committee with its charter.

The members of our audit committee are Ms. Galá, Dr. Bilenker and Mr. Cox. Ms. Galá serves as the chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the Nasdaq Global Select Market. Our board of directors has determined that Ms. Galá is an “audit committee financial expert” as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq listing standards. Our board of directors has determined each of Ms. Galá, Dr. Bilenker and Mr. Cox is independent under the applicable rules of the SEC and the Nasdaq Global Select Market. Upon the listing of our common stock on the Nasdaq Global Select Market, the audit committee will operate under a written charter that satisfies the applicable standards of the SEC and the Nasdaq Global Select Market.

### ***Compensation Committee***

Our compensation committee approves policies relating to compensation and benefits of our officers and employees. The compensation committee approves corporate goals and objectives relevant to the compensation of our Chief Executive Officer and other executive officers, evaluates the performance of these officers in light of those goals and objectives and approves the compensation of these officers based on such evaluations. The compensation committee also approves the issuance of stock options and other awards under our equity plans. The compensation committee will review and evaluate, at least annually, the performance of the compensation committee and its members, including compliance by the compensation committee with its charter.

The members of our compensation committee are Ms. Burow, Mr. Cox and Dr. Daniel. Ms. Burow serves as the chairperson of the committee. Our board of directors has determined that each of Ms. Burow, Mr. Cox and Dr. Daniel is independent under the applicable Nasdaq listing standards, is a “non-employee director” as defined in Rule 16b-3 promulgated under the Exchange Act. Upon the listing of our common stock on the Nasdaq Global Select Market, the compensation committee will operate under a written charter, which the compensation committee will review and evaluate at least annually.

### ***Nominating and Corporate Governance Committee***

The nominating and corporate governance committee is responsible for assisting our board of directors in discharging the board’s responsibilities regarding the identification of qualified candidates to become board members, the selection of nominees for election as directors at our annual meetings of stockholders (or special meetings of stockholders at which directors are to be elected), and the selection of candidates to fill any vacancies on our board of directors and any committees thereof. In addition, the nominating and corporate

## [Table of Contents](#)

governance committee is responsible for overseeing our corporate governance policies, reporting and making recommendations to our board of directors concerning governance matters and oversight of the evaluation of our board of directors. The members of our nominating and corporate governance committee are Dr. Stampacchia and Dr. Bilenker. Dr. Stampacchia serves as the chairperson of the committee. Our board has determined that each of Dr. Stampacchia and Dr. Bilenker is independent under the applicable Nasdaq listing standards. Upon the listing of our common stock on the Nasdaq Global Select Market, the nominating and corporate governance committee will operate under a written charter, which the nominating and corporate governance committee will review and evaluate at least annually.

### **Compensation Committee Interlocks and Insider Participation**

None of the members of our compensation committee has ever been one of our officers or employees. None of our executive officers currently serves, or has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee other than Mr. Cox who serves as the Chief Executive Officer of Vital Therapies, Inc., for which Mr. Hasnain serves on the compensation committee.

### **Board Diversity**

Upon the closing of this offering, our nominating and corporate governance committee will be responsible for reviewing with the board of directors, on an annual basis, the appropriate characteristics, skills and experience required for the board of directors as a whole and its individual members. In evaluating the suitability of individual candidates (both new candidates and current members) for election or appointment, the nominating and corporate governance committee and the board of directors will take into account many factors, including the following:

- personal and professional integrity, ethics and values;
- experience in corporate management, such as serving as an officer or former officer of a publicly-held company;
- experience as a board member or executive officer of another publicly-held company;
- strong finance experience;
- diversity of expertise and experience in substantive matters pertaining to our business relative to other board members;
- diversity of background and perspective, including, but not limited to, with respect to age, gender, race, place of residence and specialized experience;
- experience relevant to our business industry and with relevant social policy concerns; and
- relevant academic expertise or other proficiency in an area of our business operations.

Currently, our board of directors evaluates, and following the closing of this offering will evaluate, each individual in the context of the board of directors as a whole, with the objective of assembling a group that can best maximize the success of the business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these various areas.

### **Code of Business Conduct and Ethics**

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, which will be effective upon the completion of this offering. Upon the closing of this offering, our code of business conduct and ethics will be available under the Corporate Governance section of our website at [www.gossamerbio.com](http://www.gossamerbio.com). In addition, we intend to post on our website all disclosures that are required by law or the listing standards of the Nasdaq Global Select Market concerning any amendments to, or waivers from, any provision of the code. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

## EXECUTIVE AND DIRECTOR COMPENSATION

This section discusses the material components of the executive compensation program for our executive officers who are named in the “Summary Compensation Table” below.

Sheila Gujrathi, M.D., our President and Chief Executive Officer and former Chief Operating Officer, Faheem Hasnain, our Executive Chairman and former Chief Executive Officer, and Christian Waage, our Executive Vice President and General Counsel, were our only executive officers during 2017 and, accordingly, are our named executive officers for 2017. We did not pay any cash compensation to any executive officer or board member in 2017. Cash compensation to our executive officers commenced in January 2018 in connection with the closing of our Series A preferred stock financing. Mr. Waage, however, received a restricted stock award in November 2017 in consideration of his services to us, which is the only compensation paid to our named executive officers for 2017.

Our other current executive officers commenced employment with us during 2018. Bryan Giraudo, our Chief Financial Officer, commenced employment in May 2018. Luisa Salter-Cid, Ph.D., our Chief Scientific Officer, commenced employment in August 2018. Jakob Dupont, M.D., our Chief Medical Officer, commenced employment in December 2018. In addition to Dr. Gujrathi and Mr. Hasnain, each of whom served as our principal executive officer for a portion of 2018, Mr. Giraudo and Dr. Dupont are also named executive officers for 2018. We have voluntarily included Mr. Waage as an additional named executive officer for 2018 due to his status as a named executive officer in 2017.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the closing of this offering may differ materially from the currently planned programs summarized in this discussion.

### Summary Compensation Table

The following table presents summary information regarding the total compensation that was awarded to, earned by or paid to our named executive officers for services rendered during the years ended December 31, 2017 and 2018.

<u>Name and principal position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Bonus (\$)</u>	<u>Stock awards (\$)(1)</u>	<u>Option awards (\$)(1)</u>	<u>Non-equity Incentive Plan Compensation (\$)</u>	<u>All other compensation (\$)</u>	<u>Total (\$)</u>
Sheila Gujrathi, M.D. <i>President and Chief Executive Officer and Former Chief Operating Officer</i>	2018	469,601	(2)	17,942,611	—	—	—	18,412,211(3)
	2017	—	—	—	—	—	—	—
Faheem Hasnain <i>Executive Chairman and Former Chief Executive Officer</i>	2018	469,601	(2)	17,942,611	—	—	—	18,412,211(3)
	2017	—	—	—	—	—	—	—
Christian Waage <i>EVP and General Counsel</i>	2018	365,794	(2)	—	316,000	—	—	681,794(3)
	2017	—	—	46,995	—	—	—	46,995
Bryan Giraudo(4) <i>Chief Financial Officer</i>	2018	260,605	(2)	—	1,799,690	—	—	2,060,295(3)
Jakob Dupont, M.D.(5) <i>Chief Medical Officer</i>	2018	20,167	85,000(6)	—	3,422,122	—	3,165(7)	3,530,454

(1) This column reflects the grant date fair value of the restricted stock and option awards granted to the named executive officers in the applicable fiscal year. In accordance with SEC rules, this column reflects the aggregate fair value of the stock award granted to Mr. Waage during 2017 computed as of its grant date in accordance with Financial Accounting Standards, Standard Board Accounting Codification Topic 718 for stock-based compensation transactions (ASC 718). Assumptions used in the calculation of this amount is

## [Table of Contents](#)

included in Note 9 to our consolidated financial statements appearing elsewhere in this prospectus. This amount does not reflect the actual economic value that will be realized by the named executive officers upon the vesting or exercise of the awards or the sale of the common stock underlying such awards.

- (2) Bonuses for 2018 have not yet been determined and we expect that they will be determined by our board of directors or the compensation committee in the first quarter of 2019.
- (3) Does not include the bonus payable to the named executive officer for 2018, which has not yet been determined.
- (4) Mr. Giraudo commenced employment as our Chief Financial Officer on May 7, 2018.
- (5) Dr. Dupont commenced employment as our Chief Medical Officer on December 14, 2018.
- (6) Bonus for 2018 represents a sign-on bonus.
- (7) All other compensation for 2018 includes a commuting allowance of \$2,400 and a tax gross up payment of \$765.

### **Narrative Disclosure to Compensation Tables**

#### ***Annual Base Salary***

The compensation of our executive officers is generally determined and approved at the time of their commencement of employment by our board of directors or the compensation committee. As noted above, none of our named executive officers received any cash compensation for 2017.

In connection with the closing of our Series A preferred stock financing in January 2018, our board of directors established the initial base salaries for each of our named executive officers as follows: Dr. Gujrathi, \$475,000, Mr. Hasnain, \$475,000, and Mr. Waage, \$370,000. In connection with their commencement of employment in May, August and December 2018, respectively, the base salaries for Mr. Giraudo, Dr. Salter-Cid and Dr. Dupont were set at \$400,000, \$350,000 and \$440,000, respectively, by our board of directors.

In December 2018, our board of directors, acting on the recommendation of our compensation committee, approved increases to the base salaries for each of Dr. Gujrathi, Mr. Waage and Dr. Salter-Cid to \$520,000, \$390,000 and \$380,000, respectively, with such increases to be effective upon completion of this offering.

#### ***Bonus Compensation***

From time to time our board of directors or compensation committee may approve bonuses for our named executive officers based on individual performance, company performance or as otherwise determined appropriate. No formal bonus plan was in effect during 2017 and none of our named executive officers received a bonus in 2017.

For 2018, each named executive officer (other than Dr. Dupont) may be eligible for a performance bonus based upon the achievement of certain corporate performance goals and objectives approved by our board of directors. The employment letters with each of our executive officers set forth their target annual bonus levels, which are currently as follows: 50% of base salary for Dr. Gujrathi and Mr. Hasnain and 40% of base salary for Messrs. Waage and Giraudo and Dr. Salter-Cid.

For 2018, no formal bonus plan has been adopted by our board of directors and any bonuses payable to our executive officers will be determined in the board's discretion based on the company's performance and individual executive performance during the year. Bonuses for 2018 have not yet been determined and we expect that they will be determined by our board of directors or the compensation committee in the first quarter of 2019.

#### ***Equity-Based Incentive Awards***

Our equity-based incentive awards are designed to align our interests and the interests of our stockholders with those of our employees and consultants, including our named executive officers. Our board of directors or the compensation committee approves equity grants.

## [Table of Contents](#)

Prior to the completion of our Series A preferred stock financing in January 2018, we issued restricted stock to certain of our executive officers and consultants. Following the adoption of our 2017 equity incentive plan, or the 2017 Plan, we have generally granted equity awards pursuant to the 2017 Plan (other than awards to Dr. Gujrathi and Mr. Hasnain, which have not been granted under the 2017 Plan, as described below). Following this offering, we will grant equity incentive awards under the terms of our 2019 equity incentive plan, or the 2019 Plan. The terms of our equity plans are described below under “—Incentive Award Plans.”

Since January 2018, we have used stock options as the primary incentive for long-term compensation to our employees, directors and consultants because they are able to profit from stock options only if our stock price increases relative to the stock option’s exercise price, which exercise price is set at the fair market value of our common stock at the date of grant. We may grant equity awards at such times as our board of directors determines appropriate. With the exception of our named executive officers, each of whom received awards of restricted stock prior to our Series A preferred stock financing in connection with the formation of our company or in consideration of services to our company prior to such financing, our executives generally are awarded an initial grant in the form of a stock option in connection with their commencement of employment. Additional grants may occur periodically in order to specifically incentivize executives with respect to achieving certain corporate goals or to reward executives for exceptional performance.

We granted restricted stock awards to Dr. Gujrathi and Mr. Hasnain in connection with the formation of our company and pursuant to their employment letters, all of which awards were granted on a stand-alone basis and not under our 2017 Plan. For a description of such restricted stock awards, please see “—Employment Letters with our Named Executive Officers.” No equity awards were granted to Dr. Gujrathi or Mr. Hasnain during 2017.

Mr. Waage was granted 522,170 shares of restricted common stock on November 18, 2017 under the 2017 Plan, with such stock vesting over a period of four years from the grant date, with 25% of the restricted shares vesting on the first anniversary of the grant date, and the remainder vesting in equal monthly installments over the three years thereafter, subject to continuous service through each vesting date.

On May 21, 2018, in connection with his commencement of employment, we granted Mr. Giraudo an option to purchase 405,666 shares of our common stock under the 2017 Plan. The option vests over a period of four years from May 7, 2018 (his employment commencement date), with 25% of the option vesting on the first anniversary of such date, and the remainder vesting in equal monthly installments over the three years thereafter. The option has an exercise price per share of \$2.61, which was the fair market value at the time of grant.

On December 10, 2018, we granted Mr. Giraudo, Mr. Waage and Dr. Salter-Cid options to purchase 155,555, 44,444 and 222,222 shares of our common stock, respectively, under the 2017 Plan. The options vest over a period of four years from December 7, 2018, with 25% of the option vesting on the first anniversary of such date, and the remainder vesting in equal monthly installments over the three years thereafter. The options have an exercise price per share of \$10.71, which was the fair market value at the time of grant.

On December 14, 2018, in connection with his commencement of employment, we granted Dr. Dupont an option to purchase 481,311 shares of our common stock under the 2017 Plan. The option vests over a period of four years from December 14, 2018 (his employment commencement date), with 25% of the option vesting on the first anniversary of such date, and the remainder vesting in equal monthly installments over the three years thereafter. The option has an exercise price per share of \$10.71, which was the fair market value at the time of grant.

### **Employment Letters with our Named Executive Officers**

In 2017, none of our executive officers were parties to employment agreements or other similar arrangements with us. Each of our executive officers’ employment is “at will” and may be terminated at any time, subject to our contractual obligations to them as described below.



***Employment Letters with Dr. Gujrathi and Mr. Hasnain***

We entered into employment letters with each of Dr. Gujrathi and Mr. Hasnain on January 4, 2018, setting forth the terms of their employment.

Pursuant to her employment letter, Dr. Gujrathi served as our President and Chief Operating Officer through July 23, 2018, at which time she was appointed as our President and Chief Executive Officer. She receives an annual base salary of \$475,000 and is eligible to receive an annual bonus with a target amount equal to 50% of her then-current annual base salary. Effective upon the consummation of this offering, Dr. Gujrathi's base salary will be increased to \$520,000.

Pursuant to his employment letter, Mr. Hasnain served as our Chief Executive Officer through July 23, 2018, at which time he became our Executive Chairman. He receives an annual base salary of \$475,000 and is eligible to receive an annual bonus with a target amount equal to 50% of his then-current annual base salary.

In December 2015, each of Dr. Gujrathi and Mr. Hasnain were each issued 4,580,444 shares in connection with the formation of our company, which we refer to as the Founders' Equity. Pursuant to their employment letters, each of Dr. Gujrathi and Mr. Hasnain agreed that 50% of the Founders' Equity would be subject to new vesting terms, or the Restricted Founders' Equity, and would vest over a period of five years from the date of the closing of our Series A preferred stock financing, with 20% of the Restricted Founders' Equity vesting on January 4, 2019 and the remainder vesting in 48 equal monthly installments thereafter, subject to continued full-time employment on each vesting date.

The employment letters also provided for certain potential additional issuances of our common stock to each of Dr. Gujrathi and Mr. Hasnain 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 us and the Founders' Equity) would represent 15% of our fully-diluted capitalization until such time as we raised \$300 million in equity capital, including the capital raised in the Series A financing. In furtherance of this obligation: (1) on May 21, 2018, we issued 251,547 shares of common stock to each of Dr. Gujrathi and Mr. Hasnain; and (2) on September 6, 2018, we issued 1,795,023 shares of common stock to each of Dr. Gujrathi and Mr. Hasnain, or the Anti-Dilution Shares. Fifty percent of the Anti-Dilution Shares are fully vested and the remaining 50% of the Anti-Dilution Shares, or the Restricted Anti-Dilution Shares, vest over a period of five years measured from January 4, 2018, with 20% of the Restricted Anti-Dilution Shares vesting on January 4, 2019 and the remainder vesting in 48 equal monthly installments thereafter, subject to continued full-time employment on each vesting date. Neither Dr. Gujrathi nor Mr. Hasnain are entitled to any further grants of additional anti-dilution shares pursuant to their employment letters.

Pursuant to their employment letters, if we terminate Dr. Gujrathi's or Mr. Hasnain's employment other than for cause (as defined below) or Dr. Gujrathi or Mr. Hasnain terminates his or her employment for good reason (as defined below), and other than as a result of death or disability, in either case prior to a change in control (as defined below) or more than 12 months following a change in control, he or she is entitled to the following payments and benefits, subject to the timely execution and non-revocation of a general release of claims in our favor: (1) continued payment of his or her base salary at the then-current rate for 12 months, paid in accordance to our payroll practices; (2) a payment equal to his or her then current target annual bonus opportunity, pro-rated for the portion of the current calendar year in which the executive was employed, payable in a lump sum payment 60 days following the date of termination; (3) payment of the full premium for continued health plan coverage for up to 12 months following the date of termination or, if earlier, up to the date the executive becomes eligible to receive equivalent or increased health plan coverage by means of subsequent employment or self-employment; and (4) automatic acceleration of the vesting and exercisability of the executive's unvested stock awards, including any Founders' Equity and Anti-Dilution Shares, as to the number of stock awards that would vest over the 12-month period following the date of termination. The cash severance benefits described in clause (1) above shall be paid or commence on the first payroll period following the date

## [Table of Contents](#)

the executive's release becomes effective and the first payment shall include all accrued amounts from the date of termination, provided that if the period during which executive may deliver the release spans two calendar years, the initial payment date shall be no earlier than January 1 of the second calendar year.

If Dr. Gujrathi's or Mr. Hasnain's employment is terminated by us other than for cause or by Dr. Gujrathi or Mr. Hasnain for good reason, in each case within 12 months after a change in control, in lieu of the severance benefits described above, he or she is entitled to the following payments and benefits, subject to the timely execution and non-revocation of a general release of claims in our favor: (1) continued payment of his or her base salary at the then-current rate for 18 months, paid in accordance to our payroll practices; (2) a payment equal to his or her then current target annual bonus opportunity, pro-rated for the portion of the current calendar year in which the executive was employed, payable in a lump sum payment 60 days following the date of termination; (3) payment of the full premium for continued health plan coverage for up to 18 months following the date of termination or, if earlier, up to the date the executive becomes eligible to receive equivalent or increased health plan coverage by means of subsequent employment or self-employment; and (4) automatic full vesting and exercisability of the executive's unvested stock awards, including the Founders' Equity and the Anti-Dilution Shares. The cash severance benefits described in clause (1) above shall be paid or commence on the first payroll period following the date the executive's release becomes effective and the first payment shall include all accrued amounts from the date of termination, provided that if the period during which executive may deliver the release spans two calendar years, the initial payment date shall be no earlier than January 1 of the second calendar year.

In addition, in the event of Dr. Gujrathi's or Mr. Hasnain's termination of employment by reason of his or her death or disability, and subject to the timely execution and non-revocation of a general release of claims in our favor by the executive, then the greater of (1) 50% of the unvested portion of any equity awards then held by him or her immediately prior to such termination, including the Founders' Equity and the Anti-Dilution Shares, and (2) the portion of such equity awards, including the Founders' Equity and the Anti-Dilution Shares, that would have otherwise vested in the 12 month period following the date of such termination of employment, will vest and will no longer be subject to restrictions or forfeiture on the date of such termination.

In the event we terminate Dr. Gujrathi's or Mr. Hasnain's employment for any reason, including for cause, Dr. Gujrathi or Mr. Hasnain terminates their employment without good reason, or upon their death or permanent disability, the executive is entitled to receive his or her fully earned but unpaid base salary and accrued and unused PTO through the date of termination at the rate then in effect, plus all other amounts under any compensation plan or practice to which the executive is entitled.

Each of Dr. Gujrathi and Mr. Hasnain was reimbursed \$15,000 for their attorneys' fees in connection with the review and negotiation of their employment letters in January 2018.

The employment letters also contain a Section 280G better-off cutback provision, which provides that, in the event that the payments or benefits provided to the executive pursuant to the employment letter or otherwise constitute parachute payments with the meaning of Section 280G of the Code, the payments or benefits to the executive will either be delivered in full or reduced to the extent necessary to avoid an excise tax under Section 4999 of the Code, whichever would result in the executive receiving the largest amount of payments or benefits on an after-tax basis.

### ***Employment Letters with Other Executives***

We entered into new employment letters with each of Mr. Giraudo, Mr. Waage and Dr. Salter-Cid on December 4, 2018, setting forth the terms of their employment. In connection with his commencement of employment on December 14, 2018, we also entered into an employment letter with Dr. Dupont.

Pursuant to his employment letter, Mr. Giraudo serves as our Chief Financial Officer. He receives an annual base salary of \$400,000 and is eligible to receive an annual bonus with a target amount equal to 40% of his then-current annual base salary.

## [Table of Contents](#)

Pursuant to his employment letter, Mr. Waage serves as our Executive Vice President and General Counsel. He receives an annual base salary of \$370,000 and is eligible to receive an annual bonus with a target amount equal to 40% of his then-current annual base salary. Effective upon consummation of this offering, Mr. Waage's base salary will be increased to \$390,000.

Pursuant to her employment letter, Dr. Salter-Cid serves as our Chief Scientific Officer. She receives an annual base salary of \$350,000 and is eligible to receive an annual bonus with a target amount equal to 40% of her then-current annual base salary. Effective upon consummation of this offering, Dr. Salter-Cid's base salary will be increased to \$380,000.

Pursuant to his employment letter, Dr. Dupont serves as our Chief Medical Officer. He receives an annual base salary of \$440,000 and, commencing in 2019, is eligible to receive an annual bonus with a target amount equal to 40% of his then-current annual base salary. Pursuant to his employment letter, Dr. Dupont will also be eligible to receive a sign-on bonus of \$170,000, payable in two installments, with the first half paid within ten days of his commencement of employment and the remainder paid six months following his commencement of employment. Dr. Dupont will be required to repay his sign-on bonus in the event he resigns without good reason (as defined below) or he is terminated for cause (as defined below), in either event within the first year of his employment. Dr. Dupont is also eligible for a monthly commuting allowance of up to \$4,800 (grossed-up for taxes) for up to the first two years of his employment. Dr. Dupont will also be eligible to receive up to \$150,000 (grossed-up for taxes) in relocation assistance in connection with his relocation to the San Diego, California area by the second anniversary of his commencement of employment. Dr. Dupont will be required to repay his relocation benefits in the event he resigns without good reason (as defined below) or he is terminated for cause (as defined below), in either event within two years of the conclusion of his relocation.

Pursuant to their employment letters, if we terminate the executive's employment other than for cause (as defined below) or if the executive terminates his or her employment for good reason (as defined below), and other than as a result of death or disability, in either case prior to a change in control (as defined below) or more than 12 months following a change in control, he or she is entitled to the following payments and benefits, subject to the timely execution and non-revocation of a general release of claims in our favor: (1) continued payment of his or her base salary at the then-current rate for 9 months, paid in accordance to our payroll practices; and (2) payment of the full premium for continued health plan coverage for up to 9 months following the date of termination or, if earlier, up to the date the executive becomes eligible to receive equivalent or increased health plan coverage by means of subsequent employment or self-employment. The cash severance benefits described above shall be paid or commence on the first payroll period following the date the executive's release becomes effective and the first payment shall include all accrued amounts from the date of termination, provided that if the period during which executive may deliver the release spans two calendar years, the initial payment date shall be no earlier than January 1 of the second calendar year.

If the executive's employment is terminated by us other than for cause or by the executive for good reason, in each case within 12 months after a change in control, in lieu of the severance benefits described above, he or she is entitled to the following payments and benefits, subject to the timely execution and non-revocation of a general release of claims in our favor: (1) continued payment of his or her base salary at the then-current rate for 12 months, paid in accordance to our payroll practices; (2) a payment equal to his or her then current target annual bonus opportunity; (3) payment of the full premium for continued health plan coverage for up to 12 months following the date of termination or, if earlier, up to the date the executive becomes eligible to receive equivalent or increased health plan coverage by means of subsequent employment or self-employment; and (4) automatic full vesting and exercisability of the executive's unvested stock awards. The cash severance benefits described above shall be paid or commence on the first payroll date following the date the executive's release becomes effective and the first payment shall include all accrued amounts from the date of termination (and the full amount payable under clause (2)), provided that if the period during which executive may deliver the release spans two calendar years, the initial payment date shall be no earlier than January 1 of the second calendar year.

In addition, in the event of the executive's termination of employment by reason of his or her death or disability, and subject to the timely execution and non-revocation of a general release of claims in our favor by the executive, then the greater of (1) 50% of the unvested portion of any equity awards then held by him or her immediately prior to such termination, including the Founders' Equity and the Anti-Dilution Shares, and (2) the portion of such equity awards that would have otherwise vested in the 9 month period following the date of such termination of employment, will vest and will no longer be subject to restrictions or forfeiture on the date of such termination.

In the event we terminate the executive's employment for any reason, including for cause, the executive terminates his or her employment without good reason, or upon his or her death or permanent disability, the executive is entitled to receive his or her fully earned but unpaid base salary and accrued and unused PTO through the date of termination at the rate then in effect, plus all other amounts under any compensation plan or practice to which the executive is entitled.

The employment letters also contain a Section 280G better-off cutback provision, which provides that, in the event that the payments or benefits provided to the executive pursuant to the employment letter or otherwise constitute parachute payments with the meaning of Section 280G of the Code, the payments or benefits to the executive will either be delivered in full or reduced to the extent necessary to avoid an excise tax under Section 4999 of the Code, whichever would result in the executive receiving the largest amount of payments or benefits on an after-tax basis.

#### ***Defined Terms Applicable to Executive Employment Letters***

For purposes of the executive employment letters, "cause" means (1) a willful and material act of dishonesty by the executive in connection with the performance of the executive's duties as our employee; (2) the executive's 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 our reputation or business; (3) the executive's gross misconduct in the performance of the executive's duties as our employee; (4) the executive's willful and material unauthorized use or disclosure of any of our proprietary information or trade secrets or any other party to whom the executive owes an obligation of nondisclosure as a result of the executive's relationship with us; (5) the executive's willful and material breach of any obligations under any written agreement or written covenant with us; or (6) the executive's continued willful and substantial failure to perform the executive's material employment duties that are lawfully assigned to the executive in good faith by the executive's reporting superior (other than as a result of the executive's death or disability) after written notice.

For purposes of the employment letters with Dr. Gujrathi and Mr. Hasnain, "change in control" has the same meaning given to such term in our 2017 Plan, as described below. For purposes of the employment letters with the other executives, prior to the consummation of this offering, "change in control" has the same meaning given to such term in our 2017 Plan, as described below, and following the consummation of this offering, "change in control" will have the meaning given to such term in our 2019 Plan, as described below.

For purposes of the employment letters with Dr. Gujrathi and Mr. Hasnain, "disability" has the same meaning given to such term in our 2017 Plan, as described below. For purposes of the employment letters with the other executives, "disability" means a permanent and total disability within the meaning of Section 22(e)(3) of the Code, as it may be amended from time to time.

For purposes of the executive employment letters, "good reason" means the occurrence of any of the following events or conditions without the executive's written consent: (1) a material reduction in the executive's base salary or target annual bonus; (2) a material diminution of the executive's title, duties, responsibilities or reporting lines; (3) a material change in the principal geographic location at which the executive must perform services, more than fifty (50) miles from the our head office; or (4) a material breach by us of the terms of the

## Table of Contents

employment letter. The executive must provide written notice to us of the occurrence of any of the foregoing events or conditions within 60 days of the initial occurrence of such event and we will have a period of 30 days to cure such event or condition after receipt of such notice. An executive's separation from service by reason of resignation for good reason must occur within 60 days following the expiration of the foregoing 30 day cure period.

### Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information regarding equity awards granted to our named executive officers that remained outstanding as of December 31, 2017.

	Stock Awards	
	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)(1)
Sheila Gujrathi, M.D.	—	—
Faheem Hasnain	—	—
Christian Waage	522,170(2)	8,354,720

(1) The market value was computed using \$16.00, which is the assumed initial public offering price.

(2) The shares were granted on November 18, 2017 and vest over a period of four years from the grant date, with 25% of the shares vesting on the first anniversary of the grant date, and the remainder vesting in equal monthly installments over the three years thereafter, subject to continuous service through each vesting date.

The following table sets forth certain information regarding equity awards granted to our named executive officers that remained outstanding as of December 31, 2018.

	Grant Date	Option Awards				Stock Awards	
		Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price (\$)	Option Expiration Date	Number of Shares of Stock that Have Not Vested	Market Value of Shares that Have Not Vested (\$)(1)
Sheila Gujrathi, M.D.	5/21/2018	—	—	—	—	125,774(2)	2,012,384
	9/6/2018	—	—	—	—	897,512(2)	14,360,192
Faheem Hasnain	5/21/2018	—	—	—	—	125,774(2)	2,012,384
	9/6/2018	—	—	—	—	897,512(2)	14,360,192
Christian Waage	12/10/2018	—	44,444(3)	\$ 10.71	12/10/2028	—	—
	11/18/2017	—	—	—	—	380,749(4)	6,091,984
Bryan Giraud	12/10/2018	—	155,555(3)	\$ 10.71	12/10/2028	—	—
	5/21/2018	—	405,666(5)	\$ 2.61	5/21/2028	—	—
Jakob Dupont, M.D.	12/14/2018	—	481,311(6)	\$ 10.71	12/14/2028	—	—

(1) The market value was computed using \$16.00, which is the assumed initial public offering price.

(2) Represents shares of restricted stock granted outside of our 2017 Plan. These shares vest over a period of five years measured from January 4, 2018, with 20% of the shares vesting on January 4, 2019 and the remainder vesting in 48 equal monthly installments thereafter. All vesting is subject to the individual's continuous employment with us through the vesting dates and the potential vesting acceleration described above under "—Employment Letters with Dr. Gujrathi and Mr. Hasnain." Excludes the 50% of Founders' Equity issued in December 2015 which became subject to new vesting terms in January 2018 and remain unvested as of December 31, 2018 (2,290,222 shares for each of Dr. Gujrathi and Mr. Hasnain, which have a market value of \$36,643,552 as of December 31, 2018 using \$16.00 per share, which is the assumed initial public offering price). These Founders' Equity shares are not equity incentive plan awards and are described further above under "—Employment Letters with Dr. Gujrathi and Mr. Hasnain."

## [Table of Contents](#)

- (3) Represents options issued under our 2017 Plan, described below under “—Incentive Award Plans.” The options vest over a period of four years from December 7, 2018, with 25% of the option vesting on the first anniversary of such date, and the remainder vesting in equal monthly installments over the three years thereafter. All vesting is subject to the individual’s continuous service with us through the vesting dates and the potential vesting acceleration described above under “—Employment Letters with Other Executives.”
- (4) Represents shares of restricted stock granted under our 2017 Plan, described below under “—Incentive Award Plans.” The shares vest over a period of four years from the grant date, with 25% of the shares vesting on the first anniversary of the grant date, and the remainder vesting in equal monthly installments over the three years thereafter, subject to continuous service through each vesting date.
- (5) Represents options issued under our 2017 Plan, described below under “—Incentive Award Plans.” The options vest over a period of four years from May 7, 2018, with 25% of the option vesting on the first anniversary of such date, and the remainder vesting in equal monthly installments over the three years thereafter. All vesting is subject to the individual’s continuous service with us through the vesting dates and the potential vesting acceleration described above under “—Employment Letters with Other Executives.”
- (6) Represents options issued under our 2017 Plan, described below under “—Incentive Award Plans.” The options vest over a period of four years from the date of grant, with 25% of the option vesting on the first anniversary of such date, and the remainder vesting in equal monthly installments over the three years thereafter. All vesting is subject to the individual’s continuous service with us through the vesting dates and the potential vesting acceleration described above under “—Employment Letters with Other Executives.”

### **Narrative Disclosure to Outstanding Equity Awards at Fiscal Year-End Table**

We did not engage in any repricings or other modifications or cancellations to any of our named executive officers’ outstanding equity awards during the years ended December 31, 2017 and 2018.

### **Other Elements of Compensation**

#### ***Perquisites, Health, Welfare and Retirement Benefits***

Our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, group life, disability and accidental death and dismemberment insurance plans, in each case on the generally on same basis as all of our other employees. We provide a 401(k) plan to our employees, including our current named executive officers, as discussed in the section below entitled “—401(k) Plan.”

We generally do not provide perquisites or personal benefits to our named executive officers, except in limited circumstances. We do, however, pay the premiums for term life insurance and disability insurance for all of our employees, including our executive officers. In addition, Dr. Dupont is eligible for certain relocation and commuting assistance and related tax gross-up payments pursuant to his employment letter. Our board of directors may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our best interests.

#### ***401(k) Plan***

We maintain a defined contribution employee retirement plan, or 401(k) plan, for our employees. Our named executive officers are eligible to participate in the 401(k) plan on the same basis as our other employees. The 401(k) plan is intended to qualify as a tax-qualified plan under Section 401(k) of the Code. The 401(k) plan provides that each participant may make pre-tax deferrals from his or her compensation up to the statutory limit, which is \$18,500 for calendar year 2018, and other testing limits. Participants that are 50 years or older can also make “catch-up” contributions, which in calendar year 2018 may be up to an additional \$6,000 above the statutory limit. Although the 401(k) plan provides for discretionary matching and profit sharing contributions, we currently do not make either type of contribution to the 401(k) plan. Participant contributions are held and invested, pursuant to the participant’s instructions, by the plan’s trustee.

#### ***Nonqualified Deferred Compensation***

We do not maintain nonqualified defined contribution plans or other nonqualified deferred compensation plans. Our board of directors may elect to provide our officers and other employees with non-qualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

### ***Change in Control Benefits***

Our executive officers may become entitled to certain benefits or enhanced benefits in connection with a change in control of our company. The employment letters with each of our executive officers provide for accelerated vesting of all outstanding equity awards, as well as certain other benefits, upon a qualifying termination in connection with a change in control of our company. For additional discussion, please see “—Offer Letters with our Named Executive Officers” above.

### **Incentive Award Plans**

#### ***2019 Incentive Award Plan***

In January 2019, our board of directors adopted, and our stockholders approved, the 2019 Plan, which will become effective in connection with this offering. Under the 2019 Plan, we may grant cash and equity incentive awards to eligible employees, directors and consultants in order to attract, motivate and retain the talent for which we compete. The material terms of the 2019 Plan are summarized below.

#### ***Eligibility and Administration***

Our employees, consultants and directors, and employees and consultants of our subsidiaries, will be eligible to receive awards under the 2019 Plan. Following our initial public offering, the 2019 Plan will generally be administered by our board of directors with respect to awards to non-employee directors and by our compensation committee with respect to other participants, each of which may delegate its duties and responsibilities to committees of our directors and/or officers (referred to collectively as the plan administrator below), subject to certain limitations that may be imposed under the 2019 Plan, Section 16 of the Exchange Act and/or stock exchange rules, as applicable. The plan administrator will have the authority to make all determinations and interpretations under, prescribe all forms for use with, and adopt rules for the administration of, the 2019 Plan, subject to its express terms and conditions. The plan administrator will also set the terms and conditions of all awards under the 2019 Plan, including any vesting and vesting acceleration conditions.

#### ***Limitation on Awards and Shares Available***

An aggregate of 5,750,000 shares of our common stock will initially be available for issuance under awards granted pursuant to the 2019 Plan. The number of shares initially available for issuance will be increased by (1) the number of shares of common stock available for issuance and not subject to options granted under our 2017 Plan as of the effective date of the 2019 Plan, (2) the number of shares subject to stock options or awards granted under our 2017 Plan that expire or otherwise terminate without having been exercised in full after the effective date of the 2019 Plan and unvested shares issued pursuant to awards granted under the 2017 Plan that are forfeited to or repurchased by us after the effective date of the 2019 Plan, with the maximum number of shares to be added to the 2019 Plan pursuant to clauses (1) and (2) above equal to 6,290,016 shares, and (3) an annual increase on January 1 of each calendar year beginning in 2020 and ending in 2029, equal to the lesser of (a) 5% of the shares of common stock outstanding on the final day of the immediately preceding calendar year and (b) such smaller number of shares as determined by our board of directors. No more than 70,000,000 shares of common stock may be issued upon the exercise of incentive stock options under the 2019 Plan. Shares issued under the 2019 Plan may be authorized but unissued shares, shares purchased in the open market or treasury shares.

If an award under the 2019 Plan or the 2017 Plan expires, lapses or is terminated, exchanged for cash, surrendered, repurchased, canceled without having been fully exercised or forfeited, any shares subject to such award will, as applicable, become or again be available for new grants under the 2019 Plan. Further, shares delivered to us to satisfy the applicable exercise or purchase price of an award under the 2019 Plan or the 2017 Plan and/or to satisfy any applicable tax withholding obligations (including shares retained by us from the award

under the 2019 Plan or the 2017 Plan being exercised or purchased and/or creating the tax obligation) will become or again be available for award grants under the 2019 Plan. Awards granted under the 2019 Plan upon the assumption of, or in substitution for, awards authorized or outstanding under a qualifying equity plan maintained by an entity with which we enter into a merger or similar corporate transaction will not reduce the shares available for grant under the 2019 Plan.

### **Awards**

The 2019 Plan provides for the grant of stock options, including incentive stock options, or ISOs, and nonqualified stock options, or NSOs, restricted stock, dividend equivalents, restricted stock units, or RSUs, stock appreciation rights, or SARs, and other stock or cash-based awards. Certain awards under the 2019 Plan may constitute or provide for a deferral of compensation, subject to Section 409A of the Code, which may impose additional requirements on the terms and conditions of such awards. All awards under the 2019 Plan will be set forth in award agreements, which will detail the terms and conditions of the awards, including any applicable vesting and payment terms and post-termination exercise limitations. A brief description of each award type follows.

*Stock Options.* Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, by contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Code are satisfied. The exercise price of a stock option will not be less than 100% of the fair market value of the underlying share on the date of grant (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute options granted in connection with a corporate transaction. The term of a stock option may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders). Vesting conditions determined by the plan administrator may apply to stock options and may include continued service, performance and/or other conditions. ISOs generally may be granted only to our employees and employees of our parent or subsidiary corporations, if any.

*SARs.* SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The exercise price of a SAR will not be less than 100% of the fair market value of the underlying share on the date of grant (except with respect to certain substitute SARs granted in connection with a corporate transaction), and the term of a SAR may not be longer than ten years. Vesting conditions determined by the plan administrator may apply to SARs and may include continued service, performance and/or other conditions.

*Restricted Stock and RSUs.* Restricted stock is an award of nontransferable shares of our common stock that remain forfeitable unless and until specified conditions are met, and which may be subject to a purchase price. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met and may be accompanied by the right to receive the equivalent value of dividends paid on shares of our common stock prior to the delivery of the underlying shares. Delivery of the shares underlying RSUs may be deferred under the terms of the award or at the election of the participant, if the plan administrator permits such a deferral. Conditions applicable to restricted stock and RSUs may be based on continuing service, the attainment of performance goals and/or such other conditions as the plan administrator may determine.

*Other Stock or Cash-Based Awards.* Other stock or cash-based awards are awards of cash, fully vested shares of our common stock and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock. Other stock or cash-based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of base salary, bonus, fees or other cash compensation otherwise payable to any individual who is eligible to receive awards. The plan administrator will determine the terms and conditions of other stock or cash-based awards, which may include vesting conditions based on continued service, performance and/or other conditions.



### ***Performance Awards***

Performance awards include any of the foregoing awards that are granted subject to vesting and/or payment based on the attainment of specified performance goals or other criteria the plan administrator may determine, which may or may not be objectively determinable. Performance criteria upon which performance goals are established by the plan administrator may include: net earnings or losses (either before or after one or more of interest, taxes, depreciation, amortization and non-cash equity-based compensation expense); gross or net sales or revenue or sales or revenue growth; net income (either before or after taxes) or adjusted net income; profits (including, but not limited to, gross profits, net profits, profit growth, net operation profit or economic profit), profit return ratios or operating margin; budget or operating earnings (either before or after taxes or before or after allocation of corporate overhead and bonus); cash flow (including operating cash flow and free cash flow or cash flow return on capital); return on assets; return on capital or invested capital; cost of capital; return on stockholders' equity; total stockholder return; return on sales; costs, reductions in costs and cost control measures; expenses; working capital; earnings or loss per share; adjusted earnings or loss per share; price per share or dividends per share (or appreciation in or maintenance of such price or dividends); regulatory achievements or compliance; implementation, completion or attainment of objectives relating to research, development, regulatory, commercial or strategic milestones or developments; market share; economic value or economic value added models; division, group or corporate financial goals; customer satisfaction/growth; customer service; employee satisfaction; recruitment and maintenance of personnel; human resources management; supervision of litigation and other legal matters; strategic partnerships and transactions; financial ratios (including those measuring liquidity, activity, profitability or leverage); debt levels or reductions; sales-related goals; financing and other capital raising transactions; cash on hand; acquisition activity; investment sourcing activity; and marketing initiatives, any of which may be measured in absolute terms or as compared to any incremental increase or decrease. Such performance goals also may be based solely by reference to our performance or the performance of a subsidiary, division, business segment or business unit, or based upon performance relative to performance of other companies or upon comparisons of any of the indicators of performance relative to performance of other companies.

### ***Provisions of the 2019 Plan Relating to Director Compensation***

The 2019 Plan provides that the plan administrator may establish compensation for non-employee directors from time to time subject to the 2019 Plan's limitations. Prior to commencing this offering, our stockholders will approve the initial terms of our non-employee director compensation program, which is described below under the heading "—Director Compensation." Our board of directors or its authorized committee may modify the non-employee director compensation program from time to time in the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time, provided that the sum of any cash compensation or other compensation and the grant date fair value (as determined in accordance with ASC 718, or any successor thereto) of any equity awards granted as compensation for services as a non-employee director during any fiscal year may not exceed \$750,000, increased to \$1,000,000, in the fiscal year of a non-employee director's initial service as a non-employee director. The plan administrator may make exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the plan administrator may determine in its discretion, provided that the non-employee director receiving such additional compensation may not participate in the decision to award such compensation or in other contemporaneous compensation decisions involving non-employee directors.

### ***Certain Transactions***

In connection with certain transactions and events affecting our common stock, including a change in control, or change in any applicable laws or accounting principles, the plan administrator has broad discretion to take action under the 2019 Plan to prevent the dilution or enlargement of intended benefits, facilitate such transaction or event, or give effect to such change in applicable laws or accounting principles. This includes canceling awards in exchange for either an amount in cash or other property with a value equal to the amount that

would have been obtained upon exercise or settlement of the vested portion of such award or realization of the participant's rights under the vested portion of such award, accelerating the vesting of awards, providing for the assumption or substitution of awards by a successor entity, adjusting the number and type of shares available, replacing awards with other rights or property or terminating awards under the 2019 Plan. In the event of a change in control where the acquirer does not assume awards granted under the 2019 Plan, awards issued under the 2019 Plan shall be subject to accelerated vesting such that 100% of the awards will become vested and exercisable or payable, as applicable, and which may be subject to such terms and conditions as apply generally to holders of common stock under the change in control documents. In addition, in the event of certain non-reciprocal transactions with our stockholders, or an "equity restructuring," the plan administrator will make equitable adjustments to the 2019 Plan and outstanding awards as it deems appropriate to reflect the equity restructuring.

For purposes of the 2019 Plan, a "change in control" means and includes each of the following: (1) a transaction or series of transactions (other than an offering of our common stock to the general public through a registration statement filed with the SEC or a transaction or series of transactions that meets the requirements of clauses (x) and (y) of clause (3) below) whereby any "person" or related "group" of "persons" (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) (other than us, any of our subsidiaries, an employee benefit plan maintained by us or any of our subsidiaries or a "person" that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, us) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of our securities possessing more than 50% of the total combined voting power of our securities outstanding immediately after such acquisition; or (2) during any period of two consecutive years, individuals who, at the beginning of such period, constitute the board of directors together with any new director(s) (other than a director designated by a person who shall have entered into an agreement with us to effect a transaction described in clauses (1) or (3)) whose election by the board of directors or nomination for election by our stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof; or (3) the consummation by us (whether directly involving us or indirectly involving us through one or more intermediaries) of (a) a merger, consolidation, reorganization, or business combination or (b) a sale or other disposition of all or substantially all of our assets in any single transaction or series of related transactions or (c) the acquisition of assets or stock of another entity, in each case other than a transaction: (x) which results in our voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into our voting securities or the voting securities of a successor entity, directly or indirectly, at least a majority of the combined voting power of our outstanding voting securities or the successor entity's outstanding voting securities immediately after the transaction, and (y) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of us or the successor entity (provided that no person will be treated as beneficially owning 50% or more of the combined voting power of us or the successor entity for purposes of this clause (y) solely as a result of the voting power held in us prior to the consummation of the transaction).

#### ***Foreign Participants, Claw-Back Provisions, Transferability and Participant Payments***

With respect to foreign participants, the plan administrator may modify award terms, establish subplans and/or adjust other terms and conditions of awards, subject to the share limits described above. All awards will be subject to the provisions of any claw-back policy implemented by our company to the extent set forth in such claw-back policy or in the applicable award agreement. With limited exceptions for estate planning, domestic relations orders, certain beneficiary designations and the laws of descent and distribution, awards under the 2019 Plan are generally non-transferable prior to vesting and are exercisable only by the participant. With regard to tax withholding obligations arising in connection with awards under the 2019 Plan and exercise price obligations arising in connection with the exercise of stock options under the 2019 Plan, the plan administrator may, in its discretion, accept cash, wire transfer, or check, shares of our common stock that meet specified conditions, a "market sell order" or such other consideration as it deems suitable or any combination of the foregoing.

### ***Plan Amendment and Termination***

Our board of directors may amend or terminate the 2019 Plan at any time; however, except in connection with certain changes in our capital structure, stockholder approval will be required for any amendment that increases the number of shares available under the 2019 Plan. The plan administrator will have the authority, without the approval of our stockholders, to amend any outstanding stock option or SAR to reduce its exercise price per share. No award may be granted pursuant to the 2019 Plan after the tenth anniversary of the date on which our board of directors adopted the 2019 Plan.

### ***Securities Laws***

The 2019 Plan is intended to conform to all provisions of the Securities Act, and the Exchange Act and any and all regulations and rules promulgated by the SEC thereunder, including, without limitation, Rule 16b-3. The 2019 Plan will be administered, and awards will be granted and may be exercised, only in such a manner as to conform to such laws, rules and regulations.

### ***Federal Income Tax Consequences***

The material federal income tax consequences of the 2019 Plan under current federal income tax law are summarized in the following discussion, which deals with the general tax principles applicable to the 2019 Plan. The following discussion is based upon laws, regulations, rulings and decisions now in effect, all of which are subject to change. Foreign, state and local tax laws, and employment, estate and gift tax considerations are not discussed due to the fact that they may vary depending on individual circumstances and from locality to locality.

***Stock Options and SARs.*** A 2019 Plan participant generally will not recognize taxable income and we generally will not be entitled to a tax deduction upon the grant of a stock option or SAR. The tax consequences of exercising a stock option and the subsequent disposition of the shares received upon exercise will depend upon whether the option qualifies as an ISO or an NSO. Upon exercising an NSO when the fair market value of our stock is higher than the exercise price of the option, a 2019 Plan participant generally will recognize taxable income at ordinary income tax rates equal to the excess of the fair market value of the stock on the date of exercise over the purchase price, and we (or our subsidiaries, if any) generally will be entitled to a corresponding tax deduction for compensation expense, in the amount equal to the amount by which the fair market value of the shares purchased exceeds the purchase price for the shares. Upon a subsequent sale or other disposition of the option shares, the participant will recognize a short-term or long-term capital gain or loss in the amount of the difference between the sales price of the shares and the participant's tax basis in the shares.

Upon exercising an ISO, a 2019 Plan participant generally will not recognize taxable income, and we will not be entitled to a tax deduction for compensation expense. However, upon exercise, the amount by which the fair market value of the shares purchased exceeds the purchase price will be an item of adjustment for alternative minimum tax purposes. The participant will recognize taxable income upon a sale or other taxable disposition of the option shares. For federal income tax purposes, dispositions are divided into two categories: qualifying and disqualifying. A qualifying disposition generally occurs if the sale or other disposition is made more than two years after the date the option was granted and more than one year after the date the shares are transferred upon exercise. If the sale or disposition occurs before these two periods are satisfied, then a disqualifying disposition generally will result.

Upon a qualifying disposition of ISO shares, the participant will recognize long-term capital gain in an amount equal to the excess of the amount realized upon the sale or other disposition of the shares over their purchase price. If there is a disqualifying disposition of the shares, then the excess of the fair market value of the shares on the exercise date (or, if less, the price at which the shares are sold) over their purchase price will be taxable as ordinary income to the participant. If there is a disqualifying disposition in the same year of exercise, it eliminates the item of adjustment for alternative minimum tax purposes. Any additional gain or loss recognized upon the disposition will be recognized as a capital gain or loss by the participant.

## [Table of Contents](#)

We will not be entitled to any tax deduction if the participant makes a qualifying disposition of ISO shares. If the participant makes a disqualifying disposition of the shares, we should be entitled to a tax deduction for compensation expense in the amount of the ordinary income recognized by the participant.

Upon exercising or settling a SAR, a 2019 Plan participant will recognize taxable income at ordinary income tax rates, and we should be entitled to a corresponding tax deduction for compensation expense, in the amount paid or value of the shares issued upon exercise or settlement. Payments in shares will be valued at the fair market value of the shares at the time of the payment, and upon the subsequent disposition of the shares the participant will recognize a short-term or long-term capital gain or loss in the amount of the difference between the sales price of the shares and the participant's tax basis in the shares.

*Restricted Stock and RSUs.* A 2019 Plan participant generally will not recognize taxable income at ordinary income tax rates and we generally will not be entitled to a tax deduction upon the grant of restricted stock or RSUs. Upon the termination of restrictions on restricted stock or the payment of RSUs, the participant will recognize taxable income at ordinary income tax rates, and we should be entitled to a corresponding tax deduction for compensation expense, in the amount paid to the participant or the amount by which the then fair market value of the shares received by the participant exceeds the amount, if any, paid for them. Upon the subsequent disposition of any shares, the participant will recognize a short-term or long-term capital gain or loss in the amount of the difference between the sales price of the shares and the participant's tax basis in the shares. However, a 2019 Plan participant granted restricted stock that is subject to forfeiture or repurchase through a vesting schedule such that it is subject to a "risk of forfeiture" (as defined in Section 83 of the Code) may make an election under Section 83(b) of the Code to recognize taxable income at ordinary income tax rates, at the time of the grant, in an amount equal to the fair market value of the shares of common stock on the date of grant, less the amount paid, if any, for such shares. We will be entitled to a corresponding tax deduction for compensation, in the amount recognized as taxable income by the participant. If a timely Section 83(b) election is made, the participant will not recognize any additional ordinary income on the termination of restrictions on restricted stock, and we will not be entitled to any additional tax deduction.

*Other Stock or Cash-Based Awards.* A 2019 Plan participant will not recognize taxable income and we will not be entitled to a tax deduction upon the grant of other stock or cash-based awards until cash or shares are paid or distributed to the participant. At that time, any cash payments or the fair market value of shares that the participant receives will be taxable to the participant at ordinary income tax rates and we should be entitled to a corresponding tax deduction for compensation expense. Payments in shares will be valued at the fair market value of the shares at the time of the payment, and upon the subsequent disposition of the shares, the participant will recognize a short-term or long-term capital gain or loss in the amount of the difference between the sales price of the shares and the participant's tax basis in the shares.

### **2017 Equity Incentive Plan**

In November 2017, our board of directors and our stockholders approved the adoption of the 2017 Plan. Our board of directors and stockholders subsequently approved four amendments to the 2017 Plan to increase the share reserve thereunder in each of December 2017, May 2018, June 2018, July 2018 and December 2018.

A total of 6,290,016 shares of our common stock are reserved for issuance under the 2017 Plan. As of December 31, 2018, 6,285,521 shares of our common stock were subject to outstanding awards under the 2017 Plan and 4,525 shares of our common stock remained available for future issuance under the 2017 Plan.

After the effective date of the 2019 Plan, no additional awards will be granted under the 2017 Plan. However, the 2017 Plan will continue to govern the terms and conditions of the outstanding awards granted under it. Shares of our common stock subject to awards granted under the 2017 Plan that expire, lapse or are terminated, exchanged for cash, surrendered, repurchased or forfeited following the effective date of the 2019 Plan will be available for issuance under the 2019 Plan in accordance with its terms.

## [Table of Contents](#)

*Administration.* Our board of directors administers the 2017 Plan, unless it delegates authority for administration of the plan. Subject to the terms and conditions of the 2017 Plan, the administrator has the authority to select the persons to whom awards are to be made, to determine the type or types of awards to be granted to each person, determine the number of awards to grant, determine the number of shares to be subject to such awards, and the terms and conditions of such awards, and make all other determinations and decisions and to take all other actions necessary or advisable for the administration of the 2017 Plan. The plan administrator is also authorized to establish, adopt, amend or revise rules relating to administration of the 2017 Plan, subject to certain restrictions.

*Eligibility.* Awards under the 2017 Plan may be granted to individuals who are then our employees, consultants and members of our board of directors and our subsidiaries. Only employees may be granted ISOs.

*Awards.* The 2017 Plan provides that our administrator may grant or issue stock options (including NSOs and ISOs), restricted stock, RSUs, other stock-based awards, or any combination thereof. The administrator considers each award grant subjectively, considering factors such as the individual performance of the recipient and the anticipated contribution of the recipient to the attainment of our long-term goals. Each award is set forth in a separate agreement with the person receiving the award and indicates the type, terms and conditions of the award. As of the date of this prospectus, awards of stock options and restricted stock are outstanding under the 2019 Plan.

*Corporate Transactions.* The plan administrator has broad discretion to equitably adjust the provisions of the 2017 Plan and the terms and conditions of existing and future awards, including with respect to aggregate number and type of shares subject to the 2017 Plan and awards granted pursuant to the 2017 Plan, to prevent the dilution or enlargement of intended benefits and/or facilitate necessary or desirable changes in the event of certain transactions and events affecting our common stock, such as stock dividends, stock splits, mergers, acquisitions, consolidations and other corporate transactions. The plan administrator may also provide for the acceleration, cash-out, termination, assumption, substitution or conversion of awards in the event of a change in control or certain other unusual or nonrecurring events or transactions. In addition, in the event of certain non-reciprocal transactions with our stockholders, or an “equity restructuring,” the plan administrator will make equitable adjustments to the 2017 Plan and outstanding awards as it deems appropriate to reflect the equity restructuring.

In the event of a change of control where the acquirer does not assume awards granted under the 2017 Plan, awards issued under the 2017 Plan held by persons who have not experienced a termination of service will be subject to accelerated vesting such that 100% of the awards will become vested and exercisable or payable, as applicable, immediately prior to the change in control. Under the 2017 Plan, a change of control is generally defined as: (1) a merger or consolidation of our company with or into any other corporation or other entity or person; (2) a sale, lease, exchange or other transfer in one transaction or a series of related transactions of all or substantially all of our company’s assets; or (3) any other transaction, including the sale by us of new shares of our capital stock or a transfer of existing shares of our capital stock, the result of which is that a third party that is not an affiliate of us or our stockholders (or a group of third parties not affiliated with us or our stockholders) immediately prior to such transaction acquires or holds capital stock representing a majority of our outstanding voting power immediately following such transaction; provided that the following events shall not constitute a “change in control” under the 2017 Plan: (A) a transaction (other than a sale of all or substantially all of our assets) in which the holders of our voting securities immediately prior to the merger or consolidation hold, directly or indirectly, at least a majority of the voting securities in the successor corporation or its parent immediately after the merger or consolidation; (B) a sale, lease, exchange or other transaction in one transaction or a series of related transactions of all or substantially all of our assets to an affiliate of ours; (C) an initial public offering of any of our securities or any other transaction principally for bona fide equity financing purposes; (D) a reincorporation solely to change our jurisdiction; or (E) a transaction undertaken for the primary purpose of creating a holding company that will be owned in substantially the same proportion by the persons who held our securities immediately before such transaction.

## [Table of Contents](#)

*Amendment and Termination of the 2017 Plan.* Our board of directors may terminate, amend or modify the 2017 Plan. However, stockholder approval of any amendment to the 2017 Plan must be obtained to the extent necessary and desirable to comply with any applicable law, regulation or stock exchange rule, or for any amendment to the 2017 Plan that increases the number of shares available under the 2017 Plan. If not terminated earlier by the compensation committee or the board of directors, the 2017 Plan will terminate on November 17, 2027.

*Securities Laws and Federal Income Tax Consequences.* The 2017 Plan is designed to comply with applicable securities laws in the same manner as described above in the description of the 2019 Plan under the heading “—2019 Incentive Award Plan—Securities Laws.” The general federal tax consequences of awards under the 2017 Plan are the same as those described above in the description of the 2019 Plan under the heading “—2019 Incentive Award Plan—Federal Income Tax Consequences.”

### **2019 Employee Stock Purchase Plan**

In January 2019, our board of directors adopted, and our stockholders approved, the 2019 Employee Stock Purchase Plan, or the ESPP. The material terms of the ESPP are summarized below.

*Shares Available; Administration.* A total of 700,000 shares of our common stock are initially reserved for issuance under our ESPP. In addition, the number of shares available for issuance under the ESPP will be annually increased on January 1 of each calendar year beginning in 2020 and ending in 2029, by an amount equal to the lesser of: (a) 1% of the shares outstanding on the final day of the immediately preceding calendar year and (b) such smaller number of shares as is determined by our board of directors. In no event will more than 20,000,000 shares of our common stock be available for issuance under the ESPP.

Our board of directors or its committee will have authority to interpret the terms of the ESPP and determine eligibility of participants. We expect that the compensation committee will be the initial administrator of the ESPP.

*Eligibility.* Our employees are eligible to participate in the ESPP if they meet the eligibility requirements under the ESPP established from time to time by the plan administrator. However, an employee may not be granted rights to purchase stock under our ESPP if such employee, immediately after the grant, would own (directly or through attribution) stock possessing 5% or more of the total combined voting power or value of all classes of our common or other class of stock.

*Grant of Rights.* The ESPP is intended to qualify under Section 423 of the Code and stock will be offered under the ESPP during offering periods. The length of the offering periods under the ESPP will be determined by the plan administrator and may be up to 27 months long. Employee payroll deductions will be used to purchase shares on each purchase date during an offering period. The number of purchase periods within, and purchase dates during each offering period will be established by the plan administrator prior to the commencement of each offering period. Offering periods under the ESPP will commence when determined by the plan administrator. The plan administrator may, in its discretion, modify the terms of future offering periods.

The ESPP permits participants to purchase common stock through payroll deductions of up to 20% of their eligible compensation, which includes a participant's gross base compensation for services to us, including overtime payments and excluding sales commissions, incentive compensation, bonuses, expense reimbursements, fringe benefits and other special payments. The plan administrator will establish a maximum number of shares that may be purchased by a participant during any offering period or purchase period, which, in the absence of a contrary designation, will be 100,000 shares. In addition, no employee will be permitted to accrue the right to purchase stock under the ESPP at a rate in excess of \$25,000 worth of shares during any calendar year during which such a purchase right is outstanding (based on the fair market value per share of our common stock as of the first day of the offering period).

## [Table of Contents](#)

On the first trading day of each offering period, each participant will automatically be granted an option to purchase shares of our common stock. The option will be exercised on the applicable purchase date(s) during the offering period, to the extent of the payroll deductions accumulated during the applicable purchase period. The purchase price of the shares, in the absence of a contrary determination by the plan administrator, will be 85% of the lower of the fair market value of our common stock on the first trading day of the offering period or on the applicable purchase date, which will be the final trading day of the applicable purchase period. Participants may voluntarily end their participation in the ESPP at any time at least one week prior to the end of the applicable offering period (or such shorter or longer period specified by the plan administrator), and will be paid their accrued payroll deductions that have not yet been used to purchase shares of common stock. Participation ends automatically upon a participant's termination of employment.

A participant may not transfer rights granted under the ESPP other than by will, the laws of descent and distribution or as otherwise provided under the ESPP.

*Certain Transactions.* In the event of certain transactions or events affecting our common stock, such as any stock dividend or other distribution, change in control, reorganization, merger, consolidation or other corporate transaction, the plan administrator will make equitable adjustments to the ESPP and outstanding rights. In addition, in the event of the foregoing transactions or events or certain significant transactions, including a change in control, the plan administrator may provide for (1) either the replacement of outstanding rights with other rights or property or termination of outstanding rights in exchange for cash, (2) the assumption or substitution of outstanding rights by the successor or survivor corporation or parent or subsidiary thereof, if any, (3) the adjustment in the number and type of shares of stock subject to outstanding rights, (4) the use of participants' accumulated payroll deductions to purchase stock on a new purchase date prior to the next scheduled purchase date and termination of any rights under ongoing offering periods or (5) the termination of all outstanding rights. Under the ESPP, a change in control has the same definition as given to such term in the 2019 Plan.

*Plan Amendment; Termination.* The plan administrator may amend, suspend or terminate the ESPP at any time. However, stockholder approval of any amendment to the ESPP will be obtained for any amendment which increases the aggregate number or changes the type of shares that may be sold pursuant to rights under the ESPP, changes the corporations or classes of corporations whose employees are eligible to participate in the ESPP or changes the ESPP in any manner that would cause the ESPP to no longer be an employee stock purchase plan within the meaning of Section 423(b) of the Code. The ESPP will remain in effect until terminated by our board of directors.

*Securities Laws.* The ESPP has been designed to comply with various securities laws in the same manner as described above in the description of the 2019 Plan.

*Federal Income Taxes.* The material federal income tax consequences of the ESPP under current federal income tax law are summarized in the following discussion, which deals with the general tax principles applicable to the ESPP. The following discussion is based upon laws, regulations, rulings and decisions now in effect, all of which are subject to change. Foreign, state and local tax laws, and employment, estate and gift tax considerations are not discussed due to the fact that they may vary depending on individual circumstances and from locality to locality.

The ESPP, and the right of participants to make purchases thereunder, is intended to qualify under the provisions of Section 423 of the Code. Under the applicable Code provisions, no income will be taxable to a participant until the sale or other disposition of the shares purchased under the ESPP. This means that an eligible employee will not recognize taxable income on the date the employee is granted an option under the ESPP (i.e., the first day of the offering period). In addition, the employee will not recognize taxable income upon the purchase of shares. Upon such sale or disposition, the participant will generally be subject to tax in an amount that depends upon the length of time such shares are held by the participant prior to disposing of them. If the

shares are sold or disposed of more than two years from the first day of the offering period during which the shares were purchased and more than one year from the date of purchase, or if the participant dies while holding the shares, the participant (or his or her estate) will recognize ordinary income measured as the lesser of: (1) the excess of the fair market value of the shares at the time of such sale or disposition over the purchase price; or (2) an amount equal to 15% of the fair market value of the shares as of the first day of the offering period. Any additional gain will be treated as long-term capital gain. If the shares are held for the holding periods described above but are sold for a price that is less than the purchase price, there is no ordinary income and the participating employee has a long-term capital loss for the difference between the sale price and the purchase price.

If the shares are sold or otherwise disposed of before the expiration of the holding periods described above, the participant will recognize ordinary income generally measured as the excess of the fair market value of the shares on the date the shares are purchased over the purchase price and we will be entitled to a tax deduction for compensation expense in the amount of ordinary income recognized by the employee. Any additional gain or loss on such sale or disposition will be long-term or short-term capital gain or loss, depending on how long the shares were held following the date they were purchased by the participant prior to disposing of them. If the shares are sold or otherwise disposed of before the expiration of the holding periods described above but are sold for a price that is less than the purchase price, the participant will recognize ordinary income equal to the excess of the fair market value of the shares on the date of purchase over the purchase price (and we will be entitled to a corresponding deduction), but the participant generally will be able to report a capital loss equal to the difference between the sales price of the shares and the fair market value of the shares on the date of purchase.

### **Director Compensation**

Historically, we have not paid cash or stock-based compensation to directors for their service on our board of directors. In 2017, we did not grant any equity awards to the non-employee members of our board of directors, and none of our non-employee directors held any equity awards as of December 31, 2017. On May 21, 2018 we granted to Dr. Daniel an option to purchase 131,111 shares of our common stock pursuant to our 2017 Plan in connection with his commencement of service on our board of directors, which option vests in 36 equal monthly installments commencing on January 14, 2018. The option has an exercise price per share of \$2.61, which was the fair market value at the time of grant. On December 4, 2018, we granted to Mr. Cox an option to purchase 46,666 shares of our common stock pursuant to our 2017 Plan in connection with his commencement of service on our board of directors, which option vests in 36 equal monthly installments commencing on December 4, 2018. The option has an exercise price per share of \$10.71, which was the fair market value at the time of grant. On December 14, 2018, we granted to Ms. Galá an option to purchase 46,666 shares of our common stock pursuant to our 2017 Plan in connection with her commencement of service on our board of directors, which option vests in 36 equal monthly installments commencing on December 14, 2018. On December 14, 2018, we granted to Dr. Bilenker an option to purchase 46,666 shares of our common stock pursuant to our 2017 Plan in connection with his commencement of service on our board of directors, which option vests in 36 equal monthly installments commencing on December 14, 2018. These options have an exercise price per share of \$10.71, which was the fair market value at the time of grant.

We have reimbursed and will continue to reimburse all of our non-employee directors for their travel, lodging and other reasonable expenses incurred in attending meetings of our board of directors and committees of our board of directors.



## Table of Contents

The following table sets forth in summary form information concerning the compensation that we paid or awarded during the year ended December 31, 2018 to each of our non-employee directors.

<u>Name</u>	<u>Option Awards (\$)(1)</u>	<u>Total (\$)</u>
Joshua H. Bilenker, M.D.(2)	331,800	331,800
Kristina Burow	—	—
Russell Cox(3)	331,800	331,800
Thomas Daniel, M.D.(4)	224,200	224,200
Renée Galá(5)	331,800	331,800
Richard Lim(6)	—	—
Robert Nelsen(7)	—	—
Otello Stampacchia, Ph.D.	—	—
Wenkai Xiang, Ph.D.(8)	—	—
Qinqing Yi(9)	—	—

(1) This column reflects the grant date fair value of the option awards granted to the non-employee directors in 2018. In accordance with SEC rules, this column reflects the aggregate fair value of the option awards granted to the non-employee directors during 2018 computed as of the grant date in accordance with Financial Accounting Standards, Standard Board Accounting Codification Topic 718 for stock-based compensation transactions (ASC 718). Assumptions used in the calculation of this amount are included in Note 9 to our consolidated financial statements appearing elsewhere in this prospectus. This amount does not reflect the actual economic value that will be realized by the non-employee directors upon the vesting or exercise of the awards or the sale of the common stock underlying such awards. As of December 31, 2018, only the following non-employee directors held any outstanding equity awards: Dr. Bilenker, 46,666 options; Mr. Cox, 46,666 options; Dr. Daniel, 131,111 options; and Ms. Galá, 46,666 options.

(2) Dr. Bilenker was appointed to our board of directors effective December 14, 2018.

(3) Mr. Cox was appointed to our board of directors effective November 26, 2018.

(4) Dr. Daniel was appointed to our board of directors effective January 4, 2018.

(5) Ms. Galá was appointed to our board of directors effective December 14, 2018.

(6) Mr. Lim resigned from our board of directors effective December 4, 2018.

(7) Mr. Nelsen resigned from our board of directors effective December 4, 2018.

(8) Dr. Xiang resigned from our board of directors effective January 17, 2019.

(9) Mr. Yi resigned from our board of directors effective December 18, 2018.

In January 2019, our board of directors adopted, and our stockholders approved, the initial terms of our non-employee director compensation program. The material terms of the non-employee director compensation program are summarized below.

The non-employee director compensation policy will provide for annual retainer fees and/or long-term equity awards for our non-employee directors. We expect each non-employee director will receive an annual retainer of \$40,000. Non-employee directors serving as the chairs of the audit, compensation and nominating and corporate governance committees will receive additional annual retainers of \$15,000, \$10,000 and \$8,000, respectively. Non-employee directors serving as members of the audit, compensation and nominating and corporate governance committees will receive additional annual retainers of \$7,500, \$5,000 and \$4,000, respectively. The non-employee directors will also receive initial grants of options to purchase 47,000 shares of our common stock, vesting monthly over three years, upon election to the board of directors, and thereafter annual grants of options to purchase 23,500 shares of our common stock, vesting on the first to occur of (1) the first anniversary of the grant date or (2) the next occurring annual meeting of our stockholders.

Compensation under our non-employee director compensation policy will be subject to the annual limits on non-employee director compensation set forth in the 2019 Plan, as described above. Our board of directors or its authorized committee may modify the non-employee director compensation program from time to time in the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time, subject to the annual limit on non-employee director compensation set forth in the 2019 Plan. As provided in the 2019 Plan, our board of directors or its authorized committee may make exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the board of directors or its authorized committee may determine in its discretion, provided that the non-employee director

receiving such additional compensation may not participate in the decision to award such compensation or in other compensation decisions involving non-employee directors.

#### **Limitations of Liability and Indemnification Matters**

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by the Delaware General Corporation Law, which prohibits our amended and restated certificate of incorporation from limiting the liability of our directors for the following:

- any breach of the director's duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

Our amended and restated certificate of incorporation and our amended and restated bylaws also provide that if Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. This limitation of liability does not apply to liabilities arising under the federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation and our amended and restated bylaws also provide that we shall have the power to indemnify our employees and agents to the fullest extent permitted by law. Our amended and restated bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity, regardless of whether our amended and restated bylaws would permit indemnification. We have obtained directors' and officers' liability insurance.

We have entered into separate indemnification agreements with our directors and executive officers, in addition to indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws. These agreements, among other things, provide for indemnification of our directors and executive officers for expenses, judgments, fines and settlement amounts incurred by this person in any action or proceeding arising out of this person's services as a director or executive officer or at our request. We believe that these provisions in our amended and restated certificate of incorporation and amended and restated bylaws and indemnification agreements are necessary to attract and retain qualified persons as directors and executive officers.

The above description of the indemnification provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is not complete and is qualified in its entirety by reference to these documents, each of which is filed as an exhibit to the registration statement of which this prospectus is a part.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing

---

[Table of Contents](#)

provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

## CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following includes a summary of transactions since our inception on October 26, 2015 to which we have been a party in which the amount involved exceeded or will exceed \$120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under “Executive and Director Compensation.” We also describe below certain other transactions with our directors, executive officers and stockholders.

### **Convertible Promissory Note**

On October 2, 2017, we issued and sold in a private placement a \$6.0 million convertible promissory note, or the ARCH note, to ARCH Venture Fund IX, L.P., or ARCH IX. The ARCH note accrued interest at a rate of 8% per annum. The ARCH note, including \$0.1 million in accrued interest thereon, was automatically converted into shares of our Series A convertible preferred stock in the January 2018 Series A convertible preferred stock financing described below. ARCH IX is a beneficial owner of more than 5% of our capital stock.

### **Merger Agreement**

On December 29, 2017, we entered into a merger agreement, or the Merger Agreement, with AA BioPharma Inc. and AAB Merger Sub, Inc., or Merger Sub, a Delaware corporation and our wholly-owned subsidiary. Pursuant to the Merger Agreement, in January 2018, Merger Sub was merged into and with AA BioPharma, with AA BioPharma surviving as our wholly-owned subsidiary. Pulmagen Therapeutics (Asthma) Limited is a wholly-owned subsidiary of AA BioPharma. In connection with the Merger Agreement, all of the issued and outstanding shares of AA BioPharma were converted into shares of our stock, including 1,101,278 shares of our common stock issued to one investor and 20,000,000 shares of our Series Seed convertible preferred stock issued to Omega Fund V, L.P., or Omega V, a beneficial owner of more than 5% of our capital stock.

### **Preferred Stock Financings**

*Series A Convertible Preferred Stock Financings.* In January 2018, we entered into a Series A preferred stock purchase agreement, pursuant to which we sold to investors in an initial closing and subsequent closings from January 2018 to March 2018 in private placements an aggregate of 45,714,286 shares of our Series A convertible preferred stock at a purchase price of \$1.75 per share, for an aggregate purchase price of approximately \$80.0 million, including the conversion of the ARCH note described above for approximately \$6.1 million.

*Series B Convertible Preferred Stock Financing.* In July 2018, we entered into a Series B preferred stock purchase agreement, pursuant to which we sold to investors in July 2018 in private placements an aggregate of 71,506,513 shares of our Series B convertible preferred stock at a purchase price of \$3.2167 per share, for an aggregate purchase price of approximately \$230.0 million.

All purchasers of our convertible preferred stock are entitled to specified registration rights. See the section titled “Description of Capital Stock—Registration Rights” for more information regarding these registration rights.

## Table of Contents

The following table sets forth the aggregate number of shares acquired by the listed directors, executive officers or holders of more than 5% of our capital stock, or their affiliates. Each share of preferred stock, including the shares identified in the following table, will convert into shares of common stock at a ratio of 4.5-to-1 immediately prior to the closing of this offering.

Participants	Series Seed Convertible Preferred Stock	Series A Convertible Preferred Stock	Series B Convertible Preferred Stock
<b>Executive Officers and Directors</b>			
Sheila Gujrathi, M.D. (1)	—	371,968	93,263
Faheem Hasnain(2)	—	371,968	155,439
Bryan Giraud	—	57,142	23,316
Christian Waage(3)	—	—	15,543
Thomas Daniel. M.D.(4)	—	171,429	—
<b>5% or Greater Stockholders(5)</b>			
Entities affiliated with ARCH Venture Partners(6)	—	33,142,857	3,108,776
Omega Fund V, L.P. (7)	20,000,000	7,124,620	4,165,760
HH Goss Holdings LLC	—	—	22,383,188

(1) Represents securities acquired by family trusts. Dr. Gujrathi, our President, Chief Executive Officer and a member of our board of directors, is a trustee of one of these family trusts, and is a beneficial holder of more than 5% of our capital stock.

(2) Represents securities acquired by family trusts. Mr. Hasnain, our Executive Chairman of the board of directors, is a trustee of one of these family trusts, and is a beneficial holder of more than 5% of our capital stock.

(3) Represents securities acquired by the Waage Trust Dated June 11, 2008. Christian Waage, our Executive Vice President and General Counsel, is a trustee of the Waage Trust Dated June 11, 2008.

(4) Represents securities acquired by the Thomas Oran Daniel Living Trust. Thomas Daniel, M.D., a member of our board of directors, is a trustee of the Thomas Oran Daniel Living Trust.

(5) Additional details regarding these stockholders and their equity holdings are provided under the section in this prospectus entitled "Principal Stockholders."

(6) Represents securities acquired by ARCH IX and ARCH Venture Fund IX Overage, L.P., or ARCH Overage. Robert Nelsen and Kristina Burow were at the time of the Series B convertible preferred stock financing, members of our board of directors, and Ms. Burow is currently a member of our board of directors, and are Managing Directors of ARCH Venture Partners, which is an affiliate of ARCH IX and ARCH Overage and their affiliated funds.

(7) Richard Lim and Otello Stampacchia, Ph.D. were at the time of the Series B convertible preferred stock financing, members of our board of directors, and Dr. Stampacchia is currently a member of our board of directors, and are Managing Directors of Omega Fund Management, which is an affiliate of Omega V.

## Board Designation Agreement with Hillhouse

On July 20, 2018, we entered into a board designation agreement with HH Goss Holdings LLC, a beneficial owner of more than 5% of our capital stock and an affiliate of Hillhouse. The agreement provides that HH Goss Holdings LLC or its affiliates will, effective as of the closing of this offering, have the right to designate one member to our board of directors and have such member appointed to any board committee that it requests, in each case, subject to our obligation to comply with applicable law and Nasdaq listing standards. The Hillhouse board designation agreement terminates at such time as HH Goss Holdings LLC and its affiliates cease to beneficially own at least 5% of our outstanding voting stock, or upon the later of (a) 18 months following the closing of this offering or (b) six months following the first public read out of interim results from our planned GB001 Phase 2 clinical trial. On January 17, 2019, the parties agreed the agreement will automatically terminate immediately prior to the closing of this offering without ever having becoming effective.

## Investor Rights Agreement

We entered into an investor rights agreement in January 2018, which was amended in July 2018, with the holders of our convertible preferred stock, including entities with which certain of our directors are affiliated. This agreement provides for certain rights relating to the registration of their shares of common stock issuable

upon conversion of their convertible preferred stock and certain additional covenants made by us. Except for the registration rights (including the related provisions pursuant to which we have agreed to indemnify the parties to the investor rights agreement), all rights under this agreement will terminate upon closing of this offering. The registration rights will continue following this offering and will terminate five years following the closing of this offering. See “Description of Capital Stock—Registration Rights” for additional information.

### **Voting Agreement**

We entered into a voting agreement in January 2018, which was amended in July 2018, with certain of our stockholders, pursuant to which the following directors were each elected to serve as members on our board of directors: Sheila Gujrathi, M.D., Faheem Hasnain, Robert Nelsen, Kristina Burow, Richard Lim, Otello Stampacchia, Ph.D., Qinqing Yi and Thomas Daniel, M.D. Other than Mr. Nelsen, Mr. Lim and Mr. Yi, each of these directors continues to serve on our board of directors. Pursuant to the voting agreement, Dr. Gujrathi, as our Chief Executive Officer, and Mr. Hasnain serve on our board of directors as a representative of holders of our common stock, as designated by a majority of our common stockholders. Mr. Nelsen and Ms. Burow were initially selected to serve on our board of directors as representatives of holders of our Series A convertible preferred stock, as designated by ARCH Venture Fund IX, L.P. Messrs. Lim and Stampacchia were also initially selected to serve on our board of directors as representatives of holders of our Series A convertible preferred stock, as designated by Omega Fund V, L.P. Mr. Yi was initially selected to serve on our board of directors as a representative of holders of our Series B convertible preferred stock, as designated by HH Goss Holdings LLC. Dr. Daniel was initially selected to serve on our board of directors as a representative of holders of our common stock and preferred stock, as designated by a majority of our common and preferred stockholders, voting together as a single class.

The voting agreement will terminate upon the closing of this offering and, other than Mr. Nelsen, Mr. Lim and Mr. Yi, members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until they resign, are removed or their successors are duly elected by holders of our common stock. The composition of our board of directors after this offering is described in more detail under “Management—Board Composition and Election of Directors.”

### **Founders’ Equity Grants**

On December 3, 2015, we issued and sold to each of Sheila Gujrathi, M.D. and Faheem Hasnain 4,580,444 shares of our common stock for a per share purchase price of \$0.0045 per share. For more information regarding these and additional stock issuances to Dr. Gujrathi and Mr. Hasnain pursuant to their employment letters, see the section in this prospectus entitled “Executive and Director Compensation—Employment Letters with our Named Executive Officers.”

### **Employment Agreements**

We have entered into employment agreements with our executive officers. For more information regarding these employment agreements, see the section in this prospectus entitled “Executive and Director Compensation—Employment Letters with our Named Executive Officers.”

### **Director and Officer Indemnification**

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us or will require us to indemnify each director (and in certain cases their related venture capital funds) and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys’ fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person’s services as a director or executive officer.

## [Table of Contents](#)

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify each of our directors and officers to the fullest extent permitted by the Delaware General Corporation Law. Further, we have purchased a policy of directors' and officers' liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances. For further information, see "Executive and Director Compensation—Limitations of Liability and Indemnification Matters."

### **Stock Option Grants to Executive Officers and Directors**

We have granted restricted stock and stock options to our executive officers and certain of our directors as more fully described in the section entitled "Executive and Director Compensation."

### **Participation in this Offering**

Certain of our existing stockholders, including entities affiliated with certain of our directors, have indicated an interest in purchasing an aggregate of approximately \$100.0 million in shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because these indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any or all of these stockholders, or any or all of these stockholders may determine to purchase more, less or no shares in this offering.

### **Other Transactions and Arrangements**

Aaron Hasnain is the son of our Executive Chairman, Faheem Hasnain, and currently serves as our Director, Business Development at a salary of \$140,000 per year, a position he has held since January 2018. In November 2017, we granted 50,834 shares of restricted stock to Aaron Hasnain.

### **Policies and Procedures for Related Person Transactions**

Our board of directors has adopted a written related person transaction policy, to be effective upon the closing of this offering, setting forth the policies and procedures for the review and approval or ratification of related-person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds \$120,000 and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

## PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of December 31, 2018, and as adjusted to reflect the sale of shares of common stock in this offering, by:

- each of our named executive officers;
- each of our directors;
- all of our executive officers and directors as a group; and
- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, beneficial ownership includes any shares as to which a person has sole or shared voting power or investment power. Applicable percentage ownership is based on 46,026,910 shares of common stock outstanding on December 31, 2018, which gives effect to the automatic conversion of all outstanding shares of our preferred stock into 30,493,460 shares of our common stock and includes 7,482,031 shares subject to forfeiture. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options or other rights held by such person that are currently exercisable or will become exercisable within 60 days of December 31, 2018 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

Certain of our existing stockholders, including entities affiliated with certain of our directors, have indicated an interest in purchasing an aggregate of approximately \$100.0 million in shares of our common stock in this offering at the initial public offering price. Based on an assumed initial public offering price of \$16.00 per share, if our greater than 5% stockholders purchase all of the shares they have indicated an interest in purchasing in this offering, the number of shares of our common stock beneficially owned by our executive officers, directors and greater than 5% stockholders will, in the aggregate, increase to approximately 63.9% of our outstanding common stock (assuming no exercise of the underwriters' option to purchase additional shares and no exercise of our outstanding options). However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any or all of these stockholders, or any or all of these stockholders may determine to purchase more, less or no shares in this offering. The following table does not reflect any such potential purchases by these stockholders or their affiliated entities. If any shares are purchased by these stockholders, the number of shares of common stock beneficially owned after this offering and the percentage of common stock beneficially owned after this offering would increase from that set forth in the table below.



## Table of Contents

Unless otherwise indicated, the address of each beneficial owner listed below is c/o Gossamer Bio, Inc., 3013 Science Park Road, Suite 200, San Diego, California 92121. We believe, based on information provided to us, that each of the stockholders listed below has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Name of Beneficial Owner	Shares Beneficially Owned Before and After the Offering	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
<b>5% or Greater Stockholders</b>			
Funds affiliated with ARCH Venture Partners <sup>(1)</sup>	8,055,916	17.5%	13.3%
Omega Fund V, L.P. <sup>(2)</sup>	6,953,416	15.1%	11.5%
HH Goss Holdings LLC <sup>(3)</sup>	4,974,041	10.8%	8.2%
Trusts for the benefit of Mr. Hasnain's family <sup>(4)</sup>	3,372,102	7.3%	5.6%
Trusts for the benefit of Dr. Gujrathi's family <sup>(5)</sup>	2,692,154	5.8%	4.5%
<b>Named Executive Officers and Directors</b>			
Sheila Gujrathi, M.D. <sup>(6)</sup>	4,038,242	8.8%	6.7%
Faheem Hasnain <sup>(7)</sup>	3,372,109	7.3%	5.6%
Christian Waage <sup>(8)</sup>	525,624	1.1%	*
Bryan Giraud	17,879	*	*
Jakob Dupont, M.D.	—	*	*
Joshua H. Bilenker, M.D. <sup>(9)</sup>	2,592	*	*
Kristina Burow	—	*	*
Russell Cox <sup>(10)</sup>	2,592	*	*
Thomas Daniel, M.D. <sup>(11)</sup>	85,440	*	*
Renée Galá <sup>(12)</sup>	2,592	*	*
Otello Stampacchia, Ph.D. <sup>(13)</sup>	6,953,416	15.1%	11.5%
All executive officers and directors as a group (14 persons) <sup>(14)</sup>	15,174,542	32.9%	25.1%

\* Less than 1%.

- (1) Consists of (i) 4,027,958 shares of common stock held by ARCH Venture Fund IX, L.P., or ARCH IX, and (ii) 4,027,958 shares of common stock held by ARCH Overage. ARCH Venture Partners IX, L.P., or the GPLP, as the sole general partner of ARCH IX, may be deemed to beneficially own certain of the shares held by ARCH IX. The GPLP disclaims beneficial ownership of all shares held by ARCH IX in which the GPLP does not have an actual pecuniary interest. ARCH Venture Partners IX Overage, L.P., or the Overage GPLP, as the sole general partner of ARCH Overage, may be deemed to beneficially own certain of the shares held by ARCH Overage. The Overage GPLP disclaims beneficial ownership of all shares held by ARCH Overage. ARCH Venture Partners IX, LLC, or GPLLC, as the sole general partner of the Overage GPLP and GPLP, may be deemed to beneficially own the shares held by ARCH IX and ARCH Overage. As managing directors of GPLLC, each of Keith Crandell, Clinton Bybee and Robert Nelsen, or the ARCH Managing Directors, may be deemed to share the power to direct the disposition and vote of, and therefore to beneficially own, the shares held by ARCH IX and ARCH Overage. The ARCH Managing Directors disclaim beneficial ownership of all shares held by ARCH IX and ARCH Overage except to the extent of any actual pecuniary interest. Director Kristina Burow owns an interest in GPLP and Overage GPLP but does not have voting or investment control over the shares held by ARCH IX and ARCH Overage and disclaims beneficial ownership of such shares, except to the extent of any pecuniary interest therein. The address of ARCH IX, ARCH Overage, GPLP, Overage GPLP, GPLLC and the ARCH Managing Directors is 8755 West Higgins Road, Suite 1025, Chicago, Illinois 60631.
- (2) Consists of 6,953,416 shares of common stock. Omega Fund V GP, L.P., or Omega V GP LP, is the general partner of Omega V. Omega Fund V GP Manager, Ltd., or Omega V GP Ltd, is the general partner of Omega V GP LP. Richard Lim, Dr. Stampacchia, Claudio Nessi and Anne-Mari Paster are Managing Directors and all the shareholders and directors of Omega V GP Ltd and have shared voting and investment power over the shares held by Omega V. The address of Omega V, Omega V GP LP and Omega V GP Ltd is 185 Dartmouth Street, Suite 502, Boston, MA 02116.
- (3) Consists of 4,974,041 shares of common stock held by HH Goss Holdings LLC, a limited liability company incorporated in the Cayman Islands. HH Goss Holdings LLC is beneficially owned and controlled by Hillhouse Fund IV, L.P. which is a Cayman Islands limited partnership. Hillhouse Capital Management, Ltd. acts as the sole management company of Hillhouse Fund IV, L.P., which is in turn ultimately controlled by Mr. Lei Zhang. The registered address of HH Goss Holdings LLC is Citco Trustees (Cayman) Limited, 89 Nexus Way, Camana Bay, PO Box 31106, Grand Cayman KY1-1205, Cayman Islands.

## Table of Contents

- (4) Eric I. Weitzen is the trustee of the trusts for the benefit of Mr. Hasnain's family, and in such capacity has the sole power to vote and dispose of such shares. Mr. Weitzen disclaims beneficial ownership of the shares held by these trusts.
- (5) Ms. Adee Cohen and Dr. Sunil Gujrathi are trustees of the trusts for the benefit of Dr. Gujrathi's family, and in such capacity have joint power to vote and dispose of such shares. Ms. Adee Cohen and Dr. Sunil Gujrathi disclaim beneficial ownership of the shares held by these trusts.
- (6) Consists of 4,038,242 shares of common stock, including 3,313,508 shares subject to forfeiture, held by a separate family trust. Dr. Gujrathi is a trustee of such family trust and in such capacity has the power to vote and dispose of such shares.
- (7) Consists of 3,372,109 shares of common stock, including 3,313,508 shares subject to forfeiture, held by a family trust. Mr. Hasnain is the trustee of such family trust and in such capacity has the sole power to vote and dispose of such shares.
- (8) Consists of 525,624 shares of common stock held by family trusts, including 380,749 shares subject to forfeiture. Mr. Waage is a trustee of such family trusts and in such capacity has the power to vote and dispose of such shares.
- (9) Consists of 2,592 shares of common stock underlying options held by Dr. Bilenker that are exercisable as of December 31, 2018 or that will become exercisable within 60 days after such date.
- (10) Consists of 2,592 shares of common stock underlying options held by Mr. Cox that are exercisable as of December 31, 2018 or that will become exercisable within 60 days after such date.
- (11) Consists of 38,095 shares of common stock held by the Thomas Oran Daniel Living Trust, or the Daniel Trust, and 47,345 shares of common stock underlying options held by Dr. Daniel that are exercisable as of December 31, 2018 or that will become exercisable within 60 days after such date. Dr. Daniel is the trustee of the Daniel Trust and in such capacity has the sole power to vote and dispose of such shares.
- (12) Consists of 2,592 shares of common stock underlying options held by Ms. Galá that are exercisable as of December 31, 2018 or that will become exercisable within 60 days after such date.
- (13) Consists of the shares described in note 2 above. Dr. Stampacchia is a Managing Director of Omega V GP Ltd, which is the sole general partner of Omega V GP LP, which is the sole general partner of Omega V, and as such may be deemed to beneficially own such shares. Dr. Stampacchia disclaims beneficial ownership of such shares except to the extent of any pecuniary interest therein.
- (14) Consists of (i) the shares described in notes 6 through 13 above and (ii) 174,056 shares of common stock held by Luisa Salter-Cid, Ph.D., our Chief Scientific Officer, 126,916 of which are subject to forfeiture.

## DESCRIPTION OF CAPITAL STOCK

### General

The following description summarizes some of the terms of our amended and restated certificate of incorporation and amended and restated bylaws, the amended and restated investor rights agreement and of the Delaware General Corporation Law. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description you should refer to our amended and restated certificate of incorporation, amended and restated bylaws, and amended and restated investor rights agreement, copies of which have been filed or incorporated by reference as exhibits to the registration statement of which the prospectus is a part, as well as the relevant provisions of the Delaware General Corporation Law.

Following the closing of this offering, our authorized capital stock will consist of 700,000,000 shares of common stock, \$0.0001 par value per share, and 70,000,000 shares of preferred stock, \$0.0001 par value per share.

### Common Stock

As of September 30, 2018, there were 46,026,910 shares of our common stock outstanding and held of record by 107 stockholders, assuming the automatic conversion of all outstanding shares of our convertible preferred stock into shares of common stock, which will automatically occur immediately prior to the closing of this offering. Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of 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 amended and restated certificate of incorporation and amended and restated 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 amended and restated certificate of incorporation. See below under “—Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws —Amendment of Charter Provisions.”

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. In the event of our liquidation, dissolution or winding up, the holders of common stock will be entitled to share ratably in the assets legally available for distribution to stockholders after the payment of or provision for all of our debts and other liabilities, subject to the prior rights of any preferred stock then outstanding. Holders of 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. All outstanding shares of common stock are, and the common stock to be outstanding upon the closing of this offering will be, duly authorized, validly issued, fully paid and nonassessable. 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.

### Preferred Stock

Upon completion of this offering, all of our previously outstanding shares of convertible preferred stock will have been converted into common stock, there will be no authorized shares of our previously convertible

preferred stock and we will have no shares of preferred stock outstanding. Under the terms of our amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, our board of directors has the authority, without further action by our stockholders, to issue up to 70,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the dividend, voting and other rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

## **Options**

As of September 30, 2018, options to purchase 2,104,311 shares of our common stock were outstanding, of which 34,630 were vested and 34,630 were exercisable as of that date. For additional information regarding the terms of this plan, see “Executive Compensation—Incentive Award Plans—2017 Equity Incentive Plan.”

## **Registration Rights**

As of September 30, 2018, upon the closing of this offering holders of 30,493,460 shares of our common stock, which includes all of the shares of common stock issuable upon the automatic conversion of our convertible preferred stock immediately prior to the closing of this offering, will be entitled to the following rights with respect to the registration of such shares for public resale under the Securities Act, pursuant to the amended and restated investor rights agreement by and among us and certain of our stockholders. The registration of shares of common stock as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

### **Demand Registration Rights**

*Form S-1.* If at any time beginning six months following the effective date of the registration statement of which this prospectus forms a part, investors holding at least 666,667 shares of our common stock, which we refer to as major investors, who also hold at least 30% of the registrable securities request in writing that we effect a registration with respect to at least 50% of the registrable securities then outstanding (or a lesser percent if the anticipated aggregate offering price, net of selling expenses, would exceed \$10 million) in an offering, we may be required to register their shares. We are obligated to effect at most two registrations for the holders of registrable securities in response to these demand registration rights, subject to certain exceptions.

*Form S-3.* If at any time we become entitled under the Securities Act to register our shares on Form S-3, major investors holding at least 20% of the registrable securities request in writing that we register their shares for public resale on Form S-3 and the price to the public of the offering is \$5.0 million or more, we will be required to provide notice to all holders of registrable securities and to use all reasonable efforts to effect such registration; provided, however, that we will not be required to effect such a registration if, within the preceding 12 months, we have already effected two registrations on Form S-3 for the holders of registrable securities.

If the holders requesting registration intend to distribute their shares by means of an underwriting, the underwriter of such offering will have the right to limit the numbers of shares to be underwritten for reasons related to the marketing of the shares.

### ***Piggyback Registration Rights***

If at any time following the closing of this offering we propose to register any shares of our common stock under the Securities Act, subject to certain exceptions, the holders of registrable securities will be entitled to notice of the registration and to include their shares of registrable securities in the registration. If our proposed registration involves an underwriting, the managing underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

### ***Indemnification***

Our investor rights agreement contains customary cross indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

### ***Expenses***

Ordinarily, other than underwriting discounts and commissions, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration and filing fees, printing expenses, fees and disbursements of our counsel, reasonable fees and disbursements of a counsel for the selling securityholders, blue sky fees and expenses and the expenses of any special audits incident to the registration.

### ***Termination of Registration Rights***

The registration rights terminate upon the earlier of: (1) five years after the closing of this offering, (2) upon the closing of an acquisition of our company or (3) with respect to a particular holder, such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all shares by such holder without limitation during a three-month period without registration.

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

Some provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated 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 amended and restated bylaws provide that a special meeting of stockholders may be called only by our chairman of the board, 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 amended and restated 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 amended and restated certificate of incorporation and amended and restated bylaws eliminate the right of stockholders to act by written consent without a meeting.

### ***Staggered Board***

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term (other than the directors initially assigned to Class I whose term shall expire at our first annual meeting of stockholders), one class being elected each year by our stockholders. For more information on the classified board, see “Management—Board Composition and Election of Directors.” 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 amended and restated 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 amended and restated 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 amended and restated 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 amended and restated certificate of incorporation or amended and restated 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 Securities Exchange Act of 1934, as amended. 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 amended and restated certificate of incorporation will 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. 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 restated certificate of incorporation also provides 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 this choice of forum provision.

### ***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 amended and restated certificate of incorporation and our amended and restated 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 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.

### ***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.

### ***The Nasdaq Global Select Market Listing***

Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol "GOSS."

### ***Limitations of Liability and Indemnification Matters***

For a discussion of liability and indemnification, see "Executive and Director Compensation—Limitations of Liability and Indemnification Matters."

## SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock. Although our common stock has been approved for listing on the Nasdaq Global Select Market, we cannot assure you that there will be an active public market for our common stock.

Based on the number of shares of our common stock outstanding as of September 30, 2018, and assuming (1) the issuance of 14,375,000 shares in this offering, (2) the automatic conversion of all outstanding shares of our convertible preferred stock into 30,493,460 shares of our common stock, which will occur automatically immediately prior to the closing of the offering, (3) no exercise of the underwriters' option to purchase additional shares of common stock and (4) no exercise of outstanding options, we will have outstanding an aggregate of approximately 60,401,910 shares of common stock.

Of these shares, all shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. Shares purchased by our affiliates would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining 46,026,910 shares of common stock will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or 701 under the Securities Act, each of which is summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below.

In addition, of the 2,104,311 shares of our common stock that were subject to stock options outstanding as of September 30, 2018, options to purchase 34,630 of such shares of common stock were vested as of such date and, upon exercise, these shares will be eligible for sale subject to the lock-up agreements described below and Rules 144 and 701 under the Securities Act.

### Lock-Up Agreements

We, along with our directors, executive officers and substantially all of our other stockholders and optionholders, have agreed with the underwriters that for a period of 180 days, after the date of this prospectus, subject to specified exceptions, we or they will not offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to sale of, or otherwise dispose of or transfer any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock, request or demand that we file a registration statement related to our common stock or enter into any swap or other agreement that transfers to another, in whole or in part, directly or indirectly, the economic consequence of ownership of the common stock. Such exceptions include the ability of certain of our executive officers to sell up to \$8.0 million of shares of common stock to satisfy certain tax liabilities related to their previous acquisition of shares. Upon expiration of the lock-up period, certain of our stockholders will have the right to require us to register their shares under the Securities Act. See "—Registration Rights" below and "Description of Capital Stock—Registration Rights."

Merrill Lynch, Pierce, Fenner & Smith Incorporated, SVB Leerink LLC and Barclays Capital Inc. may, in their sole discretion and at any time or from time to time before the termination of the lock-up period, in certain cases without public notice, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement providing consent to the sale of shares prior to the expiration of the lock-up period.



## [Table of Contents](#)

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

### **Rule 10b5-1 Trading Plans**

Following the completion of this offering, certain of our officers, directors and significant stockholders may adopt written plans, known as Rule 10b5-1 trading plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis to diversify their assets and investments. Under these 10b5-1 trading plans, a broker may execute trades pursuant to parameters established by the officer, director or stockholder when entering into the plan, without further direction from such officer, director or stockholder. Such sales would not commence until the expiration of the applicable lock-up agreements entered into by such officer, director or stockholder in connection with this offering.

### **Rule 144**

#### ***Affiliate Resales of Restricted Securities***

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell in “broker’s transactions” or certain “riskless principal transactions” or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 604,019 shares immediately after this offering; or
- the average weekly trading volume in our common stock on the Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of \$50,000, the seller must file a notice on Form 144 with the SEC and the Nasdaq Global Select Market concurrently with either the placing of a sale order with the broker or the execution of a sale directly with a market maker.

#### ***Non-Affiliate Resales of Restricted Securities***

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

### **Rule 701**

In general, under Rule 701, any of an issuer’s employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written

## [Table of Contents](#)

agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

### **Equity Plans**

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our equity incentive plans and employee stock purchase plan. We expect to file the registration statement covering shares offered pursuant to these stock plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market subject to compliance with the resale provisions of Rule 144.

### **Registration Rights**

As of September 30, 2018, upon the closing of this offering, holders of 30,493,460 shares of our common stock, which includes all of the shares of common stock issuable upon the automatic conversion of our convertible preferred stock immediately prior to the closing of this offering, or their transferees will be entitled to various rights with respect to the registration of these shares under the Securities Act upon the closing of this offering. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. See “Description of Capital Stock—Registration Rights” for additional information. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreement.

## MATERIAL UNITED STATES FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder’s particular circumstances, including the impact of the alternative minimum tax or the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- “controlled foreign corporations,” “passive foreign investment companies,” and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to our common stock being taken into account in an “applicable financial statement” (as defined in the Code);
- tax-qualified retirement plans; and
- “qualified foreign pension funds” as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds.

## [Table of Contents](#)

If an entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

**THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.**

### **Definition of a Non-U.S. Holder**

For purposes of this discussion, a “Non-U.S. Holder” is any beneficial owner of our common stock that is neither a “U.S. person” nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more “United States persons” (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

### **Distributions**

As described in the section entitled “Dividend Policy,” we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder’s adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under “—Sale or Other Taxable Disposition.”

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder of our common stock will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). If a Non-U.S. Holder holds the stock through a financial institution or other agent acting on the Non-U.S. Holder’s behalf, the Non-U.S. Holder will be required to provide appropriate documentation to the agent, who then will be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

### **Sale or Other Taxable Disposition**

A Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, orUSRPI, by reason of our status as a U.S. real property holding corporation, orUSRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the Non-U.S. Holder is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually or constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

## **Information Reporting and Backup Withholding**

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to the Non-U.S. Holder, regardless of whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting, if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

## **Additional Withholding Tax on Payments Made to Foreign Accounts**

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections are commonly referred to as the Foreign Account Tax Compliance Act, or FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or subject to the proposed Treasury Regulations discussed below, gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in clause (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock. While withholding under FATCA would also have applied to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, recently proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

## UNDERWRITING

Merrill Lynch, Pierce, Fenner & Smith Incorporated, SVB Leerink LLC, Barclays Capital Inc. and Evercore Group L.L.C. are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

<u>Underwriter</u>	<u>Number of Shares</u>
Merrill Lynch, Pierce, Fenner & Smith Incorporated	
SVB Leerink LLC	
Barclays Capital Inc.	
Evercore Group L.L.C.	
Total	<u>14,375,000</u>

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officers' certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

### Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$ \_\_\_\_\_ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	<u>Per Share</u>	<u>Without Option</u>	<u>With Option</u>
Public offering price	\$	\$	\$
Underwriting discount	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

The expenses of the offering, not including the underwriting discount, payable by us are estimated to be approximately \$3.7 million. We have also agreed to reimburse the underwriters for certain of their expenses incurred in connection with, among others, the review and clearance by the Financial Industry Regulatory Authority, Inc. in an amount of up to \$35,000.

### **Option to Purchase Additional Shares**

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 2,156,250 additional shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

### **Insider Participation**

Certain of our existing stockholders, including entities affiliated with certain of our directors, have indicated an interest in purchasing an aggregate of approximately \$100.0 million in shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any or all of these stockholders, and any or all of these stockholders may determine to purchase more, less or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these stockholders as they will on any other shares sold to the public in this offering.

### **Directed Share Program**

At our request, the underwriters have reserved for sale, at the initial public offering price, up to 5% of the shares offered hereby for our directors, officers, employees, business associates and related persons who have expressed an interest in purchasing common stock in the offering. The number of shares available for sale to the general public in the offering will be reduced to the extent these persons purchase the reserved shares. Any reserved shares not so purchased will be offered by the underwriters to the general public on the same terms as the other shares.

### **No Sales of Similar Securities**

We, our executive officers and directors and our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of Merrill Lynch, Pierce, Fenner & Smith Incorporated, SVB Leerink LLC and Barclays Capital Inc. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, sell or contract to sell any common stock,
- sell any option or contract to purchase any common stock,
- purchase any option or contract to sell any common stock,
- grant any option, right or warrant for the sale of any common stock,
- lend or otherwise dispose of or transfer any common stock,
- request or demand that we file or make a confidential submission of a registration statement related to the common stock, or
- enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

The lock-up exceptions, among others, include the ability of certain of our executive officers to sell up to \$8.0 million of shares of common stock to satisfy certain tax liabilities related to their previous acquisition of shares.



## [Table of Contents](#)

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

### **Nasdaq Global Select Market Listing**

Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol “GOSS.”

### **Determination of Offering Price**

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are:

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us,
- our financial information,
- the history of, and the prospects for, our company and the industry in which we compete,
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,
- the present state of our development,
- the likelihood of approval for our product candidates, and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

### **Price Stabilization, Short Positions and Penalty Bids**

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. “Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to

## [Table of Contents](#)

the price at which they may purchase shares through the option granted to them. “Naked” short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters’ purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on the Nasdaq Global Select Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

### **Electronic Distribution**

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

### **Other Relationships**

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Affiliates of SVB Leerink LLC purchased 699,475 shares of our Series B convertible preferred stock in our July 2018 Series B convertible preferred stock financing. Those shares of Series B convertible preferred stock will automatically convert into 155,438 shares of common stock immediately prior to and in connection with the completion of this offering. All such shares are subject to the 180-day lock-up restrictions pursuant to FINRA Rule 5110(g).

### **European Economic Area**

In relation to each member state of the European Economic Area, no offer of shares which are the subject of the offering has been, or will be made to the public in that Member State, other than under the following exemptions under the Prospectus Directive:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;

## Table of Contents

- to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), subject to obtaining the prior consent of the representatives for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

*provided* that no such offer of shares referred to in (a) to (c) above shall result in a requirement for the Company or the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Directive, or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person located in a Member State to whom any offer of shares is made or who receives any communication in respect of an offer of shares, or who initially acquires any shares will be deemed to have represented, warranted, acknowledged and agreed to and with the representatives and the Company that (1) it is a “qualified investor” within the meaning of the law in that Member State implementing Article 2(1)(e) of the Prospectus Directive; and (2) in the case of any shares acquired by it as a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, the shares acquired by it in the offer have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Member State other than qualified investors, as that term is defined in the Prospectus Directive, or in circumstances in which the prior consent of the representatives has been given to the offer or resale; or where shares have been acquired by it on behalf of persons in any Member State other than qualified investors, the offer of those shares to it is not treated under the Prospectus Directive as having been made to such persons.

The Company, the representatives and their respective affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgments and agreements.

This prospectus has been prepared on the basis that any offer of shares in any Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of shares. Accordingly any person making or intending to make an offer in that Member State of shares which are the subject of the offering contemplated in this prospectus may only do so in circumstances in which no obligation arises for the Company or the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither the Company nor the representatives have authorized, nor do they authorize, the making of any offer of shares in circumstances in which an obligation arises for the Company or the representatives to publish a prospectus for such offer.

For the purposes of this provision, the expression an “offer of shares to the public” in relation to any shares in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression “Prospectus Directive” means Directive 2003/71/EC (as amended) and includes any relevant implementing measure in each Member State.

The above selling restriction is in addition to any other selling restrictions set out below.

### **Notice to Prospective Investors in the United Kingdom**

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons.

### **Notice to Prospective Investors in Switzerland**

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority, and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

### **Notice to Prospective Investors in the Dubai International Financial Centre**

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

### **Notice to Prospective Investors in Australia**

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, or ASIC, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the “Exempt Investors”) who are “sophisticated investors” (within the meaning of section 708(8) of the Corporations Act), “professional investors” (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities

recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

#### **Notice to Prospective Investors in Hong Kong**

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

#### **Notice to Prospective Investors in Japan**

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, “Japanese Person” shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

#### **Notice to Prospective Investors in Singapore**

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

## [Table of Contents](#)

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Solely for the purposes of its obligations pursuant to Section 309B of the SFA, we have determined, and hereby notify all relevant persons (as defined in the CMP Regulations 2018), that the shares are "prescribed capital markets products" (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

### **Notice to Prospective Investors in Canada**

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

## LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Latham & Watkins LLP, San Diego, California. Latham & Watkins LLP and certain attorneys and investment funds affiliated with the firm collectively own an aggregate of 57,150 shares of our convertible preferred stock, which will convert into an aggregate of 12,700 shares of our common stock upon the completion of this offering. The underwriters are being represented by Cooley LLP, San Diego, California.

## EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements at December 31, 2016 and 2017, and for the years then ended, as set forth in their report. We have included our consolidated financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. Upon the closing of this offering, we will be required to file periodic reports, proxy statements and other information with the SEC pursuant to the Exchange Act. You may read and copy this information at the Public Reference Room of the SEC, 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may obtain information on the operation of the public reference rooms by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the SEC. The address of that site is [www.sec.gov](http://www.sec.gov).

Upon the completion of this offering, we will become subject to the information and periodic reporting requirements of the Exchange Act and, in accordance therewith, will file periodic reports, proxy statements and other information with the SEC. Such periodic reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above. We maintain a website at [www.gossamerbio.com](http://www.gossamerbio.com). Upon the completion of this offering, you may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The reference to our website address does not constitute incorporation by reference of the information contained on our website, and you should not consider the contents of our website in making an investment decision with respect to our common stock.

[Table of Contents](#)

**Gossamer Bio, Inc.**  
**Index to Consolidated Financial Statements**

	<u>Page</u>
<a href="#">Report of Independent Registered Public Accounting Firm</a>	F-2
<a href="#">Consolidated Balance Sheets</a>	F-3
<a href="#">Consolidated Statements of Operations</a>	F-4
<a href="#">Consolidated Statements of Comprehensive Loss</a>	F-5
<a href="#">Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit</a>	F-6
<a href="#">Consolidated Statements of Cash Flows</a>	F-7
<a href="#">Notes to Consolidated Financial Statements</a>	F-8



## Report of Independent Registered Public Accounting Firm

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

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Gossamer Bio, Inc. (the Company) as of December 31, 2016 and 2017, the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' deficit and cash flows for the years then ended, 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, 2016 and 2017, and the results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

### Basis for Opinion

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

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

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

/s/ Ernst & Young LLP

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

San Diego, California  
October 11, 2018,  
except for the last paragraph of Note 12, as to which the date is  
January 23, 2019

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

	<u>December 31,</u>		<u>September 30,</u>	<u>Pro Forma</u>
	<u>2016</u>	<u>2017</u>	<u>2018</u>	<u>September 30,</u>
			<u>(unaudited)</u>	<u>2018</u>
				<u>(unaudited)</u>
<b>ASSETS</b>				
Current assets				
Cash and cash equivalents	\$ 60	\$ 315	\$ 141,067	
Marketable securities	—	—	115,376	
Restricted cash	—	—	200	
Prepaid expenses and other current assets	—	130	1,708	
<b>Total current assets</b>	<b>60</b>	<b>445</b>	<b>258,351</b>	
Property and equipment, net	—	—	3,007	
Other assets	—	—	823	
<b>Total assets</b>	<b>\$ 60</b>	<b>\$ 445</b>	<b>\$ 262,181</b>	
<b>LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' DEFICIT</b>				
Current liabilities				
Accounts payable	\$ 40	\$ 97	\$ 3,622	
Accrued expenses	103	926	3,413	
Accrued research and development expenses	—	126	7,904	
Accrued interest—short-term	—	117	—	
<b>Total current liabilities</b>	<b>143</b>	<b>1,266</b>	<b>14,939</b>	
Note payable to related parties	40	40	—	
Convertible note payable	—	6,000	—	
Accrued expenses—long-term	—	1	653	
<b>Total liabilities</b>	<b>183</b>	<b>7,307</b>	<b>15,592</b>	
<b>Commitments and contingencies—Note 10</b>				
Series Seed convertible preferred stock, \$0.0001 par value; 0 shares authorized as of December 31, 2016 and 2017 and 20,000,000 shares authorized as of September 30, 2018 (unaudited); 0 shares issued and outstanding as of December 31, 2016 and 2017 and 20,000,000 shares issued and outstanding as of September 30, 2018 (unaudited); liquidation preference of \$20,000 as of September 30, 2018 (unaudited); no shares issued and outstanding, pro forma (unaudited)	—	—	29,200	\$ —
Series A convertible preferred stock, \$0.0001 par value; 0 shares authorized as of December 31, 2016 and 2017 and 45,714,286 shares authorized as of September 30, 2018 (unaudited); 0 shares issued and outstanding as of December 31, 2016 and 2017 and 45,714,286 shares issued and outstanding as of September 30, 2018 (unaudited); liquidation preference of \$80,000 as of September 30, 2018 (unaudited); no shares issued and outstanding, pro forma (unaudited)	—	—	79,615	—
Series B convertible preferred stock, \$0.0001 par value; 0 shares authorized as of December 31, 2016 and 2017 and 71,506,513 shares authorized as of September 30, 2018 (unaudited); 0 shares issued and outstanding as of December 31, 2016 and 2017 and 71,506,513 shares issued and outstanding as of September 30, 2018 (unaudited); liquidation preference of \$230,000, as of September 30, 2018; no shares issued and outstanding, pro forma (unaudited)	—	—	229,552	—
<b>Stockholders' deficit</b>				
Common stock, \$0.0001 par value; 9,160,888, 27,777,777, and 49,160,177 shares authorized as of December 31, 2016, December 31, 2017 and September 30, 2018 (unaudited); 9,160,888 shares issued and outstanding as of December 31, 2016 and 2017 and 15,533,450 shares issued and 7,733,845 shares outstanding as of September 30, 2018 (unaudited); 46,026,910 shares issued and 38,227,305 outstanding, pro forma (unaudited)	—	—	2	5
Additional paid-in capital	—	32	23,054	361,418
Accumulated deficit	(123)	(6,894)	(115,069)	(115,069)
Accumulated other comprehensive income	—	—	235	235
<b>Total stockholders' equity (deficit)</b>	<b>(123)</b>	<b>(6,862)</b>	<b>(91,778)</b>	<b>246,589</b>
<b>Total liabilities, convertible preferred stock and stockholders' deficit</b>	<b>\$ 60</b>	<b>\$ 445</b>	<b>\$ 262,181</b>	

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

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

	<u>Year Ended December 31,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2016</u>	<u>2017</u>	<u>2017</u>	<u>2018</u>
	(unaudited)			
<b>Operating expenses:</b>				
Research and development	\$ —	\$ 891	\$ 216	\$ 29,411
In process research and development	—	5,500	—	49,659
General and administrative	83	262	105	30,116
<b>Total operating expense</b>	<u>83</u>	<u>6,653</u>	<u>321</u>	<u>109,186</u>
<b>Loss from operations</b>	<u>(83)</u>	<u>(6,653)</u>	<u>(321)</u>	<u>(109,186)</u>
<b>Other income (expense)</b>				
Interest income	—	—	—	1,022
Interest expense	—	(118)	—	(8)
Other expense	—	—	—	(3)
<b>Total other income (expense), net</b>	<u>—</u>	<u>(118)</u>	<u>—</u>	<u>1,011</u>
<b>Net loss</b>	<u>\$ (83)</u>	<u>\$ (6,771)</u>	<u>\$ (321)</u>	<u>\$ (108,175)</u>
Net loss per share, basic and diluted	<u>\$ (0.01)</u>	<u>\$ (0.74)</u>	<u>\$ (0.04)</u>	<u>\$ (17.64)</u>
Weighted-average shares outstanding, basic and diluted	<u>9,160,888</u>	<u>9,160,888</u>	<u>9,160,888</u>	<u>6,133,911</u>
Pro forma net loss per share, basic and diluted (unaudited)		<u>\$ (0.74)</u>		<u>\$ (4.36)</u>
Pro forma weighted-average shares outstanding, basic and diluted (unaudited)		<u>9,160,888</u>		<u>24,831,306</u>

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

**GOSSAMER BIO, INC.**  
**Consolidated Statements of Comprehensive Loss**  
**(in thousands)**

	<u>Year Ended December 31,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2016</u>	<u>2017</u>	<u>2017</u>	<u>2018</u>
<b>Net loss</b>	\$ (83)	\$ (6,771)	\$ (321)	\$ (108,175)
Other comprehensive income:			(unaudited)	
Unrealized gain on marketable securities, net of tax	—	—	—	235
Other comprehensive income	—	—	—	235
<b>Comprehensive loss</b>	<u>\$ (83)</u>	<u>\$ (6,771)</u>	<u>\$ (321)</u>	<u>\$ (107,940)</u>

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

**GOSSAMER BIO, INC.**  
**Consolidated Statements of Convertible Preferred Stock and Stockholders' 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	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
<b>Balance as of December 31, 2015</b>	—	\$ —	—	\$ —	—	\$ —	9,160,888	\$ —	\$ —	\$ (40)	\$ —	\$ (40)
Net loss	—	—	—	—	—	—	—	—	—	(83)	—	(83)
<b>Balance as of December 31, 2016</b>	—	\$ —	—	\$ —	—	\$ —	9,160,888	\$ —	\$ —	\$ (123)	\$ —	\$ (123)
Stock-based compensation	—	—	—	—	—	—	—	—	32	—	—	32
Net loss	—	—	—	—	—	—	—	—	—	(6,771)	—	(6,771)
<b>Balance as of December 31, 2017</b>	—	\$ —	—	\$ —	—	\$ —	9,160,888	\$ —	\$ 32	\$ (6,894)	\$ —	\$ (6,862)
Issuance of Series A convertible preferred stock for cash, net of \$400 in offering costs (unaudited)	—	—	42,215,077	73,491	—	—	—	—	—	—	—	—
Issuance of stock for asset acquisitions (unaudited)	20,000,000	29,200	—	—	—	—	1,101,278	1	2,874	—	—	2,875
Issuance of Series A convertible preferred stock to convert debt and accrued interest	—	—	3,499,209	6,124	—	—	—	—	—	—	—	—
Issuance of Series B convertible preferred stock for cash, net of \$500 in offering costs (unaudited)	—	—	—	—	71,506,513	229,552	—	—	—	—	—	—
Vesting of restricted stock (unaudited)	—	—	—	—	—	—	2,052,123	1	—	—	—	1
Incremental vesting conditions placed on previously issued common shares (unaudited)	—	—	—	—	—	—	(4,580,444)	—	—	—	—	—
Stock-based compensation (unaudited)	—	—	—	—	—	—	—	—	20,148	—	—	20,148
Net loss (unaudited)	—	—	—	—	—	—	—	—	—	(108,175)	—	(108,175)
Unrealized gain on marketable securities, net of tax (unaudited)	—	—	—	—	—	—	—	—	—	—	235	235
<b>Balance as of September 30, 2018 (unaudited)</b>	<u>20,000,000</u>	<u>\$ 29,200</u>	<u>45,714,286</u>	<u>\$ 79,615</u>	<u>71,506,513</u>	<u>\$ 229,552</u>	<u>7,733,845</u>	<u>\$ 2</u>	<u>\$ 23,054</u>	<u>\$ (115,069)</u>	<u>\$ 235</u>	<u>\$ (91,778)</u>

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

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

	Year Ended December 31,		Nine Months Ended September 30,	
	2016	2017	2017	2018
	(unaudited)			
<b>Cash flows from operating activities</b>				
Net loss	\$ (83)	\$ (6,771)	\$ (321)	\$ (108,175)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	—	—	—	163
Stock-based compensation expense	—	32	(4)	20,148
In process research and development expenses	—	—	—	49,659
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	—	(130)	—	(1,442)
Accounts payable	—	57	18	3,525
Accrued expenses	103	824	283	3,263
Accrued research and development expenses	—	126	—	7,778
Accrued interest—short-term	—	117	—	(117)
Other Assets	—	—	—	(267)
Security deposits	—	—	—	(556)
Net cash provided by (used in) operating activities	20	(5,745)	(24)	(26,021)
<b>Cash flows from investing activities</b>				
Research and development asset acquisitions, net of cash acquired	—	—	—	(17,721)
Purchase of marketable securities	—	—	—	(115,141)
Purchase of property and equipment	—	—	—	(3,168)
Net cash used in investing activities	—	—	—	(136,030)
<b>Cash flows from financing activities</b>				
Proceeds from issuance of convertible note	—	6,000	—	—
Proceeds from long term note payable	40	—	—	—
Proceeds from issuance of Series A convertible preferred stock, net	—	—	—	73,491
Proceeds from issuance of Series B convertible common stock, net	—	—	—	229,552
Issuance of common stock, net of fees	—	—	4	—
Repayment of notes payable to related parties	—	—	—	(40)
Net cash provided by financing activities	40	6,000	4	303,003
Net increase in cash, cash equivalents and restricted cash	60	255	(20)	140,952
Cash, cash equivalents and restricted cash, at the beginning of the period	—	60	60	315
<b>Cash, cash equivalents and restricted cash, at the end of the period</b>	<b>\$ 60</b>	<b>\$ 315</b>	<b>\$ 40</b>	<b>\$ 141,267</b>
<b>Supplemental disclosure of noncash investing and financing activities:</b>				
Acquisition of in-process research and development through the issuance of stock, net of cash acquired	\$ —	\$ —	\$ —	\$ 19,284
Issuance of Series A convertible preferred stock to convert debt and accrued interest	\$ —	\$ —	\$ —	\$ 6,124
Change in unrealized gain on marketable securities, net of tax	\$ —	\$ —	\$ —	\$ 235

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

**Gossamer Bio, Inc. Notes to Consolidated Financial Statements**  
**(Information and amounts as of September 30, 2018 and thereafter and for the**  
**nine months ended September 30, 2017 and 2018 is unaudited)**

**Note 1—Organization and Basis of Presentation**

Gossamer Bio, Inc. (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.

***Stock Split***

In December 2017, the board of directors of the Company approved a stock split of the Company’s common stock at a ratio of 20,612 shares for every one share previously held. The stock split became effective on January 4, 2018. All share and per share data included in these financial statements reflect the stock split.

***Liquidity and Capital Resources***

The Company has incurred significant operating losses since its inception. As of December 31, 2017, and September 30, 2018, the Company had an accumulated deficit of \$6.9 million and \$115.1 million, respectively.

Since inception, the Company has funded its operations primarily through equity financings. The Company raised \$310.0 million from October 2017 through July 2018 through Series A and Series B Convertible Preferred Stock and convertible note financings. 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 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.

**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”) and include all adjustments necessary for the fair presentation of the Company’s financial position for the periods presented.

***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

## [Table of Contents](#)

expenses during the reporting period. The most significant estimates in the Company's consolidated financial statements relate to accrued expenses, the valuation of preferred and common stock, the valuation of stock options and the valuation allowance of deferred tax assets resulting from net operating losses. 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.

### ***Unaudited Interim Financial Information***

The accompanying interim consolidated balance sheet as of September 30, 2018, the consolidated statements of operations and cash flows for the nine months ended September 30, 2017 and 2018 and the consolidated statement of stockholders' deficit for the nine months ended September 30, 2018 and the related consolidated footnote disclosures are unaudited. In management's opinion, the unaudited interim financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of September 30, 2018 and its results of operations and cash flows for the nine months ended September 30, 2017 and 2018 in accordance with GAAP. The results for the nine months ended September 30, 2018 are not necessarily indicative of the results expected for the full fiscal year or any other interim period.

### ***Unaudited Pro Forma Balance Sheet Information***

The unaudited pro forma balance sheet information as of September 30, 2018 assumes the conversion of all outstanding shares of convertible preferred stock into 30,493,460 shares of the Company's common stock immediately prior to completion of the Company's planned initial public offering ("IPO"). Shares of common stock issued in the IPO and any related net proceeds are excluded from the pro forma information.

### ***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. These marketable securities consist of U.S. Treasury 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 other than temporary. Realized gains and losses are calculated using the specific identification method and recorded as interest income or expense. We do not generally intend to sell the investments and it is not more likely than not that we 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 other than temporary declines in fair values of its investments as of September 30, 2018. As of September 30, 2018, the Company held U.S. Treasury securities with an amortized cost of \$115.2 million, an unrealized gain of \$326,000, an unrealized loss of \$91,000, a fair market value of \$115.4 million and are scheduled to mature in less than twelve months. As of December 31, 2017, the Company did not hold any marketable securities.



### ***Restricted Cash***

Restricted cash serves 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 securities with maturities less than three months and in money market funds that invest in U.S. Treasury securities.

The Company's available for sale securities are also invested in U.S. Treasury 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.

### ***Leases***

The Company records rent expense on a straight-line over the term of the lease. The difference between rent payments and straight-line rent expense is recorded as deferred rent.

### ***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), in process research and development expenses and license agreement 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

## [Table of Contents](#)

asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

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

The provisional impact of the Tax Cuts and Jobs Act (“Tax Act”) is the Company’s current best estimate based on a preliminary review of the new law and is subject to revision based on its existing accounting for income tax policy as further information is gathered, and interpretation and analysis of the tax legislation evolves. The Securities and Exchange Commission has issued rules allowing for a measurement period of up to one year after the enactment date of the Tax Act to finalize the recording of the related tax impacts. Any future changes to the Company’s provisional estimated impact of the Tax Act will be included as an adjustment to the provision for income taxes. 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 state jurisdictions. As of December 31, 2017, the Company’s tax years since inception are subject to examination by taxing authorities.

### ***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 remaining 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 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. 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.

### ***Recent Accounting Pronouncements—To Be Adopted***

In February 2016, the FASB issued Accounting Standards Update (“ASU”) No. 2016-02, *Leases (Topic 842)*, which requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases, along with additional qualitative and quantitative disclosures. ASU 2016-02 is effective for fiscal periods beginning after December 15, 2018, with early adoption permitted. The Company is required to adopt this new guidance beginning in 2019 using the modified retrospective method and early adoption is permitted. Although the Company is in the early stages of evaluating the impact of adoption of ASU 2016-02 on its financial statements, the Company currently believes the most significant changes will be related to the recognition of lease liabilities on the Company’s consolidated balance sheets for real estate operating leases.

### **Recently Adopted Accounting Pronouncements**

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718) – Improvements to Nonemployee Share-Based Payment Accounting*. The amendments in ASU 2018-07, expand the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards for specific guidance on inputs to an option pricing model and the period of time over which share-based payment awards vest and the pattern of cost recognition over that period. The amendments also clarify that Topic 718 does not apply to share-based payments used to effectively provide (i) financing to the issuer or (ii) awards granted in conjunction with selling goods or services to customers as part of a contracted accounted for under Topic 606, *Revenue from Contracts with Customers*. ASU 2018-07 is effective for the Company in January 2020, with early adoptions permitted, but no earlier than the Company's adoption date of Topic 606. The Company has elected to early adopt ASU 2018-07, full retrospective as of January 1, 2017. The Company has no revenues and therefore the adoption of Topic 606 did not have an impact on the Company's financial statements. The adoption of ASU 2018-07 did not have a material impact on its consolidated financial statements and related disclosures, financial position, results of operations or cash flows.

In February 2018, the FASB issued ASU No. 2018-02, *Income Statement—Reporting Comprehensive Income, (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*, which allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the newly enacted federal corporate income tax rate under the Tax Act. The amount of the reclassification would be the difference between the historical corporate income tax rate and the newly enacted 21% corporate income tax rate. The new standard is effective for fiscal years, including interim periods within those fiscal years, beginning after December 15, 2018 with early adoption in any interim period permitted. The Company has elected to early adopt ASU 2018-02, as of January 1, 2018. The adoption of ASU 2018-02 did not have a material impact on its consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*. The amendments in this update clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The definition of a business affects many areas of accounting including acquisitions, disposals, goodwill, and consolidation. The guidance is effective for fiscal periods beginning after December 15, 2017, including interim periods within those periods. The Company adopted ASU 2017-01 starting with the GB002 acquisition, which occurred prior to the effective date of ASU 2017-01 and the financial statement issuance date. The adoption of this guidance did not have a material impact on its consolidated financial statements and related disclosures.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, which clarifies the presentation of restricted cash in the statements of cash flows. Under ASU 2016-18, restricted cash is included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statements of cash flows. The Company adopted ASU 2016-18 as of January 1, 2018. Cash, cash equivalents and restricted cash total as presented in the statements of cash flows consist of cash and cash equivalents of \$32.1 million and restricted cash of \$0.2 million.

In March 2016, the FASB issued ASU No. 2016-09, *Stock Compensation Improvements to Employee Share-Based Payment Accounting*, which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 became effective for the Company on January 1, 2017. The adoption of this guidance did not have a material impact on its consolidated financial statements and related disclosures.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*, which created a single, principle-based revenue recognition model that will supersede and replace nearly all existing

## [Table of Contents](#)

U.S. GAAP revenue recognition guidance. Entities will recognize revenue in a manner that depicts the transfer of goods or services to customers at an amount that reflects the consideration to which the entity expects to be entitled to receive in exchange for those goods or services. The model provides that entities follow five steps: (i) identify the contract with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations, and (v) recognize revenue. For nonpublic business entities, the guidance becomes effective for annual reporting periods beginning after December 15, 2018. The Company has elected to early adopt ASU 2014-09, as of January 1, 2017, the adoption of this guidance did not have any impact on its consolidated financial statements and related 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. Diluted net loss per share excludes the potential impact of 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 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:

	<u>December 31,</u>		<u>September 30,</u>	
	<u>2016</u>	<u>2017</u>	<u>2017</u>	<u>2018</u>
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
Shares issuable upon exercise of stock options	—	—	—	2,104,311
Non-vested shares under restricted stock grants	—	1,305,421	—	7,799,605

### **Unaudited Pro Forma Net Loss Per Share**

The following table summarizes the Company's unaudited pro forma net loss per share (in thousands except share and per share data):

	<u>Year Ended</u> <u>December 31, 2017</u>	<u>Nine Months Ended</u> <u>September 30, 2018</u>
<b>Numerator</b>		
Net loss and pro forma net loss	\$ (6,771)	\$ (108,175)
<b>Denominator</b>		
Shares used to compute net loss per share, basic and diluted	9,160,888	6,133,911
Pro forma adjustments to reflect assumed weighted-average effect of conversion of convertible preferred stock	—	18,697,395
Shares used to compute pro forma net loss per share, basic and diluted	9,160,888	24,831,306
<b>Pro forma net loss per share, basic and diluted</b>	\$ (0.74)	\$ (4.36)

**Note 3—Accrued Expenses**

Accrued expenses consisted of the following (in thousands):

	<u>December 31,</u>		<u>September 30,</u>
	<u>2016</u>	<u>2017</u>	<u>2018</u>
Accrued compensation	\$ —	\$ 34	\$ 2,739
Accrued legal fees	103	780	548
Accrued accounting fees	—	—	12
Accrued consulting fees	—	33	69
Accrued other	—	79	45
Total accrued expenses	<u>\$ 103</u>	<u>\$ 926</u>	<u>\$ 3,413</u>

**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.

As of December 31, 2016, and 2017, the carrying amounts of the Company's financial instruments, which include cash, accounts payable and accrued expenses, approximate fair values because of their short maturities. Included in marketable securities as of September 30, 2018 are U.S. Treasury Securities with a carrying value and fair value of \$115.4 million based upon a Level 1 fair value assessment. The carrying amounts for the Company's other financial instruments approximate fair values as of September 30, 2018.

As of December 31, 2016, December 31, 2017, and September 30, 2018, the Company did not have any Level 2 or Level 3 securities.

**Note 5—Convertible Note Financing**

On October 2, 2017, the Company issued a convertible promissory note (the "Note") in an amount of \$6.0 million to an investor. The Note accrued interest at 8% per year and had a maturity date of October 2, 2018. The Note was subject to an automatic conversion upon a qualified equity financing defined as a raise of \$40.0 million, excluding the conversion of the Note and other indebtedness. The conversion was equal to the outstanding principal amount of the Note plus all accrued and previously unpaid interest thereon, divided by the lowest price per share paid by investor for qualified equity financing. The carrying value of the Note for the year ended December 31, 2017 was approximately \$6.1 million which approximated the fair value of the Note which was determined using Level 3 inputs. On January 4, 2018, the Note converted into 3,499,209 shares of Series A Convertible Preferred Stock. For the year ended December 31, 2017 and for the nine months ended September 30, 2018, the Company recorded aggregate interest expense of \$0.1 million.

**Note 6—Asset Acquisitions**

The following purchased assets were accounted for as asset acquisitions pursuant to ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*, as substantially all of the fair value of the assets acquired were concentrated in a group of similar assets, and the acquired assets did not have outputs or employees. 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 year ended December 31, 2017 and for the nine months ended September 30, 2018.

***Acquisition of License from Pulmokine, Inc. (GB002)***

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 GB002 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 \$63.0 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 in the year ended December 31, 2017, recorded as IPR&D of \$5.5 million. As of September 30, 2018, no milestones had been accrued as there were no potential milestones yet considered probable.

***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.

***Acquisition of 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 also has the right to sublicense its rights under the license agreement, subject to certain conditions. The Company is obligated to make future development and regulatory milestone payments of up to \$55.0 million, commercial milestone payments of up to \$85.0 million and sales milestone payments of up to \$260.0 million. The Company is also obligated to pay tiered royalties on sales for each licensed product, at percentages ranging from a high single-digit to mid-teens, subject to certain customary reductions. The Company made an upfront payment of \$20.0 million, which represented the purchase consideration for an asset acquisition. As of September 30, 2018, no milestones had been accrued as there were no potential milestones yet considered probable.

**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 milestones 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. As of September 30, 2018, no milestones had been accrued as there were no potential milestones yet considered probable. The Company recorded IPR&D of \$7.5 million in connection with the acquisition of Adhaere.

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

	Year Ended December 31,		Nine Months Ended September 30,	
	2016	2017	2017	2018
GB002	\$ —	\$ 5,500	\$ —	\$ —
GB001	—	—	—	19,148
GB004	—	—	—	20,000
GB1275	—	—	—	7,500
Other preclinical programs	—	—	—	3,011
Total IPR&D	<u>\$ —</u>	<u>\$ 5,500</u>	<u>\$ —</u>	<u>\$49,659</u>

**Note 7—Income Taxes**

No provision for federal or state income taxes has been recorded for the years ended December 31, 2016 and 2017. The difference between the Company’s effective tax rate of 0% and the U.S. federal statutory tax rate of 34% is largely due to the Company’s net operating losses and the effect of the federal corporate rate change beginning January 1, 2018, which are offset by the corresponding valuation allowance. 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 as of December 31, 2016 and 2017 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, 2017 was an increase of \$1.8 million.

	December 31,	
	2016	2017
(in thousands)		
Deferred tax assets:		
Amortization	\$ —	\$ 1,588
Deferred state income tax	—	—
Stock-based compensation	—	1
Net operating losses	49	306
Total gross deferred tax assets	49	1,895
Valuation allowance	(49)	(1,895)
Net deferred tax asset	<u>\$ —</u>	<u>\$ —</u>

At December 31, 2017, the Company has federal and California net operating losses (“NOL”) carryforwards of approximately \$1.1 million and \$1.1 million, respectively. The federal and state NOL carryforwards begin to expire in 2036.

The NOL carryforward may be subject to an annual limitation under Section 382 and 383 of the Internal Revenue Code of 1986, and similar state provisions if the Company experienced one or more ownership changes which would limit the amount of NOL and tax credit carryforwards that can be utilized to offset future taxable income and tax respectively. In general, an ownership change as defined by Section 382 and 383, results from the transactions increasing ownership of certain stockholders or public groups in the stock of the corporation of more than 50 percentage points over a three-year period. The Company has not completed a Section 382 and 383 analysis to assess whether an ownership change has occurred or whether there have been multiple ownership changes since the Company's formation due to the complexity and cost associated with such study and the fact there may be additional such ownership changes in the future. If a change in ownership were to have occurred or 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 and California. Due to the Company's losses incurred, the Company is subject to the income tax examination by authorities since inception. The Company's policy is to recognize interest expense and penalties related to income tax matters as tax expense. As of December 31, 2017, there were no significant accruals for interest related to unrecognized tax benefits or tax penalties.

On December 22, 2017, the President of the United States signed into law the Tax Act. The Tax Act amends the Internal Revenue Code to reduce tax rates and modify policies, credits, and deductions for individuals and businesses. For businesses, the Tax Act reduces the corporate tax rate from a maximum 35% to a flat 21% rate. The rate reduction is effective on January 1, 2018.

As a result of the rate reduction, the Company has reduced the deferred tax asset balance as of December 31, 2017 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, 2017, as the reduction in the deferred tax asset balance was fully offset by a corresponding decrease in the valuation allowance.

In conjunction with the Tax Act, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. There was no net impact on the Company's consolidated financial statements for the year ended December 31, 2017 as the corresponding adjustment was made to the valuation allowance. The ultimate impact may differ from these provisional amounts, possibly materially, due to, among other things, additional analysis, changes in interpretations and assumptions the Company has made, additional regulatory guidance that may be issued, and actions the Company may take as a result of the Tax Act.

#### **Note 8—Convertible Preferred Stock and Stockholders' Deficit**

##### ***Convertible Preferred Stock***

##### ***Series Seed Convertible Preferred Stock***

On January 4, 2018, the Company issued an aggregate of 20,000,000 shares of Series Seed Convertible Preferred Stock in connection with the merger agreement with AA Biopharma Inc. (See Note 6).

##### ***Series A Convertible Preferred Stock***

In January and March 2018, the Company issued an aggregate of 45,714,286 shares of Series A Convertible Preferred Stock at \$1.75 per share for approximately \$73.9 million in cash and the conversion of approximately \$6.1 million in principal and accrued interest under the Note (See Note 5).



### ***Series B Convertible Preferred Stock***

On July 20 2018, the Company issued an aggregate of 71,506,513 shares of Series B Convertible Preferred Stock at \$3.2167 per share for approximately \$230.0 million in gross proceeds.

#### ***Dividends***

Holders of Series Seed Convertible Preferred Stock, Series A Convertible Preferred Stock and Series B Convertible Preferred Stock (collectively, “Series Convertible Preferred Stock”), in preference to the holders of common stock, shall be entitled to receive, but only out of funds that are legally available therefor, cash dividends at the annual per share rate of 6.0% per annum (based on the original issue price). Such dividends shall be payable only when, as and if declared by the Company’s board of directors and shall be non-cumulative. No dividends have been declared as of September 30, 2018.

#### ***Liquidation***

Holders of Series B Convertible Preferred Stock are entitled to receive a liquidation preference (the “Series B Liquidation Amount”) prior to any distribution to the holders of Series Seed Convertible Preferred Stock, Series A Convertible Preferred Stock and common stock in the amount per share equal to the greater of (i) \$3.2167, plus all declared and unpaid dividends, or (ii) the amount the holders would receive if the Series B Convertible Preferred Stock were converted into common stock prior to such liquidation event. After payment of the full Series B Liquidation Amount, holders of shares of Series Seed Convertible Preferred Stock and Series A Convertible Preferred Stock are entitled to receive a liquidation preference prior to any distribution to the holders of common stock in the amount per share equal to the greater of (i) \$1.00 per share with respect to the Series Seed Convertible Preferred Stock and \$1.75 per share with respect to the Series A Convertible Preferred Stock, plus all declared and unpaid dividends, or (ii) the amount the holders would receive if the Series Convertible Preferred Stock were converted into common stock prior to such liquidation event. Thereafter, the remaining assets of the Company legally available for distribution, if any, shall be distributed ratably to the holders of the common stock.

#### ***Conversion***

The shares of Series Convertible Preferred Stock are convertible into shares of common stock at a ratio of 4.5-to-one, at the option of the holder, subject to certain anti-dilution adjustments. Each share of Series Convertible Preferred Stock is automatically converted into common stock (i) upon the closing of a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least \$100 million of gross proceeds to the Company, or if such offering is otherwise approved by vote or written consent of at least 65% of the outstanding shares of the Series Convertible Preferred Stock, or (ii) the date and time, or the occurrence of an event, specified by vote or written consent of each of the holders of (a) at least 65% of the outstanding shares of the Series Convertible Preferred Stock and (b) at least 65% of the outstanding shares of Series B Convertible Preferred Stock

#### ***Voting Rights***

The holder of each share of Series Convertible Preferred Stock is entitled to one vote for each share of common stock into which it would convert and to vote as one class with the common stockholders on all matters.

#### ***Presentation of Convertible Preferred Stock***

The Series Convertible Preferred is classified outside of stockholders’ equity (deficit) because the shares contain certain redemption features that are not solely within the control of the Company. The Company is not adjusting the carrying value of the Series Convertible Preferred as it is uncertain whether or when a redemption event will occur.

### ***Common Stock***

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. 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.

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 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.

Each share of common stock is entitled to one voting right. Common stock owners are entitled to dividends when funds are legally available and declared by the Board.

### ***Shares of Common Stock Subject to Repurchase***

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 forfeiture by the Company upon the stockholder's termination of employment or service to the Company. In January 2018, the Company's founders entered into stock restriction agreements, whereby 4,580,444 of previously unrestricted shares of common stock were subject to service vesting conditions. These shares are also subject to forfeiture by the Company upon the stockholders' termination of employment or service to the Company. 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. For the years ended December 31, 2016, December 31, 2017 and September 30, 2018, 0 shares, 1,305,421 shares and 7,799,605 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—Stock-Based Compensation**

The Company's 2017 Equity Incentive Plan (the "2017 Plan") permits the granting of incentive stock options, non-statutory stock options, restricted stock, restricted stock units and other stock-based awards. As of December 31, 2016, December 31, 2017, and September 30, 2018, 0 shares, 1,308,746 shares, and 3,804,716 shares of common stock were authorized for issuance under the 2017 Plan, respectively.

At December 31, 2017 and September 30, 2018, 1,305,421 and 3,282,455 shares outstanding have been awarded and 3,325 and 522,261 shares, respectively, remain available for issuance under the 2017 Plan.

### ***Stock Options***

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 is a private company and lacks company-specific

## [Table of Contents](#)

historical and implied volatility information. Therefore, it 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 grant date fair value of stock option awards is determined using the Black-Scholes option-pricing model. No stock options were granted for the years ended December 31, 2016 and 2017. The following assumptions were used to estimate the fair value of stock option awards:

	<b>Nine Months Ended September 30, 2018</b>
Exercise price	\$2.61 - \$4.59
Expected term (in years)	5.3 - 6.1
Expected volatility	69.13% - 77.62%
Risk-free interest rate	2.65% - 2.96%
Expected dividend yield	—

The following table summarizes stock option activity during the nine months ended September 30, 2018:

	<b>Number of Shares</b>	<b>Weighted- Average Exercise Price</b>	<b>Weighted- Average Remaining Contractual Life (in years)</b>	<b>Total Intrinsic Value</b>
Outstanding as of December 31, 2017	—	\$ —	—	\$
Granted	2,130,533	2.94	9.6	
Cancelled	26,222	2.61	9.7	
Outstanding as of September 30, 2018	<u>2,104,311</u>	<u>\$ 3.00</u>	<u>9.6</u>	<u>\$ 702</u>
Options vested and exercisable	34,630	\$ 2.61	9.3	\$ 60

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 weighted-average grant date fair value per share for the stock option grants during the nine months ended September 30, 2018 was \$1.94. At September 30, 2018, the total unrecognized compensation related to unvested stock option awards granted was \$3.7 million, which the Company expects to recognize over a weighted-average period of approximately 3.6 years.

**Restricted Stock**

The summary of the Company's restricted stock activity is as follows:

	<u>Number of Shares</u>	<u>Weighted-Average Grant Date Fair Value Per Share</u>
Nonvested at December 31, 2016	—	\$ —
Granted	1,305,421	0.09
Nonvested at December 31, 2017	1,305,421	\$ 0.09
Granted	8,673,584	5.53
Forfeitures	(127,277)	0.09
Vested	(2,052,123)	8.77
Nonvested at September 30, 2018	<u>7,799,605</u>	<u>\$ 3.82</u>

At September 30, 2018, the total unrecognized compensation related to unvested restricted stock awards granted was \$28.2 million, which the Company expects to recognize over a weighted-average period of approximately 4.0 years.

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

	<u>Year Ended December 31,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2016</u>	<u>2017</u>	<u>2017</u>	<u>2018</u>
General and administrative	\$ —	\$ 32	\$ —	\$ 19,948
Research and development	—	—	—	200
Total stock-based compensation	<u>\$ —</u>	<u>\$ 32</u>	<u>\$ —</u>	<u>\$ 20,148</u>

For the nine months ended September 30, 2018, \$17.3 million of the stock-based compensation expense related to the issuance of the anti-dilution shares.

**Note 10—Property and Equipment, Net**

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

	<u>Estimated Useful Life (in years)</u>	<u>December 31, 2017</u>	<u>September 30, 2018</u>
Office equipment	3	\$ —	\$ 817
Computer Equipment	5	—	15
Software	3	—	50
Lab Equipment	2-5	—	1,048
Leasehold improvements	6-7	—	1,240
Construction in process	N/A	—	—
Total property and equipment		—	3,170
Less: accumulated depreciation		—	163
Property and equipment, net		<u>\$ —</u>	<u>\$ 3,007</u>

No depreciation expense was recorded for the years ended December 31, 2016 and 2017. Depreciation expense for the nine months ended September 30, 2018 was approximately \$163,000 and was recorded in general and administrative expense in the Consolidated Statements of Operations.

#### **Note 11—Commitments and Contingencies**

##### *Office Lease*

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, with an option to extend for the entire premises through the expiration of the initial terms of the master lease. The sub-lease is subject to charges for common area maintenance and other costs, and base rent is subject to an annual increase in 3% of each subsequent year. The sublease did not commence until January 15, 2018, therefore there was no rent expense for the years ending December 31, 2016 and 2017. For the nine months ended September 30, 2018, the Company recorded approximately \$1.1 million in rent expense.

Future minimum payments under the non-cancelable operating lease as of September 30, 2018 were as follows (in thousands):

Remainder of 2018	\$ 341
Years ended December 31,	
2019	2,908
2020	2,997
2021	3,084
2022	3,176
Thereafter	3,348
Total	<u>\$15,854</u>

##### *Litigation*

The Company is not a party to any material legal proceedings and is not aware of any pending or threatened claims. From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities.

#### **Note 12—Subsequent Events**

For purposes of the financial statements as of December 31, 2017 and the year then ended, the Company evaluated subsequent events for recognition and measurement purposes through October 11, 2018, the date the financial statements were issued. The Company has further evaluated subsequent events for recognition and remeasurement purposes of the interim financial statements as of September 30, 2018, and for the nine months then ended, through November 29, 2018 and for disclosure purposes, through January 30, 2019. Except as described below, the Company has concluded that no events or transactions have occurred that require disclosure.

##### **Approval of the 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 will become effective on the day prior to the effectiveness of the registration statement of which this prospectus forms a part. 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

## [Table of Contents](#)

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 remain available for issuance under the 2017 Plan as of the effective date of the 2019 Plan 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 31st of the preceding calendar year or such lesser amount as determined by the Company's board of directors.

### **Approval of the 2019 Employee Stock Purchase Plan**

In January 2019, the Company's board of directors and stockholders approved and adopted the 2019 Employee Stock Purchase Plan (the "ESPP"). The ESPP will become effective on the day prior to the effectiveness of the registration statement of which this prospectus forms a part. 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 31st of the preceding calendar year or such lesser amount as determined by the Company's board of directors.

### **Reverse Stock Split**

On January 23, 2019, the Company effected a 1-for-4.5 reverse stock split of its common stock. The par value and the authorized number of shares of the common stock were not adjusted as a result of the reverse stock split. The reverse stock split resulted in an adjustment to the Series Seed, A and B preferred stock conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. The accompanying consolidated financial statements and notes to the consolidated financial statements give retroactive effect to the reverse stock split for all periods presented.

Through and including \_\_\_\_\_, 2019 (the 25th day after the date of this prospectus) all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

**14,375,000 Shares**



**Common Stock**

---

P R O S P E C T U S

---

**BofA Merrill Lynch**

**SVB Leerink**

**Barclays**

**Evercore ISI**

, 2019

---

---

**Part II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution.**

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the SEC registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and the Nasdaq Global Select Market listing fee.

	<b>Amount paid or to be paid</b>
SEC registration fee	\$ 32,058
FINRA filing fee	40,175
Nasdaq Global Select Market listing fee	290,000
Accountants' fees and expenses	1,000,000
Legal fees and expenses	1,800,000
Transfer Agent's fees and expenses	3,500
Printing and engraving expenses	425,000
Miscellaneous	74,267
<b>Total expenses</b>	<b>\$ 3,665,000</b>

**Item 14. Indemnification of Directors and Officers.**

Section 102 of the General Corporation Law of the State of Delaware permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our certificate of incorporation provides that no director of the Registrant shall be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the General Corporation Law of the State of Delaware prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the General Corporation Law of the State of Delaware provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation, or a person serving at the request of the corporation for another corporation, partnership, joint venture, trust or other enterprise in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he was or is a party or is threatened to be made a party to any threatened, ending or completed action, suit or proceeding by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.



## Table of Contents

Our amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, provides that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our amended and restated certificate of incorporation provides that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred in connection therewith. Expenses must be advanced to an Indemnitee under certain circumstances.

We have entered into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request.

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act, against certain liabilities.

### **Item 15. Recent Sales of Unregistered Securities.**

Set forth below is information regarding unregistered securities issued by us since October 26, 2015. Also included is the consideration received by us for such securities and information relating to the section of the Securities Act, or rule of the SEC, under which exemption from registration was claimed.

- (a) Issuances of Capital Stock and Convertible Promissory Notes
  1. In December 2015, we issued and sold 9,160,888 shares of common stock to our founders at purchase price of \$0.0045 per share for aggregate consideration of approximately \$41,224.
  2. In October 2017, we issued and sold to an investor a convertible promissory note, or the Note, in the aggregate principal amount of \$6,000,000. The Note, including interest thereon, converted into 3,499,209 shares of our Series A convertible preferred stock in January 2018.

## Table of Contents

3. In December 2017, we issued 1,101,278 shares of our common stock and 20,000,000 shares of our Series Seed convertible preferred stock to investors pursuant to a merger agreement.
4. In January and March 2018, we issued an aggregate of 45,714,286 shares of our Series A convertible preferred stock to investors at a purchase price of \$1.75 per share, for aggregate consideration of approximately \$80.0 million, including the conversion of the Note.
5. In May 2018, we issued 503,094 shares of common stock to our founders at a purchase price of \$2.61 per share, in consideration for services rendered for aggregate consideration of \$1.3 million.
6. In July 2018, we issued an aggregate of 71,506,513 shares of our Series B convertible preferred stock to investors at a purchase price of \$3.2167 per share, for aggregate consideration of approximately \$230.0 million.
7. In September 2018, we issued 3,590,046 shares of common stock to our founders at a purchase price of \$4.59 per share, in consideration for services rendered for aggregate consideration of \$16.5 million.

No underwriters were involved in the foregoing issuances of securities. The securities described in this section (a) of Item 15 were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All holders of securities described above represented to us in connection with their purchase or issuance that they were accredited investors and were acquiring the securities for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The holders received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

### (b) Grants of Stock Options and Restricted Stock

1. Since October 2015, we granted stock options to purchase an aggregate of 5,143,569 shares of our common stock at a weighted-average exercise price of \$7.49 per share, to certain of our employees, consultants and directors in connection with services provided to us by such persons. 36,222 of these options have been canceled and none of these options have been exercised through December 31, 2018.
2. Since October 2015, we granted an aggregate of 1,305,421 shares of our restricted common stock, 127,277 of which have been cancelled, to certain of our employees, consultants and directors pursuant to restricted stock agreements in connection with services provided to us by such persons, at a purchase price of \$0.022 per share.

The restricted stock, stock options and the common stock issuable upon the exercise of such options as described in this section (b) of Item 15 were issued pursuant to written compensatory plans or arrangements with our employees and directors, in reliance on the exemption from the registration requirements of the Securities Act provided by Rule 701 promulgated under the Securities Act or the exemption set forth in Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

## [Table of Contents](#)

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. All certificates representing the issued shares of capital stock described in this Item 15 included appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer.

### **Item 16. Exhibits and Financial Statement Schedules.**

- (a) **Exhibits.** See Exhibit Index attached to this registration statement, which is incorporated by reference herein.
- (b) **Financial Statement Schedules.** Schedules not listed above 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.

### **Item 17. Undertakings.**

The undersigned registrant hereby undertakes to provide to the underwriter, at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

**Exhibit Index**

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
1.1	<a href="#">Form of Underwriting Agreement</a>
3.1*	<a href="#">Amended and Restated Certificate of Incorporation, as amended (currently in effect)</a>
3.2*	<a href="#">Bylaws (currently in effect)</a>
3.3*	<a href="#">Form of Amended and Restated Certificate of Incorporation (to be effective immediately prior to the closing of this offering)</a>
3.4*	<a href="#">Form of Amended and Restated Bylaws (to be effective immediately prior to the closing of this offering)</a>
4.1*	<a href="#">Specimen stock certificate evidencing the shares of common stock</a>
4.2*	<a href="#">Amended and Restated Investors' Rights Agreement, dated July 20, 2018, by and among the Registrant and certain of its stockholders</a>
5.1*	<a href="#">Opinion of Latham &amp; Watkins LLP</a>
10.1#*	<a href="#">Gossamer Bio, Inc. 2017 Equity Incentive Plan, as amended</a>
10.2#*	<a href="#">Form of stock option grant notice and stock option agreement under Gossamer Bio, Inc. 2017 Equity Incentive Plan, as amended</a>
10.3#*	<a href="#">Form of restricted stock grant notice and restricted stock agreement under Gossamer Bio, Inc. 2017 Equity Incentive Plan, as amended</a>
10.4#*	<a href="#">Form of Founder restricted stock grant notice and restricted stock agreement</a>
10.5#*	<a href="#">Gossamer Bio, Inc. 2019 Incentive Award Plan and form of stock option grant notice and stock option agreement thereunder</a>
10.6#*	<a href="#">Gossamer Bio, Inc. 2019 Employee Stock Purchase Plan</a>
10.7#*	<a href="#">Gossamer Bio, Inc. Non-Employee Director Compensation Program</a>
10.8#*	<a href="#">Employment Letter, dated January 4, 2018, by and between Sheila Gujrathi, M.D. and the Registrant</a>
10.9#*	<a href="#">Employment Letter, dated January 4, 2018, by and between Faheem Hasnain and the Registrant</a>
10.10#*	<a href="#">Employment Letter, dated December 4, 2018, by and between Bryan Giraud and the Registrant</a>
10.11#*	<a href="#">Employment Letter, dated December 4, 2018, by and between Christian Waage and the Registrant</a>
10.12#*	<a href="#">Employment Letter, dated December 4, 2018, by and between Jakob Dupont, M.D. and the Registrant</a>
10.13#*	<a href="#">Employment Letter, dated December 4, 2018, by and between Luisa Salter-Cid, Ph.D. and the Registrant</a>
10.14#*	<a href="#">Form of Indemnification Agreement</a>
10.15*	<a href="#">Sublease Agreement, dated December 29, 2017, by and between The Medicines Company and the Registrant</a>
10.16*	<a href="#">First Amendment to Sublease Agreement, dated August 24, 2018, by and between The Medicines Company and the Registrant</a>
10.17†*	<a href="#">Exclusive License Agreement, dated October 2, 2017, by and between GB002, Inc., the Registrant and Pulmokine, Inc.</a>

## Table of Contents

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
10.18†*	<a href="#">License Agreement, dated June 24, 2018, by and between Aerpio Pharmaceuticals, Inc. and GB004, Inc.</a>
21.1*	<a href="#">List of subsidiaries of the Registrant</a>
23.1	<a href="#">Consent of Ernst &amp; Young, LLP, independent registered public accounting firm</a>
23.2*	<a href="#">Consent of Latham &amp; Watkins LLP (included in Exhibit 5.1)</a>
24.1*	<a href="#">Power of Attorney.</a>

\* Previously filed.

# Indicates management contract or compensatory plan.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933.

**SIGNATURES**

Pursuant to the requirements of the Securities Act, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in San Diego, State of California, on this 30th day of January, 2019.

**GOSSAMER BIO, INC.**

By: /s/ Sheila Gujrathi  
Sheila Gujrathi, M.D.  
President, Chief Executive Officer and Director

**SIGNATURES AND POWER OF ATTORNEY**

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities held on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Sheila Gujrathi</u> Sheila Gujrathi, M.D.	President, Chief Executive Officer and Director (principal executive officer)	January 30, 2019
<u>/s/ Bryan Giraudo</u> Bryan Giraudo	Chief Financial Officer (principal financial and accounting officer)	January 30, 2019
<u>*</u> Faheem Hasnain	Executive Chairman of the Board of Directors	January 30, 2019
<u>*</u> Joshua H. Bilenker, M.D.	Director	January 30, 2019
<u>*</u> Kristina Burow	Director	January 30, 2019
<u>*</u> Russell Cox	Director	January 30, 2019
<u>*</u> Thomas Daniel, M.D.	Director	January 30, 2019
<u>*</u> Renée Galá	Director	January 30, 2019
<u>*</u> Otello Stampacchia, Ph.D.	Director	January 30, 2019

\*By: /s/ Sheila Gujrathi  
Sheila Gujrathi, M.D.  
Attorney-in-Fact

GOSSAMER BIO, INC.  
(a Delaware corporation)  
[●] Shares of Common Stock  
UNDERWRITING AGREEMENT

Dated: [●], 2019

---

---

GOSSAMER BIO, INC.  
(a Delaware corporation)  
[●] Shares of Common Stock

**UNDERWRITING AGREEMENT**

[●], 2019

Merrill Lynch, Pierce, Fenner & Smith  
Incorporated  
SVB Leerink LLC  
Barclays Capital Inc.  
Evercore Group L.L.C.  
as Representatives of the several  
Underwriters

c/o Merrill Lynch, Pierce, Fenner & Smith  
Incorporated  
One Bryant Park  
New York, New York 10036

SVB Leerink LLC  
One Federal Street, 37<sup>th</sup> Floor  
Boston, Massachusetts 02110

Barclays Capital Inc.  
745 Seventh Avenue  
New York, New York 10019

Evercore Group L.L.C.  
55 East 52nd Street  
New York, New York 10055

Ladies and Gentlemen:

Gossamer Bio, Inc., a Delaware corporation (the “Company”), confirms its agreement with Merrill Lynch, Pierce, Fenner & Smith Incorporated (“Merrill Lynch”), SVB Leerink LLC (“Leerink”), Barclays Capital Inc. (“Barclays”), Evercore Group L.L.C. (“Evercore”) and each of the other Underwriters named in Schedule A hereto (collectively, the “Underwriters,” which term shall also include any underwriter substituted as hereinafter provided in Section 10 hereof), for whom Merrill Lynch, Leerink, Barclays and Evercore are acting as representatives (in such capacity, the “Representatives”), with respect to (i) the sale by the Company and the purchase by the Underwriters, acting severally and not jointly, of the respective numbers of shares of Common Stock, par value \$0.0001 per share, of the Company (“Common Stock”) set forth in Schedule A hereto and (ii) the grant by the Company to the Underwriters, acting severally and not jointly, of the option described in Section 2(b) hereof to purchase all or any part of [●] additional shares of Common Stock. The aforesaid [●] shares of Common Stock (the “Initial Securities”)



to be purchased by the Underwriters and all or any part of the [●] shares of Common Stock subject to the option described in Section 2(b) hereof (the “Option Securities”) are herein called, collectively, the “Securities.”

The Company understands that the Underwriters propose to make a public offering of the Securities as soon as the Representatives deem advisable after this Agreement has been executed and delivered.

The Company and the Underwriters agree that up to 5% of the Initial Securities to be purchased by the Underwriters (the “Reserved Securities”) shall be reserved for sale by the Underwriters to certain persons designated by the Company (the “Invitees”), as part of the distribution of the Securities by the Underwriters, subject to the terms of this Agreement, the applicable rules, regulations and interpretations of the Financial Industry Regulatory Authority, Inc. (“FINRA”) and all other applicable laws, rules and regulations. The Company solely determined, without any direct or indirect participation by the Underwriters, the Invitees who will purchase Reserved Securities (including the amount to be purchased by such persons) sold by the Underwriters. To the extent that such Reserved Securities are not orally confirmed for purchase by Invitees by 11:59 P.M. (New York City time) on the date of this Agreement, such Reserved Securities may be offered to the public as part of the public offering contemplated hereby.

The Company has filed with the Securities and Exchange Commission (the “Commission”) a registration statement on Form S-1 (No. 333-228984), including the related preliminary prospectus or prospectuses, covering the registration of the sale of the Securities under the Securities Act of 1933, as amended (the “1933 Act”). Promptly after execution and delivery of this Agreement, the Company will prepare and file a prospectus in accordance with the provisions of Rule 430A (“Rule 430A”) of the rules and regulations of the Commission under the 1933 Act (the “1933 Act Regulations”) and Rule 424(b) (“Rule 424(b)”) of the 1933 Act Regulations. The information included in such prospectus that was omitted from such registration statement at the time it became effective but that is deemed to be part of such registration statement at the time it became effective pursuant to Rule 430A(b) is herein called the “Rule 430A Information.” Such registration statement, including the amendments thereto, the exhibits thereto and any schedules thereto, at the time it became effective, and including the Rule 430A Information, is herein called the “Registration Statement.” Any registration statement filed pursuant to Rule 462(b) of the 1933 Act Regulations is herein called the “Rule 462(b) Registration Statement” and, after such filing, the term “Registration Statement” shall include the Rule 462(b) Registration Statement. Each prospectus used prior to the effectiveness of the Registration Statement, and each prospectus that omitted the Rule 430A Information that was used after such effectiveness and prior to the execution and delivery of this Agreement, is herein called a “preliminary prospectus.” The final prospectus, in the form first furnished to the Underwriters for use in connection with the offering of the Securities, is herein called the “Prospectus.” For purposes of this Agreement, all references to the Registration Statement, any preliminary prospectus, the Prospectus or any amendment or supplement to any of the foregoing shall be deemed to include the copy filed with the Commission pursuant to its Electronic Data Gathering, Analysis and Retrieval system or any successor system (“EDGAR”).

As used in this Agreement:

“Applicable Time” means [●]:00 [P./A.M.], New York City time, on [●], 2019 or such other time as agreed by the Company and the Representatives.

“General Disclosure Package” means any Issuer General Use Free Writing Prospectuses issued at or prior to the Applicable Time, the most recent preliminary prospectus that is distributed to investors prior to the Applicable Time and the information included on Schedule B-1 hereto, all considered together.

“Issuer Free Writing Prospectus” means any “issuer free writing prospectus,” as defined in Rule 433 of the 1933 Act Regulations (“Rule 433”), including without limitation any “free writing prospectus” (as defined in Rule 405 of the 1933 Act Regulations (“Rule 405”)) relating to the Securities that is (i) required to be filed with the Commission by the Company, (ii) a “road show that is a written communication” within the meaning of Rule 433(d)(8)(i), whether or not required to be filed with the Commission, or (iii) exempt from filing with the Commission pursuant to Rule 433(d)(5)(i) because it contains a description of the Securities or of the offering that does not reflect the final terms, in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company’s records pursuant to Rule 433(g).

“Issuer General Use Free Writing Prospectus” means any Issuer Free Writing Prospectus that is intended for general distribution to prospective investors (other than a “*bona fide* electronic road show,” as defined in Rule 433 (the “Bona Fide Electronic Road Show”)), as evidenced by its being specified in Schedule B-2 hereto.

“Issuer Limited Use Free Writing Prospectus” means any Issuer Free Writing Prospectus that is not an Issuer General Use Free Writing Prospectus.

“Testing-the-Waters Communication” means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the 1933 Act.

“Written Testing-the-Waters Communication” means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the 1933 Act.

#### SECTION 1. Representations and Warranties.

(a) *Representations and Warranties by the Company.* The Company represents and warrants to each Underwriter as of the date hereof, the Applicable Time, the Closing Time (as defined below) and any Date of Delivery (as defined below), and agrees with each Underwriter, as follows:

(i) Registration Statement and Prospectuses. Each of the Registration Statement and any amendment thereto has become effective under the 1933 Act. No stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto has been issued under the 1933 Act, no order preventing or suspending the use of any preliminary prospectus or the Prospectus has been issued and no proceedings for any of those purposes have been instituted or are pending or, to the Company’s knowledge, threatened by the Commission. The Company has complied with each request (if any) from the Commission for additional information.

Each of the Registration Statement and any post-effective amendment thereto, at the time it became effective, the Applicable Time, the Closing Time and any Date of Delivery, complied and will comply in all material respects with the requirements of the 1933 Act and the 1933 Act Regulations. Each preliminary prospectus, the Prospectus and any amendment or supplement thereto, at the time each was filed with the Commission, and, in each case, at the Applicable Time, the Closing Time and any Date of Delivery complied and will comply in all material respects with the requirements of the 1933 Act and the 1933 Act Regulations. Each preliminary prospectus delivered to the Underwriters for use in connection with this offering and the Prospectus was or will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(ii) Accurate Disclosure. Neither the Registration Statement nor any amendment thereto, at its effective time, on the date hereof, at the Closing Time or at any Date of Delivery, contained, contains or will contain an untrue statement of a material fact or omitted, omits or will omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. At the Applicable Time and any Date of Delivery, none of (A) the General Disclosure Package, (B) any individual Issuer Limited Use Free Writing Prospectus, when considered together with the General Disclosure Package and (C) any individual Written Testing-the-Waters Communication, when considered together with the General Disclosure Package, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. Neither the Prospectus nor any amendment or supplement thereto, as of its issue date, at the time of any filing with the Commission pursuant to Rule 424(b), at the Closing Time or at any Date of Delivery, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

The representations and warranties in this subsection shall not apply to statements in or omissions from the Registration Statement (or any amendment thereto), the General Disclosure Package or the Prospectus (or any amendment or supplement thereto) made in reliance upon and in conformity with written information furnished to the Company by any Underwriter through the Representatives expressly for use therein. For purposes of this Agreement, the only information so furnished shall be the information in the first paragraph under the heading “Underwriting–Commissions and Discounts,” the information in the second, third and fourth paragraphs under the heading “Underwriting–Price Stabilization, Short Positions and Penalty Bids” and the information under the heading “Underwriting–Electronic Distribution” in each case contained in the Prospectus (collectively, the “Underwriter Information”).

(iii) Issuer Free Writing Prospectuses. No Issuer Free Writing Prospectus, when used, conflicted with the information contained in the Registration Statement or the Prospectus, and any preliminary or other prospectus deemed to be a part thereof that had not been superseded or modified at such time. The representations and warranties in this subsection shall not apply to statements in or omissions from any Issuer Free Writing Prospectus made in reliance upon and in conformity with the Underwriter Information. The Company has made available a Bona Fide Electronic Road Show in compliance with Rule 433(d)(8)(ii) such that no filing of any “road show” (as defined in Rule 433(h)) is required in connection with the offering of the Securities.

(iv) Testing-the-Waters Materials. The Company (A) has not engaged in any Testing-the-Waters Communication other than Testing-the-Waters Communications with the consent of the Representatives with entities that are qualified institutional buyers within the meaning of Rule 144A under the 1933 Act or institutions that are accredited investors within the meaning of Rule 501 under the 1933 Act and (B) has not authorized anyone other than the Representatives to engage in Testing-the-Waters Communications. The Company reconfirms that the Representatives have been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications other than those listed on Schedule B-3 hereto.

(v) Company Not Ineligible Issuer. At the time of filing the Registration Statement and any post-effective amendment thereto, at the earliest time thereafter that the Company or another offering participant made a *bona fide* offer (within the meaning of Rule 164(h)(2) of the 1933 Act Regulations) of the Securities and at the date hereof, the Company was not and is not an

“ineligible issuer,” as defined in Rule 405, without taking account of any determination by the Commission pursuant to Rule 405 that it is not necessary that the Company be considered an ineligible issuer.

(vi) Emerging Growth Company Status. From the time of the initial confidential submission of the Registration Statement to the Commission (or, if earlier, the first date on which the Company engaged directly or through any Person authorized to act on its behalf in any Testing-the-Waters Communication) through the date hereof, the Company has been and is an “emerging growth company,” as defined in Section 2(a) of the 1933 Act (an “Emerging Growth Company”).

(vii) Independent Accountants. The accountants who certified the financial statements and supporting schedules included in the Registration Statement, the General Disclosure Package and the Prospectus are independent public accountants as required by the 1933 Act, the 1933 Act Regulations and the Public Company Accounting Oversight Board.

(viii) Financial Statements. The financial statements included in the Registration Statement, the General Disclosure Package and the Prospectus, together with the related schedules and notes, present fairly in all material respects the financial position of the Company and its consolidated subsidiaries at the dates indicated and the statement of operations, stockholders’ equity and cash flows of the Company and its consolidated subsidiaries for the periods specified; said financial statements have been prepared in conformity with U.S. generally accepted accounting principles (“GAAP”) applied on a consistent basis throughout the periods involved except, in the case of unaudited interim financial statements, subject to normal year-end audit adjustments and the exclusion of certain footnotes as permitted by the applicable rules of the Commission. The supporting schedules included in the Registration Statement, the General Disclosure Package and the Prospectus, if any, present fairly in accordance with GAAP the information required to be stated therein. The selected financial data and the summary financial information included in the Registration Statement, the General Disclosure Package and the Prospectus present fairly in all material respects the information shown therein and have been compiled on a basis consistent with that of the audited financial statements included therein. Except as included therein, no historical or pro forma financial statements or supporting schedules are required to be included in the Registration Statement, the General Disclosure Package or the Prospectus under the 1933 Act or the 1933 Act Regulations.

(ix) No Material Adverse Change in Business. Except as otherwise stated therein, since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package or the Prospectus, (A) there has been no material adverse change in the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company and its subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business (a “Material Adverse Effect”), (B) there have been no transactions entered into by the Company or any of its subsidiaries, other than those in the ordinary course of business, which are material with respect to the Company and its subsidiaries considered as one enterprise, and (C) there has been no dividend or distribution of any kind declared, paid or made by the Company on any class of its capital stock.

(x) Good Standing of the Company. The Company has been duly organized and is validly existing as a corporation in good standing under the laws of the State of Delaware and has corporate power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement, the General Disclosure Package and the Prospectus and to enter into and perform its obligations under this Agreement; and the Company is duly qualified as a foreign corporation to transact business and is in good standing in each other jurisdiction in

which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure so to qualify or to be in good standing would not result in a Material Adverse Effect.

(xi) Good Standing of Subsidiaries. Each “significant subsidiary” of the Company (as such term is defined in Rule 1-02 of Regulation S-X) (each, a “Subsidiary” and, collectively, the “Subsidiaries”) has been duly organized and is validly existing in good standing under the laws of the jurisdiction of its incorporation or organization, has corporate or similar power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement, the General Disclosure Package and the Prospectus and is duly qualified to transact business and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure to so qualify or to be in good standing would not result in a Material Adverse Effect. Except as otherwise disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, all of the issued and outstanding capital stock of each Subsidiary has been duly authorized and validly issued, is fully paid and non-assessable and is owned by the Company, directly or through subsidiaries, free and clear of any security interest, mortgage, pledge, lien, encumbrance, claim or equity. None of the outstanding shares of capital stock of any Subsidiary were issued in violation of the preemptive or similar rights of any securityholder of such Subsidiary. The only subsidiaries of the Company are (A) the subsidiaries listed on Exhibit 21.1 to the Registration Statement and (B) certain other subsidiaries which, considered in the aggregate as a single subsidiary, do not constitute a “significant subsidiary” as defined in Rule 1-02 of Regulation S-X.

(xii) Capitalization. The authorized, issued and outstanding shares of capital stock of the Company are as set forth in the Registration Statement, the General Disclosure Package and the Prospectus under the caption “Capitalization” (except for subsequent issuances, if any, pursuant to this Agreement, pursuant to reservations, agreements or employee benefit or equity incentive plans referred to in the Registration Statement, the General Disclosure Package and the Prospectus or pursuant to the exercise of convertible securities or options referred to in the Registration Statement, the General Disclosure Package and the Prospectus). The outstanding shares of capital stock of the Company have been duly authorized and validly issued and are fully paid and non-assessable. None of the outstanding shares of capital stock of the Company were issued in violation of the preemptive or other similar rights of any securityholder of the Company.

(xiii) Authorization of Agreement. This Agreement has been duly authorized, executed and delivered by the Company.

(xiv) Authorization and Description of Securities. The Securities to be purchased by the Underwriters from the Company have been duly authorized for issuance and sale to the Underwriters pursuant to this Agreement and, when issued and delivered by the Company pursuant to this Agreement against payment of the consideration set forth herein, will be validly issued and fully paid and non-assessable; and the issuance of the Securities is not subject to the preemptive or other similar rights of any securityholder of the Company. The Common Stock conforms in all material respects to all statements relating thereto contained in the Registration Statement, the General Disclosure Package and the Prospectus and such description conforms in all material respects to the rights set forth in the instruments defining the same. No holder of Securities will be subject to personal liability by reason of being such a holder.

(xv) Registration Rights. There are no persons with registration rights or other similar rights to have any securities registered for sale pursuant to the Registration Statement or otherwise

registered for sale or sold by the Company under the 1933 Act pursuant to this Agreement, other than those rights that have been disclosed in the Registration Statement, the General Disclosure Package and the Prospectus and have been waived.

(xvi) Absence of Violations, Defaults and Conflicts. Neither the Company nor any of its subsidiaries is (A) in violation of its charter, by-laws or similar organizational document, (B) in default in the performance or observance of any obligation, agreement, covenant or condition contained in any contract, indenture, mortgage, deed of trust, loan or credit agreement, note, lease or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which it or any of them may be bound or to which any of the properties or assets of the Company or any subsidiary is subject (collectively, "Agreements and Instruments"), except for such defaults that would not, singly or in the aggregate, result in a Material Adverse Effect, or (C) in violation of any law, statute, rule, regulation, judgment, order, writ or decree of any arbitrator, court, governmental body, regulatory body, administrative agency or other authority, body or agency having jurisdiction over the Company or any of its subsidiaries or any of their respective properties, assets or operations (each, a "Governmental Entity"), except for such violations that would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect. The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated herein and in the Registration Statement, the General Disclosure Package and the Prospectus (including the issuance and sale of the Securities and the use of the proceeds from the sale of the Securities as described therein under the caption "Use of Proceeds") and compliance by the Company with its obligations hereunder have been duly authorized by all necessary corporate action and do not and will not, whether with or without the giving of notice or passage of time or both, conflict with or constitute a breach of, or default or Repayment Event (as defined below) under, or result in the creation or imposition of any lien, charge or encumbrance upon any properties or assets of the Company or any subsidiary pursuant to, the Agreements and Instruments (except for such conflicts, breaches, defaults or Repayment Events or liens, charges or encumbrances that would not, singly or in the aggregate, result in a Material Adverse Effect), nor will such action result in any violation of the provisions of the charter, by-laws or similar organizational document of the Company or any of its subsidiaries or any law, statute, rule, regulation, judgment, order, writ or decree of any Governmental Entity. As used herein, a "Repayment Event" means any event or condition which gives the holder of any note, debenture or other evidence of indebtedness (or any person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a portion of such indebtedness by the Company or any of its subsidiaries.

(xvii) Absence of Labor Dispute. No labor dispute with the employees of the Company or any of its subsidiaries exists or, to the knowledge of the Company, is imminent, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its or any subsidiary's principal suppliers, manufacturers, partners, collaborators or contractors, which, in either case, would result in a Material Adverse Effect.

(xviii) Absence of Proceedings. There is no action, suit, proceeding, inquiry or investigation before or brought by any Governmental Entity now pending or, to the knowledge of the Company, threatened, against or affecting the Company or any of its subsidiaries, which would reasonably be expected to result in a Material Adverse Effect, or which would reasonably be expected to materially and adversely affect their respective properties or assets or the consummation of the transactions contemplated in this Agreement or the performance by the Company of its obligations hereunder.

(xix) Accuracy of Exhibits. There are no contracts or documents which are required to be described in the Registration Statement, the General Disclosure Package or the Prospectus or to

be filed as exhibits to the Registration Statement which have not been so described in all material respects and filed as required.

(xx) Absence of Further Requirements. No filing with, or authorization, approval, consent, license, order, registration, qualification or decree of, any Governmental Entity is necessary or required for the performance by the Company of its obligations hereunder, in connection with the offering, issuance or sale of the Securities hereunder or the consummation of the transactions contemplated by this Agreement, except (A) such as have been already obtained or as may be required under the 1933 Act, the 1933 Act Regulations, the rules of the Nasdaq Stock Market LLC, state securities laws or the rules of FINRA and (B) such as have been obtained under the laws and regulations of jurisdictions outside the United States in which the Reserved Securities were offered.

(xxi) Possession of Licenses and Permits. The Company and its subsidiaries possess such permits, licenses, approvals, consents, exemptions and other authorizations issued by the appropriate Governmental Entities necessary to conduct the business now operated by them, except where the failure to so possess would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect (collectively, "Governmental Licenses"). The Company and its subsidiaries are in compliance with the terms and conditions of all Governmental Licenses, except where the failure to so comply would not, singly or in the aggregate, result in a Material Adverse Effect. The Company has fulfilled and performed all of its material obligations with respect to the Governmental Licenses and, to the Company's knowledge, no event has occurred which allows, or after notice or lapse of time would allow, revocation or termination thereof or results in any other material impairment of the rights of the Company as a holder of any permit, except where the failure to so fulfill or perform, or the occurrence of such event, would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect. All of the Governmental Licenses are valid and in full force and effect, except where the invalidity of such Governmental Licenses or the failure of such Governmental Licenses to be in full force and effect would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect. Neither the Company nor any of its subsidiaries has received any written notice of proceedings relating to the revocation or modification of, or non-compliance with, any Governmental Licenses which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would reasonably be expected to result in a Material Adverse Effect.

(xxii) Title to Property. The Company and its subsidiaries have good and marketable title to all real property owned by them and good title to all other properties owned by them, in each case, free and clear of all mortgages, pledges, liens, security interests, claims, restrictions or encumbrances of any kind except such as (A) are described in the Registration Statement, the General Disclosure Package and the Prospectus or (B) do not, singly or in the aggregate, materially affect the value of such property and do not interfere with the use made and proposed to be made of such property by the Company or any of its subsidiaries; and all of the leases and subleases material to the business of the Company and its subsidiaries, considered as one enterprise, and under which the Company or any of its subsidiaries holds properties described in the Registration Statement, the General Disclosure Package or the Prospectus, are in full force and effect, and neither the Company nor any such subsidiary has any notice of any material claim of any sort that has been asserted by anyone adverse to the rights of the Company or any subsidiary under any of the leases or subleases mentioned above, or affecting or questioning the rights of the Company or such subsidiary to the continued possession of the leased or subleased premises under any such lease or sublease.

(xxiii) Possession of Intellectual Property. To the knowledge of the Company, the Company and its subsidiaries own, or have obtained valid, enforceable and adequate rights and licenses under patents, patent rights, patent applications, inventions, copyrights and other works of authorship, know how (including trade secrets and other proprietary or confidential information, systems or procedures), trademarks, service marks, trade names, trade and service mark registrations, trade names, designs, processes, licenses, computer programs, technical data and information, and other intellectual property (collectively, "Intellectual Property") that are reasonably be expected to be material to carry on the business of the Company as currently conducted or as proposed to be conducted (including upon commercialization of products or services as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus as under development), or to the development, manufacture, operation and sale of any products and services sold or proposed to be sold by any of the Company or its subsidiary. There are no unreleased liens or security interests which have been filed against any of the patents owned by the Company or any of its subsidiaries. Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus: (A) there are no third parties who have rights to any Intellectual Property, including no liens, security interest, or other encumbrances, except for (i) customary reversionary rights of third-party licensors with respect to Intellectual Property that is disclosed in the Registration Statement, the General Disclosure Package and the Prospectus as licensed to the Company or one or more of its subsidiaries or (ii) rights or Intellectual Property that are not material to the Company; (B) the Company has taken all reasonable steps necessary to secure its interests in the Intellectual Property from its employees and contractors; (C) to the knowledge of the Company, there is no infringement, misappropriation or violation by third parties of any Intellectual Property owned by, or licensed to, the Company or its subsidiaries; and (D) none of the Company Intellectual Property has been adjudged invalid or unenforceable in whole or in part. There is no pending or threatened action, suit, proceeding or claim by others: (1) challenging the Company's rights in or to any Intellectual Property owned by, or licensed to, the Company or its subsidiaries, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; (2) challenging the validity, enforceability or scope of any Intellectual Property owned by, or licensed to, the Company or its subsidiaries, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; or (3) asserting that the Company or any of its subsidiaries infringes or otherwise violates, or would, upon the commercialization of any product or service described in the Registration Statement, the General Disclosure Package or the Prospectus as under development, infringe or violate, any patent, trademark, trade name, service name, copyright, trade secret or other proprietary rights of others, and the Company and its subsidiaries are unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim. To the knowledge of the Company, no employee of the Company is or has been in violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee's employment with the Company. The Company and its subsidiaries have complied with the terms of each agreement pursuant to which Intellectual Property has been licensed to the Company or any subsidiary, and all such agreements are in full force and effect. To the knowledge of the Company, there is no prior art that may render any patent within the Intellectual Property invalid or that may render any patent application within the Intellectual Property unpatentable that has not been disclosed to the U.S. Patent and Trademark Office. To the knowledge of the Company, there are no material defects in any of the patents or patent applications within the Intellectual Property. The patents included in the Intellectual Property are subsisting and have not lapsed and the patent



applications in the Intellectual Property are subsisting and have not been abandoned. No technology employed by the Company or its subsidiaries has been obtained or is being used by the Company or its subsidiaries in violation of any contractual or legal obligation binding on the Company, its subsidiaries, or any of their officers, directors, employees, or contractors, or, to the knowledge of the Company, in violation of any contractual rights of any persons. The drug candidates described in the Registration Statement, the General Disclosure Package and the Prospectus as under development by the Company or any subsidiary fall within the scope of the claims of one or more patents or applications relating to the drug candidate or its intended use owned by, or exclusively licensed to, the Company or any subsidiary. To the knowledge of the Company, there is no patent or published patent application, in the U.S. or other jurisdiction, which, in the case of a patent, contains claims, or in the case of a published patent application contains patentable claims, that dominate or may dominate any of the Company's Intellectual Property described in the Preliminary Prospectus and Prospectus as being owned by or licensed to the Company or that interferes with the issued or pending claims of any of the Company's Intellectual Property.

(xxiv) Clinical Data and Regulatory Compliance. The preclinical tests and clinical trials, and other studies conducted by or on behalf of or sponsored by the Company or its subsidiaries, or in which the Company or its subsidiaries or the Company's or its subsidiaries' product candidates participated and that are described in, or the results of which are (collectively, "studies") referred to in, the Registration Statement, the General Disclosure Package or the Prospectus were and, if still pending, are being conducted in all material respects in accordance with all applicable laws, including, without limitation, the Federal Food, Drug, and Cosmetic Act and its implementing regulations at 21 C.F.R. Parts 50, 54, 56, 58, and 312; each description of the results of such studies is accurate and complete in all material respects and fairly presents the data derived from such studies, and the Company and its subsidiaries have no knowledge of any other studies that call into question the results described or referred to in the Registration Statement, the General Disclosure Package or the Prospectus; the Company and its subsidiaries have made all such filings and obtained all such Governmental Licenses as may be required by the United States Food and Drug Administration of the U.S. Department of Health and Human Services or any committee thereof or from any other U.S. or foreign government or drug or medical device regulatory agency, or health care facility Institutional Review Board (collectively, the "Regulatory Agencies") to conduct such studies; and neither the Company nor any of its subsidiaries has received any notice of, or correspondence from, any Regulatory Agency requiring the termination, suspension or material adverse modification of any clinical trials that are described or referred to in the Registration Statement, the General Disclosure Package or the Prospectus.

(xxv) Compliance with Healthcare Laws. Except as described in the Registration Statement, the General Disclosure Package and the Prospectus, or except as would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect, the Company: (i) has operated and currently operates its business in compliance with applicable provisions of the health care laws, including Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh (the Medicare statute); Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (the Medicaid statute); the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); the civil False Claims Act, 31 U.S.C. §§ 3729 et seq.; the criminal False Claims Act 42 U.S.C. § 1320a-7b(a); the criminal laws relating to health care fraud and abuse, including 18 U.S.C. Sections 286 and 287 and the health care fraud criminal provisions under the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. §§ 1320d et seq., ("HIPAA"); the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Criminal False Claims Law 42 U.S.C. § 1320a-7b(a); the Physician Payments Sunshine Act, 42 U.S.C. § 1320a-7h; the exclusion law, 42 U.S.C. § 1320a-7; HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, 42 U.S.C. §§ 17921 et seq.; the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq.; the regulations promulgated pursuant to such laws; and

any similar federal, state and local laws and regulations of any governmental authority including the Regulatory Agencies applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, storage, import, export or disposal of any of the Company's product candidates, (collectively the "Health Care Laws"); (ii) along with its employees, officers and directors, and to the Company's knowledge, independent contractors and agents, is not a party to or has any ongoing reporting obligations pursuant to any corporate integrity agreements, deferred prosecution agreements, monitoring agreements, consent decrees, settlement orders, plans of correction or similar agreements with or imposed by any governmental authority including any Regulatory Agencies; and (iii) along with its employees, officers and directors, and to the Company's knowledge, independent contractors and agents, has not been excluded, suspended or debarred from, or otherwise ineligible for participation in any government health care program or human clinical research.

(xxvi) Environmental Laws. (A) Neither the Company nor any of its subsidiaries is in violation of any federal, state, local or foreign statute, law, rule, regulation, ordinance, code, policy or rule of common law or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent, decree or judgment, relating to pollution or protection of human health, the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) or wildlife, including, without limitation, laws and regulations relating to the release or threatened release of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum or petroleum products, asbestos-containing materials or mold (collectively, "Hazardous Materials") or to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials (collectively, "Environmental Laws"), (B) the Company and its subsidiaries have all permits, authorizations and approvals required under any applicable Environmental Laws and are each in compliance with their requirements, (C) there are no pending or, to the knowledge of the Company, threatened administrative, regulatory or judicial actions, suits, demands, demand letters, claims, liens, notices of noncompliance or violation, investigations or proceedings relating to any Environmental Law against the Company or any of its subsidiaries and (D) to the knowledge of the Company, there are no events or circumstances that would reasonably be expected to form the basis of an order for clean-up or remediation, or an action, suit or proceeding by any private party or Governmental Entity, against or affecting the Company or any of its subsidiaries relating to Hazardous Materials or any Environmental Laws.

(xxvii) Accounting Controls. The Company and each of its subsidiaries maintain effective internal control over financial reporting (as defined under Rule 13-a15 and 15d-15 under the rules and regulations of the Commission under the Securities Exchange Act of 1934, as amended (the "1934 Act") (such rules and regulations, the "1934 Act Regulations") and a system of internal accounting controls sufficient to provide reasonable assurances that (A) transactions are executed in accordance with management's general or specific authorization; (B) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain accountability for assets; (C) access to assets is permitted only in accordance with management's general or specific authorization; and (D) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Since the end of the Company's most recent audited fiscal year, there has been (1) no material weakness in the Company's internal control over financial reporting (whether or not remediated) and (2) no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

(xxviii) Compliance with the Sarbanes-Oxley Act. The Company has taken all necessary actions to ensure that, upon the effectiveness of the Registration Statement, it will be in compliance

with all provisions of the Sarbanes-Oxley Act of 2002 and all rules and regulations promulgated thereunder or implementing the provisions thereof (the “Sarbanes-Oxley Act”) that are then in effect and with which the Company is required to comply as of the effectiveness of the Registration Statement, and is, or will be, actively taking steps to ensure that it will be in compliance with other provisions of the Sarbanes-Oxley Act not currently in effect, upon the effectiveness of such provisions, or which will become applicable to the Company at all times after the effectiveness of the Registration Statement.

(xxix) Payment of Taxes. All United States federal income tax returns of the Company and its subsidiaries required by law to be filed have been timely filed and all taxes shown by such returns, which are due and payable, have been paid, except for such taxes, if any, as are being contested in good faith by appropriate proceedings diligently conducted and as to which adequate reserves have been provided in accordance with GAAP. The Company and its subsidiaries have timely filed all other tax returns that are required to have been filed by them pursuant to applicable foreign, state, local or other law, except insofar as the failure to file such returns would not singly or in the aggregate, result in a Material Adverse Effect. The Company and its subsidiaries have paid all taxes due and payable pursuant to such returns or pursuant to any assessment received by the Company and its subsidiaries, except for such taxes, if any, as are being contested in good faith by appropriate proceedings diligently conducted and as to which adequate reserves have been established by the Company in accordance with GAAP or the non-payment of which would not, singly or in the aggregate, result in a Material Adverse Effect. No tax deficiency has been determined adversely to the Company (nor does the Company have any notice or knowledge of any tax deficiency which could reasonably be expected to be determined adversely to the Company), except for such tax deficiencies that would not, singly or in the aggregate, result in a Material Adverse Effect. The charges, accruals and reserves on the books of the Company in respect of any tax liability for any years not finally determined are adequate to meet any assessments or re-assessments for additional tax for any years not finally determined.

(xxx) Insurance. The Company and its subsidiaries carry or are entitled to the benefits of insurance, with financially sound and reputable insurers, in such amounts and covering such risks as is generally maintained by companies of established repute engaged in the same or similar business, and all such insurance is in full force and effect. The Company has no reason to believe that it or any of its subsidiaries will not be able (A) to renew its existing insurance coverage as and when such policies expire or (B) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not result in a Material Adverse Effect. Neither of the Company nor any of its subsidiaries has been denied any insurance coverage which it has sought or for which it has applied.

(xxxi) Investment Company Act. The Company is not required, and upon the issuance and sale of the Securities as herein contemplated and the application of the net proceeds therefrom as described in the Registration Statement, the General Disclosure Package and the Prospectus will not be required, to register as an “investment company” under the Investment Company Act of 1940, as amended (the “1940 Act”).

(xxxii) Absence of Manipulation. Neither the Company nor any affiliate of the Company has taken, nor will the Company or any affiliate take, directly or indirectly, any action which is designed, or would reasonably be expected, to cause or result in, or which constitutes, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities or to result in a violation of Regulation M under the 1934 Act.

(xxxiii) Foreign Corrupt Practices Act. None of the Company, any of its subsidiaries or, to the knowledge of the Company, any director, officer, agent, employee, affiliate or other person acting on behalf of the Company or any of its subsidiaries is aware of or has taken any action, directly or indirectly, that would result in a violation by such persons of the Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (the “FCPA”), or any other applicable anti-bribery or anti-corruption laws (the “Anti-Corruption Laws”) including, without limitation, making use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay or authorization of the payment of any money, or other property, gift, promise to give, or authorization of the giving of anything of value to any “foreign official” (as such term is defined in the FCPA) or any foreign political party or official thereof or any candidate for foreign political office, in contravention of the Anti-Corruption Laws and the Company and, to the knowledge of the Company, its affiliates have conducted their businesses in compliance with the Anti-Corruption Laws and have instituted and maintain policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith.

(xxxiv) Money Laundering Laws. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance in all material respects with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any Governmental Entity (collectively, the “Money Laundering Laws”); and no action, suit or proceeding by or before any Governmental Entity involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(xxxv) OFAC. None of the Company, any of its subsidiaries or, to the knowledge of the Company, any director, officer, agent, employee, affiliate or representative of the Company or any of its subsidiaries is an individual or entity (“Person”), or is more than 50 percent owned in the aggregate by or acting on behalf of one or more Persons that are, currently the subject or target of any sanctions administered or enforced by the United States Government, including, without limitation, the U.S. Department of the Treasury’s Office of Foreign Assets Control (“OFAC”), the United Nations Security Council (“UNSC”), the European Union, Her Majesty’s Treasury (“HMT”), or other relevant sanctions authority (collectively, “Sanctions”), nor is the Company located, organized or resident in a country or territory that is the subject of Sanctions; and the Company will not directly or indirectly use the proceeds of the sale of the Securities, or lend, contribute or otherwise make available such proceeds to any subsidiaries, joint venture partners or other Person, to fund any activities of or business (i) with any Person, or in any country or territory, that, at the time of such funding, is a designated target of Sanctions, (ii) in or involving a country or territory which at the time of such funding is the subject of comprehensive country-wide or territory-wide Sanctions, or (iii) in any other manner that will result in a violation by any Person (including any Person participating in the transaction, whether as underwriter, advisor, investor or otherwise) of Sanctions.

The Company represents and covenants that, regardless of Sanctions, it will not, directly or indirectly, use the proceeds of the transaction, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other Person, to fund any activities of or business in or involving Cuba or Iran.

(xxxvi) Sales of Reserved Securities. In connection with any offer and sale of Reserved Securities outside the United States, each preliminary prospectus, the Prospectus and any

amendment or supplement thereto, at the time it was delivered, complied and will comply in all material respects with any applicable laws or regulations of foreign jurisdictions in which the same is distributed. The Company has not offered, or caused the Representatives to offer, Reserved Securities to any person with the specific intent to unlawfully influence (i) a customer or supplier of the Company or any of its affiliates to alter the customer's or supplier's level or type of business with any such entity or (ii) a trade journalist or publication to write or publish favorable information about the Company or any of its affiliates, or their respective businesses or products.

(xxxvii) Lending Relationship. The Company (i) does not have any material lending or other relationship with any bank or lending affiliate of any Underwriter and (ii) does not intend to use any of the proceeds from the sale of the Securities to repay any outstanding debt owed to any affiliate of any Underwriter.

(xxxviii) Statistical and Market-Related Data. Any statistical and market-related data included in the Registration Statement, the General Disclosure Package or the Prospectus are based on or derived from sources that the Company believes, after reasonable inquiry, to be reliable and accurate and, to the extent required, the Company has obtained the written consent to the use of such data from such sources.

(xxxix) No Rated Debt. No securities issued or guaranteed by, or loans to, the Company are rated by any "nationally recognized statistical rating organization" (as defined by the Commission in Section 3(a)(62) of the 1934 Act).

(xl) Data Privacy and Security Laws. The Company and its subsidiaries are, and at all prior times were, in material compliance with all applicable data privacy and security laws and regulations, including without limitation HIPAA and the HITECH Act, and the Company and its subsidiaries have taken commercially reasonable actions to prepare to comply with the European Union General Data Protection Regulation ("GDPR") (EU 2016/679) and all other applicable laws and regulations with respect to Personal Data (defined below) that have been announced as of the date hereof as becoming effective within 12 months after the date hereof, and for which any non-compliance with same would be reasonably likely to create a material liability (collectively, the "Privacy Laws"). To the Company's knowledge, since May 25, 2018, the Company and its subsidiaries have been and currently are in material compliance with the GDPR. To ensure material compliance with the Privacy Laws, the Company and its subsidiaries have taken, and currently take, commercially reasonable steps reasonably designed to ensure compliance in all material respects with Privacy Laws relating to data privacy and security and the collection, storage, use, disclosure, handling, and analysis of Personal Data that the Company has collected, and collects, or is in the Company's possession. "Personal Data" means (i) a natural person's name, street address, telephone number, e-mail address, photograph, social security number or tax identification number, driver's license number, passport number, credit card number, bank information, or customer or account number; (ii) any information which would qualify as "personally identifying information" under the Federal Trade Commission Act, as amended; (iii) Protected Health Information as defined by HIPAA; (iv) "personal data" as defined by GDPR, and (v) any other piece of information that allows the identification of such natural person, or his or her family, or permits the collection or analysis of any data related to an identified person's health or sexual orientation. The Company and its subsidiaries since inception have at all times made all disclosures to users or customers required by applicable Privacy Laws, except where the failure to do so would not, individually or in the aggregate, have a Material Adverse Effect. None of such disclosures made have been inaccurate, misleading, deceptive or in violation of any Privacy Laws in any material respect. The execution, delivery and performance of this Agreement or any other agreement referred to in this Agreement will not result in a breach of violation of any Privacy Laws. The Company further certifies that neither it nor any subsidiary: (i) has received notice of any actual or potential liability under or relating to, or actual or potential violation of, any of the Privacy Laws, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice; (ii) is currently conducting or paying for, in whole or in part, any investigation, remediation, or other corrective action pursuant to any Privacy Law; or (iii) is a party to any order, decree, or agreement that imposes any obligation or liability under any Privacy Law, except, in the case of (i), (ii), or (iii), where such violation, investigation, remediation, order, decree or agreement would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(xli) Cybersecurity; Data Protection. (A) There has been no security breach or incident, unauthorized access or disclosure, or other compromise of or relating to the Company or its subsidiaries information technology and computer systems, networks, hardware, software, data and databases (including the data and information of their respective customers, employees, suppliers, vendors and any third party data maintained, processed or stored by the Company and its subsidiaries, and any such data processed or stored by third parties on behalf of the Company and its subsidiaries), equipment or technology (collectively, "IT Systems and Data"); (B) neither the Company nor its subsidiaries have been notified of, and have no knowledge of any event or condition that would result in, any security breach or incident, unauthorized access or disclosure or other compromise to their IT Systems and Data and (C) the Company and its subsidiaries have

implemented appropriate controls, policies, procedures, and technological safeguards to maintain and protect the integrity, continuous operation, redundancy and security of their IT Systems and Data reasonably consistent with industry standards and practices, or as required by applicable regulatory standards. The Company and its subsidiaries are presently in material compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Data and to the protection of such IT Systems and Data from unauthorized use, access, misappropriation or modification.

(b) *Officer's Certificates.* Any certificate signed by any officer of the Company or any of its subsidiaries delivered to the Representatives or to counsel for the Underwriters shall be deemed a representation and warranty by the Company to each Underwriter as to the matters covered thereby.

## SECTION 2. Sale and Delivery to Underwriters; Closing.

(a) *Initial Securities.* On the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, the Company agrees to sell to each Underwriter, severally and not jointly, and each Underwriter, severally and not jointly, agrees to purchase from the Company, at the price per share set forth in Schedule A, that number of Initial Securities set forth in Schedule A opposite the name of such Underwriter, plus any additional number of Initial Securities which such Underwriter may become obligated to purchase pursuant to the provisions of Section 10 hereof, subject, in each case, to such adjustments among the Underwriters as the Representatives in their sole discretion shall make to eliminate any sales or purchases of fractional shares.

(b) *Option Securities.* In addition, on the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, the Company hereby grants an option to the Underwriters, severally and not jointly, to purchase up to an additional [●] shares of Common Stock, at the price per share set forth in Schedule A, less an amount per share equal to any dividends or distributions declared by the Company and payable on the Initial Securities but not payable on the Option Securities. The option hereby granted may be exercised for 30 days after the date hereof and may be exercised in whole or in part at any time from time to time upon notice by the Representatives to the Company setting forth the number of Option Securities as to which the several Underwriters are then exercising the option and the time and date of payment and delivery for such Option Securities. Any such time and date of delivery (a "Date of Delivery") shall be determined by the Representatives, but shall not be later than seven full business days after the exercise of said option, nor in any event prior to the Closing Time. If the option is exercised as to all or any portion of the Option Securities, each of the Underwriters, acting severally and not jointly, will purchase that proportion of the total number of Option Securities then being purchased which the number of Initial Securities set forth in Schedule A opposite the name of such Underwriter bears to the total number of Initial Securities, subject, in each case, to such adjustments as the Representatives in their sole discretion shall make to eliminate any sales or purchases of fractional shares.

(c) *Payment.* Payment of the purchase price for, and delivery of certificates or security entitlements for, the Initial Securities shall be made at the offices of Cooley LLP, 4401 Eastgate Mall, San Diego, CA 92121, or at such other place as shall be agreed upon by the Representatives and the Company, at 9:00 A.M. (New York City time) on the second (third, if the pricing occurs after 4:30 P.M. (New York City time) on any given day) business day after the date hereof (unless postponed in accordance with the provisions of Section 10), or such other time not later than ten business days after such date as shall be agreed upon by the Representatives and the Company (such time and date of payment and delivery being herein called "Closing Time").

In addition, in the event that any or all of the Option Securities are purchased by the Underwriters, payment of the purchase price for, and delivery of certificates or security entitlements for, such Option Securities shall be made at the above-mentioned offices, or at such other place as shall be agreed upon by the Representatives and the Company, on each Date of Delivery as specified in the notice from the Representatives to the Company.

Payment shall be made to the Company by wire transfer of immediately available funds to a bank account designated by the Company against delivery to the Representatives for the respective accounts of the Underwriters of certificates or security entitlements for the Securities to be purchased by them. It is understood that each Underwriter has authorized the Representatives, for its account, to accept delivery of, receipt for, and make payment of the purchase price for, the Initial Securities and the Option Securities, if any, which it has agreed to purchase. Each of the Representatives, individually and not as representative of the Underwriters, may (but shall not be obligated to) make payment of the purchase price for the Initial Securities or the Option Securities, if any, to be purchased by any Underwriter whose funds have not been received by the Closing Time or the relevant Date of Delivery, as the case may be, but such payment shall not relieve such Underwriter from its obligations hereunder.

SECTION 3. Covenants of the Company. The Company covenants with each Underwriter as follows:

(a) *Compliance with Securities Regulations and Commission Requests*. The Company, subject to Section 3(b), will comply with the requirements of Rule 430A, and will notify the Representatives immediately, and confirm the notice in writing, (i) when any post-effective amendment to the Registration Statement shall become effective or any amendment or supplement to the Prospectus shall have been filed, (ii) of the receipt of any comments from the Commission, (iii) of any request by the Commission for any amendment to the Registration Statement or any amendment or supplement to the Prospectus or for additional information, (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment or of any order preventing or suspending the use of any preliminary prospectus or the Prospectus, or of the suspension of the qualification of the Securities for offering or sale in any jurisdiction, or of the initiation or threatening of any proceedings for any of such purposes or of any examination pursuant to Section 8(d) or 8(e) of the 1933 Act concerning the Registration Statement and (v) if the Company becomes the subject of a proceeding under Section 8A of the 1933 Act in connection with the offering of the Securities. The Company will effect all filings required under Rule 424(b), in the manner and within the time period required by Rule 424(b) (without reliance on Rule 424(b)(8)), and will take such steps as it deems necessary to ascertain promptly whether the form of prospectus transmitted for filing under Rule 424(b) was received for filing by the Commission and, in the event that it was not, it will promptly file such prospectus. The Company will make every reasonable effort to prevent the issuance of any stop order, prevention or suspension and, if any such order is issued, to obtain the lifting thereof as soon as practicable.

(b) *Continued Compliance with Securities Laws*. The Company will comply with the 1933 Act and the 1933 Act Regulations so as to permit the completion of the distribution of the Securities as contemplated in this Agreement and in the Registration Statement, the General Disclosure Package and the Prospectus. If at any time when a prospectus relating to the Securities is (or, but for the exception afforded by Rule 172 of the 1933 Act Regulations (“Rule 172”), would be) required by the 1933 Act to be delivered in connection with sales of the Securities, any event shall occur or condition shall exist as a result of which it is necessary, in the opinion of counsel for the Underwriters or for the Company, to (i) amend the Registration Statement in order that the Registration Statement will not include an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, (ii) amend or supplement the General Disclosure Package or the Prospectus in order that the General Disclosure Package or the Prospectus, as the case may be, will not include any untrue

statement of a material fact or omit to state a material fact necessary in order to make the statements therein not misleading in the light of the circumstances existing at the time it is delivered to a purchaser or (iii) amend the Registration Statement or amend or supplement the General Disclosure Package or the Prospectus, as the case may be, in order to comply with the requirements of the 1933 Act or the 1933 Act Regulations, the Company will promptly (A) give the Representatives notice of such event, (B) prepare any amendment or supplement as may be necessary to correct such statement or omission or to make the Registration Statement, the General Disclosure Package or the Prospectus comply with such requirements and, a reasonable amount of time prior to any proposed filing or use, furnish the Representatives with copies of any such amendment or supplement and (C) file with the Commission any such amendment or supplement; provided that the Company shall not file or use any such amendment or supplement to which the Representatives or counsel for the Underwriters shall reasonably object. The Company will furnish to the Underwriters such number of copies of such amendment or supplement as the Underwriters may reasonably request. The Company has given the Representatives notice of any filings made pursuant to the 1934 Act or 1934 Act Regulations within 48 hours prior to the Applicable Time; the Company will give the Representatives notice of its intention to make any filing pursuant to the 1934 Act or 1934 Act Regulations from the Applicable Time to the Closing Time and will furnish the Representatives with copies of any such documents a reasonable amount of time prior to such proposed filing, as the case may be, and will not file or use any such document to which the Representatives or counsel for the Underwriters shall reasonably object.

(c) *Delivery of Registration Statements.* The Company has furnished or will deliver to the Representatives and counsel for the Underwriters, if requested, without charge, signed copies of the Registration Statement as originally filed and each amendment thereto (including exhibits filed therewith) and signed copies of all consents and certificates of experts, and will also deliver to the Representatives, if requested, without charge, a conformed copy of the Registration Statement as originally filed and each amendment thereto (without exhibits) for each of the Underwriters. The copies of the Registration Statement and each amendment thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(d) *Delivery of Prospectuses.* The Company has delivered to each Underwriter, without charge, as many copies of each preliminary prospectus as such Underwriter reasonably requested, and the Company hereby consents to the use of such copies for purposes permitted by the 1933 Act. The Company will furnish to each Underwriter, without charge, during the period when a prospectus relating to the Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the 1933 Act, such number of copies of the Prospectus (as amended or supplemented) as such Underwriter may reasonably request. The Prospectus and any amendments or supplements thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(e) *Blue Sky Qualifications.* The Company will use its reasonable best efforts, in cooperation with the Underwriters, to qualify the Securities for offering and sale under the applicable securities laws of such states and other jurisdictions (domestic or foreign) as the Representatives may designate and to maintain such qualifications in effect so long as required to complete the distribution of the Securities; provided, however, that the Company shall not be obligated to file any general consent to service of process or to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise so subject.

(f) *Rule 158.* The Company will timely file such reports pursuant to the 1934 Act as are necessary in order to make generally available to its securityholders as soon as practicable an earnings



statement for the purposes of, and to provide to the Underwriters the benefits contemplated by, the last paragraph of Section 11(a) of the 1933 Act.

(g) *Use of Proceeds.* The Company will use the net proceeds received by it from the sale of the Securities in the manner specified in the Registration Statement, the General Disclosure Package and the Prospectus under “Use of Proceeds.”

(h) *Listing.* The Company will use its reasonable best efforts to effect and maintain the listing of the Common Stock (including the Securities) on the Nasdaq Global Select Market.

(i) *Restriction on Sale of Securities.* During a period of 180 days from the date of the Prospectus, the Company will not, without the prior written consent of Merrill Lynch, Leerink and Barclays, (i) directly or indirectly, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock or file or confidentially submit any registration statement under the 1933 Act with respect to any of the foregoing or (ii) enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the Common Stock, whether any such swap or transaction described in clause (i) or (ii) above is to be settled by delivery of Common Stock or other securities, in cash or otherwise. The foregoing sentence shall not apply to (A) the Securities to be sold hereunder, (B) any shares of Common Stock issued by the Company upon the exercise of an option or warrant or the conversion of a security outstanding on the date hereof and referred to in the Registration Statement, the General Disclosure Package and the Prospectus, (C) any shares of Common Stock issued or options to purchase Common Stock or other stock awards granted pursuant to existing employee benefit or equity incentive plans of the Company referred to in the Registration Statement, the General Disclosure Package and the Prospectus, (D) shares of Common Stock or any securities convertible into, or exercisable for, or exchangeable for, shares of Common Stock issued (1) to lenders or financial institutions in connection with *bona fide* debt or credit arrangements or (2) in connection with any merger, joint venture, strategic alliances, commercial or other collaborative transaction or the acquisition or license of the business, property, technology or other assets of another individual or entity or the assumption of an employee benefit plan in connection with a merger or acquisition; *provided*, however, that the aggregate number of shares of Common Stock, or any securities convertible into or exercisable or exchangeable for Common Stock, that the Company may issue or agree to issue pursuant to this clause (D) shall not exceed 5% of the total outstanding shares of Common Stock immediately following the issuance of the Securities pursuant to this Agreement, (E) the filing by the Company of a registration statement on Form S-8 covering the registration of securities issuable, outstanding, exercisable, convertible or available for issuance under any employee benefit or equity incentive plans of the Company described in the Registration Statement, the General Disclosure Package and the Prospectus, or (F) any shares of Common Stock issued pursuant to any non-employee director stock plan or dividend reinvestment plan referred to in the Registration Statement, the General Disclosure Package and the Prospectus; *provided*, that the recipient of any such shares of Common Stock or securities issued pursuant to clauses (B), (C), (D) or (F) during the 180-day restricted period described above shall enter into an agreement substantially in the form of Exhibit A hereto.

(j) *Press Releases.* If Merrill Lynch, Leerink and Barclays, in their sole discretion, agree to release or waive the restrictions set forth in a lock-up agreement described in Section 5(j) hereof for an officer or director of the Company and provide the Company with notice of the impending release or waiver at least three business days before the effective date of the release or waiver, the Company agrees to announce the impending release or waiver by a press release substantially in the form of Exhibit B hereto through a major news service at least two business days before the effective date of the release or waiver.

(k) *Reporting Requirements.* The Company, during the period when a Prospectus relating to the Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the 1933 Act, will file all documents required to be filed with the Commission pursuant to the 1934 Act within the time periods required by the 1934 Act and 1934 Act Regulations. Additionally, the Company shall report the use of proceeds from the issuance of the Securities as may be required under Rule 463 under the 1933 Act.

(l) *Issuer Free Writing Prospectuses.* The Company agrees that, unless it obtains the prior written consent of the Representatives, it will not make any offer relating to the Securities that would constitute an Issuer Free Writing Prospectus or that would otherwise constitute a “free writing prospectus,” or a portion thereof, required to be filed by the Company with the Commission or retained by the Company under Rule 433; provided that the Representatives will be deemed to have consented to the Issuer Free Writing Prospectuses listed on Schedule B-2 hereto and any “road show that is a written communication” within the meaning of Rule 433(d)(8)(i) that has been reviewed by the Representatives. The Company represents that it has treated or agrees that it will treat each such free writing prospectus consented to, or deemed consented to, by the Representatives as an “issuer free writing prospectus,” as defined in Rule 433, and that it has complied and will comply with the applicable requirements of Rule 433 with respect thereto, including timely filing with the Commission where required, legending and record keeping. If at any time following issuance of an Issuer Free Writing Prospectus there occurred or occurs an event or development as a result of which such Issuer Free Writing Prospectus conflicted or would conflict with the information contained in the Registration Statement, any preliminary prospectus or the Prospectus or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representatives and will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission; provided, however, that the Company shall not be required to notify the Representatives of any statements or omissions in an Issuer Free Writing Prospectus prepared or authorized by the Company made in reliance upon and in conformity with the Underwriter Information.

(m) *Certification Regarding Beneficial Owners.* The Company will deliver to the Representative(s), on the date of execution of this Agreement, a properly completed and executed Certification Regarding Beneficial Owners of Legal Entity Customers, together with copies of identifying documentation, and the Company undertakes to provide such additional supporting documentation as the Representative(s) may reasonably request in connection with the verification of the foregoing certification.

(n) *Compliance with FINRA Rules.* The Company hereby agrees that it will ensure that the Reserved Securities will be restricted as required by FINRA or the FINRA rules from sale, transfer, assignment, pledge or hypothecation for a period of three months following the date of this Agreement. The Underwriters will notify the Company as to which persons will need to be so restricted. At the request of the Underwriters, the Company will direct the transfer agent to place a stop transfer restriction upon such securities for such period of time. Should the Company release, or seek to release, from such restrictions any of the Reserved Securities, the Company agrees to reimburse the Underwriters for any reasonable expenses (including, without limitation, legal expenses) they incur in connection with such release.

(o) *Testing-the-Waters Materials.* If at any time following the distribution of any Written Testing-the-Waters Communication there occurred or occurs an event or development as a result of which such Written Testing-the-Waters Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representatives and will promptly amend or supplement, at its own expense, such Written Testing-the-Waters Communication to eliminate or correct such untrue statement or omission.

(p) *Emerging Growth Company Status.* The Company will promptly notify the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (i) completion of the distribution of the Securities within the meaning of the Securities Act and (ii) completion of the 180-day restricted period referred to in Section 3(i).

#### SECTION 4. Payment of Expenses.

(a) *Expenses.* The Company will pay or cause to be paid all expenses incident to the performance of its obligations under this Agreement, including (i) the preparation, printing and filing of the Registration Statement (including financial statements and exhibits) as originally filed and each amendment thereto, (ii) the preparation, printing and delivery to the Underwriters of copies of each preliminary prospectus, each Issuer Free Writing Prospectus and the Prospectus and any amendments or supplements thereto and any reasonable costs associated with electronic delivery of any of the foregoing by the Underwriters to investors, (iii) the preparation, issuance and delivery of the certificates or security entitlements for the Securities to the Underwriters, including any stock or other transfer taxes and any stamp or other duties payable upon the sale, issuance or delivery of the Securities to the Underwriters, (iv) the fees and disbursements of the Company's counsel, accountants and other advisors, (v) the qualification of the Securities under securities laws in accordance with the provisions of Section 3(e) hereof, including filing fees and the reasonable fees and disbursements of counsel for the Underwriters in connection therewith and in connection with the preparation of the Blue Sky Survey and any supplement thereto, (vi) the fees and expenses of any transfer agent or registrar for the Securities, (vii) the costs and expenses of the Company relating to investor presentations on any "road show" undertaken in connection with the marketing of the Securities, including without limitation, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations, travel and lodging expenses of the representatives and officers of the Company and any such consultants, and 50% of the cost of aircraft and other transportation chartered to be used in connection with the road show by both the Company and the Underwriters; provided, however, that the Underwriters and the Company agree that the Underwriters shall pay or cause to be paid the travel and lodging expenses of the Underwriters, (viii) the filing fees incident to, and the reasonable fees and disbursements of counsel to the Underwriters in connection with, the review by FINRA of the terms of the sale of the Securities; provided, however, that the reasonable fees and disbursements of counsel for the Underwriters relating to clauses (v) and (viii) shall not exceed \$35,000 in the aggregate, (ix) the fees and expenses incurred in connection with the listing of the Securities on the Nasdaq Global Select Market and (x) the costs and expenses (including, without limitation, any damages or other amounts payable in connection with legal or contractual liability) associated with the reforming of any contracts for sale of the Securities made by the Underwriters caused by a breach of the representation contained in the third sentence of Section 1(a)(ii) and (xi) all reasonable costs and expenses of the Underwriters, including the reasonable fees and disbursements of counsel for the Underwriters, in connection with matters related to the Reserved Securities which are designated by the Company for sale to Invitees.

(b) *Termination of Agreement.* If this Agreement is terminated by the Representatives in accordance with the provisions of Section 5, Section 9(a)(i) or (iii) or Section 10 hereof, the Company shall reimburse the non-defaulting Underwriters for all of their reasonable out-of-pocket expenses that were actually incurred, including the reasonable fees and disbursements of counsel for the Underwriters. For the avoidance of doubt, in the case of termination by the Underwriters in accordance with the provisions of Section 10 hereof, the Company shall have no obligation to reimburse any defaulting Underwriter pursuant to this Section 4(b).

SECTION 5. Conditions of Underwriters' Obligations. The obligations of the several Underwriters hereunder are subject to the accuracy of the representations and warranties of the Company contained herein or in certificates of any officer of the Company or any of its subsidiaries delivered pursuant

to the provisions hereof, to the performance by the Company of its covenants and other obligations hereunder, and to the following further conditions:

(a) *Effectiveness of Registration Statement; Rule 430A Information.* The Registration Statement, including any Rule 462(b) Registration Statement, has become effective and, at the Closing Time, no stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto has been issued under the 1933 Act, no order preventing or suspending the use of any preliminary prospectus or the Prospectus has been issued and no proceedings for any of those purposes have been instituted or are pending or, to the Company's knowledge, threatened by the Commission; and the Company has complied with each request (if any) from the Commission for additional information. A prospectus containing the Rule 430A Information shall have been filed with the Commission in the manner and within the time frame required by Rule 424(b) without reliance on Rule 424(b)(8) or a post-effective amendment providing such information shall have been filed with, and declared effective by, the Commission in accordance with the requirements of Rule 430A.

(b) *Opinion and Negative Assurance Letter of Counsel for Company.* At the Closing Time, the Representatives shall have received the favorable opinion and negative assurance letter, dated the Closing Time, of Latham & Watkins LLP, counsel for the Company, in the form and substance satisfactory to counsel for the Underwriters previously agreed upon by the Representatives and such counsel, together with signed or reproduced copies of such letter for each of the other Underwriters if requested.

(c) *Opinion of Intellectual Property Counsel for Company.* At the Closing Time, the Representatives shall have received the favorable opinion, dated the Closing Time, of Seed IP Law Group LLP, counsel for the Company with respect to intellectual property matters, in the form and substance satisfactory to counsel for the Underwriters previously agreed upon by the Representatives and such counsel, together with signed or reproduced copies of such letter for each of the other Underwriters if requested.

(d) *Opinion and Negative Assurance Letter of Counsel for Underwriters.* At the Closing Time, the Representatives shall have received the opinion and negative assurance letter, dated the Closing Time, of Cooley LLP, counsel for the Underwriters, in the form and substance reasonably satisfactory to the Representatives, together with signed or reproduced copies of such letter for each of the other Underwriters if requested.

(e) *Officers' Certificate.* At the Closing Time, there shall not have been, since the date hereof or since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package or the Prospectus, any material adverse change in the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company and its subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business, and the Representatives shall have received a certificate of the Chief Executive Officer or the President of the Company and of the chief financial or chief accounting officer of the Company, dated the Closing Time, to the effect that (i) there has been no such material adverse change, (ii) the representations and warranties of the Company in this Agreement are true and correct with the same force and effect as though expressly made at and as of the Closing Time, (iii) the Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied at or prior to the Closing Time, and (iv) no stop order suspending the effectiveness of the Registration Statement under the 1933 Act has been issued, no order preventing or suspending the use of any preliminary prospectus or the Prospectus has been issued and no proceedings for any of those purposes have been instituted or are pending or, to their knowledge, threatened by the Commission.

(f) *Accountant's Comfort Letter.* At the time of the execution of this Agreement, the Representatives shall have received from Ernst & Young LLP a letter, dated such date, in form and substance satisfactory to the Representatives, together with signed or reproduced copies of such letter for each of the other Underwriters containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement, the General Disclosure Package and the Prospectus.

(g) *Bring-down Comfort Letter.* At the Closing Time, the Representatives shall have received from Ernst & Young LLP a letter, dated as of the Closing Time, to the effect that they reaffirm the statements made in the letter furnished pursuant to subsection (f) of this Section, except that the specified date referred to shall be a date not more than three business days prior to the Closing Time.

(h) *Approval of Listing.* At the Closing Time, the Securities shall have been approved for listing on the Nasdaq Global Select Market, subject only to official notice of issuance.

(i) *No Objection.* FINRA has confirmed that it has not raised any objection with respect to the fairness and reasonableness of the underwriting terms and arrangements relating to the offering of the Securities.

(j) *Lock-up Agreements.* At the date of this Agreement, the Representatives shall have received an agreement substantially in the form of Exhibit A hereto signed by (i) each of the Company's directors and officers and (ii) substantially all of the holders of shares of Common Stock or any security convertible or exercisable for shares of Common Stock.

(k) *Chief Financial Officer Certificate.* On the date of this Agreement and at the Closing Time, as the case may be, the Company shall have furnished to the Representatives a certificate, dated the respective dates of delivery thereof and addressed to the Underwriters, of its chief financial officer with respect to certain financial data contained in the General Disclosure Package and the Prospectus, providing "management comfort" with respect to such information, in form and substance reasonably satisfactory to the Representatives.

(l) *Conditions to Purchase of Option Securities.* In the event that the Underwriters exercise their option provided in Section 2(b) hereof to purchase all or any portion of the Option Securities, the representations and warranties of the Company contained herein and the statements in any certificates furnished by the Company and any of its subsidiaries hereunder shall be true and correct as of each Date of Delivery and, at the relevant Date of Delivery, the Representatives shall have received:

(i) Officers' Certificate. A certificate, dated such Date of Delivery, of the President or a Vice President of the Company and of the chief financial or chief accounting officer of the Company confirming that the certificate delivered at the Closing Time pursuant to Section 5(e) hereof remains true and correct as of such Date of Delivery.

(ii) Opinion and Negative Assurance Letter of Counsel for Company. If requested by the Representatives, the favorable opinion and negative assurance letter of Latham & Watkins LLP, counsel for the Company, in form and substance satisfactory to counsel for the Underwriters, dated such Date of Delivery, relating to the Option Securities to be purchased on such Date of Delivery and otherwise to the same effect as the opinion required by Section 5(b) hereof.

(iii) Opinion of Intellectual Property Counsel for Company. If requested by the Representatives, the favorable opinion of Seed IP Law Group LLP, counsel for the Company with respect to intellectual property matters, in form and substance satisfactory to counsel for the Underwriters, dated such Date of Delivery, relating to the Option Securities to be purchased on such Date of Delivery and otherwise to the same effect as the opinion required by Section 5(c) hereof.

(iv) Opinion and Negative Assurance Letter of Counsel for Underwriters. If requested by the Representatives, the opinion and negative assurance letter of Cooley LLP, counsel for the Underwriters, dated such Date of Delivery, relating to the Option Securities to be purchased on

such Date of Delivery and otherwise to the same effect as the opinion required by Section 5(d) hereof.

(vi) Bring-down Comfort Letter. If requested by the Representatives, a letter from Ernst & Young LLP, in form and substance satisfactory to the Representatives and dated such Date of Delivery, substantially in the same form and substance as the letter furnished to the Representatives pursuant to Section 5(f) hereof, except that the “specified date” in the letter furnished pursuant to this paragraph shall be a date not more than three business days prior to such Date of Delivery.

(vii) Chief Financial Officer Certificate. If requested by the Representatives, a certificate from the chief financial officer of the Company, in form and substance satisfactory to the Representatives and dated such Date of Delivery, relating to the Option Securities to be purchased on such Date of Delivery and otherwise to the same effect as the opinion required by Section 5(k) hereof.

(m) *Additional Documents*. At the Closing Time and at each Date of Delivery (if any) counsel for the Underwriters shall have been furnished with such documents and opinions as they may reasonably require for the purpose of enabling them to pass upon the issuance and sale of the Securities as herein contemplated, or in order to evidence the accuracy of any of the representations or warranties, or the fulfillment of any of the conditions, herein contained; and all proceedings taken by the Company in connection with the issuance and sale of the Securities as herein contemplated shall be reasonably satisfactory in form and substance to the Representatives and counsel for the Underwriters.

(n) *Termination of Agreement*. If any condition specified in this Section shall not have been fulfilled when and as required to be fulfilled, this Agreement, or, in the case of any condition to the purchase of Option Securities on a Date of Delivery which is after the Closing Time, the obligations of the several Underwriters to purchase the relevant Option Securities, may be terminated by the Representatives by notice to the Company at any time at or prior to Closing Time or such Date of Delivery, as the case may be, and such termination shall be without liability of any party to any other party except as provided in Section 4 and except that Sections 1, 6, 7, 8, 15, 16 and 17 shall survive any such termination and remain in full force and effect.

#### SECTION 6. Indemnification.

(a) *Indemnification of Underwriters*. The Company agrees to indemnify and hold harmless each Underwriter, its affiliates (as such term is defined in Rule 501(b) under the 1933 Act (each, an “Affiliate”)), its selling agents and each person, if any, who controls any Underwriter within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act as follows:

(i) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, arising out of any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendment thereto), including the Rule 430A Information, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading or arising out of any untrue statement or alleged untrue statement of a material fact included (A) in any preliminary prospectus, any Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication, the General Disclosure Package or the Prospectus (or any amendment or supplement thereto), or (B) in any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Securities (“Marketing Materials”), including any roadshow or investor presentations made to investors by the Company (whether in person or electronically), or the omission or alleged omission in any preliminary prospectus, Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication, Prospectus or in any Marketing Materials of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading;

(ii) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, to the extent of the aggregate amount paid in settlement of any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or of any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission; provided that (subject to Section 6(d) below) any such settlement is effected with the written consent of the Company;

(iii) against any and all expense whatsoever, as incurred (including the fees and disbursements of counsel chosen by the Representatives), reasonably incurred in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission, to the extent that any such expense is not paid under (i) or (ii) above;

provided, however, that this indemnity agreement shall not apply to any loss, liability, claim, damage or expense to the extent arising out of any untrue statement or omission or alleged untrue statement or omission made in the Registration Statement (or any amendment thereto), including the Rule 430A Information, the General Disclosure Package or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with the Underwriter Information.

(b) *Indemnification of Company, Directors and Officers.* Each Underwriter severally agrees to indemnify and hold harmless the Company, its directors, each of its officers who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act, against any and all loss, liability, claim, damage and expense described in the indemnity contained in subsection (a) of this Section, as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendment thereto), including the Rule 430A Information, the General Disclosure Package or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with the Underwriter Information.

(c) *Actions against Parties; Notification.* Each indemnified party shall give notice as promptly as reasonably practicable to each indemnifying party of any action commenced against it in respect of which indemnity may be sought hereunder, but failure to so notify an indemnifying party shall not relieve such indemnifying party from any liability hereunder to the extent it is not materially prejudiced as a result thereof and in any event shall not relieve it from any liability which it may have otherwise than on account of this indemnity agreement. In the case of parties indemnified pursuant to Section 6(a) above, counsel to the indemnified parties shall be selected by the Representatives, and, in the case of parties indemnified pursuant to Section 6(b) above, counsel to the indemnified parties shall be selected by the Company. An indemnifying party may participate at its own expense in the defense of any such action; provided, however, that counsel to the indemnifying party shall not (except with the consent of the indemnified party) also be counsel to the indemnified party. In no event shall the indemnifying parties be liable for fees and expenses of more than one counsel (in addition to any local counsel) separate from their own counsel for all indemnified parties in connection with any one action or separate but similar or related actions in the same jurisdiction arising out of the same general allegations or circumstances. No indemnifying party shall, without the prior written consent of the indemnified parties, settle or compromise or consent to the entry of any judgment with respect to any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever in respect of which indemnification or contribution could be sought under this Section 6 or Section 7 hereof (whether or not the indemnified parties are actual or potential parties thereto), unless such settlement, compromise or consent (i) includes an unconditional release of each indemnified party from all liability arising out of such litigation, investigation,

proceeding or claim and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

(d) *Settlement without Consent if Failure to Reimburse.* If at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel, such indemnifying party agrees that it shall be liable for any settlement of the nature contemplated by Section 6(a)(ii) or settlement of any claim in connection with any violation referred to in Section 6(e) effected without its written consent if (i) such settlement is entered into more than 45 days after receipt by such indemnifying party of the aforesaid request, (ii) such indemnifying party shall have received notice of the terms of such settlement at least 30 days prior to such settlement being entered into and (iii) such indemnifying party shall not have reimbursed such indemnified party in accordance with such request prior to the date of such settlement.

(e) *Indemnification for Reserved Securities.* In connection with the offer and sale of the Reserved Securities, the Company agrees to indemnify and hold harmless the Underwriters, their Affiliates and selling agents and each person, if any, who controls any Underwriter within the meaning of either Section 15 of the 1933 Act or Section 20 of the 1934 Act, from and against any and all loss, liability, claim, damage and expense (including, without limitation, any legal or other expenses reasonably incurred in connection with defending, investigating or settling any such action or claim), as incurred, (i) arising out of the violation of any applicable laws or regulations of foreign jurisdictions where Reserved Securities have been offered, (ii) arising out of any untrue statement or alleged untrue statement of a material fact contained in any other material prepared by or with the consent of the Company for distribution to Invitees in connection with the offering of the Reserved Securities or caused by any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, (iii) caused by the failure of any Invitee to pay for and accept delivery of Reserved Securities which have been orally confirmed for purchase by any Invitee by 11:59 P.M. (New York City time) on the date of the Agreement or (iv) related to, or arising out of or in connection with, the offering of the Reserved Securities; *provided* that no indemnification shall be available under this section for any loss, liability, claim, damage or expense which shall have been finally judicially determined by a court of competent jurisdiction to have been caused primarily by the gross negligence or willful misconduct of Merrill Lynch or any of its affiliates. The Company shall reimburse the Underwriters promptly upon demand for any legal or other expenses reasonably incurred by them in connection with investigating or defending or preparing to defend against any such loss, liability, claim, damage or expense as such expenses are incurred.

SECTION 7. Contribution. If the indemnification provided for in Section 6 hereof is for any reason unavailable to or insufficient to hold harmless an indemnified party in respect of any losses, liabilities, claims, damages or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount of such losses, liabilities, claims, damages and expenses incurred by such indemnified party, as incurred, (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the Underwriters, on the other hand, from the offering of the Securities pursuant to this Agreement or (ii) if the allocation provided by clause (i) is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and of the Underwriters, on the other hand, in connection with the statements or omissions, or in connection with any violation of the nature referred to in Section 6(e) hereof, which resulted in such losses, liabilities, claims, damages or expenses, as well as any other relevant equitable considerations.

The relative benefits received by the Company, on the one hand, and the Underwriters, on the other hand, in connection with the offering of the Securities pursuant to this Agreement shall be deemed to be in the same respective proportions as the total net proceeds from the offering of the Securities pursuant to this Agreement (before deducting expenses) received by the Company, on the one hand, and the total



underwriting discount received by the Underwriters, on the other hand, in each case as set forth on the cover of the Prospectus, bear to the aggregate initial public offering price of the Securities as set forth on the cover of the Prospectus.

The relative fault of the Company, on the one hand, and the Underwriters, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or by the Underwriters and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission or any violation of the nature referred to in Section 6(e) hereof.

The Company and the Underwriters agree that it would not be just and equitable if contribution pursuant to this Section 7 were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to above in this Section 7. The aggregate amount of losses, liabilities, claims, damages and expenses incurred by an indemnified party and referred to above in this Section 7 shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue or alleged untrue statement or omission or alleged omission.

Notwithstanding the provisions of this Section 7, no Underwriter shall be required to contribute any amount in excess of the underwriting commissions received by such Underwriter in connection with the Securities underwritten by it and distributed to the public.

No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the 1933 Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation.

For purposes of this Section 7, each person, if any, who controls an Underwriter within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act and each Underwriter's Affiliates and selling agents shall have the same rights to contribution as such Underwriter, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act shall have the same rights to contribution as the Company. The Underwriters' respective obligations to contribute pursuant to this Section 7 are several in proportion to the number of Initial Securities set forth opposite their respective names in Schedule A hereto and not joint.

**SECTION 8. Representations, Warranties and Agreements to Survive.** All representations, warranties and agreements contained in this Agreement or in certificates of officers of the Company or any of its subsidiaries submitted pursuant hereto, shall remain operative and in full force and effect regardless of (i) any investigation made by or on behalf of any Underwriter or its Affiliates or selling agents, any person controlling any Underwriter, its officers or directors or any person controlling the Company and (ii) delivery of and payment for the Securities.

**SECTION 9. Termination of Agreement.**

(a) *Termination.* The Representatives may terminate this Agreement, by notice to the Company, at any time at or prior to the Closing Time (i) if there has been, in the judgment of the Representatives, since the time of execution of this Agreement or since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package or the Prospectus, any

material adverse change in the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company and its subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business, or (ii) if there has occurred any material adverse change in the financial markets in the United States or the international financial markets, any outbreak of hostilities or escalation thereof or other calamity or crisis or any change or development involving a prospective change in national or international political, financial or economic conditions, in each case the effect of which is such as to make it, in the judgment of the Representatives, impracticable or inadvisable to proceed with the completion of the offering or to enforce contracts for the sale of the Securities, or (iii) if trading in any securities of the Company has been suspended or materially limited by the Commission or the Nasdaq Global Select Market, or (iv) if trading generally on the NYSE MKT or the New York Stock Exchange or in the Nasdaq Global Select Market has been suspended or materially limited, or minimum or maximum prices for trading have been fixed, or maximum ranges for prices have been required, by any of said exchanges or by order of the Commission, FINRA or any other governmental authority, or (v) a material disruption has occurred in commercial banking or securities settlement or clearance services in the United States or with respect to Clearstream or Euroclear systems in Europe, or (vi) if a banking moratorium has been declared by either Federal or New York authorities.

(b) *Liabilities.* If this Agreement is terminated pursuant to this Section, such termination shall be without liability of any party to any other party except as provided in Section 4 hereof, and provided further that Sections 1, 6, 7, 8, 15, 16 and 17 shall survive such termination and remain in full force and effect.

SECTION 10. Default by One or More of the Underwriters. If one or more of the Underwriters shall fail at the Closing Time or a Date of Delivery to purchase the Securities which it or they are obligated to purchase under this Agreement (the "Defaulted Securities"), the Representatives shall have the right, within 24 hours thereafter, to make arrangements for one or more of the non-defaulting Underwriters, or any other underwriters, to purchase all, but not less than all, of the Defaulted Securities in such amounts as may be agreed upon and upon the terms herein set forth; if, however, the Representatives shall not have completed such arrangements within such 24-hour period, then:

(i) if the number of Defaulted Securities does not exceed 10% of the number of Securities to be purchased on such date, each of the non-defaulting Underwriters shall be obligated, severally and not jointly, to purchase the full amount thereof in the proportions that their respective underwriting obligations hereunder bear to the underwriting obligations of all non-defaulting Underwriters, or

(ii) if the number of Defaulted Securities exceeds 10% of the number of Securities to be purchased on such date, this Agreement or, with respect to any Date of Delivery which occurs after the Closing Time, the obligation of the Underwriters to purchase, and the Company to sell, the Option Securities to be purchased and sold on such Date of Delivery shall terminate without liability on the part of any non-defaulting Underwriter.

No action taken pursuant to this Section shall relieve any defaulting Underwriter from liability in respect of its default.

In the event of any such default which does not result in a termination of this Agreement or, in the case of a Date of Delivery which is after the Closing Time, which does not result in a termination of the obligation of the Underwriters to purchase and the Company to sell the relevant Option Securities, as the case may be, either the (i) Representatives or (ii) the Company shall have the right to postpone Closing Time or the relevant Date of Delivery, as the case may be, for a period not exceeding seven days in order to effect any required changes in the Registration Statement, the General Disclosure Package or the

Prospectus or in any other documents or arrangements. As used herein, the term “Underwriter” includes any person substituted for an Underwriter under this Section 10.

SECTION 11. Notices. All notices and other communications hereunder shall be in writing and shall be deemed to have been duly given if mailed or transmitted by any standard form of telecommunication. Notices to the Underwriters shall be directed to the Representatives at Merrill Lynch, One Bryant Park, New York, New York 10036, attention of Syndicate Department (facsimile: (646) 855-3073), with a copy to ECM Legal (facsimile: (212) 230-8730); SVB Leerink LLC, One Federal Street, 37th Floor, Boston, Massachusetts 02110, attention of John I. Fitzgerald, Esq. (facsimile: (617) 918-4664); Barclays Capital Inc., 745 Seventh Avenue, New York, New York 10019, Attention: Syndicate Registration; and Evercore Group L.L.C., 55 East 52nd Street, New York, New York 10055, Attention: General Counsel, with a copy to Attention: General Counsel (facsimile: (212) 849-3490); and notices to the Company shall be directed to it at 3013 Science Park Road, Suite 200, San Diego, California 92121, attention of Chief Executive Officer and General Counsel, with a copy to Latham & Watkins LLP, 12670 High Bluff Drive, San Diego, California 92130, Attention: Matthew T. Bush.

SECTION 12. No Advisory or Fiduciary Relationship. The Company acknowledges and agrees that (a) the purchase and sale of the Securities pursuant to this Agreement, including the determination of the initial public offering price of the Securities and any related discounts and commissions, is an arm’s-length commercial transaction between the Company, on the one hand, and the several Underwriters, on the other hand, (b) in connection with the offering of the Securities and the process leading thereto, each Underwriter is and has been acting solely as a principal and is not the agent or fiduciary of the Company, any of its subsidiaries or their respective stockholders, creditors, employees or any other party, (c) no Underwriter has assumed or will assume an advisory or fiduciary responsibility in favor of the Company with respect to the offering of the Securities or the process leading thereto (irrespective of whether such Underwriter has advised or is currently advising the Company or any of its subsidiaries on other matters) and no Underwriter has any obligation to the Company with respect to the offering of the Securities except the obligations expressly set forth in this Agreement, (d) the Underwriters and their respective affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company and (e) the Underwriters have not provided any legal, accounting, regulatory or tax advice with respect to the offering of the Securities and the Company has consulted its own respective legal, accounting, regulatory and tax advisors to the extent it deemed appropriate.

SECTION 13. Recognition of the U.S. Special Resolution Regimes.

(a) In the event that any Underwriter that is a Covered Entity becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from such Underwriter of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.

(b) In the event that any Underwriter that is a Covered Entity or a BHC Act Affiliate of such Underwriter becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against such Underwriter are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

For purposes of this Section 13, a “BHC Act Affiliate” has the meaning assigned to the term “affiliate” in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k). “Covered Entity” means any of the following: (i) a “covered entity” as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b); (ii) a “covered bank” as that term is defined in, and interpreted in accordance with, 12 C.F.R. §

47.3(b); or (iii) a “covered FSI” as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b). “Default Right” has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable. “U.S. Special Resolution Regime” means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

SECTION 14. Parties. This Agreement shall each inure to the benefit of and be binding upon the Underwriters and the Company and their respective successors. Nothing expressed or mentioned in this Agreement is intended or shall be construed to give any person, firm or corporation, other than the Underwriters and the Company and their respective successors and the controlling persons and officers and directors referred to in Sections 6 and 7 and their heirs and legal representatives, any legal or equitable right, remedy or claim under or in respect of this Agreement or any provision herein contained. This Agreement and all conditions and provisions hereof are intended to be for the sole and exclusive benefit of the Underwriters and the Company and their respective successors, and said controlling persons and officers and directors and their heirs and legal representatives, and for the benefit of no other person, firm or corporation. No purchaser of Securities from any Underwriter shall be deemed to be a successor by reason merely of such purchase.

SECTION 15. Trial by Jury. The Company (on its behalf and, to the extent permitted by applicable law, on behalf of its stockholders and affiliates) and each of the Underwriters hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

SECTION 16. GOVERNING LAW. THIS AGREEMENT AND ANY CLAIM, CONTROVERSY OR DISPUTE ARISING UNDER OR RELATED TO THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF, THE STATE OF NEW YORK WITHOUT REGARD TO ITS CHOICE OF LAW PROVISIONS.

SECTION 17. Consent to Jurisdiction. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby (“Related Proceedings”) shall be instituted in (i) the federal courts of the United States of America located in the City and County of New York, Borough of Manhattan or (ii) the courts of the State of New York located in the City and County of New York, Borough of Manhattan (collectively, the “Specified Courts”), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court (a “Related Judgment”), as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party’s address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

SECTION 18. TIME. TIME SHALL BE OF THE ESSENCE OF THIS AGREEMENT. EXCEPT AS OTHERWISE SET FORTH HEREIN, SPECIFIED TIMES OF DAY REFER TO NEW YORK CITY TIME.

SECTION 19. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, but all such counterparts shall together constitute one and the same Agreement.

SECTION 20. Effect of Headings. The Section headings herein are for convenience only and shall not affect the construction hereof.

*[Signature page follows]*

If the foregoing is in accordance with your understanding of our agreement, please sign and return to the Company a counterpart hereof, whereupon this instrument, along with all counterparts, will become a binding agreement among the Underwriters and the Company in accordance with its terms.

Very truly yours,

GOSSAMER BIO, INC.

By \_\_\_\_\_  
Title:

*[Signature page to Underwriting Agreement]*

CONFIRMED AND ACCEPTED,  
as of the date first above written:

MERRILL LYNCH, PIERCE, FENNER & SMITH  
INCORPORATED  
SVB LEERINK LLC  
BARCLAYS CAPITAL INC.  
EVERCORE GROUP L.L.C.

By: MERRILL LYNCH, PIERCE, FENNER & SMITH  
INCORPORATED

By \_\_\_\_\_  
Authorized Signatory

By: SVB LEERINK LLC

By \_\_\_\_\_  
Authorized Signatory

By: BARCLAYS CAPITAL INC.

By \_\_\_\_\_  
Authorized Signatory

By: EVERCORE GROUP L.L.C.

By \_\_\_\_\_  
Authorized Signatory

For themselves and as Representatives of the other Underwriters named in Schedule A hereto.

*[Signature page to Underwriting Agreement]*

SCHEDULE A

The initial public offering price per share for the Securities shall be \$[●].

The purchase price per share for the Securities to be paid by the several Underwriters shall be \$[●], being an amount equal to the initial public offering price set forth above less \$[●] per share, subject to adjustment in accordance with Section 2(b) for dividends or distributions declared by the Company and payable on the Initial Securities but not payable on the Option Securities.

Name of Underwriter	Number of <u>Initial Securities</u>
Merrill Lynch, Pierce, Fenner & Smith Incorporated	
SVB Leerink LLC	
Barclays Capital Inc.	
Evercore Group L.L.C.	
Total	



SCHEDULE B-1

Pricing Terms

1. The Company is selling [●] shares of Common Stock.
2. The Company has granted an option to the Underwriters, severally and not jointly, to purchase up to an additional [●] shares of Common Stock.
3. The initial public offering price per share for the Securities shall be \$[●].

Sch B - 1

SCHEDULE B-2

Free Writing Prospectuses

[SPECIFY EACH ISSUER GENERAL USE FREE WRITING PROSPECTUS]

Sch B - 2

SCHEDULE B-3

Written Testing-the-Waters Communications

Gossamer Bio Testing the Waters Presentation dated December 2018.

Sch B - 3

**Form of lock-up from directors, officers or other stockholders pursuant to Section 5(j)**

[•]

Merrill Lynch, Pierce, Fenner & Smith  
Incorporated  
SVB Leerink LLC  
Barclays Capital Inc.  
Evercore Group L.L.C.  
as Representatives of the several  
Underwriters to be named in the  
within-mentioned Underwriting Agreement

c/o Merrill Lynch, Pierce, Fenner & Smith  
Incorporated  
One Bryant Park  
New York, New York 10036

c/o SVB Leerink LLC  
One Federal Street, 37th Floor  
Boston, Massachusetts 02110

c/o Barclays Capital Inc.  
745 Seventh Avenue  
New York, New York 10019

c/o Evercore Group L.L.C.  
55 East 52nd Street  
New York, New York 10055

Re: Proposed Public Offering by Gossamer Bio, Inc.

Dear Sirs:

The undersigned, a stockholder, an officer and/or director of Gossamer Bio, Inc., a Delaware corporation (the "Company"), understands that Merrill Lynch, Pierce, Fenner & Smith Incorporated ("Merrill Lynch"), SVB Leerink LLC ("Leerink"), Barclays Capital Inc. ("Barclays") and Evercore Group L.L.C. ("Evercore" and together with Merrill Lynch, Leerink and Barclays, the "Representatives") propose to enter into an Underwriting Agreement (the "Underwriting Agreement") with the Company providing for the public offering (the "Public Offering") of shares of the Company's common stock, par value \$0.0001 per share (the "Common Stock"). In recognition of the benefit that such an offering will confer upon the undersigned as a stockholder, an officer and/or director of the Company, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned agrees with each underwriter to be named in the Underwriting Agreement that, during the period beginning on the date hereof and ending on the date that is 180 days from the date of the Underwriting Agreement (the "Lock-Up Period"), the undersigned will not, without the prior written consent of Merrill Lynch, Leerink and Barclays, (i) directly or indirectly, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of any shares of the Company's Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock, whether now owned or hereafter acquired by the undersigned or with respect to which the undersigned has or hereafter acquires the power of disposition

Exhibit A-1

(collectively, the “Lock-Up Securities”), or exercise any right with respect to the registration of any of the Lock-Up Securities, or file, cause to be filed or cause to be confidentially submitted any registration statement in connection therewith, under the Securities Act of 1933, as amended, or (ii) enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the Lock-Up Securities, whether any such swap or transaction is to be settled by delivery of Common Stock or other securities, in cash or otherwise. If the undersigned is an officer or director of the Company, the undersigned further agrees that the foregoing provisions shall be equally applicable to any issuer-directed shares of Common Stock the undersigned may purchase in the Public Offering.

SECTION 1. If the undersigned is an officer or director of the Company, (1) Merrill Lynch, Leerink and Barclays agree that, at least three business days before the effective date of any release or waiver of the foregoing restrictions in connection with a transfer of shares of the Common Stock, Merrill Lynch, Leerink and Barclays will notify the Company of the impending release or waiver, and (2) the Company has agreed in the Underwriting Agreement to announce the impending release or waiver by press release through a major news service at least two business days before the effective date of the release or waiver. Any release or waiver granted by Merrill Lynch, Leerink and Barclays hereunder to any such officer or director shall only be effective two business days after the publication date of such press release. The provisions of this paragraph will not apply if (i) the release or waiver is effected solely to permit a transfer not for consideration and (ii) the transferee has agreed in writing to be bound by the same terms described in this letter to the extent and for the duration that such terms remain in effect at the time of the transfer.

Notwithstanding the foregoing, and subject to the conditions below, the undersigned may transfer the Lock-Up Securities without the prior written consent of Merrill Lynch, Leerink and Barclays,

(a) provided that (1) Merrill Lynch, Leerink and Barclays receive a signed lock-up agreement for the balance of the Lock-Up Period from each donee, trustee, distributee, or transferee, as the case may be, (2) any such transfer shall not involve a disposition for value, (3) such transfers are not required to be reported with the Securities and Exchange Commission on Form 4 in accordance with Section 16 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and (4) the undersigned does not otherwise voluntarily effect any public filing or report regarding such transfers (other than a filing on a Form 5 made after the expiration of the Lock-Up Period):

- i. as a *bona fide* gift or gifts; or
- ii. to any trust for the direct or indirect benefit of the undersigned or the immediate family of the undersigned (for purposes of this lock-up agreement, “immediate family” shall mean any relationship by blood, marriage or adoption, not more remote than first cousin); or
- iii. if the undersigned is a trust, to the trustor or beneficiary of such trust or to the estate of a beneficiary of such trust; or
- iv. by will or intestate succession to the legal representative, heir, beneficiary or any immediate family of the undersigned; or
- v. as a distribution to limited partners, members or stockholders of the undersigned; or
- vi. to the undersigned’s affiliates or to any investment fund or other entity controlled or managed by the undersigned; or

Exhibit A-2

vii. to the Company as forfeitures to satisfy tax withholding and remittance obligations of the undersigned in connection with the exercise of equity awards granted pursuant to the Company's equity incentive plans described in the final prospectus for the Public Offering (the "Prospectus") or transfers to the Company pursuant to a net exercise or cashless exercise by the stockholder of outstanding equity awards pursuant to the Company's equity incentive plans described in the Prospectus; provided the Common Stock issued shall remain subject to the restrictions on transfer set forth in this Letter Agreement; or

viii. pursuant to a court or regulatory agency order, a qualified domestic order or in connection with a divorce settlement.

(b) to the Company as forfeitures to satisfy tax withholding and remittance obligations of the undersigned in connection with the vesting of equity awards granted pursuant to the Company's equity incentive plans described in the Prospectus; provided that any filing under Section 16 of the Exchange Act made during the Lock-Up Period shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in this clause (b);

(c) to the Company pursuant to any contractual arrangement disclosed in the Prospectus and in effect on the date of the Prospectus that provides for the repurchase by the Company or forfeiture of the undersigned's Common Stock or other Lock-Up Securities in connection with the termination of the undersigned's service to the Company; provided that no filing under Section 16 of the Exchange Act or other public filing, report or announcement reporting a reduction in beneficial ownership of shares of Common Stock shall be required or shall be voluntarily made during the Lock-Up Period within 60 days after the date the undersigned ceases to provide services to the Company, and after such 60th day, if the undersigned is required to file a report under Section 16 of the Exchange Act reporting a reduction in beneficial ownership of shares of Common Stock during the Lock-Up Period, the undersigned shall clearly indicate in the footnotes thereto that the filing relates to the termination of the undersigned's employment or other services; or

(d) upon the completion of a bona fide third-party tender offer, merger, consolidation or other similar transaction made to all holders of the Company's securities involving a change of control of the Company, provided that, in the event that such tender offer, merger, consolidation or other similar transaction is not completed, any Lock-Up Securities held by the undersigned shall remain subject to the restrictions on transfer set forth in this lock-up agreement (for purposes hereof, "change of control" shall mean the transfer (whether by tender offer, merger, consolidation or other similar transaction), in one transaction or a series of related transactions, to a person or group of affiliated persons, of shares of capital stock if, after such transfer, such person or group of affiliated persons would hold more than 50% of the outstanding voting securities of the Company (or the surviving entity)). or

Notwithstanding anything herein to the contrary, nothing herein shall prevent the undersigned from establishing a 10b5-1 trading plan that complies with Rule 10b5-1 under the Exchange Act ("10b5-1 Trading Plan") or from amending an existing 10b5-1 Trading Plan so long as there are no sales of Lock-Up Securities under such plan during the Lock-Up Period; and provided that, the establishment of a 10b5-1 Trading Plan or the amendment of a 10b5-1 Trading Plan, in either case, providing for sales of Lock-Up Securities shall only be permitted if (i) the establishment or amendment of such plan is not required to be reported in any public report or filing with the Securities and Exchange Commission, or otherwise, and (ii) the undersigned does not otherwise voluntarily effect any public filing or report regarding the establishment or amendment of such plan.

Furthermore, the undersigned may sell shares of Common Stock of the Company purchased by the undersigned in the Public Offering or on the open market following the Public Offering if and only if (i)

Exhibit A-3

such sales are not required to be reported in any public report or filing with the Securities and Exchange Commission, or otherwise, during the Lock-Up Period and (ii) the undersigned does not otherwise voluntarily effect any public filing or report regarding such sales during the Lock-Up Period.

The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of the Lock-Up Securities except in compliance with the foregoing restrictions.

The undersigned understands that, (i) if the Underwriting Agreement does not become effective by March 31, 2019 (provided, however, that the Company may extend such date by up to three months with written notice to the undersigned prior thereto if the Company is still pursuing the Public Offering), (ii) if the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Common Stock to be sold thereunder, (iii) if the Company files an application to withdraw the Registration Statement or (iv) if the Company advises the Representatives in writing that it has determined not to proceed with the Public Offering, the undersigned shall be released from all obligations under this lock-up agreement.

*[Signature page follows]*

Exhibit A-4

Very truly yours,

\_\_\_\_\_  
Name of Security Holder *(Print exact name)*

By: \_\_\_\_\_  
Signature

If not signing in an individual capacity:

\_\_\_\_\_  
Name of Authorized Signatory *(Print)*

\_\_\_\_\_  
Title of Authorized Signatory *(Print)*

*(indicate capacity of person signing if signing as  
custodian, trustee, or on behalf of an entity)*

[Signature page to Lock-Up Agreement]

Exhibit A-5



FORM OF PRESS RELEASE  
TO BE ISSUED PURSUANT TO SECTION 3(j)

GOSSAMER BIO, INC.

[Date]

GOSSAMER BIO, INC. (the “Company”) announced today that Merrill Lynch, Pierce, Fenner & Smith Incorporated, SVB Leerink LLC and Barclays Capital Inc., representatives of the several underwriters in the Company’s recent public sale of [●] shares of common stock, are [waiving] [releasing] a lock-up restriction with respect to \_\_\_\_\_ shares of the Company’s common stock held by [certain officers or directors] [an officer or director] of the Company. The [waiver] [release] will take effect on \_\_\_\_\_, \_\_\_\_\_ 20\_\_\_\_, and the shares may be sold on or after such date.

**This press release is not an offer for sale of the securities in the United States or in any other jurisdiction where such offer is prohibited, and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the United States Securities Act of 1933, as amended.**

Exhibit B-1

**Consent of Independent Registered Public Accounting Firm**

We consent to the reference to our firm under the caption “Experts” and to the use of our report dated October 11, 2018 (except for the last paragraph of Note 12, as to which the date is January 23, 2019) in Amendment No. 2 to the Registration Statement on Form S-1 (No. 333-228984) and related Prospectus of Gossamer Bio, Inc. for the registration of its common stock.

/s/ Ernst & Young LLP

San Diego, California  
January 30, 2019