

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

**FORM S-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

**GALECTO, 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)

37-1957007  
(I.R.S. Employer  
Identification No.)

Ole Maaloes Vej 3  
DK-2200 Copenhagen N  
Denmark  
(+45) 70 70 52 10

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

Hans T. Schambye, M.D., Ph.D.  
Chief Executive Officer  
Galecto, Inc.  
Ole Maaloes Vej 3  
DK-2200 Copenhagen N  
Denmark  
(+45) 70 70 52 10

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

*Copies to:*

Jonathan Freve  
Chief Financial Officer  
Galecto, Inc.  
Ole Maaloes Vej 3  
DK-2200 Copenhagen N  
Denmark  
(+45) 70 70 52 10

Megan N. Gates  
William C. Hicks  
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.  
One Financial Center  
Boston, MA 02111  
(617) 542-6000

Graham F. Defries  
Edwin M. O'Connor  
Kyra M. Ayo Caros  
Goodwin Procter LLP  
620 8th Avenue  
New York, NY 10018  
(212) 813-8800

**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this registration statement.

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee(2)
Common Stock, par value \$0.00001 per share	\$	\$

- (1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act. Includes the offering price of any additional shares that the underwriters have the option to purchase.
- (2) Calculated pursuant to Rule 457(o) under the Securities Act based on an estimate of the proposed maximum aggregate offering price.

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, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

**EXPLANATORY NOTE**

Pursuant to the applicable provisions of the Fixing America's Surface Transportation Act, we are omitting our financial statements (and related financial information) for the three months ended March 31, 2020 and 2019 because they relate to historical periods that we believe will not be required to be included in the prospectus at the time of the contemplated offering. We intend to amend this registration statement to include all required financial information at the date of such amendment before distributing a preliminary prospectus to investors.

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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 offers to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

Subject to Completion  
Preliminary Prospectus Dated \_\_\_\_\_, 2020

PROSPECTUS

**Shares**



**Common Stock**

This is Galecto, Inc.'s initial public offering. We are selling \_\_\_\_\_ shares of our common stock.

We expect the initial public offering price to be between \$ \_\_\_\_\_ and \$ \_\_\_\_\_ per share. Currently, no public market exists for our common stock. After the pricing of the offering, we expect that our common stock will trade on the Nasdaq Global Market under the symbol "GLTO."

We are an "emerging growth company" as defined under the Jumpstart Our Business Startups Act of 2012 and, as such, will be subject to reduced public company reporting requirements. See "Prospectus Summary—Implications of Being an Emerging Growth Company."

**Investing in our common stock involves risks that are described in the "[Risk Factors](#)" section beginning on page 10 of this prospectus.**

	<u>Per Share</u>	<u>Total</u>
Initial Public Offering Price	\$ _____	\$ _____
Underwriting Discounts and Commissions (1)	\$ _____	\$ _____
Proceeds, before expenses, to us	\$ _____	\$ _____

(1) We refer you to "[Underwriting](#)" beginning on page 170 for additional information regarding the underwriting compensation.

The underwriters may also exercise their option to purchase up to an additional \_\_\_\_\_ shares from us, at the public offering price, less the underwriting discounts and commissions, for 30 days after the date of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission or other regulatory body has approved or disapproved of these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The shares will be ready for delivery on or about \_\_\_\_\_, 2020.

**BofA Securities**

**SVB Leerink**

**Credit Suisse**

The date of this prospectus is \_\_\_\_\_, 2020.

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**We are responsible for the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with any other information other than in this prospectus, and we take no responsibility for, and the underwriters have not taken responsibility for, any other information others may give you. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than its date.**

For investors outside the United States: Neither we nor any of the underwriters have 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 in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus outside of the United States.

This prospectus contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that the owner will not assert, to the fullest extent under applicable law, its rights. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

## PROSPECTUS SUMMARY

*This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our financial statements and the related notes included elsewhere in this prospectus. You should also consider, among other things, the matters described in the sections entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” In this prospectus, unless the context requires otherwise, all references to “us,” “our,” “Galecto,” “we,” the “Company” and similar designations refer to Galecto, Inc. and its wholly-owned subsidiaries on a consolidated basis.*

### Overview

We are a clinical-stage biotechnology company developing therapeutics that are designed to target the biological processes that lie at the heart of fibrosis and impact a broad range of fibrotic and related diseases, including cancer. Our initial focus is on the development of small-molecule inhibitors of galectin-3 and lysyl oxidase-like 2, or LOXL2, which play key roles in regulating fibrosis. We believe our product candidates are distinct from the current generation of antifibrotic agents and have the potential to significantly improve patients’ clinical outcomes and enhance their quality of life.

Our lead product candidate, GB0139, is an inhaled inhibitor of galectin-3. We are developing GB0139 for the treatment of severe fibrotic lung diseases such as idiopathic pulmonary fibrosis, or IPF, a life-threatening progressive fibrotic disease of the lung that affects approximately 100,000 people in the United States. While there are currently two approved therapies for the treatment of lung fibrosis, neither has been associated with improvements in overall survival, and both therapies have been associated with significant side effects leading to poor therapeutic adherence. In our clinical trials to date, we have demonstrated that orally inhaled GB0139 is well-tolerated and inhibits galectin-3 in the lungs, in a dose-dependent manner, and that it significantly decreases levels of a range of plasma biomarkers, such as YKL-40, that have been linked to mortality, severity and/or progression in IPF. We have conducted a Phase 2a study in 24 IPF patients, and we have initiated a potentially registrational, randomized Phase 2b trial in 450 IPF patients. We expect topline results from this ongoing trial to be available in

Our product candidate portfolio also includes GB1211, a selective oral galectin-3 inhibitor that we are developing for the treatment of fibrosis related to non-alcoholic steatohepatitis, or NASH, and GB2064, a selective oral inhibitor of LOXL2 that we initially plan to develop for the treatment of myelofibrosis, a malignant disease of the bone marrow in which fibrosis reduces the ability to form blood cells. We expect to initiate Phase 2 clinical trials for both GB1211 and GB2064 in . We plan to further expand our development of GB1211 into other related indications, including cancer.

### Fibrosis background

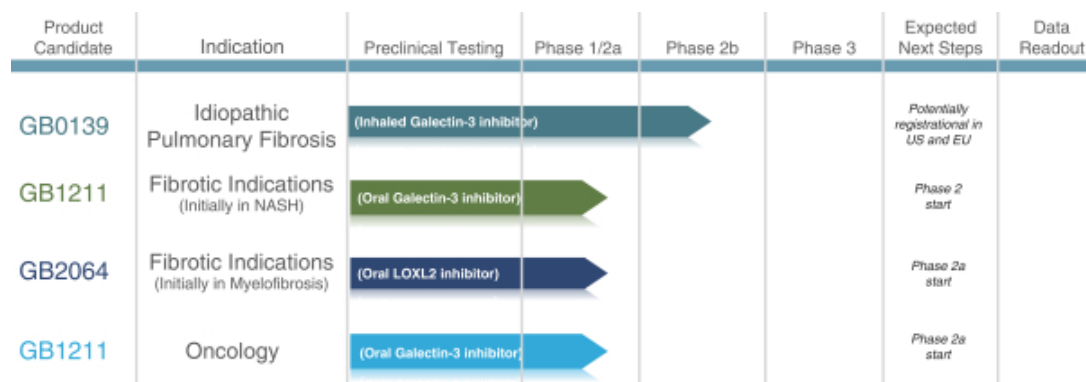
Fibrosis is the development of abnormal fibrous connective tissue in response to injury, damage or dysfunctional gene regulation. This fibrous connective tissue consists of elongated proteins such as collagen and elastin fibers that provide support to surrounding key functional cells in all tissue and all organs. Production and break-down of collagen is tightly regulated to preserve optimal organ function. The deposition of excess collagen and the formation of fibrosis can cause remodeling of surrounding healthy tissue and the loss of normal organ or tissue function. Fibrotic disease can affect tissues throughout the body including the lungs, liver, heart, kidneys and vascular system. Fibrosis typically progresses slowly and can ultimately lead to organ failure and death. Fibrosis is also a hallmark of solid tumors, with up to 20 percent of cancers linked to chronic inflammation-linked fibrosis. It has been estimated that fibrosis contributes to up to 45 percent of all deaths in the developed world.

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The currently approved therapeutic treatments for IPF are associated with significant side effects, leading to significant discontinuation rates with median time on treatment only between 7.5 and 8.9 months, and they have not been linked to improvements in overall survival. Scientific literature supports the understanding that there are common biological mechanisms that drive fibrosis that are distinct from those regulating inflammation. It is these mechanisms that we are targeting with our proprietary product candidates. We are developing small-molecule fibrosis inhibitors focusing on galectin-3 and LOXL2, two of the targets that are believed to underlie the biological processes that drive fibrosis.

### ***Our Pipeline:***

We have retained global development and commercialization rights to all of the product candidates in our pipeline. The chart below summarizes key information about our programs. We are also progressing several preclinical assets against other proteins that have been associated with disease.



Our initial focus is developing GB0139 for the treatment of IPF, but we plan to further develop GB0139 with the goal of treating most of the forms of lung fibrosis. GB0139 targets galectin-3, one of the key regulators of lung fibrosis. The overexpression of galectin-3 is ubiquitous in fibrotic tissue, including in fibrotic lung tissue, and is linked to both disease severity and disease progression, as well as acute exacerbations of IPF. However, there are no therapeutics approved that specifically target galectin-3. In our clinical, preclinical and *in vitro* testing to date, we have demonstrated that GB0139 directly targets galectin-3 in the lungs and markedly lowers the plasma levels of biomarkers of fibrosis in patients.

In our Phase 1/2a trial in both healthy volunteers and IPF patients, GB0139 was well-tolerated, showed consistent pharmacokinetics measured as plasma levels of the compound, and inhibited galectin-3 in the lungs of IPF patients in a dose-dependent manner. We are currently conducting a Phase 2b randomized, double-blind placebo-controlled clinical trial of GB0139 in 450 IPF patients. The primary endpoint of the trial is to assess annual rate of decline in forced vital capacity, or FVC. Reduction in the decline of FVC is the endpoint that was accepted by the FDA for the approval of both of the current therapeutic treatments for IPF. We anticipate that results from this trial will become available in . We believe, pending feedback from regulatory authorities, that a positive result in this trial has the potential to support an application for conditional approval of GB0139 in the EU. We believe that this trial also has the potential to be regarded as a registrational trial in the United States. In addition, on August 27, 2020, we announced that GB0139 for the treatment of IPF had been granted Orphan Drug Designation by both United States and European regulatory authorities.

We are also developing GB1211, an orally delivered molecule that we believe has the potential to treat multiple types of fibrotic and related diseases, including NASH, renal fibrosis, cardiac fibrosis and various

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cancers. Our initial target indication for GB1211 is fibrosis related to NASH, a highly prevalent progressive liver disease with no available FDA-approved therapies. GB1211 showed antifibrotic activity in multiple preclinical models and has successfully completed a Phase 1 trial in 78 healthy volunteers. In the Phase 1 trial, GB1211 was well-tolerated and had dose-dependent pharmacokinetics. We are planning to initiate a Phase 2a trial of GB1211 in fibrosis related to NASH in 72 patients, with data expected in . In addition to our Phase 2a trial, we plan to further expand our development of GB1211 into other related indications, including cancer.

GB2064 is a selective oral inhibitor of LOXL2 that has demonstrated antifibrotic activity in lung, liver and kidney preclinical models of fibrosis. Our initial focus is developing GB2064 in myelofibrosis, one of the several types of cancer and multiple fibrotic diseases in which expression of LOXL2 is significantly increased. Myelofibrosis is a disease with significant morbidity and mortality that affects between 16,000 and 18,500 patients in the United States. The current standard of care for myelofibrosis consists of inhibitors of the JAK2 protein kinase, which alleviate the disease symptoms through inhibition of cell proliferation but do not directly target fibrosis. GB2064 has successfully completed a Phase 1 trial in 78 healthy volunteers, in which GB2064 administered orally led to dose-dependent inhibition of LOXL2 in serum. We believe that GB2064 has the potential to have a direct impact on the fibrotic process and to slow the progression of the disease as opposed merely to treating the underlying symptoms. We anticipate initiating a Phase 2 trial of GB2064 in myelofibrosis in , with data expected in .

### ***Our Strategy***

Our goal is to become a leader in developing and commercializing therapeutics that directly target the biological processes at the heart of fibrosis across a broad range of fibrotic and related diseases with significant unmet medical need. Our strategy is focused on the following key components:

- Efficiently advance GB0139 in IPF through clinical development.
- Build on our understanding of the galectin-3 target to advance GB1211 through a Phase 2a trial in fibrosis related to NASH and in additional indications.
- Leverage our understanding of the LOXL2 pathway to advance GB2064 through a Phase 2 trial in myelofibrosis and continue evaluating GB2064 in subsequent indications.
- Expand our antifibrotic portfolio by opportunistically advancing our research and development efforts beyond our current expertise in the Galectin-3 and LOXL2 pathways.
- Continue to build a patient-focused company targeting fibrosis across a broad range of fibrotic and related diseases.
- Maximize the commercial value of our product candidates.

### **Recent Developments**

The coronavirus disease 2019, or COVID-19, pandemic, which began in December 2019 and has spread worldwide, has caused many governments to implement measures to slow the spread of the outbreak through quarantines, travel restrictions, heightened border scrutiny and other measures. The outbreak and government measures taken in response have also had a significant impact, both directly and indirectly, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the outbreak and its effects on our business and operations are uncertain.

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In response to the impact of COVID-19, we have implemented certain measures intended to help us manage its impact and position ourselves to resume operations quickly and efficiently once these restrictions are lifted, such as executing a work-from-home strategy for administrative functions and operations.

Despite our implementation of such measures, the actual and perceived impact of the COVID-19 pandemic is changing daily, and its ultimate effect on us cannot be predicted. As a result, we cannot assure you that we will not experience additional negative impacts associated with COVID-19, which could be significant. The COVID-19 pandemic may negatively impact our business, financial condition and results of operations by decreasing or delaying the enrollment of patients in our clinical trials or otherwise causing interruptions or delays in our programs and services. See “Risk Factors—Risks Related to Managing Our Business and Operations —The global pandemic of the novel coronavirus disease, COVID-19, could adversely impact our business, including our preclinical studies and clinical trials” for more information regarding the potential impact of COVID-19 on our business and operations.

### **Risks Associated with Our Business**

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the “Risk Factors” section of this prospectus. These risks include the following:

- We have incurred significant net losses since inception and we expect to continue to incur significant net losses for the foreseeable future.
- We have a limited operating history, which may make it difficult to evaluate our prospects and likelihood of success.
- Our business is highly dependent on the success of our lead product candidate, GB0139, as well as GB1211, GB2064 and any other product candidates that we advance into the clinic.
- All of our product candidates may require significant additional preclinical and clinical development before we may be able to seek regulatory approval for and launch a product commercially.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- The design or execution of our ongoing and future clinical trials may not support marketing approval.
- We may not be successful in our efforts to identify or discover additional product candidates in the future.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.
- Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.



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- We rely on third parties to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.
- The global pandemic of the novel coronavirus disease, COVID-19, could adversely impact our business, including our preclinical studies and clinical trials.
- There has been no prior public market for our common stock, the stock price of our common stock may be volatile or may decline regardless of our operating performance and you may not be able to resell your shares at or above the initial public offering price.
- If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

## **Corporate Information**

We were formed under the laws of the State of Delaware in October 2019. Subsequently, shares in Galecto Biotech AB, a Swedish operating company, were exchanged at a one-to-one ratio for shares in Galecto, Inc. On December 31, 2019, we consummated a purchase agreement by and among Galecto, Inc., PK Merger Sub, Inc., and PharmAkea, Inc., or PharmAkea, whereby we acquired PharmAkea in principally an all-stock transaction. As of December 31, 2019, our wholly-owned subsidiaries were PharmAkea and Galecto Biotech AB, and Galecto ApS, a Danish operating company, was Galecto Biotech AB's wholly-owned subsidiary.

Our principal executive offices are located at Ole Maaloes Vej 3, DK-2200 Copenhagen N Denmark, and our telephone number is (+45) 70 70 52 10. Our website address is <http://www.galecto.com>. The information contained on, or that can be accessed through, our website is not a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

In this prospectus, unless otherwise indicated or the context otherwise requires, references to “Galecto,” “we,” “us,” “our” and similar references refer to Galecto, Inc. and its consolidated subsidiaries.

## **Implications of Being an Emerging Growth Company and a Smaller Reporting Company**

As a company with less than \$1.07 billion in revenue during our last fiscal year, we qualify as an emerging growth company, or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act. We may remain an EGC until the last day of the fiscal year in which the fifth anniversary of the closing of this offering occurs, although if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of June 30 of any year before that time or if we have annual gross revenues of \$1.07 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than \$1 billion of non-convertible debt over a three-year period. For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. 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 EGC. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock. We have elected to use the extended transition period for complying with new or revised accounting standards and will do so until such time that we either (1) irrevocably elect to “opt out” of such extended transition period or (2) no longer qualify as an EGC. As a result of this election, our consolidated financial statements may not be comparable to companies that comply with public company Financial Accounting Standards Board, or FASB, standards' effective dates.

## THE OFFERING

Common stock offered by us	shares.
Option to purchase additional shares	We have granted the underwriters an option to purchase up to additional shares of common stock from us. The underwriters can exercise this option at any time within 30 days from the date of this prospectus.
Common stock to be outstanding immediately after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares in full).
Use of proceeds	We estimate that we will receive net proceeds from the sale of our common stock in this offering of approximately \$ million, or \$ million if the underwriters exercise in full their option to purchase additional shares, assuming an initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering to fund the clinical development of our lead product candidate, GB0139, including to conduct our Phase 3 clinical trial in IPF, to fund the clinical development of our programs in myelofibrosis, NASH and oncology, for additional early-stage research and development activities, business development activities, working capital and other general corporate purposes. See the section entitled "Use of Proceeds" for additional information.
Risk factors	You should read carefully the section entitled "Risk Factors" and other information included in this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock.
Proposed Nasdaq Global Market symbol	"GLTO"

The number of shares of our common stock to be outstanding after this offering is based on shares of common stock outstanding as of and excludes:

- shares of our common stock issuable upon the exercise of options outstanding as of , under the 2020 Stock Option and Grant Plan, or the 2020 Plan, at a weighted-average exercise price of \$ per share;
- shares of our common stock reserved for future issuance under the 2020 Plan as of ; and
- shares of our common stock reserved for future issuance under our 2020 Incentive Equity Plan.

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Unless otherwise indicated, this prospectus reflects and assumes the following:

- a 1-for- reverse stock split of our common stock to be effected on , 2020;
- the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of shares of our common stock immediately prior to the completion of this offering;
- no exercise of the outstanding options or purchase rights described above;
- no exercise by the underwriters of their option to purchase up to additional shares of our common stock in this offering; and
- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, which will occur immediately prior to the completion of this offering.

### Summary Financial Data

You should read the following summary financial data together with our financial statements and the related notes appearing elsewhere in this prospectus and the “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections of this prospectus. We have derived the statement of operations data for the years ended December 31, 2019 and 2018 from our audited financial statements appearing elsewhere in this prospectus. The unaudited interim condensed financial statements have been prepared on the same basis as our audited financial statements and reflect, in the opinion of management, all adjustments of a normal, recurring nature that are necessary for a fair statement of the financial information included in those unaudited interim condensed financial statements. Our historical results are not necessarily indicative of the results that may be expected the future, and our results for any interim period are not necessarily indicative of results that may be expected for any full year.

	<u>Year Ended December 31,</u>	
	<u>2019</u>	<u>2018</u>
Operating expenses		
Research and development	\$ 19,738	\$ 10,093
Purchased in-process research and development	16,788	—
General and administrative	2,445	2,814
Total operating expenses	<u>38,971</u>	<u>12,907</u>
Loss from operations	(38,971)	(12,907)
Other income (expense), net	2,464	(2,962)
Net loss	\$ (36,507)	\$ (15,869)
Cumulative dividends on convertible preferred stock	(5,560)	(3,136)
Net loss attributable to common stockholders	\$ (42,067)	\$ (19,005)
Net loss per common share – basic and diluted (1)	\$ (420.67)	\$ (190.05)
Weighted-average number of shares used in computing net loss per common share – basic and diluted (1)	100,000	100,000
Pro forma net loss per common share – basic and diluted (1)	\$ (13.21)	
Weighted-average number of shares used in computing pro forma net loss per share – basic and diluted (1)	<u>2,763,166</u>	

- (1) See Notes 14 and 15 to our consolidated financial statements as of and for the years ended December 31, 2019 and 2018 appearing elsewhere in this prospectus for details on the calculation of basic and diluted net loss per share attributable to common shareholders and unaudited basic and diluted pro forma net loss per common share.

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	As of December 31, 2019		
	Actual	Pro Forma(1)	Pro Forma As Adjusted(2)
Balance Sheet Data:			
Cash and cash equivalents	\$ 11,294	\$ 50,794	
Total assets	56,609	56,609	
Working capital (3)	48,682	48,682	
Total liabilities	8,138	8,138	
Convertible preferred stock	119,619	—	
Accumulated deficit	(69,523)	(69,523)	
Total stockholders' (deficit) equity	(71,148)	87,971	

- (1) The pro forma balance sheet data give effect to (i) our issuance in January 2020 of an aggregate of 1,199,143 Series C-4 preferred shares and 342,612 Series C-5 preferred shares for gross proceeds of \$39.7 million and (ii) the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 4,809,124 shares of our common stock upon the closing of this offering.
- (2) The pro forma as adjusted balance sheet data give further effect to our issuance and sale of \_\_\_\_\_ shares of our common stock in this offering at the initial public offering price of \$ \_\_\_\_\_ per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.
- (3) We define working capital as current assets less current liabilities.

The pro forma as adjusted information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. A \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, working capital, total assets and total stockholders' (deficit) equity by \$ \_\_\_\_\_, 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 estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, an increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, working capital, total assets and total stockholders' (deficit) equity by \$ \_\_\_\_\_, assuming no change in the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our financial statements and related notes appearing elsewhere in this prospectus and in the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.*

### **Risks Related to Our Financial Position and Need for Additional Capital**

*We have incurred significant net losses since inception and we expect to continue to incur significant net losses for the foreseeable future.*

We have incurred significant net losses since our inception and have financed our operations principally through equity and debt financing. We continue to incur significant research and development and other expenses related to our ongoing operations. For the years ended December 31, 2019 and 2018, we reported a net loss of \$36.5 million and \$15.9 million, respectively. As of December 31, 2019, we had an accumulated deficit of \$69.5 million. We have devoted substantially all of our resources and efforts to research and development, and we expect that it will be several years, if ever, before we generate revenue from product sales. Even if we receive marketing approval for and commercialize one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to develop and market additional potential product candidates.

We expect to continue to incur significant losses for the foreseeable future, and we anticipate that our expenses will increase substantially if, and as, we:

- advance our lead product candidate, GB0139, our other current product candidates and any future product candidates through clinical development, and, if successful, later-stage clinical trials;
- advance our preclinical development programs into clinical development;
- experience delays or interruptions to preclinical studies, clinical trials, our receipt of services from our third-party service providers on whom we rely, or our supply chain, including delays due to the COVID-19 pandemic;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- commercialize GB0139, our other current product candidates and any future product candidates, if approved;
- increase the amount of research and development activities to discover and develop product candidates;
- hire additional clinical development, quality control, scientific and management personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development and manufacturing efforts, general and administrative functions and our operations as a public company;

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- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties;
- maintain, expand and protect our intellectual property portfolio; and
- invest in or in-license other technologies or product candidates.

To become and remain profitable, we must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, marketing and selling products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

***Even if this offering is successful, we will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs, future commercialization efforts or other operations.***

Developing biotechnology and biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our planned clinical trials of GB0139, our other current product candidates and any future product candidates that we may develop, seek regulatory approvals for any of our product candidates and to launch and commercialize any products for which we receive regulatory approval. Following this offering, we also expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and drug development programs or future commercialization efforts.

As of December 31, 2019, we had approximately \$11.3 million in cash, cash equivalents and short-term investments. Based on our current operating plan, we believe that the net proceeds from this offering, together with existing cash, cash equivalents and short-term investments, will be sufficient to fund our operating expenses and capital expenditure requirements into . However, our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect, and in any event, we will require additional capital in order to complete clinical development of any of our current programs. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development, marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates;
- the clinical development plans we establish for these product candidates;

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- the timelines of our clinical trials and the overall costs to finish the clinical trials due to the COVID-19 pandemic;
- the number and characteristics of product candidates that we develop;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the European Medicines Agency, or EMA, and other comparable foreign regulatory authorities;
- whether we are able to enter into and maintain collaboration agreements, including the terms of and timing of payments under any such agreements;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the effect of competing clinical, technological and market developments;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, if at all. Until we can generate sufficient revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also may be required to seek collaborators for any of our product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. Market volatility resulting from the COVID-19 pandemic or other factors could also adversely impact our ability to access capital as and when needed. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.



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***The amount of our future losses is uncertain and our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.***

Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and success or failure of 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;
- our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts;
- our ability to obtain marketing approval for our product candidates, and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates;
- general market conditions or extraordinary external events, such as a recession or the COVID-19 pandemic;
- the changing and volatile U.S. and global economic environments; and
- future accounting pronouncements or changes in our accounting policies.

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. 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 guidance we may provide.

***We, as well as our independent registered public accounting firm, have expressed substantial doubt about our ability to continue as a going concern.***

Our recurring losses from operations and negative cash flow raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an

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explanatory paragraph in its report on our financial statements for the years ended December 31, 2019 and 2018 with respect to this uncertainty. Our ability to continue as a going concern will require us to obtain additional funding. We believe that the net proceeds from this offering and our existing cash will be sufficient to fund our current operating plans through . We have based these estimates, however, on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect and need to raise additional funds sooner than we anticipate. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate our research and development programs and commercialization efforts.

### **Risks Related to Research and Development and the Biotechnology and Biopharmaceutical Industry**

*We have a limited operating history, which may make it difficult to evaluate our prospects and likelihood of success.*

We are a clinical-stage biotechnology company with a limited operating history. We were founded as Galecto Biotech AB, a Swedish operating company, in 2011 and incorporated in Delaware as Galecto, Inc. in October 2019, have no products approved for commercial sale and have not generated any revenue. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and performing research and development of our product candidates. Our approach to the discovery and development of product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value. In addition, our product candidates, including our lead product candidate, GB0139, for the treatment of IPF, GB1211, for the treatment of NASH, and GB2064 for the treatment of myelofibrosis, are in the early stages of clinical development. These three programs will require substantial additional development and clinical research time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We have not yet demonstrated the ability to progress any product candidate through later-stage clinical trials leading to successful marketing authorization. We may be unable to obtain regulatory approval, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, achieve market access, and acceptance with insurers and health care providers, or conduct sales and marketing activities necessary for successful product commercialization. Investment in biotechnology and biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage biotechnology and biopharmaceutical companies in rapidly evolving fields. Consequently, we have no meaningful history of operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing drug products.

*Our business is highly dependent on the success of our lead product candidate, GB0139, as well as GB1211, GB2064 and any other product candidates that we advance into the clinic. All of our product candidates may require significant additional preclinical and clinical development before we may be able to seek regulatory approval for and launch a product commercially.*

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We are very early in our development efforts, and our product candidates, including GB0139, are in early clinical development. Because GB0139 is our lead product candidate, if GB0139 encounters safety or efficacy problems, development delays, regulatory issues or other problems, our development plans and business would be significantly harmed. We have conducted a placebo-controlled Phase 2a multi-dose trial of GB0139 in 24 IPF patients. We are currently conducting a Phase 2b placebo-controlled clinical trial of GB0139 in 450 IPF patients. The primary endpoint of the trial is to assess annual rate of decline in FVC after one year of dosing. Reduction in decline of FVC is the surrogate endpoint that was accepted by the FDA for the approval of both of the

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currently approved treatments for IPF. We anticipate that results from this trial will become available in . We believe that a positive result in this trial has the potential to support an application for conditional approval of GB0139 in the European Union, or EU, and that the trial also has the potential to be regarded as a registrational trial in the United States, but the EMA and FDA ultimately may not agree with our beliefs.

Before we can generate any revenue from sales of our lead product candidate, GB0139, or any of our other product candidates, we must undergo additional preclinical and clinical development, regulatory review and approval in one or more jurisdictions. In addition, if one or more of our product candidates are approved, we must ensure access to sufficient commercial manufacturing capacity and conduct significant marketing efforts in connection with any commercial launch. These efforts will require substantial investment, and we may not have the financial resources to continue development of our product candidates.

We may experience setbacks that could delay or prevent regulatory approval of, or our ability to commercialize, our product candidates, including:

- negative or inconclusive results from our preclinical studies or clinical trials or positive results from the clinical trials of others for product candidates similar to ours leading to their approval, and evolving to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- product-related side effects experienced by patients or subjects in our clinical trials or by individuals using drugs or therapeutics that we, the FDA, other regulators or others view as relevant to the development of our product candidates;
- delays in submitting investigational new drug, or IND, applications or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials, including our clinical endpoints;
- delays in enrolling subjects in clinical trials, including due to the COVID-19 pandemic;
- high drop-out rates of subjects from clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;
- greater than anticipated clinical trial costs;
- inability to compete with other therapies;
- poor efficacy of our product candidates during clinical trials;
- trial results taking longer than anticipated;
- trials being subjected to fraud or data capture failure or other technical mishaps leading to the invalidation of our trials in whole or in part;
- the results of our trials not supporting application for conditional approval in the EU;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;

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- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays related to the impact of the spread of the COVID-19 pandemic, including the impact of COVID-19 on the FDA's ability to continue its normal operations;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical development generally or with respect to our technology in particular; or
- varying interpretations of data by the FDA and similar foreign regulatory agencies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and our manufacturing, marketing, distribution and sales efforts or that of any future collaborator.

***Clinical development involves a lengthy, complex and expensive process, with an uncertain outcome, and the results of preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials.***

To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. In particular, the general approach for FDA approval of a new drug is dispositive data from two well-controlled, Phase 3 clinical trials of the relevant drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. A product candidate can fail at any stage of testing, even after observing promising signals of activity in earlier preclinical studies or clinical trials. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biotechnology and biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as therapeutic products, and there can be no assurance that any of our future clinical trials will ultimately be successful or support further clinical development of GB0139 or any of our other product candidates. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- preclinical studies or clinical trials may show the product candidates to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or to have unacceptable side effects or toxicities;
- failure to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- failure to receive the necessary regulatory approvals;
- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make a product candidate uneconomical; and

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- the proprietary rights of others and their competing products and technologies that may prevent one of our product candidates from being commercialized.

In addition, differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products.

Additionally, we expect that some of our trials will be open-label studies, where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Therefore, it is possible that positive results observed in open-label trials will not be replicated in later placebo-controlled trials.

In addition, the standards that the FDA and comparable foreign regulatory authorities use when regulating our product candidates require judgment and can change, which makes it difficult to predict with certainty how they will be applied. Although we are initially focusing our efforts on development of small-molecule drug products, we may in the future pursue development of biological products, which could make us subject to additional regulatory requirements. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations. Examples of such regulations include future legislation or administrative action, or changes in FDA policy during the period of product development and FDA regulatory review. We cannot predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidates that we develop.

We are currently conducting clinical trials in foreign countries, as well as in the United States. If we continue to seek to conduct clinical trials in foreign countries or pursue marketing approvals in foreign jurisdictions, we must comply with numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval from foreign regulatory agencies may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the United States and vice versa.

Successful completion of clinical trials is a prerequisite to submitting a marketing application to the FDA and similar marketing applications to comparable foreign regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates. We may experience negative or inconclusive results, which may result in our deciding, or our being required by regulators, to conduct additional clinical studies or trials or abandon some or all of our product development programs, which could have a material adverse effect on our business.

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### ***We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of GB0139 or any of our other product candidates in development.***

We may experience delays in initiating or completing clinical trials. We also may experience numerous unforeseen events during, or as a result of, any future clinical trials that could delay or prevent our ability to receive marketing approval for, or to commercialize, GB0139 or any of our other product candidates in development, including:

- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA or other comparable regulatory authorities may disagree with our clinical trial design, including with respect to dosing levels administered in our planned clinical trials, which may delay or prevent us from initiating our clinical trials with our originally intended trial design;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- due to the impact of the COVID-19 pandemic, we have experienced, and may continue to experience, delays and interruptions to our preclinical studies and clinical trials, we may experience delays or interruptions to our manufacturing supply chain, or we could suffer delays in reaching, or we may fail to reach, agreement on acceptable terms with third-party service providers on whom we rely;
- additional delays and interruptions to our clinical trials could extend the duration of the trials and increase the overall costs to finish the trials as our fixed costs are not substantially reduced during delays;
- we may elect to, or regulators, IRBs, Data Safety Monitoring Boards, or DSMBs, or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- we may not have the financial resources available to begin and complete the planned trials, or the cost of clinical trials of any product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate to initiate or complete a given clinical trial; and
- the FDA or other comparable foreign regulatory authorities may require us to submit additional data such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

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Our product development costs will increase if we experience additional delays in clinical testing or in obtaining marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. If we do not achieve our product development goals in the time frames we announce and expect, the approval and commercialization of our product candidates may be delayed or prevented entirely. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly.

***Our ongoing and future clinical trials may reveal significant adverse events or unexpected drug-drug interactions not seen in our preclinical studies and may result in a safety profile that could delay or prevent regulatory approval or market acceptance of any of our product candidates.***

We have completed a placebo-controlled Phase 2a multi-dose trial of GB0139 in 24 IPF patients and, with the exception of a number of minor reported adverse events (fever, upper respiratory tract infection, abnormal taste in mouth, dry throat), GB0139 was observed to be well-tolerated in these patients with no serious drug-related adverse events. We are currently conducting a double-blind placebo-controlled Phase 2b trial of GB0139 with the goal of enrolling 450 IPF patients. If significant adverse events or other side effects are observed in any of our ongoing or future clinical trials, including of GB0139 for the treatment of IPF, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts altogether. Some potential therapeutics developed in the biotechnology and biopharmaceutical industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies.

***If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.***

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- the willingness or availability (including legality under applicable COVID-19 shelter-in-place regulations) of patients to participate in our trials (including due to fears of contracting COVID-19);
- the willingness of investigators and other third parties to support patient enrollment due to concerns surrounding the COVID-19 pandemic;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;

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- 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 products that may be approved for the indications we are investigating;
- the availability of competing commercially available therapies and other competing product candidates' clinical trials;
- our ability to obtain and maintain patient informed consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

For example, we are initially developing GB0139 for the treatment of IPF, which is an orphan indication. In the United States, IPF is estimated to affect approximately 140,000 patients. As a result, we may encounter difficulties enrolling subjects in our clinical trials of GB0139 due, in part, to the small size of this patient population. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Certain of our planned clinical trials may also involve invasive procedures such as bronchoscopy and bronchoalveolar lavage, or BAL, procedure, which may lead some patients to drop out of trials to avoid these follow-up procedures.

Further, timely enrollment in clinical trials is reliant on clinical trial sites which may be adversely affected by global health matters, including, among other things, pandemics. For example, the COVID-19 pandemic has affected certain of our clinical trial sites as they have not been allowed to enroll or recruit patients and other sites have not been able to receive patient visits, which has resulted in the need to amend our protocol. Further, certain sites have not been able to receive visits from us or our representatives and the opening of such sites has been stalled. In addition, after enrollment in these trials, if patients contract COVID-19 during participation in our trials or are subject to isolation or shelter-in-place restrictions, they may drop out of our trials, miss scheduled doses or follow-up visits or otherwise fail to follow trial protocols. If patients are unable to follow the trial protocols or if our trial results are otherwise disputed due to the effects of the COVID-19 pandemic or actions taken to mitigate its spread, the integrity of data from our trials may be compromised or not accepted by the FDA or other regulatory authorities, which would represent a significant setback for the applicable program.

Some factors from the COVID-19 pandemic that we believe may adversely affect enrollment in our trials include:

- the diversion of healthcare resources away from the conduct of clinical trial matters to focus on pandemic concerns, including the attention of infectious disease physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- given that our clinical trial of GB0139 will be enrolling patients who have a respiratory illness, some patients who would otherwise be candidates for enrollment in this clinical trial are at increased risk of severe effects of the coronavirus, which may kill some patients and render others too ill to participate, limiting the available pool of participants for our trials;
- the inability of patients to come to hospitals and universities to participate in our trials, which may force us to change our protocols, rendering the trials more difficult and costly to conduct;



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- the fact that there can be no guarantee that any proposed changes to our protocols, if necessary, would be acceptable to regulators;
- limitations on travel that interrupt key trial activities, such as clinical trial site initiations and monitoring;
- interruption in global shipping affecting the transport of clinical trial materials being used in our trials; and
- employee furlough days that delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

These and other factors arising from the COVID-19 pandemic could worsen in countries that are already afflicted with the virus or could continue to spread to additional countries, each of which may further adversely impact our clinical trials. The global outbreak of the COVID-19 pandemic continues to evolve and the conduct of our trials may continue to be adversely affected, despite efforts to mitigate this impact.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our future clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

### ***The design or execution of our ongoing and future clinical trials may not support marketing approval.***

The design or execution of a clinical trial can determine whether its results will support marketing approval, and flaws in the design or execution of a clinical trial may not become apparent until the clinical trial is well advanced. Additionally, in some instances, there can be significant variability in safety or efficacy results between different trials with the same product candidate due to numerous factors, including differences in trial protocols, size and type of the patient populations, variable adherence to the dosing regimen or other protocol requirements and the rate of dropout among clinical trial participants. We do not know whether any clinical trials we conduct will demonstrate consistent or adequate efficacy and safety to obtain marketing approval to market our product candidates. For example, we have designed our product candidates to be selective, but they may not be selective enough to achieve the desired safety or efficacy or gain marketing approval.

Additionally, we are currently testing GB0139 both as a monotherapy and in combination with nintedanib or pirfenidone. Although we may be able to observe activity of GB0139 as a monotherapy, it may be difficult to observe activity of GB0139 when it is administered with an agent approved for decelerating a reduction in lung function in IPF patients. Similarly, the addition of GB0139 to nintedanib or pirfenidone may give rise to side effects that were not anticipated based on preclinical studies or early clinical studies in which GB0139 was given as a monotherapy. We are unable to predict how the future results of our combination therapy trial cohorts could affect the prospects for securing marketing approval of GB0139.

Further, the FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether marketing approval will be obtained for any of our product candidates. Our product candidates may not be approved even if they achieve their primary endpoints in future Phase 3 clinical trials or registrational trials. The FDA or comparable foreign regulatory authorities may disagree with our trial designs and our interpretation of data from preclinical studies or clinical trials. In addition, any of these regulatory authorities may change the requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 or registrational clinical trial. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. The FDA or comparable foreign regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates, if approved.

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*We have obtained orphan drug designation for GB0139; however, we may be unable to maintain this designation or obtain orphan drug designation for our other product candidates, and we may not be able to realize the benefits of such designation, including potential marketing exclusivity of our product candidates, if approved.*

As part of our business strategy, we sought and have received orphan drug designation for treatment of IPF for GB0139; however, we may not be able to maintain this status. We may also seek orphan drug designation for future product candidates, and we may be unsuccessful in obtaining this designation. Regulatory authorities in some jurisdictions, including the United States and other major markets, may designate drugs intended to treat conditions or diseases affecting relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in Europe, the European Commission grants orphan drug designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an orphan drug designation application. Orphan drug designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, orphan drug designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Generally, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or EMA from approving another marketing application for a product that constitutes the same drug treating the same indication for that marketing exclusivity period, except in limited circumstances. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug or biologic no longer meets the criteria for orphan drug designation or if the drug or biologic is sufficiently profitable such that market exclusivity is no longer justified. Orphan drug exclusivity may be revoked if any regulatory agency determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Even though we have obtained orphan drug designation for GB0139, and even if we are able to obtain orphan drug exclusivity for a future product candidate, that exclusivity may not effectively protect the relevant product candidate from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off-label for the orphan disease. Even after an orphan drug is approved, the FDA may subsequently approve another product for the same condition if the FDA concludes that the latter product is not the same product or is clinically superior to the protected orphan drug because it is shown to be safer or more effective, or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the orphan indication for which it was designated. Moreover, 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 if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug

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nor gives the drug any advantage in the regulatory review or approval process. While we have obtained orphan drug designation for GB0139, we may not be able to maintain such designations; and while we may seek orphan drug designation for applicable indications for any future product candidates, we may never receive such designations. Even though we have received such designations for GB0139, and may receive further such designations in the future, there is no guarantee that we will enjoy the benefits of those designations.

***Breakthrough Therapy designation and Fast Track designation by the FDA, neither of which has been obtained, even if granted for any of our current or future product candidates, may not lead to a faster development or regulatory review process, and such designations do not increase the likelihood that any of our product candidates will receive marketing approval in the United States.***

We intend to evaluate regulatory strategies that could enable us to take advantage of expedited development pathways for certain of our product candidates, although we cannot be certain that our product candidates will qualify for any expedited development pathways or that regulatory authorities will grant, or allow us to maintain, the relevant designations. Potential expedited development pathways that we could pursue include breakthrough therapy and Fast Track designation.

Breakthrough Therapy designation is intended to expedite the development and review of product candidates that are designed to treat serious or life-threatening diseases when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation of a product candidate as a breakthrough therapy provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate and ensure collection of appropriate data needed to support approval; more frequent written correspondence from FDA about such things as the design of the proposed clinical trials and use of biomarkers; intensive guidance on an efficient drug development program, beginning as early as Phase 1; organizational commitment involving senior managers; and eligibility for rolling review and priority review.

Fast Track designation is designed for product candidates intended for the treatment of a serious or life-threatening disease or condition, where nonclinical or clinical data demonstrate the potential to address an unmet medical need for this disease or condition. The designation of a product candidate as Fast Track provides potential benefits that include more opportunities for frequent interaction and communication with FDA during product development and eligibility for rolling review and priority review.

Even if we believe a particular product candidate is eligible for Breakthrough Therapy or Fast Track designation, we cannot assure you that the FDA would decide to grant such a designation in response to our written requests. Breakthrough Therapy designation and Fast Track designation do not change the standards for product approval, and there is no assurance that such designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the Breakthrough Therapy designation or Fast Track designation. Thus, even if we do receive Breakthrough Therapy or Fast Track designation for any of our product candidates, we may not experience a faster development process, review or marketing approval compared to conventional FDA procedures. The FDA may withdraw Breakthrough Therapy or Fast Track designation if it believes that the product no longer meets the qualifying criteria. Our business may be harmed if we are unable to avail ourselves of these or any other expedited development and regulatory pathways.

***Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.***

As product candidates progress through preclinical to late-stage clinical trials to marketing approval and commercialization, various aspects of the development program, such as manufacturing methods and the product's formulation, may be altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. These changes carry the risk that they will not achieve

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their intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate revenue.

In addition, there are risks associated with process development and large-scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Even if we obtain marketing approval for any of our product candidates, there is no assurance that our third-party manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. Additionally, if we advance a biological candidate into IND-enabling studies, the manufacturing processes for biological products is more complex and expensive than with small-molecule products and additional manufacturing suppliers may be needed to manufacture clinical supplies for these programs. If our contract manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

***We may not be successful in our efforts to identify or discover additional product candidates in the future.***

Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our inability to design such product candidates with the pharmacological properties that we desire or attractive pharmacokinetics;
- our inability to design and develop a suitable manufacturing process; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be medicines that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable compounds for preclinical and clinical development, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price.

***Due to our limited resources and access to capital, we must make decisions on the allocation of resources to certain programs and product candidates; these decisions may prove to be wrong and may adversely affect our business.***

We have limited financial and human resources and intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. In addition, we may seek to accelerate our development timelines, including by initiating certain clinical trials of our product candidates before earlier-stage studies have been completed. This approach may cause us to commit significant resources to prepare for and conduct later-stage trials for one or more product candidates that subsequently fail earlier-stage clinical testing. Therefore, our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities, or expend resources on product candidates that are not viable.

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There can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

***If product liability lawsuits are brought against us, we may incur substantial financial or other liabilities and may be required to limit commercialization of our product candidates.***

We face an inherent risk of product liability as a result of testing GB0139 and any of our other product candidates in clinical trials and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, 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, negligence, strict liability or a breach of warranties. 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 commercialization of our product candidates. Even a successful defense of these claims would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- inability to bring a product candidate to the market;
- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- fines, injunctions or criminal penalties;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate, if approved; and
- decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We will need to obtain additional insurance for clinical trials as GB0139, and any of our other product candidates continue clinical development and as additional product candidates enter the clinic. However, we may be unable to obtain, or may obtain on unfavorable terms, clinical trial insurance in amounts adequate to cover any liabilities

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from any of our clinical trials. Our insurance policies may 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. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

### ***We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us.***

The development and commercialization of new drug products is highly competitive. We may face competition with respect to any product candidates that we seek to develop or commercialize in the future from major biotechnology and biopharmaceutical companies, specialty biotechnology and biopharmaceutical companies, and other biotechnology and biopharmaceutical companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

There are a number of large biotechnology and biopharmaceutical companies that are currently pursuing the development of products for the treatment of the biological processes that drive fibrosis and other indications we are pursuing. Companies that we are aware of that are targeting the treatment of various fibrosis indications include large companies with significant financial resources such as Pharmaxis Ltd, Biogen, Inc., AbbVie Inc., Gilead Sciences, Inc., Pliant Therapeutics, Inc., Galectin Therapeutics, Inc., FibroGen, Inc., Liminal BioSciences, Inc., Galapagos NV, Bristol Myers Squibb Co., Madrigal, Constellation Pharmaceuticals, Inventiva, Akerio Therapeutics, Inc., Roche Holding AG and Novartis AG. However, we know of no other companies currently in clinical development with an inhaled or orally available small-molecule inhibitor of galectin-3 or an orally available small-molecule inhibitor of LOXL2 for myelofibrosis. For additional information regarding our competition, see “Business—Competition.”

Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do.

Mergers and acquisitions in the biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, more convenient, or less expensive than any products that we may develop. Furthermore, products currently approved for other indications could be discovered to be effective treatments of the biological processes that drive fibrosis as well, which could give such products significant regulatory and market timing advantages over GB0139 or other product candidates that we may identify. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we do, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete and we may not be successful in marketing any product candidates we may develop against competitors. The availability of competitive products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

***We have identified a material weakness in our internal control over financial reporting. If our remediation of this material weakness is not effective, or if we experience additional material weaknesses or otherwise fail to***

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*maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations.*

In connection with our preparation and the audits of our financial statements as of and for the years ended December 31, 2019 and 2018, our independent registered public accounting firm identified a material weakness as defined under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and by the Public Company Accounting Oversight Board (United States) in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's financial statements will not be prevented or detected on a timely basis.

The material weakness related to our financial statement closing process, primarily related to the lack of sufficient skilled personnel with U.S. generally accepted accounting principles, or U.S. GAAP, and Securities and Exchange Commission, or SEC, reporting knowledge and expertise for purposes of timely and reliable financial reporting and our dependence on third-party service providers for the preparation and closing of our financial records. Specifically, the material weakness identified relates to the lack of appropriate internal controls over the work performed by the third-party service providers and that, as a result thereof, management failed to timely identify material misstatements in accounting for our debt and equity instruments, research and development, and taxation.

We are working to remediate the material weakness and are taking steps to strengthen our internal control over financial reporting such as the hiring of Jonathan Freve as Chief Financial Officer in Q2 2020. Additionally, we plan to further develop and implement formal policies, processes and documentation procedures relating to our financial reporting, including the oversight of third-party service providers. The actions that we are taking are subject to ongoing executive management review and will also be subject to audit committee oversight. If we are unable to successfully remediate the material weakness, or if in the future, we identify further material weaknesses in our internal controls over financial reporting, we may not detect errors on a timely basis, and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company, we will be required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Global Select Market or other adverse consequences that would materially harm our business. In addition, we could become subject to investigations by Nasdaq, the SEC, and other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and our financial condition, or divert financial and management resources from our core business.

Neither our management nor an independent registered public accounting firm has performed an evaluation of our internal control over financial reporting in accordance with the provision of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, because no such evaluation has been required. Had we or our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses may have been identified.

## Risks Related to Marketing, Reimbursement, Healthcare Regulations and Ongoing Regulatory Compliance

*Even if a product candidate we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.*

Even if GB0139 or any other product candidate we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, such as Medicare and Medicaid programs and managed care organizations, and others in the medical community. In addition, the availability of coverage by third-party payors may be affected by existing and future health care reform measures designed to reduce the cost of health care. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable.

The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages of our current or future product candidates compared to alternative treatments;
- limitations or warnings contained in the labeling approved for our current or future product candidates by the FDA or other applicable regulatory authorities;
- the clinical indications for which our current or future product candidates are approved;
- availability of alternative treatments already approved or commercially launched in the future;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the recommendations with respect to our product candidates in guidelines published by various scientific organizations applicable to us and our product candidates;
- the strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement; and
- the prevalence and severity of any side effects.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our products are safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable. If government and other third-party payors do not provide coverage and adequate reimbursement levels for any products we commercialize, market acceptance and commercial success would be reduced.



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*Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably.*

In the United States and in other countries, patients who are prescribed treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States, sales of any products for which we may receive regulatory marketing approval will depend, in part, on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities such as Medicare, Medicaid, TRICARE, and the Veterans Administration, managed care providers, private health insurers, and other organizations. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Government authorities and other third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

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

Our ability to commercialize any products successfully will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government health care programs and private health insurers. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for our products can differ significantly from payor to payor. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the

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use of product candidates, once approved. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates, if approved.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug and biologic benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs and biologics. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs and biologics, and each drug plan can develop its own formulary that identifies which drugs and biologics it will cover, and at what tier or level. However, Part D prescription drug formularies must include products within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs and biologics in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs and biologics may increase demand for products for which we obtain marketing approval. Any negotiated prices for any of our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug or biologic product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the average manufacturer price, or AMP, and Medicaid rebate amounts reported by the manufacturer. As of 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, expanded the types of entities eligible to receive discounted 340B pricing, although under the current state of the law these newly eligible entities (with the exception of children's hospitals) will not be eligible to receive discounted 340B pricing on orphan drugs. As the required 340B discount is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. The Centers for Medicare & Medicaid Services, or CMS, has previously and may in the future implement reductions in Medicare Part B reimbursement for 340B drugs through notice and comment rulemaking. It is unclear how such reimbursement reductions could affect covered hospitals who might purchase our products in the future, and affect the rates we may charge such facilities for our approved products.

Changes to these current laws and state and federal healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

***Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.***

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the

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introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

***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 any products for which we obtain regulatory approval, 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 expect to establish 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. We have no prior experience as a company in the marketing, sale and distribution of pharmaceutical 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 also choose to 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 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 and for which we receive regulatory approval 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 relationships with healthcare providers, physicians, prescribers, purchasers, third-party payors, charitable organizations and patients will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of biotechnology and biopharmaceutical products. Arrangements with third-party payors and customers can expose biotechnology and biopharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute, or AKS, and the federal False Claims Act, or FCA, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute biotechnology and biopharmaceutical products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

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- the AKS, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation 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 the Medicare and Medicaid programs. The term “remuneration” has been broadly interpreted to include anything of value. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, a claim submitted for payment to any federal health care program that includes items or services that were made as a result of a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA. The AKS has been interpreted to apply to arrangements between biotechnology and biopharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers, among others, on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- the federal civil and criminal false claims laws, including the FCA, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs; knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. A claim that includes items or services resulting from a violation of the AKS constitutes a false or fraudulent claim under the FCA. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring *qui tam* actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the AKS, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, requirements relating to the privacy, security and transmission of individually identifiable health information on certain covered healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their respective “business associates,” those independent contractors or agents of covered entities that perform services for covered entities that involve the creation, use, receipt, maintenance or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions;

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- the federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which require some 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 CMS information related to payments or 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 physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made in the previous year to certain non-physician providers such as physician assistants and nurse practitioners;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state and foreign laws that require biotechnology and biopharmaceutical companies to comply with the biotechnology and biopharmaceutical 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 and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state and local laws that require the registration of biotechnology and biopharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The distribution of biotechnology and biopharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of biotechnology and biopharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from other aspects of its business.

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, reputational harm, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Any action for violation of these laws, even if successfully defended, could cause a biotechnology and biopharmaceutical manufacturer to incur significant legal expenses and divert management's

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attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

***Even if we receive regulatory approval of any product candidates, we will be subject to ongoing post-marketing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.***

If any of our product candidates are approved, they will be subject to ongoing post-marketing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with current good manufacturing practice, or cGMP, for any drug products we distribute and with good clinical practice, or GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and their facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, 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, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or product recalls;
- fines, warning 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 withdrawal of approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- consent decrees or injunctions or the imposition of civil or criminal penalties.

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Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is not inconsistent with the labeling. 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 liability. The policies of the FDA and of other regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

***Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.***

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, changes to our manufacturing arrangements; additions or modifications to product labeling; the recall or discontinuation of our products; or additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and likely will continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U.S. biotechnology and biopharmaceutical industries. The ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, 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, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts from the 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.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are scheduled for November 10, 2020. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business. In addition, the Trump administration has issued various Executive Orders, which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Additionally, Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. On December 20, 2019, President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repeals the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, created measures for spending reductions by

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Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs, including aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, or BBA, will remain in effect through 2030, unless additional congressional action is taken. However, these Medicare sequester reductions will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. The BBA also amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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 product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

At the federal level, the Trump administration's budget for fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. The Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained 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, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule that would allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. On July 24, 2020, President Trump signed four Executive Orders aimed at lowering drug prices. The Executive Orders direct the Secretary of HHS to: (1) eliminate protection under an AKS safe harbor for certain retrospective price reductions provided by drug manufacturers to sponsors of Medicare Part D plans or pharmacy benefit managers that are not applied at the point-of-sale; (2) allow the importation of certain drugs from other countries through individual waivers, permit the re-importation of insulin products, and prioritize finalization of the proposed rule to permit the importation of drugs from Canada; (3) ensure that payment by the Medicare program for certain Medicare Part B drugs is not higher than the payment by other comparable countries (depending on whether pharmaceutical manufacturers agree to other measures); and (4) require Federally Qualified Health Centers, or FQHCs, participating in the 340B drug program to provide insulin and injectable epinephrine to certain low-income individuals at the discounted price paid by the FQHC, plus a minimal administrative fee. On August 6, 2020, President Trump signed an additional Executive Order directing U.S. government agencies to encourage the domestic procurement of Essential Medicines, Medical Countermeasures, and Critical Inputs, which include among other things, active pharmaceutical ingredients and drugs intended for use in the diagnosis, cure, mitigation, treatment, or prevention of COVID-19. The FDA has been directed to release a full list of Essential



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Medicines, Medical Countermeasures, and Critical Inputs affected by this Order by November 5, 2020. Although a number of these and other measures may require additional authorization 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. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biologic 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.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Additionally, we expect to experience pricing pressures in connection with the sale of any future approved product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

***Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to temporarily postpone most inspections of foreign manufacturing facilities and products. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials, which has since been further updated. As of June 23, 2020, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to maintain this pace and delays or setbacks are possible in the future. On July 10, 2020, the FDA announced its goal of restarting domestic on-site inspections, but such activities will depend on data about the virus' trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, upon completion of this offering and in our operations as a

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public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

### ***EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the European member states.***

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future health care reform measures.

Much like the AKS prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of EU member states, and in respect of the United Kingdom, or U.K. (which is no longer a member of the EU), the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU member states. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in most foreign countries, including the European Economic Area, or EEA, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for biotechnology and biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the United States, and generally, prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales and the potential profitability of any of our product candidates in those countries would be negatively affected.

***We may incur substantial costs in our efforts to comply with evolving global data protection laws and regulations, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations.***

The global data protection landscape is rapidly evolving, and we may be or become subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, transfer, security and processing of personal data, such as information that we collect about participants and healthcare providers in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, which may create uncertainty in our business, affect our or our service providers' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, result in liability or impose additional compliance or other costs on us. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. Recently, California passed the California Data Privacy Protection Act of 2018, or the CCPA, which went into effect in January 2020 and provides new data privacy rights for consumers and new operational requirements for companies, which may increase our compliance costs and potential liability. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities. The CCPA may lead to similar laws in other U.S. states or at a national level, which could increase our potential liability and adversely affect our business.

In addition to our operations in the United States, which may be subject to healthcare and other laws relating to the privacy and security of health information and other personal information, we have operations in Europe and are subject to European data privacy laws, regulations and guidelines. The General Data Protection Regulation, (EU) 2016/679, or GDPR, became effective on May 25, 2018, and deals with the collection, use, storage, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals in the EEA. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the United States, providing details to those individuals regarding the processing of their personal health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to €10 million or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to €20 million or up to 4% of our total worldwide annual turnover, whichever is greater, for more serious offenses. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers.

Further, national laws of member states of the EU are in the process of being adapted to the requirements under the GDPR, thereby implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the EEA. Also, as it relates to processing and transfer of genetic data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty. The U.K.'s decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the

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U.K. In particular, it is unclear how data transfers to and from the U.K. will be regulated now that the U.K. has left the EU.

We are conducting clinical trials in the EEA, and the GDPR increases our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we are required to have in place additional mechanisms and safeguards to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR is a rigorous and time-intensive process that increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. We expect that we will continue to face uncertainty as to whether our efforts to comply with any obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or biotechnology and biopharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national vendors or biotechnology and biopharmaceutical partners to continue to use our products due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such vendors or biotechnology and biopharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the forgoing could materially harm our business, prospects, financial condition and results of operations.

***Legal, political and economic uncertainty surrounding the exit of the U.K. from the EU may be a source of instability in international markets, create significant currency fluctuations, adversely affect our operations in the U.K. and pose additional risks to our business, revenue, financial condition, and results of operations.***

On June 23, 2016, the U.K. held a referendum in which a majority of the eligible members of the electorate voted to leave the EU, commonly referred to as Brexit. Pursuant to Article 50 of the Treaty on EU, the U.K. ceased being a member state of the EU on January 31, 2020. However, the terms of the withdrawal have yet to be fully negotiated. The implementation period began February 1, 2020 and will continue until December 31, 2020. During this 11-month period, the U.K. will continue to follow all of the EU's rules, the EU's pharmaceutical law remains applicable to the U.K. and the U.K.'s trading relationship will remain the same. However, regulations (including financial laws and regulations, tax and free trade agreements, intellectual property rights, data protection laws, supply chain logistics, environmental, health and safety laws and regulations medicine licensing and regulations, immigration laws and employment laws), have yet to be addressed. This lack of clarity on future U.K. laws and regulations and their interaction with the EU laws and regulations may negatively impact foreign direct investment in the U.K., increase costs, depress economic activity and restrict access to capital.

The uncertainty concerning the U.K.'s legal, political and economic relationship with the EU after Brexit may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border co-operation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise) beyond the date of Brexit.

These developments, or the perception that any of them could occur, may have a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the U.K. financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility.

If the U.K. and the EU are unable to negotiate acceptable agreements or if other EU member states pursue withdrawal, barrier-free access between the U.K. and other EU member states or among the EEA overall

could be diminished or eliminated. The long-term effects of Brexit will depend on any agreements (or lack thereof) between the U.K. and the EU and, in particular, any arrangements for the U.K. to retain access to EU markets either during a transitional period from January 1, 2021 or more permanently.

Such a withdrawal from the EU is unprecedented, and it is unclear how the U.K.'s access to the European single market for goods, capital, services and labor within the EU, or single market, and the wider commercial, legal and regulatory environment, will impact our current and future operations (including business activities conducted by third parties and contract manufacturers on our behalf) and clinical activities in the U.K. In addition to the foregoing, our U.K. operations support our current and future operations and clinical activities in the EU and EEA, and these operations and clinical activities could be disrupted by Brexit.

We may also face new regulatory costs and challenges that could have an adverse effect on our operations. Depending on the terms of the U.K.'s withdrawal from the EU, the U.K. could lose the benefits of global trade agreements negotiated by the EU on behalf of its members, which may result in increased trade barriers that could make our doing business in the EU and the EEA more difficult. Since the regulatory framework in the U.K. covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime with respect to the approval of our product candidates in the U.K. For instance, in November 2017, EU member states voted to move the EMA, the EU's regulatory body, from London to Amsterdam. Operations in Amsterdam commenced in March 2019, and the move itself may cause significant disruption to the regulatory approval process in Europe. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the U.K. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the U.K. and/or the EU and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the U.K. and/or EU for our product candidates, which could significantly and materially harm our business. Even prior to any change to the U.K.'s relationship with the EU, the announcement of Brexit has created economic uncertainty surrounding the terms of Brexit, and its consequences could adversely impact customer confidence resulting in customers reducing their spending budgets on our product candidates, if approved, which could adversely affect our business, financial condition, results of operations and could adversely affect the market price of our common stock.

***Additional laws and regulations governing international operations, and the complexity associated with maintaining geographically diverse operations, could negatively impact or restrict our operations and ability to grow.***

We have offices and operations in six cities and in five countries. If we are unable to manage the risks of our global operations, including the potential for fluctuations in foreign exchange and inflation rates, international hostilities, the need for our executives to travel internationally, natural disasters, security breaches, failure to maintain compliance with internal control requirements and multiple legal and regulatory systems, our results of operations and ability to grow could be materially adversely affected.

We must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The U.S. Foreign Corrupt Practices Act, or the FCPA, prohibits any U.S. individual or business entity from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the biotechnology and biopharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals and healthcare

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providers in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information products classified for national security purposes, as well as certain products, technology and technical data relating to those products. As we expand our operations throughout the world, we will be required to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC may also suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

***We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.***

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals, and we could be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

### **Risks Related to Our Intellectual Property**

***Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.***

Our business will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our product candidates, their respective components, synthetic intermediates, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities and whether a court would issue an injunctive remedy. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected.

The patenting process is 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. The patenting process is subject to numerous risks and there can be no assurance that we will be successful in obtaining patents for which we have applied. In addition, we may not pursue, obtain, or maintain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is

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too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees.

The strength of patents in the biotechnology and biopharmaceutical fields involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our technology, including our product candidates, or prevent others from designing around the claims in our patents. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

We cannot be certain that we were the first to file any patent application related to our technology, including our product candidates, and, if we were not, we may be precluded from obtaining patent protection for our technology, including our product candidates.

We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. Furthermore, for United States applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the United States Patent and Trademark Office, or USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. Similarly, for United States applications in which at least one claim is not entitled to a priority date before March 16, 2013, derivation proceedings can be instituted to determine whether the subject matter of a patent claim was derived from a prior inventor's disclosure.

We may be required to disclaim part or all of the term of certain patents. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent or patent application claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, would adequately protect our product candidates, or would be found by a court to be infringed by a competitor's technology or product. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. The possibility exists that others will develop products that have the same effect as our products on an independent basis and that do not infringe our patents or other intellectual property rights, or will design around the claims of patents that may issue that cover our products.

Recent or future 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. Under the enacted Leahy-Smith America Invents Act, or the America Invents Act, after March 2013, the United States moved from a "first-to-invent" to a "first-inventor-to-file" system. Under a "first-inventor-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The

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effects of these changes are currently unclear, as the USPTO only recently developed new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the “first-inventor-to-file” provisions. In addition, the courts have yet to address many of these provisions and the applicability of the America Invents Act and new regulations on specific patents discussed herein, for which issues have not been determined and would need to be reviewed. However, the America Invents 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 and financial condition.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds that are similar to the compositions of our product candidates but that are not covered by the claims of our patents or those of our licensors;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regards to any in-licensed patents and patent applications invented or developed using U.S. government funding, leading to the loss of patent rights;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors’ patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors’, as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;



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- we have engaged in scientific collaborations in the past, and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

***We may enter into license or other collaboration agreements in the future that may impose certain obligations on us. If we fail to comply with our obligations under such future agreements with third parties, we could lose license rights that may be important to our future business.***

In connection with our efforts to expand our pipeline of product candidates, we may enter into certain licenses or other collaboration agreements in the future pertaining to the in-license of rights to additional product candidates. Such agreements may impose various diligence, milestone payment, royalty, insurance or other obligations on us. If we fail to comply with these obligations, our licensor or collaboration partners may have the right to terminate the relevant agreement, in which event we would not be able to develop or market the products covered by such licenses or agreements.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we may license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

In addition, we may have limited control over the maintenance and prosecution of these in-licensed patents and patent applications, or any other intellectual property that may be related to our in-licensed

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intellectual property. For example, we cannot be certain that such activities by any future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

***If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be negatively impacted, and our business and competitive position would be harmed.***

In addition to patent protection, we rely heavily upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

In addition, courts may be unwilling to protect trade secrets. If we choose to go to court to stop a third-party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. We also plan to adopt policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets.

***Third-party claims of intellectual property infringement may be costly and time consuming to defend, and could prevent or delay our product discovery, development and commercialization efforts.***

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and biopharmaceutical industries, as well as administrative proceedings for challenging patents,

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including interference, derivation, *inter partes* review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and biopharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our product candidates and any license that is available may be non-exclusive, which could result in our competitors gaining access to the same intellectual property; and
- the need to redesign our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. 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.

### ***Third parties may assert that we are employing their proprietary technology without authorization.***

There may be third-party patents of which we are currently unaware with claims to compositions of matter, materials, formulations, methods of manufacture or methods for treatment that encompass the

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composition, use or manufacture of our product candidates. There may be currently pending patent applications of which we are currently unaware which may later result in issued patents that our product candidates or their use or manufacture may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patent were held by a court of competent jurisdiction to cover our product candidates, intermediates used in the manufacture of our product candidates or our materials generally, aspects of our formulations or methods of manufacture or use, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize 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. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

***Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.***

As is common in the biotechnology and biopharmaceutical industries, we employ individuals who were previously employed at universities or other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, and although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. 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. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

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*Others may claim an ownership interest in our intellectual property, which could expose us to litigation and have a significant adverse effect on our prospects.*

A third party may claim an ownership interest in one or more of our or our licensors' patents or other proprietary or intellectual property rights. A third party could bring legal actions against us and seek monetary damages and/or enjoin clinical testing, manufacturing and marketing of the affected product or products. While we are presently unaware of any claims or assertions by third parties with respect to our patents or other intellectual property, we cannot guarantee that a third party will not assert a claim or an interest in any of such patents or intellectual property. If we become involved in any litigation, it could consume a substantial portion of our resources and cause a significant diversion of effort by our technical and management personnel. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product, in which case we may be required to pay substantial royalties or grant cross-licenses to our patents. We cannot, however, assure you that any such license will be available on commercially acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product candidate or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree.

*We may not be successful in obtaining or maintaining necessary rights to develop any future product candidates on acceptable terms.*

Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. We may develop products containing our compounds and pre-existing biotechnology and biopharmaceutical compounds. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. 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.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established, or that have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

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***We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, or challenging the patent rights of others, which could be expensive, time-consuming and unsuccessful.***

Competitors or other third parties such as chemical and reagent suppliers may infringe our patents or the patents of our current or future licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question or for other reasons. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. 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 may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-examination, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the European Patent Office, or EPO, or other foreign patent offices. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent offices then we may be exposed to litigation by a third-party alleging that the patent may be infringed by our product candidates or proprietary technologies.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent or first to file a patent application covering the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference or derivation proceeding declared by the USPTO to determine priority of invention in the United States. If we or one of our licensors is a party to an interference or derivation proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert management's time and expend other resources, even if we are successful.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and 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 or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions

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or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on our owned and in-licensed issued patents and patent applications are or will be due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, 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. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In certain circumstances, even inadvertent noncompliance events may permanently and irrevocably jeopardize patent rights. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

***Any patents, if issued, covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.***

If we or one of our licensors initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post-grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. 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, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

Our earliest patents may expire before, or soon after, our first product achieves marketing approval in the United States or foreign jurisdictions. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could have a similar material adverse effect on our business, results of operations, financial condition and prospects.

***Changes in patent law in the United States and in other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.***

Changes in either the patent laws or interpretation of the patent laws in the United States or in other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to

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March 16, 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. On March 16, 2013, under the America Invents Act, enacted in September 2011, the United States transitioned to a “first-inventor-to-file” system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO on or after March 16, 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 of the time from invention to filing of a patent application. 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 or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor’s patents or patent applications.

The America Invents 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 post-grant review, *inter partes* review, and derivation proceedings. 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. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biotechnology and biopharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

***We have limited foreign intellectual property rights and may not be able to protect and enforce our intellectual property rights throughout the world.***

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on product candidates 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 where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.



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Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of, and may require a compulsory license to, patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology and biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. 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.

***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 claimed U.S. non-provisional filing date. Various extensions such as patent term adjustments and/or 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 new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed 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 and data exclusivity or similar non-U.S. legislation extending the term of protection covering any product candidates we may develop, our business may be materially harmed.***

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, also known as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for 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, only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failure to exercise due diligence during the testing phase or regulatory review process, failure to apply within applicable deadlines, failure to apply prior to expiration of relevant patents, or otherwise failure 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 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 business, financial condition, results of operations, and prospects could be materially harmed.

***If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.***

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade

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names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

### **Risks Related to Our Reliance on Third Parties**

*We rely on third parties to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.*

We depend, or may depend in the future, upon third parties to conduct certain aspects of our preclinical studies and clinical trials, under agreements with universities, medical institutions, CROs, strategic collaborators and others. We expect to have to negotiate budgets and contracts with such third parties, which may result in delays to our development timelines and increased costs.

We will rely especially heavily on third parties over the course of our clinical trials, and, as a result, will have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP requirements.

Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting aspects of our preclinical studies or clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our preclinical studies and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons or if, due to federal or state orders or absenteeism due to the COVID-19 pandemic, they are unable to meet their contractual and regulatory obligations, our development timelines, including clinical development timelines, may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms.

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Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar 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 materials, including tissue samples, required for our research and development activities, and if we are unable to reach agreements with these third parties, our research and development activities would be delayed.***

We rely on third parties, primarily hospitals, health clinics and academic institutions, for the provision of tissue samples and other materials required in our research and development activities. Obtaining these materials requires various approvals as well as reaching a commercial agreement on acceptable terms with the hospital or other provider of the materials. While we currently have agreements in place with the institutions from which we receive our tissue samples, we do not have any exclusive arrangements with such sources, and there is no guarantee that we will be able to maintain or renew such agreements on commercially reasonable terms, if at all. If we were unable to maintain or renew such agreements, we would be forced to seek new arrangements with new hospitals, clinics or health institutions. If so, we may not be able to reach agreements with alternative partners or do so on terms acceptable to us. If we are unable to enter into such agreements, our research and development activities will be delayed and our ability to implement a key part of our development strategy will be compromised.

***We rely on third-party manufacturing and supply vendors, and our supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.***

We rely on third-party contract manufacturers to manufacture our product candidates for preclinical studies and clinical trials. We do not own manufacturing facilities for producing any clinical trial product supplies. There can be no assurance that our preclinical and clinical development product supplies will not be limited or interrupted, or that they will be of satisfactory quality or continue to be available at acceptable prices. For example, the extent to which the COVID-19 pandemic impacts our ability to procure sufficient supplies for the development of our product candidates will depend on the severity and duration of the spread of the virus and the actions undertaken to contain COVID-19 or treat its effects. In particular, any replacement of our manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements.

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

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We expect to continue to rely on third-party manufacturers if we receive regulatory approval for GB0139 or any other product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements and comply with cGMP could adversely affect our business in a number of ways, including:

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

We rely on a sole supplier or, in some cases, a limited number of suppliers for the manufacture of components of GB0139 and our other current product candidates. If these suppliers are unable to supply necessary materials to us in the quantities we require, or at all, or otherwise default on their supply obligations to us, we may not be able to obtain alternative supplies from other suppliers on acceptable terms, in a timely manner, or at all. We also do not have long-term supply agreements with any of our suppliers. Our current contracts with certain suppliers may be canceled or not extended by such suppliers and, therefore, do not afford us with protection against a reduction or interruption in supplies. Moreover, in the event any of these suppliers breach their contracts with us, our legal remedies associated with such a breach may be insufficient to compensate us for any damages we may suffer.

In addition, we contract with fill and finishing providers with the appropriate expertise, facilities and scale to meet our needs. Failure to maintain cGMP can result in a contractor receiving FDA sanctions, which can impact our ability to operate or lead to delays in any clinical development programs. We believe that our current fill and finish contractor is operating in accordance with cGMP, but we can give no assurance that FDA or other regulatory agencies will not conclude that a lack of compliance exists. In addition, any delay in contracting for fill and finish services, or failure of the contract manufacturer to perform the services as needed, may delay any clinical trials, registration and launches, which could negatively affect our business. In the future, if we were to advance a biological product candidate into IND-enabling studies, we would need to identify and contract with suppliers who are able to produce biological product candidates and adhere to additional cGMP compliance obligations required for biologicals.

***We may in the future seek to enter into collaborations with third parties for the development and commercialization of our product candidates, and our future collaborations will be important to our business. If we are unable to enter into collaborations, or if these collaborations are not successful, our business could be adversely affected.***

A part of our strategy is to consider partnerships in indications and geographies where we believe partners can add significant commercial and/or development capabilities. Further, we have limited capabilities

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for product development and do not yet have any capability for commercialization. Accordingly, we have entered and may in the future enter into collaborations with other companies to provide us with important technologies and funding for our programs and technology.

Any future collaborations we enter into may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not provide us with timely and accurate information regarding development progress and activity under any future license agreement, which could adversely impact our ability to report progress to our investors and otherwise plan development of our product candidates;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;

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- if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us; and
- collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If any future collaborations we enter into do not result in the successful discovery, development and commercialization of product candidates, if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such collaboration. All of the risks relating to product development, regulatory approval and commercialization described in this prospectus also apply to the activities of our collaborators.

Additionally, if one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

We face significant competition in seeking appropriate collaborators for our product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully establish a collaboration for one or more of our product candidates, potential collaborators must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available products for licensing by other companies. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large biotechnology and biopharmaceutical companies that have resulted in a reduced number of potential future collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into future collaborations or do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates, bring them to market and generate revenue from sales of drugs or continue to develop our technology, and our business may be materially and adversely affected. Even if we are successful in our efforts to establish new strategic collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any delay in entering into new strategic collaboration agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

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

*The global pandemic of the novel coronavirus disease, COVID-19, could adversely impact our business, including our preclinical studies and clinical trials.*

In December 2019, a novel strain of coronavirus disease that causes COVID-19 was identified in Wuhan, China. As of September 2020, the novel coronavirus (also called SARS-CoV-2) has spread to a number of countries globally, including the United States, and the disease outbreak was declared a pandemic by the

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World Health Organization in March 2020. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19, we closed our executive offices with our administrative employees continuing their work outside of the office. As of June 15, 2020, we have reopened our executive office and are analyzing the plan to open the remainder on a case-by-case basis in compliance with applicable local regulation. As a result of the COVID-19 pandemic, we have experienced disruptions such as the delay of our planned Phase 2a clinical trial of GB1211 and opening of our clinical trial sites, and may continue to experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays or difficulties in commencing enrollment of patients in our clinical trials, including our Phase 2b clinical trial of GB0139 in IPF and our planned Phase 2 clinical trials of GB1211 and GB2064;
- the impact from potential delays, including potential difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures that are deemed non-essential, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in preclinical studies due to restricted or limited operations at our laboratory facility;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- interruption or delays to our sourced discovery and clinical activities.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the outbreak impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

***We may encounter difficulties in managing our growth, which could adversely affect our operations.***

As of September 1, 2020, we had 16 full-time employees. As our clinical development and commercialization plans and strategies develop, and as we transition into operating as a public company, we will

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need to expand our managerial, clinical, regulatory, sales, marketing, financial, development, manufacturing and legal 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 collaborators, suppliers and other third parties. Our future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our development and commercialization efforts effectively, including the clinical and FDA review process for GB0139 and any other product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our ability to continue to develop and, if approved, commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including contract manufacturers and companies focused on research and development and discovery activities. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality, accuracy or quantity of the services provided is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain, or may be substantially delayed in obtaining, regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize GB0139 or any other product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We recently acquired PharmAkea and may acquire additional technology and complementary businesses in the future. Acquisitions involve many risks, any of which could materially harm our business, including the diversion of management's attention from core business concerns, failure to effectively exploit acquired technologies, failure to successfully integrate the acquired business or realize expected synergies or the loss of key employees from either our business or the acquired businesses.

***If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to develop current product candidates or identify and develop new product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.***

Our ability to compete in the highly competitive biotechnology and biopharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including Hans Schambye, M.D., Ph.D., our Chief Executive Officer and President, Anders Pedersen, our Chief Operating Officer, Bertil Lindmark, M.D., Ph.D., our Chief Medical Officer and Jonathan Freve, our Chief Financial Officer. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.



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We conduct our operations globally from several locations including Copenhagen, Denmark, the United States, the U.K. and Canada. Competition for skilled personnel in our industry is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain with us, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Our key employees are at-will employees, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “key person” insurance policies but plan to enter into such policies prior to the completion of this offering, on the lives of these individuals or the lives of certain of our employees. There is no guarantee that any “key person” insurance policy we may enter into would adequately compensate us for the loss of any key employee. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior scientific and medical personnel.

***We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.***

Our internal computer systems and those of any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, phishing or other unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, financial loss, to a loss of our trade secrets or other proprietary information and damage to our reputation and otherwise negatively impact us. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. 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, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data, such as names, mailing addresses, email addresses, phone numbers and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial of service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients’ personal data could result in significant liability under state (*e.g.*, state breach notification laws), federal (*e.g.*, HIPAA, as amended by HITECH), and international (*e.g.*, the GDPR) law and may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business.

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We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyberattacks, and any such attacks could result in the losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business. By way of example, the CCPA, which went into effect on January 1, 2020, creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. By way of example regarding foreign laws and regulations with respect to data privacy and security, the GDPR went into effect in the EU in May 2018 and introduces strict requirements for processing the personal data of EU data subjects. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater.

***We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters, and our business continuity and disaster recovery plans may not adequately protect us from any such serious disaster.***

Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event were to occur that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time.

The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed.

***Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.***

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Portions of our future clinical trials may be conducted outside of the United States and unfavorable economic conditions resulting in the weakening of the U.S. dollar would make those clinical trials more costly to operate. Furthermore, the most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, including due to the impact of the COVID-19 pandemic, could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or international trade disputes could also strain our suppliers, some of which are located outside of the United States, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

***The increasing use of social media platforms presents new risks and challenges.***

Social media is increasingly being used to communicate about our clinical development programs and the diseases our therapeutics are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of our product candidates, if any. Social media practices in the biotechnology and biopharmaceutical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing or other prohibited activities and heightened scrutiny by the FDA, the SEC and other regulators. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. If such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we may fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. In addition, we may encounter attacks on social media regarding our company, management, product candidates or products. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

***The estimates of market opportunity and forecasts of market growth included in this prospectus or that we may otherwise provide may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.***

Market opportunity estimates and growth forecasts included in this prospectus or that we may otherwise provide are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. The estimates and forecasts included in this prospectus relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet the size estimates and growth forecasts included in this prospectus, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

***Our employees, independent contractors, consultants, commercial partners, collaborators and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, collaborators and vendors. Misconduct by these parties could include

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intentional, reckless and/or negligent conduct that fails to comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws will also increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In connection with this offering, we will adopt a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by our employees, independent contractors, consultants, commercial partners and vendors, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and the curtailment of our operations.

### ***We use and generate materials that may expose us to material liability.***

Our research programs involve the use of hazardous materials and chemicals, which are currently only handled by third parties. We are subject to foreign, federal, state and local environmental and health and safety laws and regulations governing, among other matters, the use, manufacture, handling, storage and disposal of hazardous materials and waste products such as human tissue samples that may have the potential to transmit diseases. We may incur significant costs to comply with these current or future environmental and health and safety laws and regulations. In addition, we cannot completely eliminate the risk of contamination or injury from hazardous materials and may incur material liability as a result of such contamination or injury. In the event of an accident, an injured party may seek to hold us liable for any damages that result. Any liability could exceed the limits or fall outside the coverage of our workers' compensation, property and business interruption insurance and we may not be able to maintain insurance on acceptable terms, if at all. We currently carry no insurance specifically covering environmental claims.

### ***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We or our CROs generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future

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compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. 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.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage, workers' compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

***Compliance with governmental regulations regarding the treatment of animals used in research could increase our operating costs, which would adversely affect the commercialization of our products.***

The Animal Welfare Act, or AWA, is the federal law that covers the treatment of certain animals used in research. Currently, the AWA imposes a wide variety of specific regulations that govern the humane handling, care, treatment and transportation of certain animals by producers and users of research animals, most notably relating to personnel, facilities, sanitation, cage size, and feeding, watering and shipping conditions. Third parties with whom we contract are subject to registration, inspections and reporting requirements under the AWA and comparable rules, regulations, and or obligations that may exist in many foreign jurisdictions. Furthermore, some states have their own regulations, including general anti-cruelty legislation, which establish certain standards in handling animals. Comparable rules, regulations, and/or obligations exist in many foreign jurisdictions. If we or our contractors fail to comply with regulations concerning the treatment of animals used in research, we may be subject to fines and penalties and adverse publicity, and our operations could be adversely affected.

***Changes in U.S. tax law could adversely affect our financial condition and results of operations.***

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, or IRS, and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, on March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act or the CARES Act, which included certain changes in tax law intended to stimulate the U.S. economy in light of the COVID-19 coronavirus outbreak, including temporary beneficial changes to the treatment of net operating losses, interest deductibility limitations and payroll tax matters. Future changes in U.S. tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisors regarding the implications of potential changes in U.S. tax laws on an investment in our common stock.

***Unanticipated changes in effective tax rates or adverse outcomes resulting from examination of our income or other tax returns could expose us to greater than anticipated tax liabilities.***

The tax laws applicable to our business, including the laws of Denmark, Sweden, the United States, and other jurisdictions, are subject to interpretation and certain jurisdictions may aggressively interpret their laws in an effort to raise additional tax revenue. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for valuing intercompany arrangements or our revenue recognition policies, which could increase our worldwide effective tax rate and harm our financial position and results of operations. It is possible that tax authorities may disagree with certain positions we have taken and any adverse outcome of such a review or audit could have a negative effect on our financial position and results of operations. Further, the determination of our worldwide provision for income taxes and other tax liabilities requires significant judgment by management, and there are transactions where the ultimate tax determination is uncertain. Although we

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believe that our estimates are reasonable, the ultimate tax outcome may differ from the amounts recorded in our consolidated financial statements and may materially affect our financial results in the period or periods for which such determination is made.

***Our corporate structure and intercompany arrangements are subject to the tax laws of various jurisdictions, and we could be obligated to pay additional taxes, which would harm our results of operations.***

Based on our current corporate structure, we are subject to taxation in several jurisdictions around the world with increasingly complex tax laws, the application of which can be uncertain. The amount of taxes we pay in these jurisdictions could increase substantially as a result of changes in the applicable tax principles, including increased tax rates, new tax laws or revised interpretations of existing tax laws and precedents. The authorities in these jurisdictions could review our tax returns or require us to file tax returns in jurisdictions in which we are not currently filing, and could impose additional tax, interest, and penalties. These authorities could also claim that various withholding requirements apply to us or our subsidiaries and assert that benefits of tax treaties are not available to us or our subsidiaries. The relevant taxing authorities may determine that the manner in which we operate our business does not achieve the intended tax consequences. If such a disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest, and penalties. Such authorities could claim that various withholding requirements apply to us or our subsidiaries or assert that benefits of tax treaties are not available to us or our subsidiaries. Any increase in the amount of taxes we pay or that are imposed on us could increase our worldwide effective tax rate.

Several countries in which we are located allow for tax incentives to attract and retain business. We have obtained incentives where available and practicable. Our taxes could increase if certain tax incentives are retracted, which could occur if we are unable to satisfy the conditions on which such incentives are based, if they are not renewed upon expiration, or if tax rates applicable to us in such jurisdictions otherwise increase. It is not anticipated that any material tax incentives will expire within the next year. However, due to the possibility of changes in existing tax law and our operations, we are unable to predict how any expirations will impact us in the future. In addition, acquisitions may cause our effective tax rate to increase, depending on the jurisdictions in which the acquired operations are located.

Certain of our subsidiaries may provide financing, products and services to, and may undertake certain significant transactions with, us or other of our subsidiaries in different jurisdictions. Several jurisdictions in which we operate have tax laws with detailed transfer pricing rules that require all transactions with non-resident related parties be priced using arm's length pricing principles, and that contemporaneous documentation must exist to support such pricing. There is a risk that the taxing authorities may not deem our transfer pricing documentation acceptable. In addition, the Organization for Economic Cooperation and Development continues to issue guidelines and proposals related to Base Erosion and Profit Shifting which may result in legislative changes that could reshape international tax rules in numerous countries and negatively impact our effective tax rate.

***Our ability to use our net operating loss carryforwards and certain tax credit carryforwards may be subject to limitation.***

We have net operating loss carryforwards and tax credit carryforwards for U.S. federal and state income tax purposes which begin to expire in future years. Additionally, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, changes in our ownership may limit the amount of our net operating loss carryforwards and tax credit carryforwards that could be utilized annually to offset our future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of our company of more than 50 percentage points within a three-year period. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and tax credit carryforwards before they expire. Private placements and other transactions that have occurred since our inception, as well as this offering, may trigger such an ownership change pursuant to Section 382. Any such limitation, whether as

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the result of this offering, prior private placements, sales of our common stock by our existing stockholders or additional sales of our common stock by us, could have a material adverse effect on our results of operations in future years. The reduction of the corporate tax rate under the Tax Cuts and Jobs Act of 2017, or the Tax Cuts and Jobs Act, may cause a reduction in the economic benefit of our net operating loss carryforwards and other deferred tax assets available to us. Our ability to utilize those net operating loss carryforwards could be limited by an “ownership change” as described above, which could result in increased tax liability to us.

### **Risks Related to Our Common Stock and this Offering**

***There has been no prior public market for our common stock, the stock price of our common stock may be volatile or may decline regardless of our operating performance, and you may not be able to resell your shares at or above the initial public offering price.***

Prior to this offering, there has been no public market for shares of our common stock. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. The initial public offering price for our common stock will be determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of the common stock after the offering. An active or liquid market in our common stock may not develop upon the completion of this offering or, if it does develop, it may not be sustainable. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price.

Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

***The price of our stock may be volatile, and you could lose all or part of your investment.***

The trading price of our common stock following this offering is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this prospectus, these factors include:

- the commencement, enrollment or results of our current Phase 2b clinical trial of GB0139;
- any delay in identifying and advancing a clinical candidate for our other development programs;
- any delay in our regulatory filings for GB0139 or our other product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority’s review of such filings, including, without limitation, the FDA’s issuance of a “refusal to file” letter or a request for additional information;
- adverse results or delays in future clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of GB0139 or any other product candidate;
- changes in laws or regulations applicable to GB0139 or any other product candidate, including, but not limited to, clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;

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- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations, if needed;
- our failure to commercialize our product candidates, if approved;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of GB0139 or any other product candidate;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or product candidates in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- changes in the structure of the healthcare payment systems;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for biotechnology and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated



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or disproportionate to the operating performance of these companies, including as a result of the COVID-19 pandemic. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. If the market price of our common stock after this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources.

***We do not intend to pay dividends on our common stock, so any returns will be limited to the value of our 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. Furthermore, future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.***

Immediately following the completion of this offering, our executive officers, directors and their affiliates will beneficially hold, in the aggregate, approximately % of our outstanding voting stock. These stockholders, acting together, would be able to significantly influence all matters requiring stockholder approval. For example, these stockholders would be able to significantly influence elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

***If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.***

The initial public offering price will be substantially higher than the pro forma as adjusted net tangible book value per share of our common stock after this offering. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the pro forma as adjusted net tangible book value per share after this offering. As a result, investors purchasing common stock in this offering will incur immediate dilution of \$ per share, based on an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, representing the difference between our pro forma as adjusted net tangible book value per share after giving effect to this offering and the assumed initial public offering price. Further, investors purchasing common stock in this offering will contribute approximately % of the total amount invested by stockholders since our inception but will own only approximately % of the shares of common stock outstanding after this offering.

This dilution is due to our investors who purchased shares prior to this offering having paid substantially less when they purchased their shares than the price offered to the public in this offering. To the extent outstanding options are exercised, there will be further dilution to new investors. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. For a further description of the dilution that you will experience immediately after this offering, see the section entitled "Dilution."

***We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.***

We are an EGC as defined in the JOBS Act, enacted in April 2012. For as long as we continue to be an EGC, we may take advantage of exemptions from various reporting requirements that are applicable to other

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public companies that are not EGCs, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, or Section 404, reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an EGC for up to five years following the year in which we complete this offering, although circumstances could cause us to lose that status earlier. We will remain an EGC until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenue of at least \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed \$700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this prospectus. In particular, we have not included all of the executive compensation information that would be required if we were not an EGC. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, EGCs can also delay adopting new or revised accounting standards until such time as those standards apply to private companies, which may make our financial statements less comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

***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 SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the Nasdaq Global Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial reporting controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access. Recent legislation permits EGCs to implement many of these requirements over a longer period and up to five years from the pricing of this offering. 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 an adverse effect on our business. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, 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.

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***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.***

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis, and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an EGC, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an EGC for up to five years. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

***Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.***

Upon completion of this offering, we will become subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

***Substantial amounts of our outstanding shares may be sold into the market when lock-up or market standoff periods end. If there are substantial sales of shares of our common stock, the price of our common stock could decline.***

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. Based on shares of common stock outstanding as of December 31, 2019, upon the completion of this offering, we will have outstanding a total of \_\_\_\_\_ shares of common stock. Of these shares, only the 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.

The lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus, subject to earlier release of all or a portion of the shares subject to such agreements by the representatives of the

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underwriters in this offering in their sole discretion. After the lock-up agreements expire, based upon the number of shares of common stock, on an as-converted basis, outstanding as of December 31, 2019, up to an additional \_\_\_\_\_ shares of common stock will be eligible for sale in the public market. Approximately \_\_\_\_\_ % of these additional shares are beneficially held by directors, executive officers and their affiliates and will be subject to certain limitations of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our existing equity compensation 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 \_\_\_\_\_ shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act as provided under the terms of the Investors' Rights Agreement, dated as of December 31, 2019 between us and the holders of our redeemable convertible preferred stock, or the Investors' Rights Agreement, subject to 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 have broad discretion in the use of our existing cash, cash equivalents and short-term investments and the net proceeds from this offering and may not use them effectively.***

Our management will have broad discretion in the application of our existing cash, cash equivalents and short-term investments and the net proceeds from this offering, including for any of the purposes described in the section entitled "Use of Proceeds," and you will not have the opportunity as part of your investment decision to assess whether such proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of our existing cash, cash equivalents and short-term investments and the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our existing cash, cash equivalents and short-term investments and the net proceeds from this offering in ways that ultimately increase the value of your investment. 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-term, investment-grade, interest-bearing securities. 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 financial results, which could cause our stock price to decline.

***Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.***

Our amended and restated certificate of incorporation and amended and restated bylaws, which are to become effective upon the completion of this offering, contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;

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- a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement 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 all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue convertible preferred stock on terms determined by the board of directors without stockholder approval and which convertible preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, or DGCL, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

***If securities or industry analysts do not publish research or publish inaccurate or unfavorable research 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 or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

***Our amended and restated bylaws will designate certain courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to litigate disputes with us in a different judicial forum.***

Pursuant to our amended and restated bylaws, as will be in effect upon the completion of this offering, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for: (i) any derivative action or proceeding brought on our behalf; (ii) 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; (iii) any action

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asserting a claim arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (v) any action asserting a claim governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein, or the Delaware forum provision. The Delaware forum provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Unless we consent in writing to the selection of an alternate forum, the United States District Court for the District of Delaware shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the federal forum provision, as we are incorporated in the State of Delaware. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the Delaware forum provision and the federal forum provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

The Delaware forum provision and the federal forum provision may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware. In addition, these forum selection clauses in our bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our federal forum provision. The federal forum provision may also impose additional litigation costs on stockholders who assert the provision is not enforceable or invalid, and if the federal forum provision is found to be unenforceable, we may also incur additional costs associated with resolving such matters. The Court of Chancery of the State of Delaware and the United States District Court for the District of Delaware may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

***Our issuance of additional capital stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.***

We expect to issue additional capital stock in the future that will result in dilution to all other stockholders. We expect to grant equity awards to employees, directors, and consultants under our stock incentive plans. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire or make investments in complementary companies, products, or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition that are based on our management’s belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- the success, cost and timing of our product development activities and clinical trials of our lead product candidate, GB0139, as well as our other current product candidates and any future product candidates;
- our need to raise additional funding before we can expect to generate any revenues from product sales;
- our ability to obtain regulatory approval for our current or future product candidates that we may identify or develop;
- our ability to ensure adequate supply of our current or future product candidates;
- our ability to maintain third-party relationships necessary to conduct our business;
- our heavy dependence upon the success of our research to generate and advance additional product candidates;
- our ability to establish an adequate safety or efficacy profile for our current or future product candidates that we may pursue;
- the implementation of our strategic plans for our business, our current or future product candidates we may develop and our technology;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- the rate and degree of market acceptance and clinical utility for our current or future product candidates we may develop;
- our estimates about the size of our market opportunity;
- our ability to use the proceeds of this offering in ways that increase the value of your investment;
- our expectations related to the use of proceeds from this offering, and estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our ability to maintain and establish collaborations;

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- our financial performance and liquidity;
- our ability to effectively manage our potential growth;
- developments relating to our competitors and our industry, including the impact of government regulation;
- our ability to retain the continued service of our key professionals and consultants and to identify, hire and retain additional qualified professionals;
- the effect of the COVID-19 pandemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations and those of our collaborators, service providers and other vendors;
- our ability to maintain adequate internal controls over financial reporting; and
- other risks and uncertainties, including those listed under the section titled “Risk Factors.”

In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue” or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed in the section entitled “Risk Factors” and elsewhere in this prospectus. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement, of which this prospectus is a part, in their entirety and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we assume no obligation to update or revise any forward-looking statements except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

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 AND FORECASTS

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. 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 the section entitled “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 from our issuance and sale of \_\_\_\_\_ shares of our common stock in this offering will be approximately \$ \_\_\_\_\_ million, or approximately \$ \_\_\_\_\_ million if the underwriters exercise in full their option to purchase \_\_\_\_\_ additional shares, assuming an initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the net proceeds to us from this offering by approximately \$ \_\_\_\_\_ 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 underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase or decrease of 1.0 million shares in the number of shares we are offering would increase or decrease, as applicable, the net proceeds to us from this offering by approximately \$ \_\_\_\_\_ million, assuming the assumed initial public offering price to the public remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We do not expect that a change in the initial price to the public or the number of shares by these amounts would have a material effect on the uses of the proceeds from this offering, although it may accelerate the time at which we will need to seek additional capital.

The principal purposes of this offering are to increase our financial flexibility, create a public market for our common stock and facilitate our future access to capital markets.

We currently intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments as follows:

- approximately \$ \_\_\_\_\_ million to fund the clinical development of our lead product candidate, GB0139, including for conducting our Phase 3 clinical trial in IPF;
- approximately \$ \_\_\_\_\_ million to fund the clinical development of our programs in myelofibrosis, NASH and oncology; and
- the remainder, if any, for additional early-stage research and development activities, business development activities, working capital and other general corporate purposes.

Based on our current plans, we believe our existing cash, cash equivalents and short-term investments, together with the net proceeds from this offering, will be sufficient to fund our operating expenses and capital expenditure requirements through \_\_\_\_\_.

We may also use a portion of the net proceeds to in-license, acquire or invest in new businesses, technology or assets. Although we have no current agreements, commitments or understandings with respect to any such in-license or acquisition, we evaluate such opportunities and engage in related discussions with third parties from time to time.

The expected use of net proceeds from this offering represents our intentions based upon our present plans and business conditions. We cannot specify with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering. Due to uncertainties inherent in the product development process, it is difficult to estimate the exact amounts of the net proceeds that will be used for any particular purpose. We may use our existing cash, cash equivalents and short-term investments and the future payments, if any, generated from any future collaboration agreements to fund our operations, either of which may alter the amount of net proceeds used for a particular purpose. In addition, the amount, allocation and timing of our actual expenditures

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will depend upon numerous factors, including the results of our research and development efforts, the timing and success of clinical trials and the timing of regulatory submissions. Accordingly, we will have broad discretion in using these proceeds.

Pending the uses described above, we plan to invest the net proceeds of this offering in short- and immediate-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 do not anticipate paying any dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. Any future determination to declare dividends will be subject to the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, financial condition, future prospects and any other factors deemed relevant by our board of directors. Investors should not purchase our common stock with the expectation of receiving cash dividends.

## CAPITALIZATION

The following table sets forth our cash, cash equivalents and short-term investments and our capitalization as of December 31, 2019:

- on an actual basis;
- on a pro forma basis to give effect to (i) the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of \_\_\_\_\_ shares of our common stock as if such conversion had occurred on December 31, 2019 and (ii) the filing and effectiveness of our amended and restated certificate of incorporation immediately prior to the completion of this offering; and
- on a pro forma as adjusted basis to give effect to (i) the pro forma adjustments described above, and (ii) the issuance and sale of \_\_\_\_\_ shares of our common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Our capitalization following the completion of this offering will be adjusted based on the actual public offering price and other terms of the offering determined at pricing. You should read this information together with our financial statements and related notes appearing elsewhere in this prospectus and the information set forth in the sections entitled “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	<u>December 31, 2019</u>		<u>Pro forma As Adjusted</u>
	<u>Actual</u>	<u>Pro forma</u>	
Cash and cash equivalents	\$ 11,294	\$ 50,794	
Convertible preferred shares:			
Series B convertible preferred stock, or Series B preferred stock, \$0.00001 par value; 684,068 shares, authorized, issued and outstanding, actual; no shares outstanding, pro forma and pro forma as adjusted	13,414	—	—
Series C convertible preferred stock, \$0.00001 par value; 4,817,547 shares authorized; or Series C preferred stock, 4,125,056 shares issued and outstanding actual; no shares outstanding, pro forma and pro forma as adjusted	106,205	—	—
Stockholders’ (Deficit) Equity:			
Common stock, par value of \$0.00001 per share; 5,350,404 shares authorized, 100,000 shares issued and outstanding, actual; 4,909,124 shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted	—	49	
Additional paid-in capital	826	159,896	
Accumulated other comprehensive loss	(2,451)	(2,451)	
Accumulated deficit	(69,523)	(69,523)	
Total stockholders’ (deficit) equity	(71,148)	87,971	
<b>Total Capitalization</b>	<b>\$ 48,471</b>	<b>\$ 87,971</b>	

(1) Each \$1.00 increase or decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as

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applicable, each of pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' (deficit) equity, and total capitalization by approximately \$            million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of shares we are offering. Each increase or decrease of 1.0 million shares in the number of shares we are offering would increase or decrease, as applicable, each of pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' (deficit) equity, and total capitalization by approximately \$            million, assuming the assumed initial public offering price per share, as set forth on the cover page of this prospectus, remains the same. The pro forma as adjusted information is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

The number of shares of common stock issued and outstanding pro forma and pro forma as adjusted in the table above is based on            shares of common stock (including our redeemable convertible preferred stock on an as-converted basis) outstanding as of            , and excludes:

- shares of common stock issuable upon exercise of outstanding options issued as of            under our 2020 Plan, at a weighted-average exercise price of \$            per share;
- shares of common stock reserved for future issuance under our 2020 Plan as of            ; and
- shares of our common stock reserved for future issuance under our 2020 Incentive Equity Plan.

## DILUTION

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

Our historical net tangible book value (deficit) per share as of \_\_\_\_\_, 2020 is determined by dividing our total tangible assets less our total liabilities and redeemable convertible preferred stock, which are not included within stockholders' equity (deficit), by the number of shares of common stock outstanding as of such date. Our historical net tangible book value (deficit) was \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share as of \_\_\_\_\_, 2020.

Our pro forma net tangible book value (deficit) as of \_\_\_\_\_, 2020 was \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share. Our pro forma net tangible book value (deficit) per share represents the amount of our total tangible assets reduced by the amount of our total liabilities and divided by the total number of shares of our common stock outstanding as of \_\_\_\_\_, 2020, assuming the automatic conversion of all outstanding shares of our redeemable convertible preferred stock and unvested outstanding restricted shares as of \_\_\_\_\_, 2020 into an aggregate of \_\_\_\_\_ shares of common stock, which conversion will occur immediately prior to the completion of this offering.

Our pro forma as adjusted net tangible book value (deficit) represents our pro forma net tangible book (deficit) value, plus the effect of the sale of shares of common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Net tangible book value dilution per share to new investors represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the pro forma as adjusted net tangible book value per share of common stock immediately after completion of this offering. After giving effect to our sale of shares of common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of \_\_\_\_\_, 2020 would have been \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share. This represents an immediate increase in net tangible book value of \$ \_\_\_\_\_ per share to existing stockholders and an immediate dilution in net tangible book value of \$ \_\_\_\_\_ per share to purchasers of common stock in this offering, as illustrated in the following table:

Assumed initial public offering price per share	\$
Historical net tangible book value (deficit) per share as of _____, 2020	\$
Increase per share attributable to the pro forma adjustments described above	
Pro forma net tangible book value per share as of _____, 2020, before giving effect to this offering	
Increase in pro forma as adjusted net tangible book value per share attributable to new investors purchasing common stock in this offering	
Pro forma as adjusted net tangible book value per share after giving effect to this offering	
Dilution in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering	\$

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Each \$1.00 increase or decrease in the assumed public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, our pro forma as adjusted net tangible book value by \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share, and dilution per share to investors in this offering by \$ \_\_\_\_\_ per share, assuming that the number of shares offered by us, as set forth on the cover of this prospectus, remains the same, and after deducting underwriting discounts and commissions, and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase or decrease of 1.0 million shares in the number of shares we are offering would increase or decrease, as applicable, our pro forma as adjusted net tangible book value by approximately \$ \_\_\_\_\_ million, or approximately \$ \_\_\_\_\_ per share and would increase or decrease, as applicable, dilution per share to investors in this offering by approximately \$ \_\_\_\_\_ per share, assuming the assumed initial public offering price per share remains the same and after deducting underwriting discounts and commissions, and estimated offering expenses payable by us.

If the underwriters' option to purchase additional shares from us is exercised in full, the pro forma as adjusted net tangible book value per share after this offering would be \$ \_\_\_\_\_ per share and would be decreased or increased, as applicable, accordingly by \$ \_\_\_\_\_ per share; the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be \$ \_\_\_\_\_ per share; and the dilution to new investors purchasing shares in this offering would be \$ \_\_\_\_\_ per share.

The following table shows, as of \_\_\_\_\_, 2020, on a pro forma as adjusted basis described above (but before deducting underwriting discounts and commissions and estimated offering expenses payable by us), the differences between the existing stockholders and the purchasers of shares in this offering with respect to the number of shares purchased from us, the total consideration paid, which includes net proceeds received from the issuance of common and redeemable convertible preferred stock, cash received from the exercise of stock options, and the value of any stock issued for services and the average price paid per share (in thousands, except per share amounts and percentages):

	Shares purchased		Total consideration		Average price per share
	Number	Percentage	Amount	Percentage	
Existing stockholders		%	\$	%	\$
New investors					
Total		100%		\$ 100%	\$

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to \_\_\_\_\_ % of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors participating in the offering would be increased to \_\_\_\_\_ % 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 (deficit) calculations) are based on \_\_\_\_\_ shares of common stock (including our redeemable convertible preferred stock on an as converted basis) outstanding as of \_\_\_\_\_, and excludes:

- shares of common stock issuable upon exercise of outstanding options issued as of \_\_\_\_\_ under our 2020 Plan, at a weighted-average exercise price of \$ \_\_\_\_\_ per share;
- shares of common stock reserved for future issuance under our 2020 Plan as of \_\_\_\_\_; and



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- shares of our common stock reserved for future issuance under our 2020 Incentive Equity Plan.

To the extent that any outstanding options are exercised, new options are issued under our stock-based compensation plans or we issue additional shares of common stock or convertible debt in the future, there will be further dilution to investors participating in this offering.

**SELECTED FINANCIAL INFORMATION**

The statements of operations for the years ended December 31, 2019 and 2018 and the balance sheet data as of December 31, 2019 and 2018 have been derived from our audited consolidated financial statements included at the end of this prospectus. You should read this data together with our consolidated financial statements and related notes included at the end of this prospectus and in the section of this prospectus titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our historical results are not necessarily indicative of the results to be expected in the future.

	<b>Year Ended December 31,</b>	
	<b>2019</b>	<b>2018</b>
<b>Operating expenses</b>		
Research and development	\$ 19,738	\$ 10,093
Purchased in-process research and development	16,788	—
General and administrative	2,445	2,814
<b>Total operating expenses</b>	<b>38,971</b>	<b>12,907</b>
Loss from operations	(38,971)	(12,907)
Other income (expense), net	2,464	(2,962)
Net loss	\$ (36,507)	\$ (15,869)
Cumulative dividends on convertible preferred stock	(5,560)	(3,136)
Net loss attributable to common stockholders	\$ (42,067)	\$ (19,005)
Net loss per common share—basic and diluted (1)	\$ (420.67)	\$ (190.05)
Weighted-average number of shares used in computing net loss per common share—basic and diluted (1)	100,000	100,000
Pro forma net loss per common share—basic and diluted (1)	\$ (13.21)	
Weighted-average number of shares used in computing pro forma net loss per share—basic and diluted (1)	2,763,166	

- (1) See Notes 2, 14 and 15 to our consolidated financial statements as of and for the years ended December 31, 2019 and 2018 appearing at the end of this prospectus for a description of how we compute basic and diluted net loss per share and basic and diluted pro forma net loss per share, and the weighted-average number of shares used in the computation of these per share amounts.

	<b>As of December 31,</b>	
	<b>2019</b>	<b>2018</b>
<b>Balance Sheet Data:</b>		
Cash and cash equivalents	\$ 11,294	\$ 30,987
Total assets	56,609	35,104
Working capital (2)	48,682	30,660
Total liabilities	8,138	4,444
Convertible preferred stock	119,619	64,495
Accumulated deficit	(69,523)	(33,017)
Total stockholders’ deficit	(71,148)	(33,835)

- (2) We define working capital as current assets less current liabilities. See our consolidated financial statements and related notes included at the end of 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 the section entitled "Selected Financial Information" and our consolidated financial statements and related notes appearing at the end of this prospectus. Some of the information contained in this discussion and analysis or set forth at the end of 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 section entitled "Risk Factors," 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. You should carefully read the section entitled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Cautionary Note Regarding Forward-Looking Statements and Industry Data."*

### Overview

We are a clinical-stage biotechnology company developing therapeutics that are designed to target the biological processes that lie at the heart of fibrosis and fibrotic inflammation and impact a broad range of fibrotic and related diseases, including cancer. Our initial focus is on the development of small-molecule inhibitors of galectin-3 and lysyl oxidase-like 2, or LOXL2, which play key roles in regulating fibrosis. We believe our product candidates are distinct from the current generation of antifibrotic agents and have the potential to significantly improve patients' clinical outcomes and enhance their quality of life.

Our lead product candidate is in Phase 2b clinical development and our other product candidates, and our research initiatives are in early stages of clinical and preclinical development. Our ability to generate revenue from product sales sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. Our operations to date have been financed primarily by aggregate net proceeds of \$102.2 million from the issuance of redeemable convertible preferred shares, convertible notes and common stock. Since inception, we have had significant operating losses. Our net loss was \$36.5 million and \$15.9 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of \$69.5 million and \$11.3 million in cash, cash equivalents and short-term investments.

Galecto, Inc. was incorporated in Delaware in October 2019. Shares in Galecto Biotech AB, a Swedish operating company, were exchanged at a one-to-one ratio for shares in Galecto Inc. in a common control/tax-free reorganization. On December 31, 2019, Galecto, Inc. and PharmAkea consummated the Purchase, whereby Galecto, Inc. acquired PharmAkea in principally an all-stock transaction. As of December 31, 2019, the Company's wholly-owned subsidiaries were PharmAkea and Galecto Biotech AB, and Galecto ApS, a Danish operating company, was Galecto, Biotech AB's wholly-owned subsidiary. The consolidated financial statements are those of Galecto, Inc. as of December 31, 2019, as successor, and of Galecto Biotech AB as the predecessor entity for the years ended December 31, 2019 and 2018.

Our independent registered public accounting firm included an explanatory paragraph in its audit report on our consolidated financial statements as of and for the years ended December 31, 2019 and 2018 stating that our recurring losses from operations and negative cash flows since inception and our need to raise additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern.

Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our accounts payable and accrued expenses. We expect to continue to incur net losses

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for the foreseeable future, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. In particular, we expect our expenses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, as well as hire additional personnel, pay fees to outside consultants, lawyers and accountants, and incur other increased costs associated with being a public company. In addition, if and when we seek and obtain regulatory approval to commercialize any product candidate, we will also incur increased expenses in connection with commercialization and marketing of any such product. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

Based upon our current operating plan, we believe that the net proceeds from this offering together with our existing cash and cash equivalents of \$11.3 million as of December 31, 2019 and the \$39.7 million proceeds received in January 2020 on the sale and issuance of our Series C-4 preferred stock and Series C-5 preferred stock, will be sufficient to continue funding our development activities through . We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured.

To date, we have not had any products approved for sale and, therefore, have not generated any product revenue. We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates. 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. As a result, until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including collaborations, licenses or similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms, if at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies, including our research and development activities. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

The COVID-19 pandemic, which began in December 2019 and has spread worldwide, has caused many governments to implement measures to slow the spread of the outbreak through quarantines, travel restrictions, heightened border scrutiny and other measures. The outbreak and government measures taken in response have also had a significant impact, both directly and indirectly, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the outbreak and its effects on our business and operations are uncertain.

In response to the impact of COVID-19, we have implemented certain measures intended to help us manage its impact and position ourselves to resume operations quickly and efficiently once these restrictions are lifted, such as executing a work-from-home strategy for administrative functions and operations.

Despite our implementation of such measures, the actual and perceived impact of the COVID-19 pandemic is changing daily, and its ultimate effect on us cannot be predicted. As a result, we cannot assure you that we will not experience additional negative impacts associated with COVID-19, which could be significant. The COVID-19 pandemic may negatively impact our business, financial condition and results of operations by decreasing or delaying the enrollment of patients in our clinical trials or otherwise causing interruptions or delays in our programs and services. See “Risk Factors—Risks Related to Managing Our Business and Operations—The global pandemic of the novel coronavirus disease, COVID-19, could adversely impact our business, including our preclinical studies and clinical trials” for more information regarding the potential impact of COVID-19 on our business and operations.

## Components of Operating Results

### *Operating Expenses*

Our operating expenses since inception have consisted primarily of research and development expenses and general and administrative costs.

#### *Research and Development*

Our research and development expenses consist primarily of costs incurred for the development of our product candidates and our drug discovery efforts, which include:

- personnel costs, which include salaries, benefits and equity-based compensation expense;
- expenses incurred under agreements with consultants, and third-party contract organizations that conduct research and development activities on our behalf;
- costs related to sponsored research service agreements;
- costs related to production of preclinical and clinical materials, including fees paid to contract manufacturers;
- laboratory and vendor expenses related to the execution of preclinical studies and planned clinical trials;
- laboratory supplies and equipment used for internal research and development activities; and
- acquired in-process research and development programs.

We expense all research and development costs in the periods in which they are incurred, including for acquired in-process research and development. Costs for certain research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and third-party service providers.

From time to time, we obtain grants from public and private funds for our research and development projects. The grant income for a given period is recognized as a cost reimbursement and is typically based on the time and the costs that we have spent on the specific project during that period.

We have historically met the requirements to receive a tax credit in Denmark for losses resulting from research and development costs of up to 25 million Danish Krone. The tax credit is reported as a reduction to research and development expense in the consolidated statements of operations.

Our direct research and development expenses are not currently tracked on a program-by-program basis. We use our personnel and infrastructure resources across multiple research and development programs directed toward identifying and developing product candidates. Substantially all our clinical spending in the years ended December 31, 2019 and 2018 was on GB0139. In the years ended December 31, 2019 and 2018, we advanced our GB1211 program from discovery through preclinical development. We acquired our GB2064 program from PharmAkea on December 31, 2019.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in conducting clinical trials, manufacturing and otherwise advancing our programs. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain.

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Because of the numerous risks and uncertainties associated with product development and the current stage of development of our product candidates and programs, we cannot reasonably estimate or know the nature, timing and estimated costs necessary to complete the remainder of the development of our product candidates or programs. We are also unable to predict if, when, or to what extent we will obtain approval and generate revenues from the commercialization and sale of our product candidates. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, including:

- successful completion of preclinical studies and initiation of clinical trials for GB0139, our other current product candidates and any future product candidates ;
- successful enrollment and completion of our Phase 2b clinical trial for GB0139, our Phase 2 clinical trials for both GB1211 and GB2064 and any clinical trials for future product candidates;
- data from our clinical programs that support an acceptable risk-benefit profile of our product candidates in the intended patient populations;
- acceptance by the FDA, regulatory authorities in Europe, Health Canada or other regulatory agencies of the IND applications, clinical trial applications and/or other regulatory filings for GB0139, our other current product candidates and any future product candidates;
- expansion and maintenance of a workforce of experienced scientists and others to continue to develop our product candidates;
- successful application for and receipt of marketing approvals from applicable regulatory authorities;
- obtainment and maintenance of intellectual property protection and regulatory exclusivity for our product candidates;
- arrangements with third-party manufacturers for, or establishment of, commercial manufacturing capabilities;
- establishment of sales, marketing and distribution capabilities and successful launch of commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effective competition with other therapies;
- obtainment and maintenance of coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;
- maintenance, enforcement, defense and protection of our rights in our intellectual property portfolio;
- avoidance of infringement, misappropriation or other violations with respect to others' intellectual property or proprietary rights; and
- maintenance of a continued acceptable safety profile of our products following receipt of any marketing approvals.

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We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our preclinical studies and clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current and future preclinical and clinical product candidates. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in execution of or enrollment in any of our preclinical studies or clinical trials, we could be required to expend significant additional financial resources and time on the completion of preclinical and clinical development.

Research and development activities account for a significant portion of our operating expenses. We expect our research and development expenses to increase for the foreseeable future as we continue to implement our business strategy, which includes advancing GB0139 through clinical development and other product candidates further into clinical development, expanding our research and development efforts, including hiring additional personnel to support our research and development efforts, and seeking regulatory approvals for our product candidates that successfully complete clinical trials. In addition, product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development.

### *General and Administrative Expenses*

Our general and administrative expenses consist primarily of personnel costs, depreciation expense and other expenses for outside professional services, including legal, human resources, audit and accounting services and facility-related fees not otherwise included in research and development expenses. Personnel costs consist of salaries, benefits and equity-based compensation expense, for our personnel in executive, finance and accounting, business operations and other administrative functions. We expect our general and administrative expenses to increase over the next several years to support our continued research and development activities, manufacturing activities, increased costs of expanding our operations and operating as a public company. These increases will likely include increases related to the hiring of additional personnel and legal, regulatory and other fees and services associated with maintaining compliance with Nasdaq listing rules and SEC requirements, director and officer insurance premiums and investor relations costs associated with being a public company.

### *Other Income (Expense), Net*

Our other income (expense), net is comprised of:

- Foreign exchange: The functional currency of our subsidiaries in Denmark and Sweden is the Euro. Transactions denominated in currencies other than the Euro result in exchange gains and losses that are recorded in our statements of operations.
- Fair value adjustment on derivative and tranche obligations: We have recorded tranche obligations with respect to milestone closings our sale and issuance of Series C-2 preferred stock in October 2018. The milestone closings of the Series C preferred stock were committed to in December 2019 with the Series C preferred stock and proceeds received in January 2020. We also recorded a derivative obligation attendant to convertible notes that were issued in 2017 and 2018, then converted for shares of Series C-1 preferred stock on the issuance of Series C-2 preferred stock in October 2018.

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- Interest expense: For the year ended December 31, 2018 we incurred interest expense on notes that were converted into Series C-1 preferred stock October 2018.

## Results of Operations

### Comparison of the Years Ended December 31, 2019 and 2018

The following sets forth our results of operations for the years ended December 31, 2019 and 2018:

	Year Ended December 31,		Change	
	2019	2018	Amount	Percent
	(in thousands)			
Operating expenses				
Research and development	\$ 19,738	\$ 10,093	\$ 9,645	95.6%
Purchased in-process research and development	16,788	—	16,788	—
General and administrative	2,445	2,814	(369)	-13.1%
Total operating expenses	<u>38,971</u>	<u>12,907</u>	<u>26,064</u>	<u>201.9%</u>
Loss from operations	(38,971)	(12,907)	(26,064)	201.9%
Other income (expense), net	2,464	(2,962)	5,426	-183.2%
Net loss	<u>\$ (36,507)</u>	<u>\$ (15,869)</u>	<u>\$ (20,638)</u>	<u>130.1%</u>

#### *Research and development expenses*

Research and development expenses were \$19.7 million for the year ended December 31, 2019, compared to \$10.1 million for the year ended December 31, 2018. The increase of \$9.6 million was due primarily to an increase in preclinical studies and clinical trial-related activities of \$5.8 million; and an increase of \$2.8 million in chemistry, manufacturing and control, or CMC, activities in advance of our Phase 2b study of GB0139 and with respect to GB1211; and a \$1.0 million increase in staff, consultants and other costs.

#### *Purchased in-process research and development expense*

Purchased in-process research and development expense for the year ended December 31, 2019 relates to our GB2064 program, which we acquired from PharmAkea on December 31, 2019.

#### *General and administrative expenses*

General and administrative expenses were \$2.4 million for the year ended December 31, 2019, compared to \$2.8 million for the year ended December 31, 2018. The decrease of \$369,000 was primarily related to a reduction in consultant costs as we build our in-house staff, partially offset by an increase in legal costs of \$755,000 to support our expanding the product portfolio and incorporation in the United States and increased costs for general and administrative services of \$388,000.

#### *Other income(expense), net*

Other income (expense), net for the year ended December 31, 2019 and 2018 were a net income of \$2.5 million for the year ended December 31, 2019, compared to a net expense of \$3.0 million for the year ended December 31, 2018. The increase of \$5.4 million was due to the following:

- Net foreign exchange gains were \$551,000 and \$487,000 for the years ended December 31, 2019 and 2018, respectively.



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- Fair value adjustments on our tranche obligations relating to the sale of our Series C-2 preferred stock in October 2018 were a \$1.9 million gain and a \$115,000 loss for the years ended December 31, 2019 and 2018, respectively.
- We had no derivative obligations in the year ended December 31, 2019. Fair value adjustments to our derivative obligation attendant to the notes that converted into Series C-1 preferred stock in October 2018 was a loss of \$364,000 for the year ended December 31, 2018.
- We incurred no interest expense in the year ended December 31, 2019. Interest expense during the year ended December 31, 2018 on our notes that converted into Series C-1 preferred stock in October 2018 was \$3.0 million.

## Liquidity and Capital Resources

### Sources of Liquidity

Our operations to date have been financed primarily by aggregate net proceeds of \$102.2 million from the issuance of convertible preferred shares, convertible notes and common stock. Since inception, we have had significant operating losses. Our net loss was \$36.5 million and \$15.9 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of \$69.5 million and \$11.3 million in cash and cash equivalents. 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.

Our independent registered public accounting firm included an explanatory paragraph in its audit report on our consolidated financial statements as of and for the years ended December 31, 2019 and 2018 stating that our recurring losses from operations and negative cash flows since inception and our need to raise additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern.

### Cash Flows

The following table summarizes our cash flows for the periods indicated:

	<u>Year Ended December 31,</u>	
	<u>2019</u>	<u>2018</u>
	<u>(in thousands)</u>	
Net cash used in operating activities	\$ (19,326)	\$ (13,691)
Net cash used in investing activities	(326)	—
Net cash provided by financing activities	—	42,874
Net increase in cash and cash equivalents	<u>\$ (19,652)</u>	<u>\$ 29,183</u>

### Net Cash Used in Operating Activities

Cash used in operating activities of \$19.3 million during the year ended December 31, 2019 was attributable to our net loss of \$36.5 million together with non-cash items of \$1.9 million principally with respect to fair value adjustments on our tranche obligations, offset by purchased in-process research and development of \$16.8 million and a net increase of \$2.2 million in our working capital.

Cash used in operating activities of \$13.7 million during the year ended December 31, 2018 was attributable to our net loss of \$15.9 million together with a net decrease of \$933,000 in our working capital, offset by non-cash charges of \$3.1 million principally with respect to interest expense.

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### ***Net Cash Used in Investing Activities***

Investing activities in the year ended December 31, 2019 are comprised of transaction costs with respect to our acquisition of PharmAkea less PharmAkea's book balance of cash on the date of acquisition.

We had no investing activities in the year ended December 31, 2018.

### ***Net Cash (Used In) Provided by Financing Activities***

We had no cash used in or provided by financing activities in the year ended December 31, 2019.

Cash provided by financing activities for the year ended December 31, 2018 was \$42.9 million comprised of \$34.5 million of net proceeds from the sale and issuance of our Series C convertible preferred shares in October 2018, and \$8.5 million of net proceeds from the issuance of convertible notes in February and May 2018.

### **Funding Requirements**

Any product candidates we may develop may never achieve commercialization and we anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. As a result, until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses; costs related to third-party clinical research, manufacturing and development services; costs relating to the build-out of our headquarters and other offices, our laboratories and our manufacturing facility; license payments or milestone obligations that may arise; laboratory expenses and costs for related supplies; clinical costs; manufacturing costs; legal and other regulatory expenses and general overhead costs.

Based upon our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents of \$11.3 million as of December 31, 2019 and the \$39.7 million proceeds received in January 2020 on the sale and issuance of our Series C-4 preferred stock and Series C-5 preferred stock will be sufficient to continue funding our development activities through . To finance our operations beyond that point we will need to raise additional capital, which cannot be assured. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We will continue to require additional financing to advance our current product candidates through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. We will continue to seek funds 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. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders, including investors in this offering, will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and 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 capital, we will need to delay, reduce or terminate planned activities to reduce costs.

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Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the impacts of the COVID-19 pandemic;
- the progress, costs and results of our ongoing Phase 2b clinical trial of GB0139 and our planned trials for our other product candidates;
- the scope, progress, results and costs of discovery research, preclinical development, laboratory testing and clinical trials for our product candidates, including our ongoing Phase 2b clinical trial of GB0139;
- the number of, and development requirements for, other product candidates that we pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to enter into contract manufacturing arrangements for supply of active pharmaceutical ingredient, or API, and manufacture of our product candidates and the terms of such arrangements;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the payment or receipt of milestones and receipt of other collaboration-based revenues, if any;
- the costs and timing of any future commercialization activities, including product manufacturing, sales, marketing and distribution, for any of our product candidates for which we may receive marketing approval;
- the amount and timing of revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property-related claims;
- the extent to which we acquire or in-license other products, product candidates, technologies or data referencing rights;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations; and
- the costs of operating as a public company.

Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

## **Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

### **Going Concern**

Our evaluation of our ability to continue as a going concern requires us to evaluate our future sources and uses of cash sufficient to fund our currently expected operations in conducting research and development activities one year from the date our consolidated financial statements are issued. We evaluate the probability associated with each source and use of cash resources in making our going concern determination. The research and development of pharmaceutical products is inherently subject to uncertainty.

### **Research and Development Costs**

We incur substantial expenses associated with clinical trials. Accounting for clinical trials relating to activities performed by CROs and other external vendors requires management to exercise significant estimates in regard to the timing and accounting for these expenses. We estimate costs of research and development activities conducted by service providers, which include, the conduct of sponsored research, preclinical studies and contract manufacturing activities. The diverse nature of services being provided under CRO and other arrangements, the different compensation arrangements that exist for each type of service and the lack of timely information related to certain clinical activities complicates the estimation of accruals for services rendered by CROs and other vendors in connection with clinical trials. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and include these costs in the accrued and other current liabilities or prepaid expenses on the balance sheets and within research and development expense on the consolidated statements of operations. In estimating the duration of a clinical study, we evaluate the start-up, treatment and wrap-up periods, compensation arrangements and services rendered attributable to each clinical trial and fluctuations are regularly tested against payment plans and trial completion assumptions.

We estimate these costs based on factors such as estimates of the work completed and budget provided and in accordance with agreements established with our collaboration partners and third-party service providers. We make significant judgments and estimates in determining the accrued liabilities and prepaid expense balances in each reporting period. As actual costs become known, we adjust our accrued liabilities or prepaid expenses. We have not experienced any material differences between accrued costs and actual costs incurred since our inception.

Our expenses related to clinical trials are based on estimates of patient enrollment and related expenses at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that may be used to conduct and manage clinical trials on our behalf. We generally accrue expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

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We acquired the right to develop and commercialize PharmAkea's product candidate PAT-1251, which we now refers to as GB2064. GB2064 is in clinical development and has not achieved regulatory approval for marketing and absent obtaining such approval, has no alternative future use. As such the costs of acquiring GB2064 are immediately expensed as purchased in-process research and development costs in our consolidated statements of operations.

### ***Equity-based Compensation***

Prior to this offering, we issued equity-based compensation awards through the granting of stock options, which generally vest over a four-year period. We account for equity-based compensation in accordance with ASC 718, *Compensation-Stock Compensation*, or ASC 718. In accordance with ASC 718, compensation cost is measured at estimated fair value and is included as compensation expense over the vesting period during which service is provided in exchange for the award.

We use a Black-Scholes option pricing model to determine fair value of our stock options. The Black-Scholes option pricing model includes various assumptions, including the fair value of common shares, expected life of stock options, the expected volatility and the expected risk-free interest rate. These assumptions reflect our best estimates, but they involve inherent uncertainties based on market conditions generally outside our control. As a result, if other assumptions had been used, equity-based compensation cost could have been materially impacted. Furthermore, if we use different assumptions for future grants, share-based compensation cost could be materially impacted in future periods.

We did not grant any stock options in the year ended December 31, 2019. The fair value of our award in the year ended December 31, 2018 has been estimated using Black-Scholes based on the following assumptions: term of 5 years; volatility of 80%; risk-free rate of 2.8%; and no expectation of dividends.

We will continue to use judgment in evaluating the assumptions utilized for our equity-based compensation expense calculations on a prospective basis. In addition to the assumptions used in the Black-Scholes model, the amount of equity-based compensation expense we recognize in our consolidated financial statements includes stock option forfeitures as they occurred.

As there has been no public market for our common shares to date, our board of directors, with input from management, has determined the estimated fair value of our common shares as of the date of each incentive share grant considering our then-most recently available third-party valuation of common shares. Valuations are updated when facts and circumstances indicate that the most recent valuation is no longer valid, such as changes in the stage of our development efforts, various exit strategies and their timing, and other scientific developments that could be related to our valuation, or, at a minimum, annually. Third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*.

For grants of options we made in 2018, we employed a market approach and utilized a back-solve method for inferring the equity value predicated on the closing of our Series C redeemable convertible preferred shares in October 2018, and we allocated value among different classes of equity securities under a Black-Scholes option pricing methodology.

The estimates of fair value of our common shares are highly complex and subjective. There are significant judgments and estimates inherent in the determination of the fair value of our common shares. These judgments and estimates include assumptions regarding our future operating performance, the time to completing an initial public offering, or IPO, or other liquidity event, the related valuations associated with these events, and the determinations of the appropriate valuation methods at each valuation date. The assumptions underlying these valuations represent our best estimates, which involve inherent uncertainties and the application of management

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judgment. If we had made different assumptions, our equity-based compensation expense, net loss and net loss per share applicable to common shareholders could have been materially different.

Following the completion of this offering, we intend to determine the fair value of our common stock based on the closing price of our common stock on the date of grant as reported on the Nasdaq Global Market.

The following table details equity-based awards that we granted and awarded in the years ended December 31, 2019 and 2018:

<u>Grant Date</u>	<u>Number of Shares Subject to Awards Granted</u>	<u>Per Share Exercise Price</u>	<u>Estimate of Common Share Fair Value Per Share on Grant Date</u>	<u>Black Scholes Value Per Share on Grant Date</u>
July 2, 2018	8,000	\$ 16.06	\$ 10.39	\$ 9.79

### ***Income Taxes***

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating losses and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted statutory tax rates expected to apply to taxable income in the jurisdictions and years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

Based on the level of historical operating results and projections for the taxable income for the future, we have determined that it is more likely than not that our net deferred tax assets will not be realized. Accordingly, we have recorded a full valuation allowance to reduce our net deferred tax assets.

We recognize tax benefits from uncertain tax positions only if (based on the technical merits of the position) it is more likely than not that the tax positions will be sustained on examination by the tax authority. The tax benefits recognized in the financial statements from such positions are measured based on the largest amount that is more than 50% likely to be realized upon ultimate settlement. We recognize interest and penalties related to unrecognized tax benefits within the provision for taxes in our consolidated statements of operations and comprehensive loss.

We operate in multiple jurisdictions, both within and outside the United States, and may be subject to audits from various tax authorities. Management's judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities, liabilities for uncertain tax positions, and any valuation allowance recorded against our net deferred tax assets. We will monitor the extent to which our deferred tax assets may be realized and adjust the valuation allowance accordingly.

### ***Recently Adopted Accounting Pronouncements***

Refer to Note 2, "Summary of Significant Accounting Policies," in the accompanying notes to our consolidated financial statements for the years ended December 31, 2019 and 2018 appearing elsewhere in this prospectus for a discussion of recent accounting pronouncements.

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### Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2019:

	Payments due by period (in thousands)				
	Total	Less than one year	One to three years	Three to five years	More than five years
Leases	\$ 353	\$ 107	\$ 128	\$ 118	\$ —
Total contractual obligations	<u>\$ 353</u>	<u>\$ 107</u>	<u>\$ 128</u>	<u>\$ 118</u>	<u>\$ —</u>

We enter into contracts in the normal course of business with third-party service providers for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. We have not included our payment obligations under these contracts in the table, as these contracts generally provide for termination upon notice, and therefore, we believe that our non-cancelable obligations under these agreements are not material and we cannot reasonably estimate the timing of if and when they will occur. We could also enter into additional research, manufacturing, supplier and other agreements in the future, which may require up-front payments and even long-term commitments of cash.

### Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

### Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company as defined by Item 10 of Regulation S-K and are not required to provide the information otherwise required under this item.

### Emerging Growth Company Status

As an EGC under the JOBS Act, we may delay the adoption of certain accounting standards until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for EGCs include presentation of only two years of audited consolidated financial statements in a registration statement for an IPO, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements.

In addition, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an EGC to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We may remain classified as an EGC until the end of the fiscal year following the fifth anniversary of this offering, although if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of June 30 of any year before that time, or if we have annual gross revenues of \$1.07 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than \$1.0 billion of non-convertible debt over a three-year period.

**BUSINESS**

**Overview**

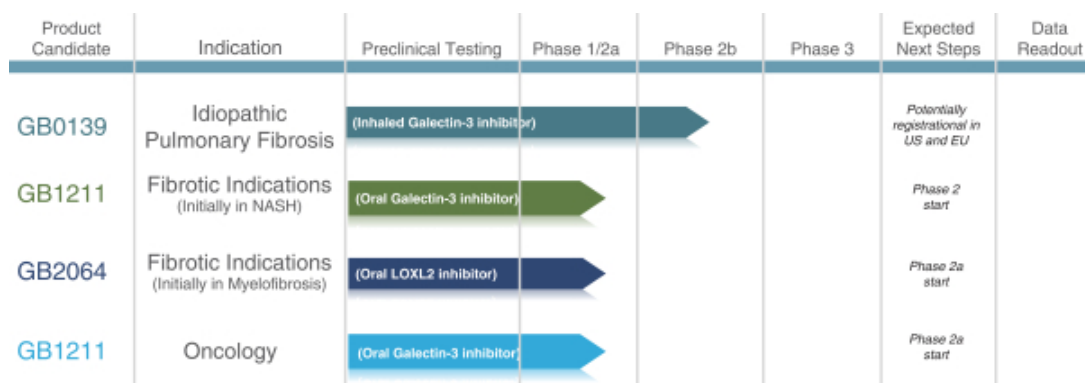
We are a clinical-stage biotechnology company developing therapeutics that are designed to target the biological processes that lie at the heart of fibrosis and impact a broad range of fibrotic and related diseases, including cancer. Our initial focus is on the development of small-molecule inhibitors of galectin-3 and LOXL2, which play key roles in regulating fibrosis. We believe our product candidates are distinct from the current generation of antifibrotic agents and have the potential to significantly improve patients’ clinical outcomes and enhance their quality of life.

Our lead product candidate, GB0139, is an inhaled inhibitor of galectin-3. We are developing GB0139 for the treatment of severe fibrotic lung diseases such as IPF, a life-threatening progressive fibrotic disease of the lung that affects approximately 100,000 people in the United States. While there are currently two approved therapies for the treatment of lung fibrosis, neither has been associated with improvements in overall survival, and both therapies have been associated with significant side effects leading to poor therapeutic adherence. In our clinical trials to date, we have demonstrated that orally inhaled GB0139 is well-tolerated and inhibits galectin-3 in the lungs, in a dose-dependent manner, and that it significantly decreases levels of a range of plasma biomarkers, such as YKL-40, that have been linked to mortality, severity and/or progression in IPF. We have conducted a Phase 2a study in 24 IPF patients and we have initiated a potentially registrational, randomized Phase 2b trial in 450 IPF patients. We expect topline results from this ongoing trial to be available in

Our product candidate portfolio also includes: GB1211, a selective oral galectin-3 inhibitor that we are developing for the treatment of fibrosis related to NASH, and GB2064, a selective oral inhibitor of LOXL2 that we initially plan to develop for the treatment of myelofibrosis, a malignant disease of the bone marrow in which fibrosis reduces the ability to form blood cells. We expect to initiate Phase 2 clinical trials for both GB1211 and GB2064 in . We plan to further expand our development of GB1211 into other related indications including cancer.

**Our Pipeline**

We have retained global development and commercialization rights to all of the product candidates in our pipeline. The chart below summarizes key information about our programs. We are also progressing several preclinical assets against other proteins that have been associated with disease.





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Our initial focus is developing GB0139 for the treatment of IPF, but we plan to further develop GB0139 with the goal of treating most of the forms of lung fibrosis. GB0139 targets galectin-3, one of the key regulators of lung fibrosis. The overexpression of galectin-3 is ubiquitous in fibrotic tissue, including in fibrotic lung tissue, and is linked to both disease severity and disease progression, as well as acute exacerbations of IPF. However, there are no therapeutics approved that specifically target galectin-3. In our clinical, preclinical and *in vitro* testing to date, we have demonstrated that GB0139 directly targets galectin-3 in the lungs and markedly lowers the plasma levels of biomarkers of fibrosis in patients.

In our Phase 1/2a trial in both healthy volunteers and IPF patients, GB0139 was well-tolerated, showed consistent and tight pharmacokinetics measured as plasma levels of the compound, and inhibited galectin-3 in the lungs of IPF patients in a dose-dependent manner. We are currently conducting a Phase 2b randomized, double-blind placebo-controlled clinical trial of GB0139 in 450 IPF patients. The primary endpoint of the trial is to assess annual rate of decline in FVC. Reduction in the decline of FVC is the endpoint that was accepted by the FDA for the approval of both of the current therapeutic treatments for IPF. We anticipate that results from this trial will become available in . We believe, pending feedback from regulatory authorities, that a positive result in this trial has the potential to support an application for conditional approval of GB0139 in the EU. We believe that this trial also has the potential to be regarded as a registrational trial in the United States. In addition, on August 27, 2020, we announced that GB0139 for the treatment of IPF had been granted Orphan Drug Designation by both U.S. and European regulatory authorities.

We are also developing GB1211, an orally delivered molecule that we believe has the potential to treat multiple types of fibrotic and related diseases, including NASH, renal fibrosis, cardiac fibrosis and various cancers. Our initial target indication for GB1211 is fibrosis related to NASH, a highly prevalent progressive liver disease with no available FDA-approved therapies. GB1211 showed antifibrotic activity in multiple preclinical models and has successfully completed a Phase 1 trial in 78 healthy volunteers. In the Phase 1 trial, GB1211 was well-tolerated and had dose-dependent pharmacokinetics. We are planning to initiate a Phase 2a trial of GB1211 in fibrosis related to NASH in 72 patients, with data expected in . In addition to our Phase 2a trial, we plan to further expand our development of GB1211 into other related indications, including cancer.

GB2064 is a selective oral inhibitor of LOXL2 that has demonstrated antifibrotic activity in lung, liver and kidney preclinical models of fibrosis. Our initial focus is developing GB2064 in myelofibrosis, one of the several types of cancer and multiple fibrotic diseases in which expression of LOXL2 is significantly increased. Myelofibrosis is a disease with significant morbidity and mortality that affects between 16,000 and 18,500 patients in the United States. The current standard of care for myelofibrosis consists of inhibitors of the JAK2 protein kinase, which alleviate the disease symptoms through inhibition of cell proliferation but do not directly target fibrosis. GB2064 has successfully completed a Phase 1 trial in 78 healthy volunteers, in which GB2064 administered orally led to dose-dependent inhibition of LOXL2 in serum. We believe that GB2064 has the potential to have a direct impact on the fibrotic process and to slow the progression of the disease as opposed merely to treating the underlying symptoms. We anticipate initiating a Phase 2a trial of GB2064 in myelofibrosis in , with data expected in .

We are built upon more than ten years of research into galectin and fibrosis modulators and were founded by leading researchers on the galectin family of proteins, including one of the discoverers of the galectin family of proteins, the first chemist to develop selective galectin inhibitors and the discoverer of galectin-3's role in fibrosis. We have developed from a university spin-out, with only one part-time employee at inception in December 2011, to a company with three different potential drugs in clinical development.

We believe that our founders' and management's experience provides unique insights into the targets that underlie the biological processes of fibrosis and other related diseases. We are led by Hans Schambye, MD, Ph.D., our Chief Executive Officer, a biotechnology executive who previously served as CEO of Recepticon and Gastrotech Pharma. Professor Bertil Lindmark, M.D., Ph.D., our Chief Medical Officer, has extensive experience in the pharmaceutical industry and previously held globally leading positions at AstraZeneca and Almirall.

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Anders Pedersen, our Chief Operating Officer, has over 25 years of experience in process development and discovery of pharmaceuticals including at CMC Biologics and Novo Nordisk. Jonathan Freve, our Chief Financial Officer, served as CFO with Spring Bank Pharmaceuticals and has extensive experience in public and private financings, licensing deals and acquisitions. We are supported by our board of directors and clinical advisory boards, and have been funded to date by leading life sciences investors including Bay City Capital, Bristol-Myers Squibb, HBM Healthcare Investments, M Ventures, Maverick Ventures, Novo Holdings A/S, OrbiMed, SEED Capital, Seventure, Sunstone Capital and Ysios Capital.

### **Our Strategy**

Our goal is to become a leader in developing and commercializing therapeutics that directly target the biological processes at the heart of fibrosis across a broad range of fibrotic and related diseases with significant unmet medical need. Our strategy is focused on the following key components:

- **Efficiently advance GB0139 in IPF through clinical development.** We are currently conducting a randomized double-blind placebo-controlled Phase 2b trial of GB0139 in 450 patients with IPF with data expected in . This orphan disease is therapeutically underserved, and we believe that GB0139 may have the ability to become the first true disease modifying therapy. Pending feedback from regulatory authorities, we believe that a positive result in this trial has the potential to support an application for conditional approval of GB0139 in the EU and that the trial also has the potential to be regarded as a registrational trial in the United States. Assuming positive results from the Phase 2b trial, we intend to expeditiously initiate a Phase 3 trial in IPF.
- **Build on our understanding of the galectin-3 target to advance GB1211 through a Phase 2a trial in fibrosis related to NASH and in additional indications.** We are developing GB1211 for the treatment of fibrosis related to NASH and intend to conduct a Phase 2a trial with data expected in . We believe our understanding of the galectin-3 target may be applicable to other fibrotic liver diseases such as non-alcoholic cirrhosis and alcoholic cirrhosis, where there is a vast medical need. Additionally, we believe that GB1211 has the potential to treat fibrosis arising from multiple other diseases. We are also developing GB1211 for use in oncology and are continuously evaluating its potential in additional indications.
- **Leverage our understanding of the LOXL2 pathway to advance GB2064 through a Phase 2 trial in myelofibrosis and continue evaluating GB2064 in subsequent indications.** We intend to initiate a Phase 2a trial of GB2064, our lead product candidate targeting LOXL2, in myelofibrosis in . We expect to report data for this trial in , which may potentially lead to an accelerated development path for GB2064 in this orphan and underserved disease. We will subsequently evaluate GB2064 in other fibrotic indications as a monotherapy or in combination with our other product candidates.
- **Expand our antifibrotic portfolio by opportunistically advancing our research and development efforts beyond our current expertise in the Galectin-3 and LOXL2 pathways.** We intend to expand our leadership as a company dedicated to developing therapies that directly target the biological processes at the heart of fibrosis by developing product candidates against other targets involved in the regulation, formation, or maintenance of fibrosis. We also intend to selectively pursue business development opportunities to expand our antifibrotic product portfolio.
- **Continue to build a patient-focused company targeting fibrosis across a broad range of fibrotic diseases.** In building a patient-focused company to address the needs of patients with fibrotic diseases, we will work with clinicians, patient advocacy groups, medical centers of excellence and medical key opinion leaders to better understand the symptoms and consequences of fibrotic diseases, to expeditiously develop and provide better treatments to patients, and to increase awareness of these diseases.

- **Maximize the commercial value of our product candidates.** We have retained worldwide development and commercial rights to all of our product candidates. We intend to commercialize any products in our portfolio for which we receive regulatory approvals in certain rare indications in the United States and the EU with a limited and targeted commercial team. We also intend to retain the flexibility to evaluate strategic collaborations and to seek partners to commercialize our products in other geographies and for our products in highly prevalent indications such as fibrosis related to NASH, which require significant investment to build a commercial infrastructure.

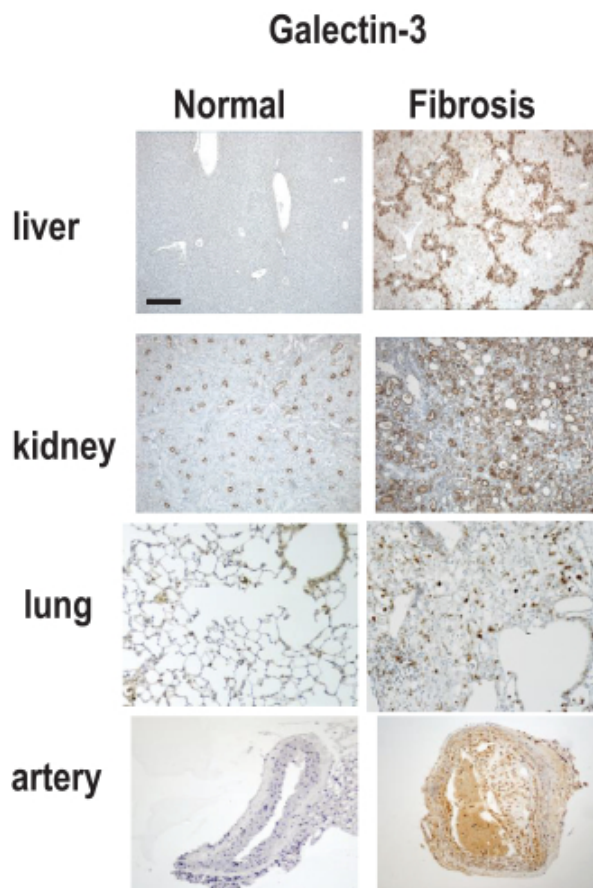
### **Fibrosis background**

Fibrosis is the development of abnormal fibrous connective tissue in response to injury, damage or dysfunctional gene regulation. This fibrous connective tissue consists of elongated proteins such as collagen and elastin fibers that provide support to surrounding key functional cells in all tissue and all organs. Production and break-down of collagen is tightly regulated to preserve optimal organ function. The deposition of excess collagen and the formation of fibrosis can cause remodeling of surrounding healthy tissue and the loss of normal organ or tissue function. Fibrotic disease can affect tissues throughout the body including the lungs, liver, heart, kidneys and vascular system. Fibrosis typically progresses slowly and can ultimately lead to organ failure and death. Fibrosis is also a hallmark of solid tumors, with up to 20 percent of cancers linked to chronic inflammation-linked fibrosis. It has been estimated that fibrosis contributes to up to 45 percent of all deaths in the developed world.

The currently approved therapeutic treatments for IPF are associated with significant side effects leading to significant discontinuation rates with median time on treatment only between 7.5 and 8.9 months, and they have not been linked to improvements in overall survival. Scientific literature supports the understanding that there are common biological mechanisms that drive fibrosis that are distinct from those regulating inflammation. It is these mechanisms that we are targeting with our proprietary product candidates. We are developing small-molecule fibrosis inhibitors focusing on galectin-3 and LOXL2, two of the targets that are believed to underlie the biological processes that drive fibrosis.

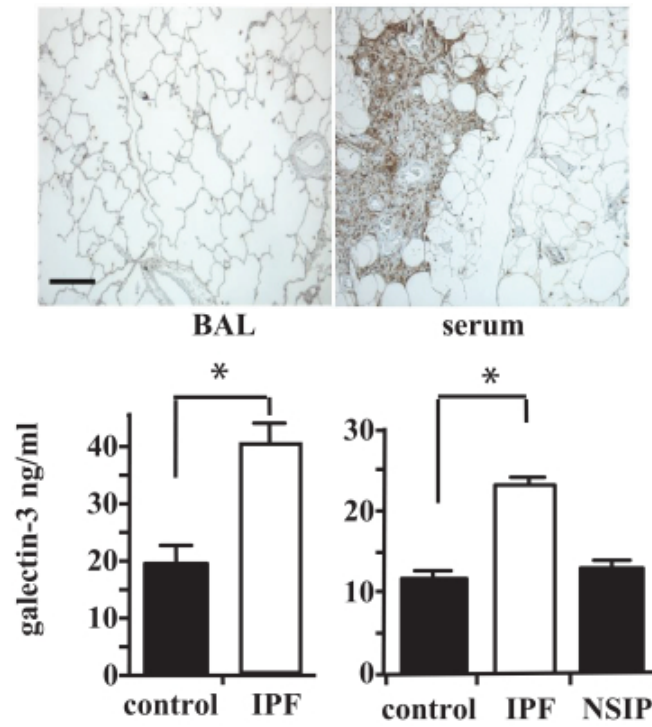
### ***Galectin-3***

Galectin-3 is a lectin central to the development of fibrotic disease across multiple tissue types and is part of a pre-innate galectin immune defense developmentally conserved for over 500 million years, which steers local inflammation and when chronically activated, drives the development of fibrosis via several pathways and several cell inflammatory cell types and fibrocytes.



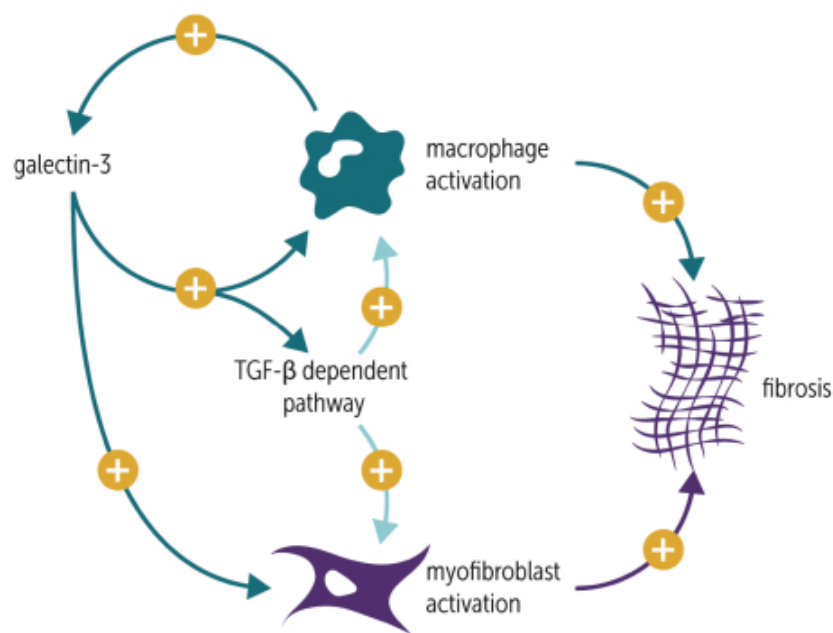
**Figure 1. Galectin-3 increase in fibrotic tissues from patients with liver, kidney, lung and artery fibrosis**

While it is expressed in various tissues throughout the body at a low level, galectin-3 is overexpressed, sometimes profoundly, in damaged or inflamed tissues. Galectin-3 drives fibrosis by activating multiple pathways involved in tissue repair. The presence of excess galectin-3 triggers the fibrotic process by converting quiescent fibroblast cells into cells called myofibroblasts. This triggering effect takes place when galectin-3 modulates growth factor receptors such as TGF-beta, a master regulator of cell growth. Myofibroblasts are harmful in the context of fibrosis, since they secrete excess collagen and elastin, and as such are the key cellular drivers of fibrosis. Furthermore, galectin-3 reduces apoptosis, or programmed cell death, of inflammatory cells called neutrophils, allowing these cells to persist and potentially cause further pathology in fibrotic tissue. Finally, galectin-3 also promotes the activation of macrophages, resulting in increased fibrosis as well as further galectin-3 expression, which leads to a feed-forward cycle that can accelerate the fibrotic process.



**Figure 2. Comparison of galectin-3 in a normal lung versus a fibrotic lung**

The galectin-3 mediated fibrosis is central to IPF and to several cancer types. The galectin-3 inhibitors inhibit the carbohydrate recognition domain stopping the attachment of galectin-3 to sugar moieties on cell surfaces receptors, and therefore stops its activation of key molecules like the receptors for TGF-beta and VEGF. Given its central role in fibrosis, there are FDA-cleared diagnostics for the detection of galectin-3 used for assessing the prognosis of patients diagnosed with chronic heart failure.



**Figure 1. Multiple roles of galectin-3 in fibrosis**

Interestingly, studies have shown that galectin-3 is not expressed during the first trimester of pregnancy and surgery during this time period leaves no scars. The inability of first trimester fetuses to scar further demonstrates that fibrotic tissue cannot develop if galectin-3 is missing or blocked. Preclinical studies have also shown that mice deficient in galectin-3 exhibit decreased fibrosis in models of liver, kidney, and lung disease. Furthermore, inhibition of galectin-3 has been shown to slow the development of lung, liver and cardiac fibrosis in preclinical models.

In patients with IPF, elevated galectin-3 is found in the fibrotic patches in the lung, in BAL fluid and in plasma. Patients with liver cirrhosis have highly elevated galectin-3 levels in biopsies of their liver nodules. Elevated galectin-3 is also found in serum of patients with fibrosis related to NASH and other diseases characterized by fibrosis such as cancer, cardiac disease and renal disease. The level of galectin-3 expression in fibrotic tissue correlates with the degree of fibrosis.

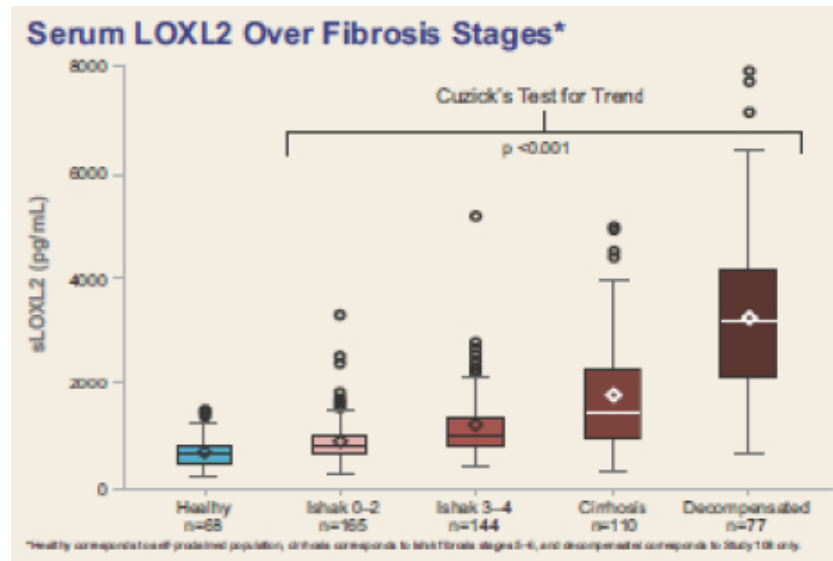
Despite galectin-3's proximity to and involvement in fibrosis disease pathology, no approved drugs specifically target galectin-3. However, there are FDA-cleared diagnostics for the detection of galectin-3 in plasma to assess the prognosis of patients diagnosed with chronic heart failure.

### ***LOXL2***

Lysyl oxidases are a family of enzymes that are secreted from the cell. Once outside the cell membrane, these enzymes help create and strengthen connective tissue by catalyzing the crosslinking of proteins such as collagen and elastin in the extracellular matrix, which is essential for normal tissue function, but can become fibrotic and lead to organ dysfunction in the diseased state. There are five members of the LOX family in humans, LOX and LOXL1 through LOXL4. Each of these family members is believed to play a specific role in the formation and maintenance of the extracellular matrix. Any therapy that is not sufficiently specific to LOXL2 (i.e., that also interacts with other members of the LOX family) is at risk for creating toxicity. Mice deficient in

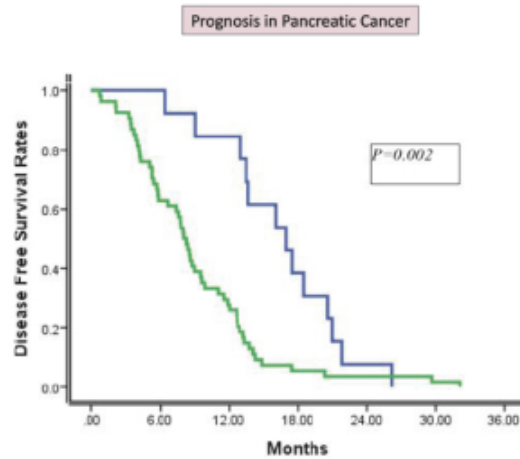
the gene for LOX, for example, die soon after birth as a result of defects in the formation of the cardiovascular and respiratory systems.

We have chosen to target only the LOXL2 enzyme because it plays a key role in the development of fibrosis. In fibrotic diseases such as lung, liver, and kidney fibrosis, increased levels of LOXL2 are observed. The level of LOXL2 expression correlates with the degree of liver fibrosis, with the highest levels of LOXL2 being found in cirrhosis and in decompensated liver disease.



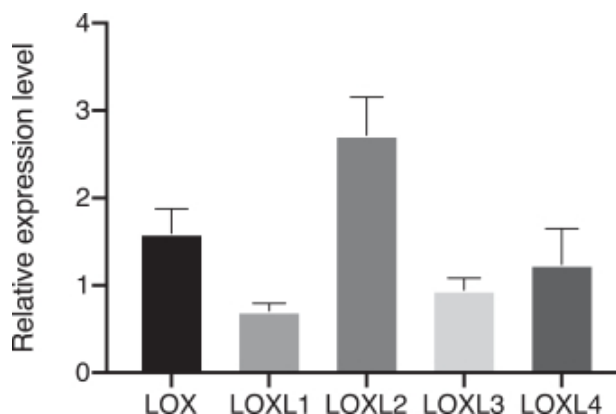
**Figure 2. LOXL2 expression correlates with degree of liver damage in patients with chronic hepatitis B**

LOXL2 is also increased in cancer-related fibrosis across a wide range of cancers, including breast, colon, and pancreatic cancers. The presence of LOXL2 is a negative prognostic for survival in pancreatic cancer with patients with tumors expressing LOXL2 having an overall survival of approximately half of those with LOXL2 negative tumors.



**Figure 3. Pancreatic tumors expressing LOXL2 are associated with a poor prognosis**

LOXL2 is significantly upregulated in mesenchymal stromal cells, which are bone marrow cells that support hematopoietic stem cell differentiation, isolated from patients with myelofibrosis compared to healthy adults. The levels of other LOX family members do not significantly change between healthy and diseased mesenchymal stromal cells.



**Figure 4. LOXL2 is highly overexpressed in myelofibrosis stromal cells (expression level in myeloid biopsies from myelofibrosis patients relative to expression in healthy individuals)**

Clinical experience with drugs specifically targeting LOXL2 has been limited. Simtuzumab, an antibody targeting LOXL2 that is administered by a subcutaneous or intravenous injection, has been evaluated in a number of clinical trials, including two Phase 2b trials in patients with advanced NASH and in myelofibrosis. These trials failed to show a positive effect on the reduction of fibrosis and further development of simtuzumab has been discontinued. Simtuzumab binds to LOXL2 without fully inhibiting its catalytic activity. This activity is, we believe, the critical feature of LOXL2 that needs to be blocked in order to achieve maximal antifibrotic activity. Small molecules that directly inhibit the catalytic activity of LOXL2, such as our product candidate GB2064, and which have the ability to penetrate deeper into fibrotic tissue than a large molecule antibody, may show greater activity as antifibrotic agents, given that small molecules can more readily bind to the catalytic site of an enzyme deep in fibrotic tissue. Inhibitors that preferentially target LOXL2 over other LOX family members may avoid triggering adverse events due to the ubiquitous and important roles that lysyl oxidases have in maintaining tissue structure throughout the body.

#### **Our product candidate portfolio**

##### **GB0139 for the treatment of IPF**

GB0139 is an inhaled small-molecule inhibitor of galectin-3 that we are developing for the treatment of IPF. The molecule is delivered via oral inhalation utilizing a dry powder inhaler, a standard capsule based inhaler that has been previously approved by the FDA for use in the delivery of other compounds.

##### **IPF Background and Market Opportunity**

IPF is a rare life-threatening disease characterized by progressive fibrosis of the lungs leading to their deterioration and destruction. The most common symptoms of IPF are shortness of breath and a dry persistent cough, and a decreasing ability to perform normal daily activities. Over time, as a result of the unrelenting progress of the disease, breathing difficulties increase and lack of oxygen to tissues triggers weight loss, aching muscles, chronic fatigue, generally deteriorating health and can ultimately lead to death, often within 2 to 5 years.



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IPF is a rare disease affecting approximately 100,000 people in the United States and occurs primarily in persons between the ages of 50 and 70. Between 30,000 and 40,000 new cases are diagnosed in the United States each year. The exact cause of IPF is not known, but a family history of the disease and environmental exposure to toxins, such as smoking, are known to increase the likelihood of developing the disease. Some patients with IPF develop other serious lung conditions such as lung cancer, pulmonary embolisms, pneumonia and pulmonary hypertension. Patients with IPF generally have a poor prognosis with a mean survival between two to five years depending on the stage of diagnosis and the rate of lung deterioration.

### ***Current treatments for IPF and their limitations***

Some IPF patients with mild or moderate symptoms are treated with either nintedanib, marketed as Ofev by Boehringer Ingelheim, or pirfenidone, marketed as Esbriet by Roche/Genentech. These drugs have been shown to slow progression of decrease in lung function associated with IPF and deterioration of pulmonary function, but neither drug has been associated with improvements in overall survival, and both have been associated with significant side effects. Over 60 percent of patients dosed with nintedanib have diarrhea and 14 percent experience elevated levels of liver enzymes. Thirty percent of patients treated with pirfenidone have skin rash, and nine percent experience photosensitivity, both of which can lead to dose reductions or discontinuations. Both agents have some efficacy in patients with more advanced disease, but high rates of discontinuations due to adverse events in these more frail patients limit their use. A survey of 290 physicians published by a third party in 2017 found that over half of IPF patients are not being treated with either agent for multiple reasons, including physicians not having sufficient confidence in clinical benefit and concerns about safety. A retrospective cohort analysis of prescription records conducted by researchers at the Mayo Clinic and presented in 2019 found that the adoption of pirfenidone and nintedanib by IPF patients was approximately ten percent for each therapy, supporting the earlier observation that the majority of IPF patients are not actively being treated. Despite this, total worldwide sales of pirfenidone and nintedanib in 2019 were over \$1.2 billion and \$1.6 billion, respectively.

Given the poor prognosis and the lack of therapies that impact survival, patients diagnosed with IPF are routinely referred for lung transplantations and it is generally recommended that all patients without contraindications for surgery be added to transplant lists. IPF patients represent the majority of all lung transplantations. However, the survival rate of IPF patients following transplant is lower than that observed for other diseases due to their advanced age and associated comorbidities.

### ***Our solution - GB0139***

We are developing GB0139 for inhaled delivery to target the IPF disease site directly in the periphery of the lung while limiting potential systemic toxicity. GB0139 is differentiated from current IPF therapies because it is designed to directly target galectin-3. GB0139 has been well-tolerated in clinical trials to date both in healthy adults and in IPF patients. In both populations, dosing with GB0139 resulted in highly consistent drug exposure and led to reductions in galectin-3 levels in macrophages isolated by BAL. In our Phase 2a clinical trial, local therapy in the lungs of IPF patients with GB0139 also led to markedly decreased levels of plasma biomarkers, such as YKL-40, that have been linked to mortality, severity and/or progression in IPF. We initiated a 52-week, 450-patient randomized double-blind placebo-controlled Phase 2b trial of GB0139 in IPF in January 2019. We anticipate data on the primary endpoint of annual rate of decline in FVC in these patients following 12-month dosing with GB0139 to be available in .

### ***Overview of Clinical Trials***

Our clinical data to date on GB0139 in IPF patients demonstrated that:

- High exposure of GB0139 can be delivered to the target tissue with low systemic exposure;
- Inhalation dosing of IPF patients is feasible and results in highly reproducible drug levels;

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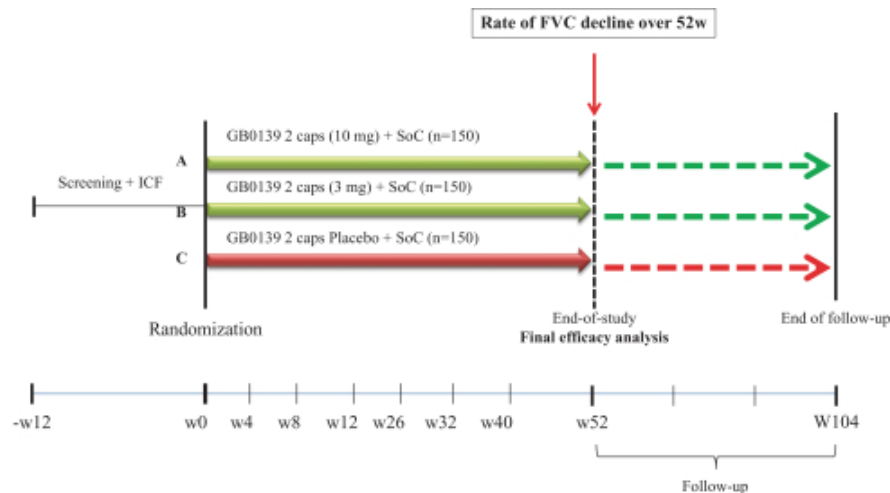
- GB0139 is well-tolerated, including daily dosing;
- GB0139 leads to dose-dependent decreases in galectin-3 levels; and
- GB0139 leads to decreases in multiple fibrosis biomarkers, including YKL-40, which is consistent with GB0139 having direct antifibrotic activity.

### Ongoing Phase 2b Clinical Trial

In our Phase 2b clinical trial, we are seeking to evaluate whether GB0139 leads to improvements in clinically meaningful outcomes in IPF patients.

We are currently conducting a 52-week randomized, double-blind placebo-controlled Phase 2b trial in IPF patients. The primary endpoint is the annual rate of decline in FVC at one year. FVC is a common test that measures the total amount of air that a person can expel from the lungs. A decline in FVC is an indirect measure of worsening fibrosis and increased lung stiffness and has become the most commonly accepted measure of disease progression in IPF. Reduction in decline of FVC is the endpoint that was accepted by the FDA for the approval of both pirfenidone and nintedanib.

Patients in this trial are receiving inhaled daily doses of 3 mg or 10 mg of GB0139 or placebo for one year. The annual rate of decline in FVC will be assessed as the primary endpoint using baseline FVC and several FVC measurements during the year to establish the rate of decline, and to compare that measure between patients on active treatment, with the annual rate of decline in FVC measured in patients who were treated with placebo. Secondary endpoints we will measure include the absolute decline in FVC; time to first hospitalization related to IPF, including acute IPF exacerbation; overall survival; and patient outcome measures such as 6-minute walk test distance and quality of life as determined by standard instruments. All patients will continue receiving their blinded treatments for up to two years until the last patient completes one year of dosing enabling the generation of extended safety and efficacy data.



ICF - Informed Consent Form, FVC - Forced Vital Capacity, R - Randomization, w - week, n - sample size, SoC - standard of care  
"2 caps" - GB0139 5mg x 2 or TD139 1.5mg x 2, respectively GB0139 Placebo

### Figure 5. GB0139 Phase 2b trial design

We plan to enroll 450 IPF patients in this trial across approximately 116 clinical sites in the United States, the EU, the U.K., Canada and Israel. We anticipate completion of this trial in . Pending feedback from the EMA, we believe that a positive result in this trial has the potential to support an application for conditional approval of GB0139 in the EU and, pending feedback from the FDA, that the trial also has the potential to be regarded as a registrational trial in the United States.

#### Completed Phase 1/2a Clinical Trial - Phase 2a Part in IPF Patients

We have conducted a randomized placebo-controlled Phase 1/2a multi-dose trial of GB0139 in the U.K., with the Phase 2a part conducted in 24 IPF patients. Patients in this part received 0.3, 3, or 10 mg of GB0139 or placebo control by inhalation once daily for 14 days. All patients completed the 14-day dosing, and BAL samples were obtained for all patients before dosing and at the conclusion of dosing.

GB0139 was well-tolerated in these patients with no serious drug-related adverse events, and there were no discontinuations in the trial. There were four incidents of mild adverse events (fever, upper respiratory tract infection, abnormal taste in mouth, dry throat) that were deemed possibly or probably drug-related.

Despite the presence of lung damage from IPF in patients entering this trial, inhalation of GB0139 resulted in highly reproducible drug levels (see Fig. 6 which shows very tight standard deviation intervals) that were very consistent between patients, and demonstrated higher uptake of GB0139 than in healthy adult males in the Phase 1 part of the trial. This indicates that IPF patients are able to receive an inhaled drug to the peripheral parts of their lungs, which is the site of disease. The higher plasma levels of GB0139 observed in the IPF patients is probably due to a loss of alveolar barrier integrity with increased epithelial permeability, which is present in the fibrotic lung.

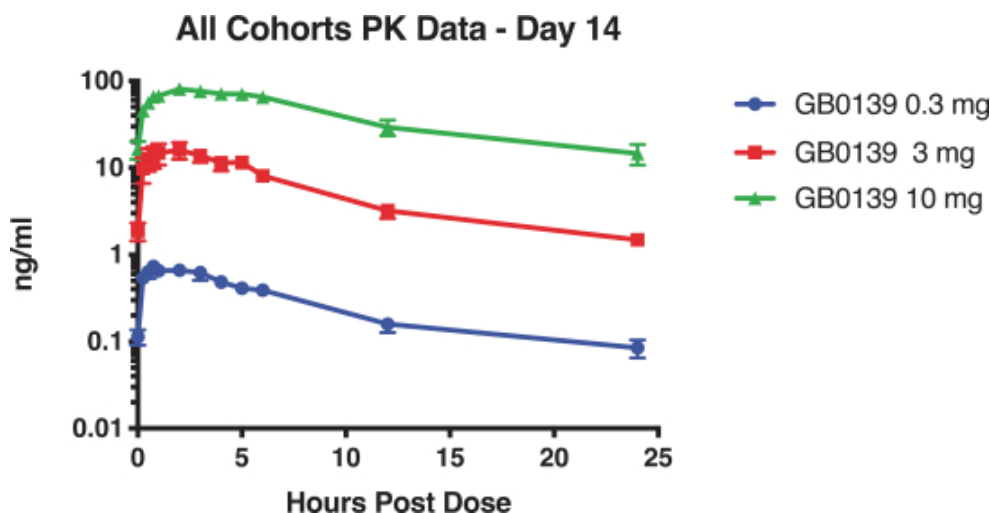
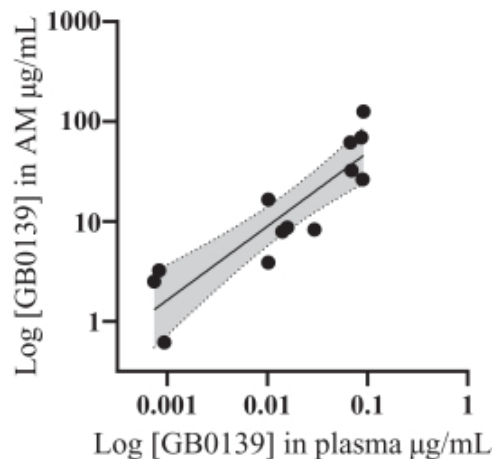


Figure 6. Consistent exposure of GB0139 among IPF patients in Phase 2a part of Phase 1/2a trial

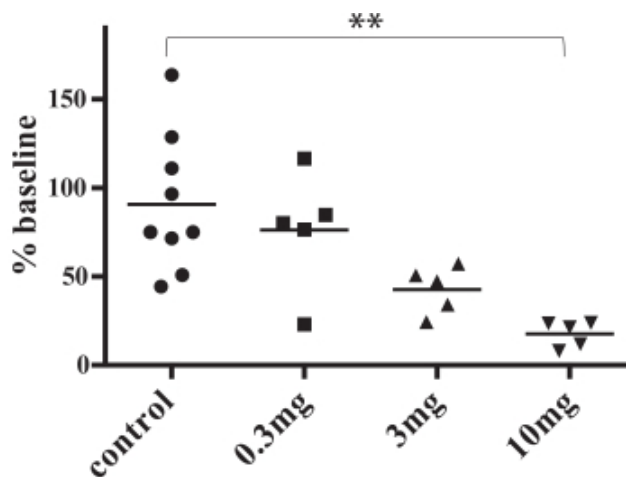
We also observed dose-dependent increases in GB0139 levels in alveolar macrophages obtained from the BAL fluid, confirming drug exposure in situ in the lung. There was a significant correlation between plasma levels of GB0139 and levels in the macrophages in BAL fluid (Pearson correlation coefficient 0.89 with  $p < 0.0001$ ). However, inhaled dosing of GB0139 resulted in drug levels that were between 567 and 1,930 times higher in alveolar macrophages than in plasma at two hours post-dose on day 14. This large difference in drug

levels between plasma and alveolar lung macrophages supports our approach of delivering GB0139 through inhalation to maximize the exposure of the target lung tissue to the drug, while minimizing systemic exposure, which we believe will improve patient safety and tolerability.



**Figure 7. Correlation between GB0139 levels in alveolar macrophages (AM) and plasma.**

Dosing with GB0139 led to dose-dependent decreases in galectin-3 levels on the cell surface of macrophages harvested from the BAL fluid, providing further evidence that GB0139 was able to reach the target tissue and significantly reduce the levels of the galectin-3 target protein attached to macrophages. These cells play an active part in the pathobiology in IPF.

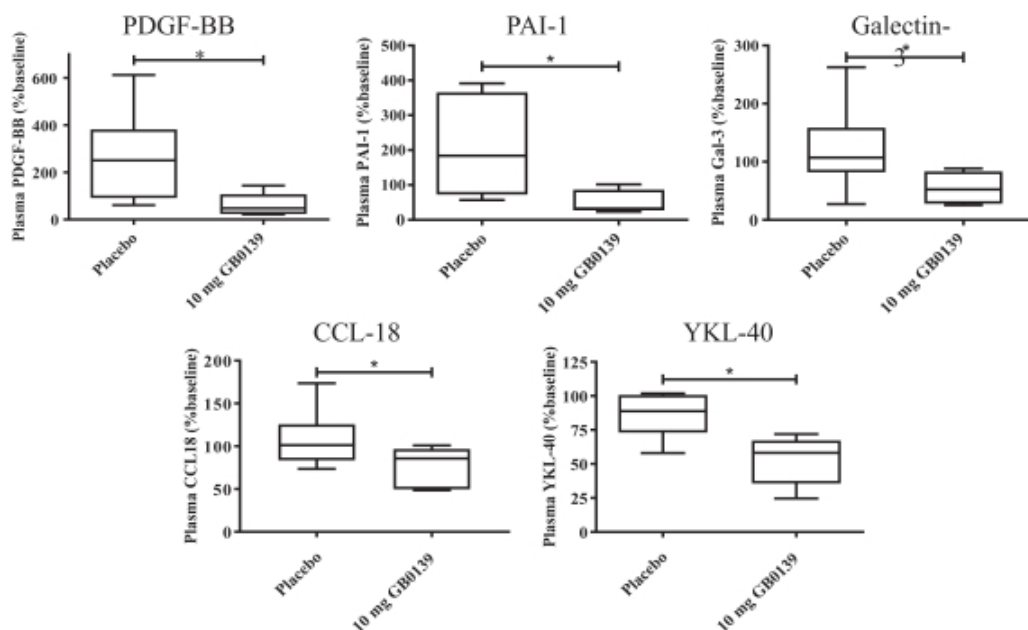


**Figure 8. GB0139 led to dose-dependent decrease of galectin-3 in alveolar macrophages**

Treatment of IPF patients with GB0139 also resulted in decreases in serum levels of a broad panel of biomarkers associated with fibrosis and progression of IPF, as well as decreases in levels of galectin-3. These include:

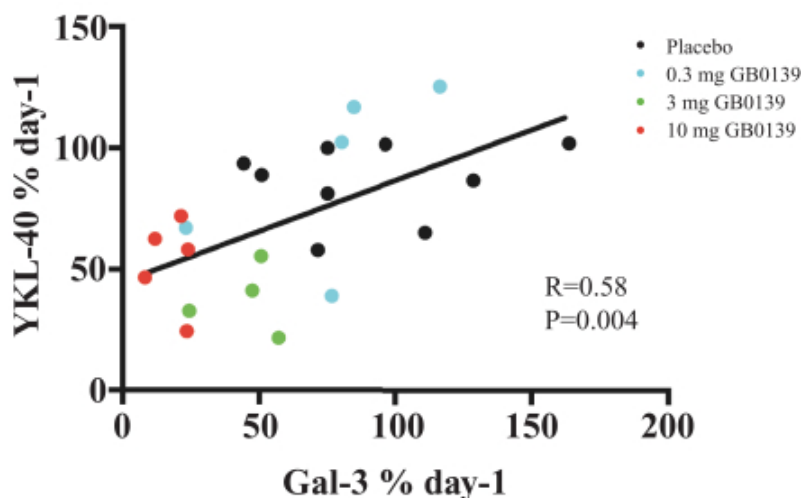
- YKL-40, an inflammation-related glycoprotein, the levels of which have been used to predict survival in IPF patients;
- PAI-1, or plasminogen activator inhibitor type -1, a regulator of tissue homeostasis and wound repair that is elevated in fibrosis;
- PDGF-BB, or platelet-derived growth factor, a stimulator of fibroblast growth; and
- CCL-18, or CC Chemokine Ligand 18, a small protein derived from alveolar macrophages that acts as a chemo-attractant, and is negatively correlated to pulmonary function tests in IPF patients.

**Figure 9. GB0139 leads to reduction in serum levels of a panel of fibrosis biomarkers.**



The observation that these fibrosis-related biomarkers are concertedly and markedly reduced upon dosing IPF patients with GB0139 supports the key role of galectin-3 in IPF and the potential of GB0139 to generate antifibrotic activity in these patients. The levels of galectin-3 in alveolar macrophages directly correlate with the levels of serum biomarkers of fibrosis, including YKL-40, which has been shown to have prognostic significance in IPF. Four highly relevant disease biomarkers, PDGF, CCL18, PAI-1 and YKL-40, have been shown to have prognostic significance in IPF and have a well described relationship with myofibroblast activity *in vitro*. In our completed Phase 2a clinical trial, these biomarkers were reduced from baseline for the 10 mg dose group compared to placebo and may offer a less invasive measure of pharmacodynamic effects going forward. In a post-hoc analysis of the ASCEND and CAPACITY trials, which were the three phase 3 clinical trials used for the approval of pirfenidone, both YKL-40 and CCL18 were prognostic for progression in the test cohort, but only

CCL18 was consistently prognostic for a change in FVC in both the test and replication cohorts. However, there was no association between pirfenidone treatment and the longitudinal concentration of any biomarker. In another study comparing treatment naïve IPF patients with those on anti-fibrotic treatment (pirfenidone or nintedanib), CA-125, CXCL13, MMP7, YKL-40 and OPN predicted differential transplant free survival in treated patients, but at higher thresholds than treatment naïve individuals. There is therefore substantial evidence that several biomarkers are related to disease severity and prognosis, particularly YKL-40 and CCL-18



**Figure 10. Changes in lung macrophage galectin-3 levels correlate with changes in plasma YKL-40.**

*Completed Phase 1/2a Clinical Trial - Phase 1 Part in Healthy Adult Males*

In the Phase 1 part of our Phase 1/2a clinical trial conducted in the U.K., we conducted a single ascending dose escalation study in 36 healthy adult males investigating six doses of GB0139 ranging from 0.15 mg to 50 mg. Inhaled GB0139 was well-tolerated in this trial with a half-life of 7 hours, and we observed predictable and well-characterized pharmacokinetics. No drug-related severe adverse events were reported, and other adverse events were mild in severity, and all resolved without intervention.

**GB1211 for the treatment of fibrosis related to NASH**

We are developing GB1211, an oral selective galectin-3 inhibitor, for the treatment of fibrosis related to NASH, a fibrotic disease of the liver with no approved therapies, and potentially for the treatment of other fibrotic and related diseases, including cancer, cardiac and renal fibrosis.

***NASH disease background***

Non-alcoholic fatty liver disease, or NAFLD, is the buildup of extra fat in liver cells that is not caused by alcohol. It is normal for the liver to contain some fat. However, if more than five to ten percent of the liver's weight is fat, then it is called a "fatty liver." NASH is the more severe form of NAFLD and is a common and progressive chronic liver disease in which the liver swells and becomes damaged. NASH may progress to liver cirrhosis, liver cancer, liver failure and, ultimately, death. It is estimated that NASH affects approximately 12 percent of the U.S. adult population. In approximately 20 percent of NASH patients, NASH will eventually lead to cirrhosis.

### Current treatments for NASH and their limitations

There are currently no drugs approved for the treatment of NAFLD or NASH. The current standard of care for the treatment of NASH includes lifestyle changes, exercise to reduce body weight, and simultaneous treatment of concomitant diabetes and dyslipidemia. Unfortunately, the majority of patients abandon these lifestyle changes as they are not sustainable long term, and disease outcomes are not altered. For NASH patients that develop cirrhosis, liver transplantation may represent the only viable treatment, but this option may not be widely available due to high cost, scarcity of suitable donors, significant morbidities and the need for additional lifelong immune therapies. NASH is the second leading indication leading to liver transplantation in the United States, behind alcoholic liver disease, but because it is growing more rapidly, NASH is expected eventually to become the primary cause. NASH is already the leading cause of liver transplantation in women.

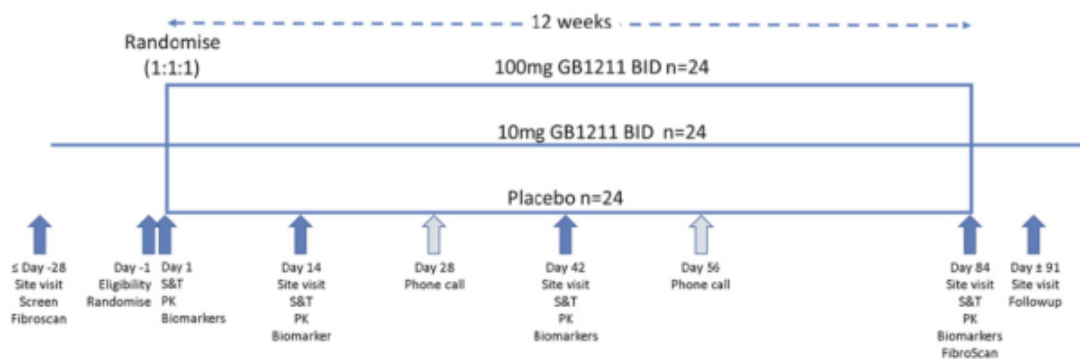
### Our solution – GB1211

We have demonstrated activity of GB1211 in preclinical models of liver fibrosis and have completed a Phase 1 safety trial in 72 healthy volunteers, where GB1211 had good pharmacokinetics and was well-tolerated. We anticipate initiating a Phase 2a clinical trial in NASH patients in

### Overview of Clinical trials

#### Planned Phase 2 Clinical Trial

In our planned Phase 2 clinical trial in 72 patients with NASH, patients will be randomized equally across three arms and dosed with either 10mg or 100mg of GB1211 twice daily or placebo for twelve weeks, with the primary endpoints being incidence and severity of adverse events, incidence of laboratory abnormalities and other physical parameters. Secondary endpoints include pharmacokinetic parameters, and exploratory endpoints include evaluating the effect of GB1211 on serum levels of galectin-3 and biomarkers of fibrosis related to NASH, liver disease, inflammation and metabolism and other pharmacokinetic parameters of GB1211 in patients with NASH.



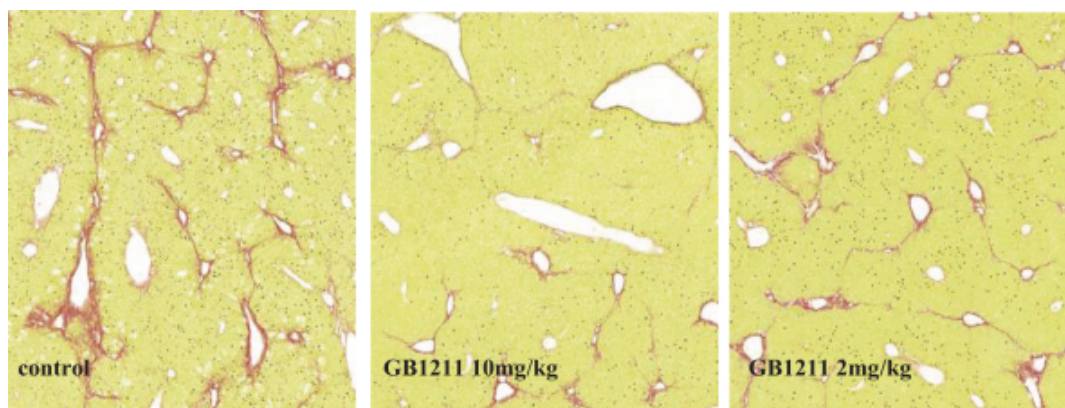
**Figure 11. GB1211 Phase 2 trial design in NASH patients (safety and tolerability represented by “S&T”)**

#### Completed Phase 1 Clinical Trial

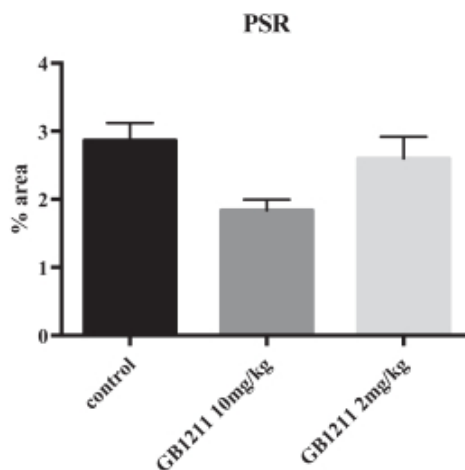
We have completed a Phase 1 single ascending dose and multiple ascending dose trial of GB1211 in 72 healthy volunteers in the U.K. GB1211 was well-tolerated with no drug-related serious adverse events at any doses up to the maximum dose tested of 400 mg.

*Preclinical data*

The effect of GB1211 was evaluated in a mouse model of carbon-tetrachloride-induced liver fibrosis. In two separate studies, fibrosis was induced in mice, which were then given either GB1211 or placebo. Mice dosed with 10 mg/kg GB1211 twice a day had significantly lower levels of liver fibrosis compared to mice given placebo as detected by histological staining of liver sections with a collagen-specific dye, picrosirius red, as demonstrated by figure 8 below. This reduction in fibrosis was observed in the absence of changes in liver weight or body weight. These findings were consistent when compared with a standard measurement of collagen content using levels of hydroxyproline, a major component of collagen.



**Figure 12. Oral GB1211 blocks carbon tetrachloride-induced-liver fibrosis (indicated as red contour stains) as determined by histological staining for collagen in liver sections**



**Figure 13. GB1211 leads to a significant reduction in collagen levels in a carbon tetrachloride fibrosis model**

**GB2064 for the treatment of myelofibrosis**

We are leveraging our knowledge of mechanisms underlying fibrosis and other related diseases to develop product candidates for indications beyond lung and liver fibrosis and targeting pathways that are



complementary to galectin-3. We are currently developing GB2064, an oral selective LOXL2 inhibitor, for the treatment of myelofibrosis.

### ***Myelofibrosis disease background***

Myelofibrosis is one of a number of progressive blood cancers known as myeloproliferative neoplasms and is associated with significantly reduced quality of life and shortened survival. In myelofibrosis, the bone marrow produces fewer blood cells, which leads to multiple negative impacts, including thrombocytopenia, or greater incidence of low platelet counts; anemia, or low red blood cell counts; and an increased need for red-blood-cell transfusions. When bone-marrow based production of blood cells is significantly reduced, myelofibrosis patients also suffer from enlarged spleens due to overabundance of blood-forming stem cells. Myelofibrosis is considered to be a chronic leukemia which, in a subset of patients, can transform into an acute form of leukemia. Median overall survival is approximately 2.25 to 11.25 years. Transformation to acute leukemia is the most common cause of death from myelofibrosis, followed by cardiovascular complications.

Myelofibrosis affects between 16,000 and 18,500 patients in the United States with significant morbidity and mortality. Although the precise cause of myelofibrosis remains unknown, overactive Janus-associated kinase, or JAK, pathway signaling is present in all patients with the disease.

### ***Current treatments for myelofibrosis and their limitations***

The only currently approved specific therapeutic treatments for myelofibrosis are inhibitors of JAK2, consisting of ruxolitinib marketed as Jakafi by Incyte and fedratinib, marketed as Inrebic by Celgene/BMS. These kinase inhibitors provide symptomatic benefit, but only modest reductions in bone marrow fibrosis. In patients dosed for four or more years with ruxolitinib, for example, only one-third of patients showed reductions in fibrosis.

The only curative treatment for myelofibrosis is an allogeneic hematopoietic stem cell transplant, or HSCT. However, HSCT in myelofibrosis patients is a procedure associated with a high treatment-related mortality rate. Even when HSCT is restricted to the subpopulation of patients who are deemed healthy enough to withstand the treatment, there is a one-year treatment-related mortality rate of between 12 percent and 25 percent. Due to the only modest reductions in fibrosis demonstrated by JAK inhibitors and the high mortality rate associated with HSCT, we believe that significant unmet need remains for new therapeutic options.

### ***Our solution - GB2064***

We have chosen to pursue myelofibrosis as our first indication for GB2054 due to the upregulation of the LOXL2 in a number of fibrotic diseases, including myelofibrosis, the drug activity seen in preclinical data, the rapid rate of progression of the disease and the relative ease of following disease progression through serum samples and bone marrow biopsies. In preclinical models, GB2064 is approximately 400-fold more selective for human LOXL2 over other human LOX enzymes. GB2064 has shown activity in a number of preclinical models of fibrosis; has demonstrated good pharmacokinetics; and was well-tolerated in a Phase 1 trial in healthy adults.

### ***Overview of Clinical trials***

We are planning to initiate a Phase 2a clinical trial of GB2064 in myelofibrosis in . The trial will include 16 patients with myelofibrosis, who will be dosed for nine months with 1000 mg of GB2064 BID. Endpoints include safety and tolerability as well as bone marrow fibrosis, spleen size, transfusion dependency, fibrosis markers, and quality of life.

### ***Completed Phase 1 Clinical Trial***

We have completed a Phase 1 single ascending dose and multiple ascending dose trial of GB2064 in 78 healthy volunteers. Volunteers received single doses of 150, 450, 1000, 2000 or 2500 mg of GB2064 or daily

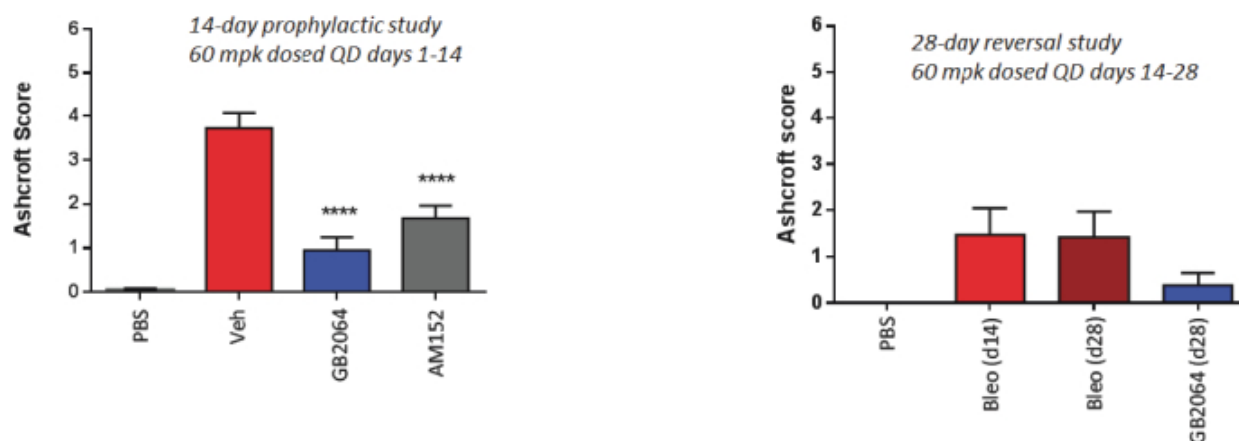
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doses of 150, 750, 2000 mg or placebo for seven days. Dose-dependent increases in serum levels of GB2064 were observed, and using a proprietary assay, we determined that our oral selective inhibitor GB2064 led to dose-dependent inhibition of LOXL2 in serum.

No serious adverse events were reported, and the reported adverse events included nausea, headache, and dizziness that were mild in severity and frequency.

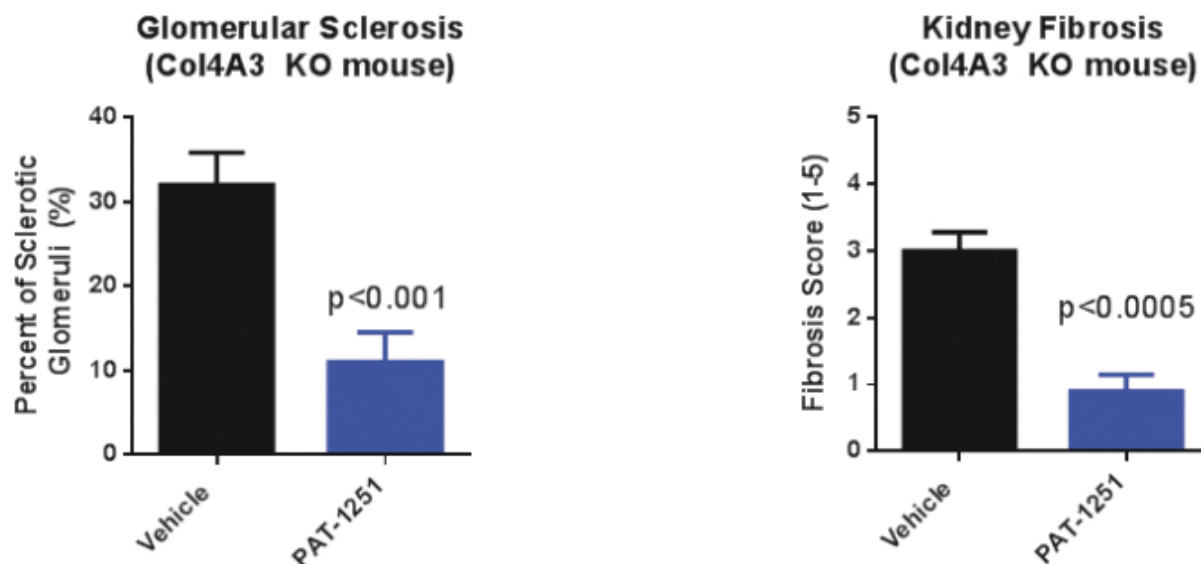
### *Preclinical data*

In preclinical studies, GB2064 showed activity in multiple models of fibrosis including lung, liver and kidney fibrosis. In a bleomycin-induced model of lung fibrosis, treatment of mice with bleomycin leads to lung fibrosis. Prophylactic dosing of GB2064 led to a significant reduction in fibrosis development in this model. Where fibrosis had already developed, therapeutic dosing of GB2064 led to reductions in further fibrosis development. In Figure 14 below, AM152 refers to an LOXL2 antibody that was used by both Gilead Sciences, Inc. and Arresto Biosciences, Inc. (which was acquired by Gilead Sciences, Inc. in 2010) to study the effect of LOXL2 inhibition in mice. PharmAkea manufactured a copy of this to test GB2064 against the antibody.



**Figure 14. GB2064 can both prevent and reverse fibrosis in a bleomycin-induced lung fibrosis model**

LOXL2 is highly expressed in other fibrotic diseases such as renal fibrotic disease. The mouse Col4A3 model of kidney disease is based on a genetic mutation that is found in patients with Alport Syndrome, a rare disease characterized by fibrosis that leads to progressive loss of kidney function among other symptoms such as progressive loss of hearing and retinopathy. LOXL2 expression is significantly elevated in both the kidney cortex and glomeruli in this mouse model. In preclinical studies, treatment of Col4A3 mice with GB2064 has demonstrated an ability to prevent glomerular sclerosis and a scarring of the blood filtering vessels in the kidney, and resulted in lower fibrosis scores in the kidney.



**Figure 15. GB2064 (PAT-1251) prevents the development of renal fibrosis in a mouse model of Alport syndrome**

### Competition

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, the expertise of our management team, clinical capabilities, research and development experience and scientific knowledge provide us with competitive advantages, we face increasing competition from many different sources, including biotechnology and biopharmaceutical companies, academic institutions, governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

There are a number of large biotechnology and biopharmaceutical companies that are currently pursuing the development of products for the treatment of fibrosis. Companies that we are aware of that are targeting the treatment of fibrotic and related diseases include large companies with significant financial resources such as Pharmaxis Ltd, Biogen, Inc., AbbVie Inc., Gilead Sciences, Inc., Pliant Therapeutics, Inc., Galectin Therapeutics, Inc., FibroGen, Inc., Liminal BioSciences, Inc., Galapagos NV, Bristol Myers Squibb Co., Madrigal, Constellation Pharmaceuticals, Inventiva, Akero Therapeutics, Inc., Roche Holding AG and Novartis AG. However, we know of no other companies currently in clinical development with an inhaled or orally available small-molecule inhibitor of galectin-3 or an orally available small-molecule inhibitor of LOXL2 for myelofibrosis.

Many of our competitors, either alone or with their collaborators, have significantly greater resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific, sales, marketing and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Additional mergers and acquisitions may result in even more resources being concentrated in our competitors.

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Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than products that we may develop. Our competitors also may obtain FDA or regulatory approval from comparable foreign regulatory authorities for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated. The key competitive factors affecting the success of our product candidates are likely to be efficacy, safety, cost, and convenience.

### **Intellectual property**

Our owned patents and patent applications relate to our fibrosis-inhibiting compounds and include patents and patent applications directed to new compositions of matter and to methods of treating lung, kidney and liver disorders. As we continue to develop our product candidates, we intend to seek additional patent protection in the United States, EU and in other key commercial markets worldwide.

#### ***GB0139***

As of September 1, 2020, we owned five patent families that included seven issued U.S. patents, two pending U.S. patent applications, and issued and pending foreign counterpart patents and patent applications, relating to our product candidate, GB0139. These patent families include U.S. Patent No. 9,243,021, which is directed to composition of matter of and methods of treatment using compound GB0139; and U.S. Patent Nos. 10,307,403 and 10,369,136, which are directed to composition of matter of and methods of treatment using a polymorphic form of compound GB0139. U.S. Patent No. 9,243,021 is expected to expire in 2033, and U.S. Patent Nos. 10,307,403 and 10,369,136 are expected to expire in 2036, absent any patent term extension. The other issued U.S. patents are expected to expire between 2025 and 2036, absent any patent term extension. If we continue to pursue patent protection, and if any patents issue based on our pending applications, we expect such patents to expire between 2033 and 2036, absent any patent term adjustment and patent term extension in the United States.

#### ***GB1211***

As of September 1, 2020, we owned two patent families that included one issued U.S. patent, one pending U.S. patent application, and pending foreign counterpart patent applications, and one international patent application filed under the Patent Cooperation Treaty, or PCT, relating to our product candidate, GB1211. One patent family includes U.S. Patent No. 10,526,360, which is directed to composition of matter of D-galactopyranose compounds of which compound GB1211 is a species. The issued U.S. patent is expected to expire in 2036, absent any patent term extension. If we continue to pursue patent protection, and if any patents issue based on our pending applications, we expect such patents to expire in 2036, absent any patent term extension in the United States.

The other patent family includes the international PCT patent application, which is not eligible to become an issued patent until, among other things, we file a patent application in regional or national patent offices within 30 or 31 months of the earliest-filed patent application in the chain of priority. If we continue to pursue patent protection and file one or more patent applications with respect to our international PCT patent application, and if any patents issue based on the international PCT patent application, we expect such patents, if issued, to expire in 2039, absent any patent term adjustment and patent term extension in the United States.

#### ***GB2064***

As of September 1, 2020, we owned three patent families that included two issued U.S. patents, four pending U.S. patent applications, and issued and pending foreign counterpart patent and patent applications, relating to our product candidate, GB2064. These patent families include U.S. Patent Nos. 10,150,732 and

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10,570,094, which are directed to composition of matter of and methods of treatment using compound GB2064. The issued U.S. patents are expected to expire in 2036, absent any patent term extension. If we continue to pursue patent protection, and if any patents issue based on our pending applications, we expect such patents to expire between 2036 and 2037, absent any patent term adjustment and patent term extension in the United States.

For a discussion of the risks associated with our intellectual property, see “Risk Factors—Risks Related to Our Intellectual Property.”

### **Government Regulation**

The FDA and comparable regulatory authorities in state and local jurisdictions and in other countries impose requirements upon companies involved in the clinical development, manufacture, marketing and distribution of drugs, such as those we are developing. These agencies and other federal, state and local entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, distribution, post-approval monitoring and reporting, sampling and export and import of our product candidates.

#### ***U.S. government regulation of drug products***

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The FDA also regulates biological products under the FDCA and the Public Health Service Act, or PHSA. If we advance clinical development of a biologic candidate in the future, these development activities will be subject to additional regulatory requirements specific to biologics. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA’s refusal to approve pending New Drug Applications, or NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of 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.

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 compliance with the FDA’s good laboratory practice, or GLP, regulations;
- Submission to the FDA of an IND application, which must become effective before human clinical trials may begin;
- Approval by an independent IRB at each clinical site before each trial may be initiated;
- Performance of adequate and well-controlled human clinical trials in accordance with GCP, requirements to establish the safety and efficacy of the proposed drug product for each indication;
- Submission to the FDA of an NDA, including payment of application user fees;
- A determination by the FDA within 60 days of its receipt of an NDA to accept the marketing application for review;
- Satisfactory completion of an FDA advisory committee review, if applicable;

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- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practice, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- Satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data; and
- FDA review and approval of the NDA.

### ***Preclinical studies***

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as *in vitro* and animal studies to assess potential safety and efficacy. The conduct of preclinical studies is subject to federal regulations and requirements, including good laboratory practice regulations for safety/toxicology studies.

An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Some preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and 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. As a result, submission of an IND may not result in the FDA allowing clinical trials to initiate.

### ***Clinical trials***

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it is initiated at that institution. The IRB also must review and approve the informed consent form that must be provided to each clinical trial subject or his or her legal representative, and must monitor the clinical trial until completion.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their [www.clinicaltrials.gov](http://www.clinicaltrials.gov) website. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Although sponsors are obligated to disclose the results of their clinical trials after completion, disclosure of the results can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. The NIH's Final Rule on [ClinicalTrials.gov](http://ClinicalTrials.gov) registration and reporting requirements became effective in 2017, and both the NIH and FDA recently signaled the government's willingness to begin enforcing those requirements against non-compliant clinical trial sponsors.

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

- Phase 1: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.
- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, 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 on an NDA.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information.

Phase 1, Phase 2 and Phase 3 trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution 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. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the trial.

Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the drug as well as 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 product and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug does not undergo unacceptable deterioration over its shelf life.

### ***NDA submission and marketing approval***

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and

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proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. The FDA will initially review an NDA for completeness before it accepts it for “filing.” Under the FDA’s procedures, the agency has 60 days from its receipt of the NDA to determine whether the application will be accepted for filing based on the agency’s threshold determination that the application is sufficiently complete to permit substantive review. 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, and six months from the filing date of a new molecular entity NDA with priority review. Accordingly, this review process typically takes 12 months and eight months, respectively from the date the NDA is submitted to the FDA. The FDA does not always meet its PDUFA goal dates for standard or priority NDAs, and the review process is often extended by FDA requests for additional information or clarification. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product’s continued safety, quality and purity.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, as amended, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. A sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

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 application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product’s continued safety, quality and purity.

The FDA may refer an application for a novel drug or a drug that presents difficult questions of safety or efficacy to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA also may require the submission of a REMS if it determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks and to assure the safe use of the drug. A REMS may include one or more elements, including medication guides, physician communication plans, patient package insert and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk



minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. 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 a REMS, if required.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with 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 evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a Complete Response Letter. A Complete Response Letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for FDA to reconsider the application. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

### ***Orphan drug designation and exclusivity***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug product intended to treat a rare disease or condition, which is generally a disease or condition that affects either (i) fewer than 200,000 individuals in the United States, or (ii) more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product. A company must request orphan drug designation before submitting an NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product is entitled to orphan product exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications to market the same product for the same indication for seven years, except in certain limited circumstances. If a drug designated as an orphan drug ultimately receives marketing approval for an indication broader than what it was designated for, it may not be entitled to exclusivity. Orphan exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved

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product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. Further, the FDA may approve more than one product for the same orphan indication or disease as long as the products contain different active ingredients. Moreover, 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 drug has exclusivity.

### *Expedited development and priority review programs*

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval, and the purpose of these programs is to either expedite the development or review of important new drugs to get them to patients earlier than under standard FDA development and review procedures.

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to both the product and the specific indication for which it is being studied. The sponsor can request the FDA to designate the product for Fast Track status any time before receiving NDA approval, but ideally no later than the pre-NDA meeting. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed, meaning that the agency may review portions of the marketing application before the sponsor submits the complete application, as well as priority review, discussed below.

Additionally, a drug may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of Breakthrough Therapy designation include the same benefits as Fast Track designation, plus intensive guidance from the FDA to ensure an efficient drug development program. A product may also be eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA determines at the time that the marketing application is submitted, on a case-by-case basis, whether the proposed drug represents a significant improvement in treatment, prevention or diagnosis of disease when compared with other available therapies. 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 and to shorten the FDA's goal for taking action on an NDA for a new molecular entity from ten months to six months from the date of filing.

A product may also be eligible for accelerated approval if it treats a serious or life-threatening disease or condition, generally provides a meaningful advantage over available therapies and demonstrates 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, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of accelerated approval, the FDA requires that a sponsor perform adequate and well-controlled post-marketing clinical trials. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions, as it deems necessary to assure safe use of the product.

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

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not be shortened. Fast Track designation, Breakthrough Therapy designation and Priority Review designation do not change the standards for approval, but may expedite the development or review process. Drugs granted accelerated approval also must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

### ***U.S. marketing exclusivity***

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain follow-on applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain 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 accept for review an Abbreviated New Drug Application, or ANDA, for a generic version of the drug or a 505(b)(2) NDA for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, such a follow-on application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of market exclusivity for an NDA, 505(b)(2) 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 period covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving follow-on applications that do not reference the protected clinical data. 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 regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing regulatory exclusivity periods or listed patents. This six-month exclusivity may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

### ***Post-approval requirements***

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

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.

FDA regulations require that products be manufactured in specific facilities and in accordance with cGMP regulations which require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP

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requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

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

- Restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- Fines, warning letters or holds on post-approval clinical trials;
- Refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or withdrawal of product approvals;
- Product seizure or detention, or refusal to permit the import or export of products; and
- Injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted by a manufacturer and any third parties acting on behalf of a manufacturer only for the approved indications and in a manner consistent with the approved label for the product. 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 liability.

### ***Other healthcare laws***

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of drug products for which we obtain marketing approval. Arrangements with third-party payors, healthcare providers and physicians, in connection with the clinical research, sales, marketing and promotion of products, once approved, and related activities, may expose a pharmaceutical manufacturer to broadly applicable fraud and abuse and other healthcare laws and regulations. In the United States, these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below:

- the AKS, which makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer or pay any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, that is intended to induce or reward, referrals including the purchase, recommendation, order or prescription of a particular drug for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The AKS has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. 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. Further, courts have found that if “one purpose” of remuneration is to induce referrals, the

AKS is violated. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal FCA;

- the federal civil and criminal false claims laws, including the FCA, which can be enforced by private citizens through “qui tam” or “whistleblower” actions, and civil monetary penalty laws, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Pharmaceutical and other healthcare companies have been, and continue to be, prosecuted under these laws, among other things, for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product and for causing false claims to be submitted because of the companies’ marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses. Similar to the AKS, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation.
- HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Like the AKS, the ACA amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the creation, use, receipt, maintenance or disclosure of individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys’ fees and costs associated with pursuing federal civil actions;
- the federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which require manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services, or CMS, under the Open Payments Program, information related to payments or 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 physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made during the previous year to certain non-physician providers such as physician assistants and nurse practitioners; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical

business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; 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 that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of a pharmaceutical manufacturer's business activities could be subject to challenge under one or more of such laws. Efforts to ensure that business arrangements comply with applicable healthcare laws involve substantial costs. It is possible that governmental and enforcement authorities will conclude that a pharmaceutical manufacturer's business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against a pharmaceutical manufacturer, and it is not successful in defending itself or asserting its rights, those actions could have a significant impact on its business, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, imprisonment, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reporting obligations and oversight if we become subject to integrity and oversight agreements to resolve allegations of non-compliance, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of operations, any of which could adversely affect a pharmaceutical manufacturer's ability to operate its business and the results of operations. In addition, commercialization of any drug product outside the United States will also likely be subject to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of health-related and other personal information. For example, in June 2018, the State of California enacted the CCPA, which came into effect on January 1, 2020 and provides new data privacy rights for consumers and new operational requirements for companies, which may increase our compliance costs and potential liability. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities. The CCPA could mark the beginning of a trend toward more stringent state privacy legislation in the United States, which could increase our potential liability and adversely affect our business.

In the event we decide to conduct clinical trials or continue to enroll subjects in our ongoing or future clinical trials, we may be subject to additional privacy restrictions. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EEA, including personal health data, is subject to the GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to

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countries outside the EEA, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. Further, the U.K.'s decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the U.K.. In particular, it is unclear how data transfers to and from the U.K. will be regulated now that the U.K. has left the EU.

### ***Current and future healthcare reform legislation***

In both the United States and certain foreign jurisdictions, there have been, and continue to be, a number of legislative and regulatory changes to the health care system. Among policy makers and payors in the United States and elsewhere, 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 particular, in 2010, the ACA was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research.

There remain judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are scheduled for November 10, 2020. In addition, the Trump Administration has issued various Executive Orders that eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Additionally, Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in 2013, and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. However, the Medicare sequester reductions under the Budget Control Act of 2011

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have been suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Bipartisan Budget Act of 2018, also amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.”

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. At the federal level, the U.S. Presidential administration’s budget proposal for the fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent “principles” for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Moreover, the U.S. Presidential administration previously released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contained 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. On July 24, 2020, President Trump signed four Executive Orders aimed at lowering drug prices. The Executive Orders direct the Secretary of the HHS, to: (1) eliminate protection under an AKS safe harbor for certain retrospective price reductions provided by drug manufacturers to sponsors of Medicare Part D plans or pharmacy benefit managers that are not applied at the point-of-sale; (2) allow the importation of certain drugs from other countries through individual waivers, permit the re-importation of insulin products, and prioritize finalization of FDA’s December 2019 proposed rule to permit the importation of drugs from Canada; (3) ensure that payment by the Medicare program for certain Medicare Part B drugs is not higher than the payment by other comparable countries (depending on whether pharmaceutical manufacturers agree to other measures); and (4) require FQHCs participating in the 340B drug program to provide insulin and injectable epinephrine to certain low-income individuals at the discounted price paid by the FQHC, plus a minimal administrative fee. Although a number of these and other measures may require additional authorization to become effective, Congress and the U.S. Presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payers. In addition, individual states in the United States have also 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.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, although the FDA recently published a notice of proposed rulemaking that would require manufacturers who do so to make annual reports of those programs to the FDA.

Legislative and regulatory proposals and enactment of laws, at the foreign federal and state levels, directed at containing or lowering the cost of healthcare, will continue into the future. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement or significant revisions to the ACA.



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The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

### ***Regulation outside the United States***

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. The cost of establishing a regulatory compliance system for numerous varying jurisdictions can be very significant. Although many of the issues discussed above with respect to the United States apply similarly in the context of the EU and in other jurisdictions, 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.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the EU, for example, a clinical trial authorization application, or CTA, must be submitted for each clinical protocol to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is accepted in accordance with a country's requirements, the clinical trial may proceed.

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

To obtain regulatory approval of an investigational medicinal product under EU regulatory systems, we must submit a marketing authorization application. The content of the NDA filed in the United States is similar to that required in the EU, with the exception of, among other things, country-specific document requirements.

For other countries outside of the EU and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing product development, the conduct of clinical trials, manufacturing, distribution, marketing approval, product licensing, pricing and reimbursement vary from country to country.

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Countries that are part of the EU, as well as countries outside of the EU, have their own governing bodies, requirements, and processes with respect to the approval of drug products. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Additionally, to the extent that any of our product candidates, once approved, are sold in a foreign country, we may be subject to applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals.

### ***Authorization Procedures in the EU***

In the U.K. and the EEA (comprised of the 27 EU member states plus Iceland, Liechtenstein and Norway), medicinal products must be authorized for marketing by using either the centralized authorization procedure or national authorization procedures.

- *Centralized procedure*—If pursuing marketing authorization of a product candidate for a therapeutic indication under the centralized procedure, following the opinion of the EMA’s Committee for Medicinal Products for Human Use, or, CHMP, the European Commission issues a single marketing authorization valid across the EEA. The centralized procedure is compulsory for human medicines derived from biotechnology processes or advanced therapy medicinal products (such as gene therapy, somatic cell therapy and tissue engineered products), products that contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune diseases and other immune dysfunctions, viral diseases, and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned contains a new active substance not yet authorized in the EEA, or is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health in the EEA. Under the centralized procedure, the maximum timeframe for the evaluation of a marketing authorization application, or MAA, by the EMA is 210 days, excluding “clock stops”, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP, and which can add materially to the timeframe. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is 150 days, excluding clock stops.
- *National authorization procedures*—There are also two other possible routes to authorize products for therapeutic indications in several countries, which are available for products that fall outside the scope of the centralized procedure:
- *Decentralized procedure*—Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure.
- *Mutual recognition procedure*—In the mutual recognition procedure, a medicine is first authorized in one EU member state, in accordance with the national procedures of that country. Following this, additional marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned recognize the validity of the original, national marketing authorization.

In the EEA, new products for therapeutic indications that are authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon

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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 ten years have elapsed from the initial authorization of the reference product in the EU. The ten-year market exclusivity period can be extended to a maximum of 11 years if, during the first eight years of those ten 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.

The criteria for designating an “orphan medicinal product” in the EEA are similar in principle to those in the United States. In the EEA, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. During this ten-year orphan market exclusivity period, no marketing authorization application shall be accepted, and no marketing authorization shall be granted for a similar medicinal product for the same indication. An orphan product can also obtain an additional two years of market exclusivity in the EU for pediatric studies. The ten-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (ii) the applicant consents to a second orphan medicinal product application; or (iii) the applicant cannot supply enough orphan medicinal product.

As in the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on GCP and the related national implementing provisions of the individual EU member states govern the system for the approval of clinical trials in the EU. Under this system, an applicant must obtain prior approval from the competent national authority of the EU member states in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific trial site after the competent ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by, among other documents, an investigational medicinal product dossier (the Common Technical Document) with supporting information prescribed by Directive 2001/20/EC, Directive 2005/28/EC, and, where relevant, the implementing national provisions of the individual EU member states and further detailed in applicable guidance documents.

In April 2014, the new Clinical Trials Regulation (EU) No 536/2014 or Clinical Trials Regulation, was adopted. It is expected that the Clinical Trials Regulation will apply following confirmation of full functionality of the Clinical Trials Information System, the centralized EU portal and database for clinical trials foreseen by the regulation, through an independent audit. The regulation becomes applicable six months after the European Commission publishes notice of this confirmation. The Clinical Trials Regulation will be directly applicable in all the EU member states, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the EU will continue to be bound by currently applicable provisions until the Clinical Trials Regulation becomes applicable. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation becomes applicable and on the duration of the

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individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable, the Clinical Trials Regulation will at that time begin to apply to the clinical trial. The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the EU.

The main characteristics of the regulation include (i) a streamlined application procedure via a single-entry point, the “EU portal,” a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and (ii) a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is jointly assessed by the competent authorities of all EU member states in which an application for authorization of a clinical trial has been submitted (member states concerned). Part II is assessed separately by each member state concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU member state. However, overall related timelines will be defined by the Clinical Trials Regulation.

Should we utilize third-party distributors, compliance with such foreign governmental regulations would generally be the responsibility of such distributors, who may be independent contractors over whom we have limited control.

### *Coverage and reimbursement*

Successful commercialization of new drug products depends in part on the extent to which reimbursement for those drug products will be available from government health administration authorities, private health insurers, and other organizations. In the United States, government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drug products they will pay for and establish reimbursement levels. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford a drug product. Sales of drug products depend substantially, both domestically and abroad, on the extent to which the costs of drugs products are paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular drug products. Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A payor’s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor’s determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on its investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

In many countries, the prices of drug products are subject to varying price control mechanisms as part of national health systems. In general, the prices of drug products under such systems are substantially lower than in

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the United States. Other countries allow companies to fix their own prices for drug products, but monitor and control company profits. Accordingly, in markets outside the United States, the reimbursement for drug products may be reduced compared with the United States.

In the United States, the principal decisions about reimbursement for new drug products are typically made by CMS, an agency within the HHS. CMS decides whether and to what extent a new drug product will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists among third-party payors and coverage and reimbursement levels for drug products can differ significantly from payor to payor. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a drug product is:

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

We cannot be sure that coverage or reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Coverage may also be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Reimbursement may impact the demand for, or the price of, any product for which we obtain regulatory approval.

The MMA established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each Part D prescription drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for drugs for which we obtain marketing approval. Any negotiated prices for any of our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the average manufacturer price, or AMP, and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although under the current state of the law these newly eligible entities (with the exception of children's hospitals) will not be eligible to receive discounted 340B pricing on orphan drugs. As the required 340B discount is determined based on average manufacturer price, or AMP, and Medicaid rebate data, the revisions to the Medicaid rebate formula

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and AMP definition described above could cause the required 340B discount to increase. The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. The plan for the research was published in 2012 by HHS, the Agency for Healthcare Research and Quality and the NIH, and periodic reports on the status of the research and related expenditures are made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of our product candidates, if any such drug or the condition that they are intended to treat are the subject of a trial. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's drug could adversely affect the sales of our product candidate. If third-party payors do not consider our drugs to be cost-effective compared to other available therapies, they may not cover our drugs after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our drugs on a profitable basis.

These laws and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Outside of the United States, the pricing of pharmaceutical products and medical devices is subject to governmental control in many countries. For example, in the EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular therapy to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. Other countries may allow companies to fix their own prices for products, but monitor and control product volumes and issue guidance to physicians to limit prescriptions. Efforts to control prices and utilization of pharmaceutical products and medical devices will likely continue as countries attempt to manage healthcare expenditures.

### **Employees**

As of September 1, 2020, we had 20 full-time employees, who together hold 7 Ph.D. or M.D. degrees and 17 of whom are engaged in research and development activities. 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.

### **Facilities**

We lease a facility containing 1,300 square feet of laboratory and office space, which is located at Ole Maaloes Vej 3, DK-2200 Copenhagen, Denmark. The lease expires on October 31, 2021. We also lease a facility containing 749 square feet of office space at Evergreen House North, Grafton Place, London, NW1 2DX. This lease expires on August 31, 2022. We believe that our current facilities are sufficient to meet our current and near-term needs and that, should it be needed, suitable additional space will be available.

### **Legal Proceedings**

As of the date of this prospectus, we are not party to any material legal matters or claims. We may become party to legal matters and claims arising in the ordinary course of business. We cannot predict the outcome of any such legal matters or claims, and despite the potential outcomes, the existence thereof may have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

## MANAGEMENT

### Executive Officers and Directors

The following table sets forth certain information about our executive officers and directors, including their ages, as of September 1, 2020.

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
<b><i>Executive Officers:</i></b>		
Hans T. Schambye, M.D., Ph.D.	55	Chief Executive Officer
Anders Pedersen	60	Chief Operating Officer
Bertil Lindmark, M.D., Ph.D.	55	Chief Medical Officer
Jonathan Freve.	42	Chief Financial Officer
<b><i>Non-Employee Directors:</i></b>		
Amit D. Munshi	52	Director, Chairman of the Board
Karen Wagner, Ph.D.	50	Director
Chau Khuong	44	Director
Søren Lemonius	55	Director
Chandra Leo, M.D.	50	Director
Erez Chimovits	56	Director
Carl Goldfischer, M.D.	62	Director
Søren Møller, Ph.D.	53	Director
David Shapiro, M.D.	66	Director

(1) Member of the Audit Committee.

(2) Member of the Remuneration Committee.

(3) Member of the Nominating and Corporate Governance Committee.

### *Executive Officers*

**Hans T. Schambye, M.D., Ph.D.** has served as Chief Executive Officer of the Galecto group since November 2011, including as Chief Executive Officer of Galecto, Inc. since 2020, and as a member of our board of directors since 2020. Prior to joining us, Dr. Schambye served as the Chief Executive Officer of ReceptIcon A/S, a Danish biotechnology company, from September 2006 to November 2009. Before ReceptIcon A/S, Dr. Schambye worked at Gastrotech Pharma A/S, a Danish biotechnology company, where he served in increasing roles of responsibility, including Senior Vice President, Research & Development from March 2004 to February 2005 and as Chief Executive Officer from February 2005 to August 2006. Earlier in his career, Dr. Schambye served as Director of Biology and Pharmacology and Head of Portfolio Management at Maxygen, a U.S. biotechnology company. Dr. Schambye has co-founded several biotechnology companies, including ProFound Pharma A/S, a Danish biotechnology company, which was acquired by Maxygen in 2000. Dr. Schambye holds an M.D. from Odense University and a Ph.D. in Health Care and Medicine from Copenhagen University.

**Anders Pedersen** has served as Chief Operating Officer of the Galecto group since April 2013, including as Chief Operating Officer of Galecto, Inc. since 2020. Prior to joining us, Mr. Pedersen served as senior vice president of development at CMC Biologics A/S, a Danish biotechnology company, from February 2010 to March 2013. Before CMC, Mr. Pedersen worked at ReceptIcon A/S, a Danish biotechnology company, as Chief Operating Officer from December 2006 to November 2009. Earlier in his career, Mr. Pedersen served as Vice President of Project and Portfolio Management at Lifecycle Pharma A/S, a Danish biotechnology company, from March 2005 to November 2006 and spent 13 years at Novo Nordisk A/S, a Danish biopharmaceutical company. Additionally, Mr. Pedersen co-founded ProFound Pharma A/S, a Danish biotechnology company, which was acquired by Maxygen Inc., which dissolved in 2013. Mr. Pedersen holds a B.S. in Chemical Engineering from Danish Technical University in Copenhagen.

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**Bertil Lindmark, M.D., Ph.D.** has served as our Chief Medical Officer since 2020. Prior to joining us, Dr. Lindmark served as Chief Medical Officer of eTheRNA Immunotherapies, a Belgian biotechnology company, from February 2019 to January 2020. Before eTheRNA, Dr. Lindmark worked at ASLAN Pharmaceuticals Pts Ltd, a Singapore biopharmaceutical company, where he served as Chief Scientific Officer and Chief Medical Officer from February 2015 to January 2019. Earlier in his career, Dr. Lindmark served as Global Executive Director of R&D and Chief Scientific and Medical Officer of Almirall SA, a Spanish biopharmaceutical company, from January 2011 to January 2015 and for 19 years at AstraZeneca PLC, a British-Swedish biopharmaceutical company, in globally leading roles in the respiratory and inflammation therapy area, and as Head of Clinical Development at AstraZeneca Japan, a Japanese biopharmaceutical company. Dr. Lindmark holds specialties in internal medicine and gastroenterology, an M.D. and a Ph.D. in Molecular Epidemiology from Lund University, and a guest professorship at Gothenburg University in Innovation and Entrepreneurship.

**Jonathan Freve** has served as our Chief Financial Officer since 2020. Prior to joining us, Mr. Freve served as Chief Financial Officer and Treasurer of Spring Bank Pharmaceuticals, Inc., a Delaware biopharmaceutical company, from December 2014 to April 2020. Prior to joining Spring Bank, Mr. Freve worked at Santaris Pharma, a Danish biotechnology company, as Sr. Director of Finance from February 2014 to November 2014. Earlier in his career, Mr. Freve worked at the FASB and at PricewaterhouseCoopers LLC, where he worked in audit and transaction services. Mr. Freve holds a B.A. in Business Administration from the University of Massachusetts Amherst.

### **Non-Employee Directors**

**Amit D. Munshi** has served as Chairman of our board of directors since 2020. Mr. Munshi currently serves as President and Chief Executive Officer of Arena Pharmaceuticals, Inc., a biopharmaceutical company, since May 2016. Prior to that, Mr. Munshi served as President and Chief Executive Officer of Epirus Biopharmaceuticals, Inc., a biopharmaceutical company, from May 2012 to May 2016. He served as President and Chief Executive Officer of Percivia LLC, a biotechnology company later acquired by JNJ, from April 2011 to May 2012. Earlier in his career, Mr. Munshi co-founded and served as Chief Business Officer of Kythera Biopharmaceuticals, Inc., later acquired by AGN, from August 2005 to January 2011, and held multiple leadership positions at Amgen Inc. from September 1997 to January 2005, including General Manager, Nephrology Europe. Mr. Munshi also co-founded Oxeia Biopharmaceuticals, Inc., a clinical-stage biotechnology company, in August 2014. Mr. Munshi currently serves on the board of directors of Pulmatrix, Inc. (Nasdaq: PULM). In July 2016, Epirus filed a voluntary Chapter 7 petition in the United States Bankruptcy Court for the District of Massachusetts. Mr. Munshi holds a B.S. in Economics and a B.A. in History from the University of California, Riverside, and an M.B.A. from the Peter F. Drucker School of Management at Claremont Graduate University. We believe Mr. Munshi is qualified to serve on our board of directors based on his experience as an executive in the biopharmaceutical industry.

**Karen Wagner, Ph.D.** has served as a member of our board of directors since 2020. Dr. Wagner is currently a General Partner at Ysios BioFund II Invierte FCR, a venture capital firm. Prior to joining Ysios at inception in 2008, Dr. Wagner was the sole owner of a consultancy firm providing business development and strategy support to biotechnology companies. Dr. Wagner currently serves on the board of directors of several life sciences companies. Dr. Wagner holds a Masters Degree in Molecular Biology and a Ph.D. in Cell Biology, both from the University of Konstanz, Germany. We believe that Dr. Wagner is qualified to serve on our board of directors based on her experience in the biotechnology industry, specifically in business development.

**Chau Q. Khuong** has served as a member of our board of directors since 2020. Mr. Khuong is currently a Private Equity Partner at OrbiMed Advisors LLC, an investment firm. Mr. Khuong currently serves as a director of several publicly traded companies, including Fusion Pharmaceuticals Inc., a pharmaceutical company, since March 2019, Inspire Medical Systems, Inc. since May 2014, NextCure, Inc., a biopharmaceutical company, since December 2015, and Synlogic, Inc., a biotechnology company, since February 2016, as well as several private companies. Mr. Khuong holds a B.S. in molecular, cellular and development biology and an M.P.H. with a concentration in infectious diseases, both from Yale University. We believe that Mr. Khuong is qualified to



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serve on our board of directors based on his roles on several public and private boards of directors as well as his extensive experience in investing in healthcare companies.

**Søren Lemonius** has served as a member of our board of directors since 2020. Mr. Lemonius is currently a managing general partner at Sunstone Life Science Ventures, a venture capital firm. Prior to that, Mr. Lemonius served as Chief Technology Officer at Danionics A/S, a Danish technology company, from November 1998 to September 2003. Earlier in his career, Mr. Lemonius was Innovation Manager at FOSS Analytical A/S, a Danish analytics company, from September 1991 to October 1998. Mr. Lemonius holds a Master's Degree in Experimental Cell Biology from University of Southern Denmark. We believe that Mr. Lemonius is qualified to serve as a member of our board of directors due to his extensive market experience.

**Chandra Leo, M.D.** has served as a member of our board of directors since 2020. Dr. Leo currently serves as an Investment Advisor at HBM Partners, a Swiss investment firm. His board and investment experience at HBM Partners includes biotechnology and medtech companies such as ESBATech AG (acquired by Alcon/Novartis), a Swiss biotechnology company, Homology Medicines Inc. (IPO NASDAQ), a genetic medicines company, ObsEva SA (IPO NASDAQ), a Swiss biopharmaceutical company, Symbiomix Therapeutics, LLC (acquired by Lupin), a medical technology company, CardiacAssist Inc. (acquired by LivaNova), a medical device company, and Gynesonics, Inc, a healthcare company. Prior to that, Dr. Leo worked as a Principal at Wellington Partners, a venture capital firm, from 2003 to 2007. Earlier in his career, Dr. Leo served as a Physician at the University Hospital Leipzig from 1999 to 2001, and as a postdoctoral scientist at Stanford University Medical Center from 1997 to 1999. Dr. Leo holds a Medical Doctoral Degree from the Freie Universität Berlin and an M.B.A. with distinction from INSEAD. We believe that Dr. Leo is qualified to serve as a member of our board of directors due to his investment and biomedical experience.

**Erez Chimovits** has served as a member of our board of directors since 2020. Mr. Chimovits is a Partner at OrbiMed Israel, an investment firm. Mr. Chimovits currently serves as a director of several publicly traded companies including BiomX, Inc., a biotechnology company, LogicBio Therapeutics, Inc., a biotechnology company, and Novus Therapeutics, Inc., a pharmaceutical company, as well as several private companies. Mr. Chimovits has extensive operational experience, including senior managerial experience at public companies. Prior to joining OrbiMed, he was Chief Executive Officer of NasVax Ltd., a Swiss biotechnology company, and served different roles at Compugen USA Inc., a biotechnology company, formerly as President and as Executive Vice President in Commercial Operations. Mr. Chimovits earned his M.B.A., M.Sc. in Microbiology, and his B.Sc. from Tel Aviv University. We believe that Mr. Chimovits is qualified to serve on our board of directors based on his roles on several public and private boards of directors as well as his extensive experience in investing in healthcare companies.

**Carl Goldfischer, M.D.** has served as a member of our board of directors since 2020. Dr. Goldfischer currently serves as an Investment Partner and Managing Director of Bay City Capital, a venture capital firm. Prior to joining Bay City Capital, Dr. Goldfischer was, until mid-2000, Chief Financial Officer of ImClone Systems, a biopharmaceutical company. Dr. Goldfischer serves on the board of directors of numerous private and public companies, including Epizyme, Inc., a biopharmaceutical company, and Imara, Inc., a biopharmaceutical company, where he serves as chair of the audit committee. Dr. Goldfischer holds a B.A. from Sarah Lawrence College and an M.D with honors in Scientific Research from Albert Einstein College of Medicine. We believe that Dr. Goldfischer is qualified to serve as a member of our board of directors due to his prior management and board experience in the biotech industry.

**Søren Møller, Ph.D.** has served as a member of our board of directors since 2020. Dr. Møller is currently employed as a Managing Partner of Novo Holdings A/S, a venture capital firm. Dr. Møller serves on the board of directors of several companies, including NorthSea Therapeutics BV, a Dutch biotechnology company, Reapplied A/S, a Danish biotechnology company, Forendo Pharma Ltd, a Finnish pharmaceutical company, and Epitherapeutics ApS (acquired by Gilead), a biotechnology company. Prior to that, Dr. Møller served as global manager of Genomics at Novozymes A/S, a Danish biotechnology company. Before

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Novozymes A/S from 2010 to 2015, Dr. Møller was Chief Scientific Officer and Vice President of R&D at Exiqon A/S, a Danish diagnostics company, which was acquired by QIAGEN in 2016. Earlier in his career, Dr. Møller worked in cancer drug development as head of Lead Identification at BioImage A/S, a Danish biotechnology company, and as research scientist at Novo Nordisk A/S, a Danish pharmaceutical company, from 1988 to 2000. Dr. Møller holds a MSc from the Technical University of Denmark and a Ph.D. in molecular biology from the Technical University of Denmark. We believe that Dr. Møller is qualified to serve as a member of our board of directors due to his global profile in the biotechnology industry.

*David Shapiro, M.D.* has served as a member of our board of directors since 2020. Dr. Shapiro currently serves as the President and Chief Executive Officer of Integrated Quality Resources, a biotechnology and pharmaceutical development consulting company. Dr. Shapiro served as Chief Medical Officer and head of R&D at Intercept Pharmaceuticals, Inc., a biopharmaceutical company, from April 2007 to May 2019. Earlier in his career, Dr. Shapiro was Chief Medical Officer, EVP Medical Affairs at Idun Pharmaceuticals, Inc., a biotechnology company which was acquired by Pfizer in 2005, from 2001 to 2005. David served as President of the Scripps Medical Research Center at Scripps Clinic from 1995 to 1997 and has held senior appointments at several biotechnology companies. Prior to joining the biotechnology sector, he led Merck & Co.'s hypertension clinical research program. David holds an M.D. from Dundee University and Medical School and an MRCP in Internal Medicine from Oxford University Teaching Hospitals. We believe that Dr. Shapiro is qualified to serve as a member of our board of directors due to his prior management experience in the biotechnology industry.

### **Family Relationships**

There are no family relationships among any of our executive officers or directors.

### **Composition of Our Board of Directors**

The authorized number of our board of directors is set at nine and currently contains nine members with no vacancy. Each of the members of our board of directors serves pursuant to the board composition provisions of our certificate of incorporation and agreements with our stockholders. These board composition provisions and the vacancy will terminate upon the completion of this offering. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our directors. Our nominating and corporate governance committee and our board of directors may consider a broad range of factors relating to the qualifications and background of nominees. Our nominating and corporate governance committee's and our board of directors' priority in selecting board members is to identify persons who will further the interests of our stockholders through his or her established record of professional accomplishments, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape, diversity of background and perspective and professional and personal experiences and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal. Our amended and restated certificate of incorporation and amended and restated bylaws that will become effective immediately prior to the closing of this offering also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

### **Director Independence**

We intend to apply to list our common stock on the Nasdaq Global Market. Applicable Nasdaq rules require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, the Nasdaq rules require that (i) on the date of the initial listing, at least one member of each of a listed company's audit, compensation and nominating and corporate governance committees be independent, (ii) within 90 days of the date of the initial listing, a majority of the members of such committees be

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independent and (iii) within one year of the date of the initial listing, all the members of such committees be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. Under applicable Nasdaq rules, a director will only qualify as an “independent director” if, in the opinion of the listed company’s board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries.

Our board of directors has determined that a majority of the members of the board of directors will be upon completion of this offering independent directors, including for purposes of the rules of Nasdaq and the SEC. In making such independence determination, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director. In considering the independence of the directors listed above, our board of directors considered the association of our directors with the holders of more than 5% of our common stock. Upon the completion of this offering, we expect that the composition and functioning of our board of directors and each of our committees will comply with all applicable requirements of Nasdaq and the rules and regulations of the SEC.

### ***Staggered Board***

In accordance with the terms of our amended and restated certificate of incorporation and amended and restated bylaws that will become effective immediately prior to the closing of this offering, our board of directors will be divided into three staggered classes of directors and each will be assigned to one of the three classes. At each annual meeting of the stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2021 for Class I directors, 2022 for Class II directors and 2023 for Class III directors.

- Our Class I directors will be \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_.
- Our Class II directors will be \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_.
- Our Class III directors will be \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_.

Our amended and restated certificate of incorporation and amended and restated bylaws that will become effective immediately prior to the closing of this offering will provide that the number of directors shall be fixed from time to time by a resolution of the majority of our board of directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our board of directors or a change in control.

### **Board Leadership Structure and Board’s Role in Risk Oversight**

The roles of lead director or chairman and the chief executive officer are separated. Amit D. Munshi is our current chairman of the board of directors and Hans T. Schambye, M.D., Ph.D. is our current Chief Executive Officer. We plan to keep these roles separated following the completion of this offering. We believe that separating these positions allows our Chief Executive Officer to focus on setting our overall strategic direction, expanding the organization to deliver on our strategy and overseeing our day-to-day business, while allowing a

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lead director of the board to lead the board of directors in its fundamental role of providing strategic advice. Our board of directors recognizes the time, effort and energy that the Chief Executive Officer is required to devote to his position in the current business environment, as well as the commitment required to serve as our chairman, particularly as the board of directors' oversight responsibilities continue to grow. While our amended and restated bylaws and corporate governance guidelines do not require that our lead director and Chief Executive Officer positions be separate, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including risks relating to our financial condition, development and commercialization activities, operations, strategic direction and intellectual property as more fully discussed in the section entitled "Risk Factors" appearing elsewhere in this prospectus. Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The role of the board of directors in overseeing the management of our risks is conducted through our board of directors, including through its committees, as disclosed in the descriptions of each of the committees below and in the charters of each of the committees. The full board of directors (or the appropriate board committee in the case of risks that are under the purview of a particular committee) discusses with management our major risk exposures, their potential impact on us, and the steps we take to manage them. When a board committee is responsible for evaluating and overseeing the management of a particular risk or risks, the chairperson of the relevant committee reports on the discussion to the full board of directors during the committee reports portion of the next board meeting. This enables the board of directors and its committees to coordinate the risk oversight role, particularly with respect to risk interrelationships.

### **Committees of Our Board of Directors**

Our board of directors has established an audit committee, a remuneration committee and a nominating and corporate governance committee, each of which will operate pursuant to a charter adopted by our board of directors and will be effective upon the effectiveness of the registration statement of which this prospectus is a part. Upon the effectiveness of the registration statement of which this prospectus is a part, the composition and functioning of all of our committees will comply with all applicable requirements of the Sarbanes-Oxley Act, and with Nasdaq and SEC rules and regulations.

#### *Audit Committee*

Effective upon the effectiveness of the registration statement of which this prospectus is a part, \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_ will serve on the audit committee, which will be chaired by \_\_\_\_\_. Our board of directors has determined that each of are "independent" for audit committee purposes as that term is defined in the rules of the SEC and the applicable Nasdaq rules, and each has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has designated \_\_\_\_\_ as an "audit committee financial expert," as defined under the applicable Nasdaq rules. The audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;

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- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending based upon the audit committee's review and discussions with management and our independent registered public accounting firm whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;
- reviewing material related person transactions for potential conflict of interest situations and approving such transactions; and
- at least annually, reviewing and reassessing the adequacy of the audit committee charter and recommending to the board of directors any amendments or modifications to the charter that the audit committee deems appropriate.

### ***Remuneration Committee***

Effective upon the effectiveness of the registration statement of which this prospectus is a part, \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_ will serve on the remuneration committee, which will be chaired by \_\_\_\_\_. Our board of directors has determined that each member of the nominating and corporate governance committee is "independent" as defined in the applicable Nasdaq rules. The remuneration committee's responsibilities include:

- reviewing on a periodic basis the operation of our executive compensation programs to determine whether they remain supportive of our business objectives;
- reviewing the performance of our chief executive officer and approving the compensation of our chief executive officer;
- reviewing the performance of our other executive officers, and approving or recommending to the board of directors the compensation of our other executive officers;
- overseeing and administering our compensation and similar plans;
- reviewing and approving structures and guidelines for various incentive compensation and benefit plans;
- reviewing and recommending to the board of directors the compensation of our outside directors;
- preparing the remuneration committee report required by SEC rules, if and when required, to be included in our annual proxy statement;

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- reviewing and approving the retention, termination or compensation of any consulting firm or outside advisor to assist in the evaluation of compensation matters; and
- at least annually, reviewing and reassessing the adequacy of the remuneration committee charter and recommending to the board of directors any amendments or modifications to the charter that the remuneration committee deems appropriate.

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

Effective upon the effectiveness of the registration statement of which this prospectus is a part, \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_ will serve on the nominating and corporate governance committee, which will be chaired by \_\_\_\_\_. Our board of directors has determined that each member of the nominating and corporate governance committee is “independent” as defined in the applicable Nasdaq rules. The nominating and corporate governance committee’s responsibilities include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- reviewing the composition of the board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board’s committees;
- developing and recommending to the board of directors a code of business conduct and ethics and a set of corporate governance guidelines;
- overseeing the evaluation of our board of directors; and
- at least annually, reviewing and reassessing the adequacy of the nominating and corporate governance committee charter and recommending to the board of directors any amendments or modifications to the charter that the nominating and corporate governance committee deems appropriate.

Our board of directors may from time to time establish other committees.

### **Remuneration Committee Interlocks and Insider Participation**

None of the members of our remuneration committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or remuneration committee of any entity that has one or more executive officers serving on our board of directors or remuneration committee.

### **Corporate Governance**

We intend to adopt a written code of business conduct and ethics, effective upon the effectiveness of the registration statement of which this prospectus is a part, that applies to our directors, officers and employees,

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including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Following the effectiveness of the registration statement of which this prospectus is a part, a current copy of the code will be posted on the investor relations section of our website, which is located at <https://galecto.com>. The inclusion of our website address in this prospectus does not incorporate by reference the information on or accessible through our website into this prospectus. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

### **Limitation on Liability and Indemnification Matters**

Our amended and restated certificate of incorporation, which will become effective immediately prior to the completion of this offering, will contain provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by Delaware law. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or
- any transaction from which the director derived an improper personal benefit.

Our amended and restated bylaws, which will become effective immediately prior to the completion of this offering, will provide that we are required to indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. Our amended and restated bylaws will also obligate us to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and 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 that capacity regardless of whether we would otherwise be permitted to indemnify him or her under Delaware law. We expect to enter into agreements to indemnify our directors, executive officers and other officers as determined by our board of directors or our remuneration committee. With specified exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in certain actions or proceedings.

We believe that these certificate of incorporation and bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors' and officers' liability insurance.

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 our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and our stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage.

## EXECUTIVE COMPENSATION

The following discussion relates to the compensation of Hans T. Schambye, M.D., Ph.D., our Chief Executive Officer, and Anders Pedersen, our Chief Operating Officer, in each case, for the last completed fiscal year. Dr. Schambye and Mr. Pedersen are collectively referred to in this prospectus as our named executive officers. We note that our additional officers, Jonathan Freve, our current Chief Financial Officer, and Bertil Lindmark, M.D., Ph.D., our current Chief Medical Officer, both joined us in 2020 and accordingly, their compensation is not required by SEC rules to be discussed in this prospectus.

### Summary Compensation Table

The following table sets forth information regarding compensation awarded to, earned by or paid to each of our named executive officers for the year ended December 31, 2019.

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary</u> <u>(\$)</u>	<u>Bonus</u> <u>(\$)</u>	<u>Total</u> <u>(\$)(1)</u>
Hans T. Schambye, M.D., Ph.D. <i>Chief Executive Officer</i>	2019	360,000	119,000	479,000
Anders Pedersen <i>Chief Operating Officer</i>	2019	270,000	85,000	355,000

(1) Values stated herein have been converted from Danish Krone to U.S. dollar as of December 31, 2019, at a rate of 6.6632:1.

### Narrative Disclosure to Summary Compensation Table

The amounts provided above were paid pursuant to the terms of each named executive officer's letter agreement, in each case, as described below.

#### ***Letter Agreement with Hans T. Schambye, M.D., Ph.D.***

In connection with our initial hiring of Dr. Schambye as our chief executive officer, we entered into a letter agreement with him dated March 2013. Under the letter agreement, Dr. Schambye's employment with us can be terminated at any time and for any reason by him with three months' written notice or us with nine months' written notice of termination on the last day of a month. The letter agreement provides that Dr. Schambye is entitled to an annualized base salary of \$225,117, subject to adjustment in accordance with normal business practices and at our sole discretion, during his employment with us and that he is eligible, at our sole discretion, to earn an annual bonus targeted at up to 40% of his base salary.

In 2019, we paid Dr. Schambye an annualized base salary of \$360,000, and we awarded him a bonus of \$119,000, which bonus amount was determined by the board of directors in its discretion based on the achievement of predetermined Company performance metrics. In January 2020, we increased Dr. Schambye's annual base salary to \$369,000.

#### ***Letter Agreement with Anders Pedersen***

In connection with our initial hiring of Mr. Pedersen as our chief operating officer, we entered into a letter agreement with him dated December 2012. Under the letter agreement, Mr. Pedersen's employment with us can be terminated at any time and for any reason by him with two months' written notice or us with six months' written notice. The required notice period upon termination by us will be extended to seven months beginning in October 2021. The letter agreement provides that Mr. Pedersen is entitled to an annualized base salary of \$171,000, subject to adjustment in accordance with normal business practices and at our sole discretion, during his employment with us and that he is eligible, at our sole discretion, to earn an annual bonus targeted at up to 25% of his base salary.



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In 2019, we paid Mr. Pedersen an annualized base salary of \$270,000, and we awarded him a bonus of \$85,000, which bonus amount was determined by the board of directors in its discretion based on the achievement of predetermined Company performance metrics and Mr. Schambye's recommendations. In January 2020, we increased Mr. Pedersen's annual base salary to \$277,000.

### **Outstanding Equity Awards at December 31, 2019**

The following table sets forth information regarding outstanding stock options held by our named executive officers as of December 31, 2019.

<u>Name</u>	<u>Number of securities underlying unexercised Options Exercisable (#)</u>	<u>Number of securities underlying unexercised Options Unexercisable (#)</u>	<u>Option Exercise Price (\$/share) (6)</u>	<u>Option Expiration Date</u>
Hans T. Schambye, M.D., Ph.D.	2,600(1)	—	\$ 10.70	12/17/2023
	7,000(1)	—	\$ 12.84	12/17/2023
	7,000(1)	—	\$ 16.05	3/25/2024
	500(2)	—	\$ 16.05	3/25/2024
Anders Pedersen.	4,500(3)	—	\$ 12.84	12/17/2023
	500(4)	—	\$ 12.84	12/17/2023
	7,000(3)	—	\$ 16.05	3/25/2024
	500(5)	—	\$ 16.05	3/25/2024

- (1) This option was initially granted on December 17, 2013, pursuant to the 2013 Plan (as defined below), and was vested in full on December 1, 2014. The amounts above were each terminated in connection with the acquisition of PharmAkea. New options were granted on March 22, 2020 under the Spring 2020 Plan, (as defined below), which options were fully vested on the grant date. Such new option grants were "out of the money" at the time of grant.
- (2) This option was initially granted on June 20, 2014, pursuant to the 2013 Plan, and was vested in full on June 1, 2017. The amounts above were each terminated in connection with the acquisition of PharmAkea. New options were granted on March 22, 2020 under the Spring 2020 Plan, which options were fully vested on the grant date. Such new option grants were "out of the money" at the time of grant.
- (3) This option was initially granted on December 17, 2013, pursuant to the 2013 Plan, and was vested in full on April 1, 2016. The amounts above were each terminated in connection with the acquisition of PharmAkea. New options were granted on March 22, 2020 under the Spring 2020 Plan, which options were fully vested on the grant date. Such new option grants were "out of the money" at the time of grant.
- (4) This option was initially granted on October 14, 2014, pursuant to the 2013 Plan, and was vested in full on June 1, 2017. The amounts above were each terminated in connection with the acquisition of PharmAkea. New options were granted on March 22, 2020 under the Spring 2020 Plan, which options were fully vested on the grant date. Such new option grants were "out of the money" at the time of grant.
- (5) This option was initially granted on June 1, 2015, pursuant to the 2013 Plan, and was vested in full on June 1, 2017. The amounts above were each terminated in connection with the acquisition of PharmAkea. New options were granted on March 22, 2020 under the Spring 2020 Plan, which options were fully vested on the grant date. Such new option grants were "out of the money" at the time of grant.
- (6) Values stated herein have been converted from Swedish Krona to U.S. dollar as of December 31, 2019, at a rate of 0.10699:1.

### **Employee Benefits and Equity Compensation Plans**

#### ***2020 Stock Option and Grant Plan***

Our 2020 Stock Option and Grant Plan, or the Spring 2020 Plan, was established in connection with the acquisition of PharmAkea and formally approved by our board of directors or our shareholders in March, 2020.

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The Spring 2020 Plan enables us to provide non-employee directors, employees and consultants with opportunities to purchase common shares pursuant to options that may be granted, and receive grants of restricted shares and other share-based awards granted, from time to time, by the board of directors or a committee approved by the board of directors.

As of December 31, 2019, no awards had been granted to our named executive officers pursuant to the Spring 2020 Plan, as the amounts reflected in the “Outstanding Equity Awards at December 31, 2019” table were outstanding under Galecto Biotech AB’s Options Programme 2013, or the 2013 Plan. In connection with the acquisition of PharmAkea, such amounts granted under the 2013 Plan were cancelled. In addition, new options were granted under the Spring 2020 Plan, or the New Options. The New Options were fully vested upon grant, at which point they were “out of the money.” The named executive officers are not entitled to any additional rights in connection with a termination of employment or otherwise in connection with a change in control of us. Prior to the offering, we expect to adopt a new equity plan to provide for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, awards of restricted stock, restricted stock units and other stock based awards, to our named executive officers and directors. Such adoption will be subject to stockholder approval. Following the approval of the new plan, it is not anticipated that we will make additional awards under the Spring 2020 Plan.

### DIRECTOR COMPENSATION

We paid Magnus Persson, our former chairman of our board of directors, a cash fee of \$45,362 in 2019. No compensation was paid to any of our other non-employee directors during 2019. We have historically reimbursed our non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending board of director and committee meetings.

<u>Name</u>	<u>Fees Earned or Paid in Cash (S) (2)</u>	<u>Option Awards (\$) (1)(2)</u>	<u>Total (S) (2)</u>
Magnus Persson	\$ 45,362	\$ 0	\$45,362

- (1) Mr. Persson held an aggregate of 8,500 option awards at fiscal year end. These options were granted in three tranches, of 4,000, 4,000 and 500, with the exercise prices being \$10.70, \$12.84 and \$16.05, respectively. The amounts above were each terminated in connection with the acquisition of PharmAkea. New options were granted on March 22, 2020 under the Spring 2020 Plan, which options were fully vested on the grant date. Such new option grants were “out of the money” at the time of grant.
- (2) This has been converted from Swedish Krona to U.S. dollar as of December 31, 2019, at a rate of 0.10699:1.

We expect our board of directors to approve a director compensation program that will become effective on the effective date of the registration statement of which this prospectus forms a part. Under this director compensation program, we expect will pay our non-employee directors a cash retainer for service on the board of directors and for service on each committee on which the director is a member. We expect the chairman of the board of directors and of each committee will receive higher retainers for such service. We expect these fees will be payable in arrears in four equal quarterly installments on the last day of each quarter, provided that the amount of such payment will be prorated for any portion of such quarter that the director is not serving on our board of directors and no fee will be payable in respect of any period prior to the completion of this offering. We expect the fees paid to non-employee directors for service on the board of directors and for service on each committee of the board of directors on which the director is a member are as follows:

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	<u>Member Annual Fee</u>	<u>Chairman Annual Fee</u>
Board of Directors	\$	\$
Audit Committee	\$	\$
Remuneration Committee	\$	\$
Nominating and Corporate Governance Committee	\$	\$

We also expect to continue to reimburse our non-employee directors for reasonable travel and other expenses incurred in connection with attending meetings of our board of directors and any committee of our board of directors on which he or she serves.

In addition, under our director compensation program to be effective on the effective date of the registration statement of which this prospectus forms a part, we expect that each non-employee director will receive, upon his or her initial election or appointment to our board of directors, an option to purchase \_\_\_\_\_ shares of our common stock under the \_\_\_\_\_. We expect that each of these options will vest as to \_\_\_\_\_ % of the shares of our common stock underlying such option at the end of each successive one month period following the grant date until the third anniversary of the grant date, subject to the non-employee director's continued service as a director.

Further, on the date of the first board meeting held after each annual meeting of stockholders, we expect that each non-employee director who has served on our board of directors for at least six months will receive, under the \_\_\_\_\_, an option to purchase \_\_\_\_\_ shares of our common stock under the \_\_\_\_\_. We expect each of these options will vest with respect to all of the shares underlying such option on the first anniversary of the grant date or, if earlier, immediately prior to the first annual meeting of stockholders occurring after the grant date, subject to the non-employee director's continued service as a director. We expect that all options issued to our non-employee directors under our director compensation program will be issued at exercise prices equal to the fair market value of our common stock on the date of grant and will become exercisable in full upon specified change in control events.

**CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS**

In addition to the compensation arrangements, including employment, termination of employment and change in control arrangements, with our directors and executive officers, including those discussed in the sections entitled “Management” and “Executive Compensation” and the registration rights described in the section entitled “Description of Capital Stock—Registration Rights,” the following is a description of each transaction since January 1, 2017 and each currently proposed transaction in which:

- we have been or are to be a participant;
- the amounts involved exceeded or will exceed the lesser of \$120,000 or 1% of the average of our total assets at year end for the last two completed fiscal years; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

**Private Placements of Securities*****Series C Preferred Stock Financing***

In October 2018, we sold 688,408 shares of our Series C-1 preferred stock, or the Series C-1 Preferred Stock, at a purchase price of \$22.58 per share for an aggregate amount of approximately \$15.5 million and 1,284,795 shares of our Series C-2 preferred stock, or the Series C-2 Preferred Stock, at a purchase price of \$26.88 per share for an aggregate amount of approximately \$36.2 million. In December 2019, we sold 618,521 shares of our Series C-3 preferred stock, or the Series C-3 Preferred Stock, at a purchase price of \$25.61 per share for an aggregate of approximately \$15.8 million in connection with our acquisition of PharmAkea. In January 2020 we sold 1,199,143 shares of our Series C-4 preferred stock, or the Series C-4 Preferred Stock, at a purchase price of \$25.73 per share for an aggregate amount of \$30.9 million and 342,612 shares of our Series C-5 preferred Stock, or the Series C-5 Preferred Stock, and together with the Series C-1 Preferred Stock, the Series C-2 Preferred Stock, the Series C-3 Preferred Stock and the Series C-4 Preferred Stock, the Series C Preferred Stock, at a purchase price of \$25.73 per share for an aggregate amount of \$8.8 million in connection with certain milestone achievements. The following table summarizes purchases of our Series C Preferred Stock by related persons:

<b>STOCKHOLDER</b>	<b>SHARES OF SERIES C-1 PREFERRED STOCK</b>	<b>SHARES OF SERIES C-2 PREFERRED STOCK</b>	<b>SHARES OF SERIES C-3 PREFERRED STOCK</b>	<b>SHARES OF SERIES C-4 PREFERRED STOCK</b>	<b>SHARES OF SERIES C-5 PREFERRED STOCK</b>	<b>TOTAL PURCHASE PRICE</b>
Hans T. Schambye, M.D. Ph.D. (1)	5,359					\$ 121,006.22
Anders Pedersen (2)	1,441					\$ 32,537.78
Novo Holdings A/S (3)	133,991	194,666		181,688	51,911	\$14,268,641.13
Entities affiliated with OrbiMed (4)		408,799		381,546	109,013	\$23,610,600.19
Sunstone Life Science Ventures Fund III K/S (5)	133,421	97,333		90,844	25,955	\$ 8,634,195.49

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<b>STOCKHOLDER</b>	<b>SHARES OF SERIES C-1 PREFERRED STOCK</b>	<b>SHARES OF SERIES C-2 PREFERRED STOCK</b>	<b>SHARES OF SERIES C-3 PREFERRED STOCK</b>	<b>SHARES OF SERIES C-4 PREFERRED STOCK</b>	<b>SHARES OF SERIES C-5 PREFERRED STOCK</b>	<b>TOTAL PURCHASE PRICE</b>
Merck Ventures BV (6)	133,954	77,866		72,675	20,764	\$ 7,521,904.87
Entities affiliated with Bay City Capital (7)			399,842			\$ 10,239,953.62
Ysios BioFund II Innvierte FCR (8)		155,733		145,351	41,529	\$ 8,994,525.44
Bristol-Myers Squibb Company (9)	124,156	97,333		90,844	25,955	\$ 8,424,991.79
Seed Capital Denmark II K/S (10)	133,421					\$ 3,012,646.18
HBM Healthcare Investments (Cayman) Ltd. (11)		136,266		127,182	36,338	\$ 7,870,199.68

- (1) Hans T. Schambye, M.D., Ph.D. is our Chief Executive Officer and is a member of our board of directors.
- (2) Anders Pedersen is our Chief Operating Officer.
- (3) Novo Holdings A/S, or Novo, holds more than 5% of our voting securities. Dr. Møller, a member of our board of directors, is currently employed as a Managing Partner of Novo. Dr. Møller is not deemed to hold any beneficial ownership or reportable pecuniary interest in the shares held by Novo.
- (4) Entities affiliated with OrbiMed, including OrbiMed Private Investments VII, LP and OrbiMed Israel Partners II, LP, hold more than 5% of our voting securities. Mr. Khuong, a member of our board of directors, is a Partner at OrbiMed.
- (5) Sunstone Life Science Ventures Fund III K/S, or Sunstone, holds more than 5% of our voting securities. Mr. Lemonius, a member of our board of directors, is a Partner at Sunstone.
- (6) Merck Ventures BV holds more than 5% of our voting securities.
- (7) Entities affiliated with Bay City Capital, including Bay City Capital Fund V, L.P. and Bay City Capital Fund V Co-Investment Fund, L.P., hold more than 5% of our voting securities. Dr. Goldfischer, a member of our board of directors, is a Partner and Managing Directors at Bay City Capital.
- (8) Ysios BioFund II Innvierte FCR, or Ysios, holds more than 5% of our voting securities. Dr. Wagner, a member of our board of directors, is a General Partner at Ysios Capital, a corporation that is affiliated with Ysios.
- (9) Bristol-Myers Squibb Company holds more than 5% of our voting securities.
- (10) Seed Capital Denmark II K/S holds more than 5% of our voting securities.
- (11) HBM Healthcare Investments (Cayman) Ltd., or HBM, holds more than 5% of our voting securities. Dr. Leo, a member of our board of directors, is a member of the Private Equity Team at HBM Partners, a corporation that is affiliated with HBM.

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### **Agreements with Stockholders**

In connection with our Series C-4/C-5 preferred stock financing, we entered into investors' rights, voting and right of first refusal and co-sale agreements containing registration rights, information rights, voting rights and rights of first refusal, among other things, with certain holders of our preferred stock and certain holders of our common stock. These stockholder agreements will terminate upon the closing of this offering, except for the registration rights granted under the Investors' Rights Agreement, as more fully described in "Description of Capital Stock—Registration Rights."

### **Executive Officer and Director Compensation**

See the sections entitled "Executive Compensation" and "Director Compensation" for information regarding compensation of our executive officers and directors.

### **Other Relationships**

Other than as described above, since January 1, 2017, we have not entered into any transactions, nor are there any currently proposed transactions, between us and a related party where the amount involved exceeds, or would exceed, the lesser of \$120,000 or 1% of the average of our total assets at year end for the last two completed fiscal years and in which any related person had or will have a direct or indirect material interest.

### **Indemnification Agreements**

In connection with this offering, we intend to enter into new agreements to indemnify our directors, executive officers, and other officers as determined from time to time by our board of directors or our remuneration committee. These agreements and our amended and restated bylaws will, among other things, require us to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in certain actions or proceeding, including any action, on account of any services undertaken by such person on behalf of us or that person's status as a member of our board of directors to the maximum extent allowed under Delaware law. We will also be required by these agreements to indemnify these individuals for certain expenses (including attorney's fees) in certain action or proceeding by or in our right.

### **Policies for Approval of Related Party Transactions**

Prior to this offering, we expect to adopt a written Related Person Transaction Policy, to be effective upon the effectiveness of the registration statement of which this prospectus is a part. The policy will set forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy only, a related person transaction is any transaction in which we are a participant and a related person has a direct or indirect material interest. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director, director nominee, or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members.

Under the policy, we shall provide our audit committee with all material information regarding such related person transaction. Our audit committee will review the material facts of all related person transactions, taking into account, among other factors that it deems appropriate, whether the related person transaction is on terms no less favorable to us than terms generally available in a transaction with an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction. To facilitate identification of related person transactions, we will compile a list of all related persons and related person affiliates, and updated the list at least annually, based on questionnaires completed by our directors and officers. Each of our directors, officers and director nominees shall also be responsible for promptly notifying us of any change in the identity of relevant related party affiliates.

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In addition, under our Code of Conduct, which we intend to adopt in connection with this offering, our employees and directors have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest.

In considering related person transactions, our audit committee, or other independent body of our board of directors, will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs, and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director, or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify, or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion. All of the transactions described above were entered into prior to the adoption of the written policy, but all were approved by our board of directors considering similar factors to those described above.

**PRINCIPAL STOCKHOLDERS**

The following table presents information concerning the beneficial ownership of the shares of our common stock as of \_\_\_\_\_, 2020 by:

- each person we know to be the beneficial owner of 5% or more of our outstanding shares of our capital stock;
- each of our directors;
- each of our named executive officers; and
- all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with SEC rules. The information does not necessarily indicate beneficial ownership for any other purpose. Under these rules, a person is deemed to be a beneficial owner of our common stock if that person has a right to acquire ownership within 60 days by the exercise of options or the conversion of our redeemable convertible preferred stock. A person is also deemed to be a beneficial owner of our common stock if that person has or shares voting power, which includes the power to vote or direct the voting of our common stock, or investment power, which includes the power to dispose of or to direct the disposition of such capital stock. Except in cases where community property laws apply or as indicated in the footnotes to this table, we believe that each stockholder identified in the table possesses sole voting and investment power over all shares of common stock shown as beneficially owned by the stockholder.

Percentage of beneficial ownership in the table below is based on \_\_\_\_\_ shares of common stock deemed to be outstanding as of \_\_\_\_\_, 2020, assuming the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into common stock, immediately prior to the completion of this offering. The table below assumes that the underwriters do not exercise their option to purchase additional shares. Shares of common stock subject to options that are currently exercisable or exercisable within 60 days of \_\_\_\_\_ are considered outstanding and beneficially owned by the person holding the options for the purpose of computing the percentage ownership of that person but are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated below, the address of each individual listed below is Ole Maaloes Vej 3, DK-2200 Copenhagen N Denmark.

<u>Name and address of beneficial owner</u>	<u>Number of shares beneficially owned</u>	<u>Percentage of shares beneficially owned before offering</u>	<u>Percentage of shares beneficially owned after offering</u>
<b>5% or Greater Stockholders:</b>			
Novo Holdings A/S			
Sunstone Life Science Ventures Fund III K/S			
Merck Ventures BV			
Seed Capital Denmark II K/S			
Entities Affiliated with OrbiMed			
Entities Affiliated with Bay City Capital			
Bristol-Myers Squibb Company			
Ysios BioFund II Innvierte FCR			
HBM Healthcare Investments (Cayman) Ltd.			



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<u>Name and address of beneficial owner</u>	<u>Number of shares beneficially owned</u>	<u>Percentage of shares beneficially owned before offering</u>	<u>Percentage of shares beneficially owned after offering</u>
<b>Named Executive Officers and Directors:</b>			
Hans T. Schambye, M.D., Ph.D.			
Anders Pedersen			
Bertil Lindmark, M.D., Ph.D.			
Jonathan Freve			
Amit D. Munshi			
Karen Wagner, Ph.D.			
Chau Khuong			
Søren Lemonius			
Chandra Leo, M.D.			
Erez Chimovitz			
Carl Goldfischer, M.D.			
Søren Møller, Ph.D.			
David Shapiro, M.D.			
All executive officers and directors as a group (13 persons)(16)			

\* Represents beneficial ownership of less than one percent.

## DESCRIPTION OF CAPITAL STOCK

Upon the completion of this offering, our authorized capital stock will consist of \_\_\_\_\_ shares of common stock, par value \$0.00001 per share, and \_\_\_\_\_ shares of preferred stock, par value \$0.00001 per share, all of which will be undesignated, and there will be \_\_\_\_\_ shares of common stock outstanding and no shares of preferred stock outstanding. As of \_\_\_\_\_, 2020, we had approximately \_\_\_\_\_ record holders of our capital stock. All of our outstanding shares of redeemable convertible preferred stock will convert into shares of our common stock immediately prior to the completion of this offering. In addition, upon the completion of this offering, options to purchase \_\_\_\_\_ shares of our common stock will be outstanding and \_\_\_\_\_ shares of our common stock will be reserved for future grants under our equity incentive plans.

The following description of our capital stock and provisions of our amended and restated certificate of incorporation and bylaws are summaries of material terms and provisions and are qualified by reference to our amended and restated certificate of incorporation and bylaws, copies of which have been filed with the SEC as exhibits to the registration statement of which this prospectus is a part. The descriptions of our common stock and preferred stock reflect amendments to our amended and restated certificate of incorporation and bylaws that will become effective immediately prior to the completion of this offering.

### General

Upon completion of this offering, our authorized capital stock will consist of \_\_\_\_\_ shares of common stock, par value \$0.00001 per share, and \_\_\_\_\_ shares of preferred stock, par value \$0.00001 per share, all of which shares of preferred stock will be undesignated.

As of \_\_\_\_\_, 2020, \_\_\_\_\_ shares of our common stock (of which \_\_\_\_\_ shares are subject to a right of repurchase by us pursuant to a stock restriction agreement between us and the holders of such shares) were outstanding and held of record by \_\_\_\_\_ stockholders, and \_\_\_\_\_ shares of Series B-1 preferred stock, \_\_\_\_\_ shares of Series B-2 preferred stock, \_\_\_\_\_ shares of Series B-3 preferred stock, \_\_\_\_\_ shares of Series B-4 preferred stock, \_\_\_\_\_ shares of Series C-1 preferred stock, \_\_\_\_\_ shares of Series C-2 preferred stock, \_\_\_\_\_ shares of Series C-3 preferred stock, \_\_\_\_\_ shares of Series C-4 preferred stock and \_\_\_\_\_ shares of Series C-5 preferred stock were outstanding and held of record by \_\_\_\_\_ stockholders. This amount does not take into account the conversion of all outstanding shares of our preferred stock into common stock upon the closing of this offering.

### Common Stock

Upon the completion of this offering, we will be authorized to issue one class of common stock. Holders of our common stock are entitled to one vote for each share of common stock held of record for the election of directors and on all matters submitted to a vote of stockholders. Except as described under “Anti-takeover Effects of Delaware Law and Provisions of our Amended and Restated Certificate of Incorporation and Bylaws” below, a majority vote of the holders of common stock is generally required to take action under our amended and restated certificate of incorporation and bylaws. Holders of our common stock are entitled to receive dividends ratably, if any, as may be declared by our board of directors out of legally available funds, subject to any preferential dividend rights of any preferred stock then outstanding. Upon our dissolution, liquidation or winding up, holders of our common stock are entitled to share ratably in our net assets legally available after the payment of all our debts and other liabilities, subject to the preferential rights of any preferred stock then outstanding. Holders of our common stock have no preemptive, subscription, redemption or conversion rights and no sinking fund provisions are applicable to our common stock. The rights, preferences and privileges of holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

## Preferred Stock

Immediately prior to completion of this offering, all outstanding shares of our redeemable convertible preferred stock will be converted into shares of our common stock. Upon the completion of this offering, our board of directors will be authorized, without action by the stockholders, to designate and issue up to an aggregate of \_\_\_\_\_ shares of preferred stock in one or more series. Our board of directors can designate the rights, preferences and privileges of the shares of each series and any of its qualifications, limitations or restrictions. 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 common stock. The issuance of preferred stock, while providing flexibility in connection with possible future financings and acquisitions and other corporate purposes could, under certain circumstances, have the effect of restricting dividends on our common stock, diluting the voting power of our common stock, impairing the liquidation rights of our common stock, or delaying, deferring or preventing a change in control of us, which might harm the market price of our common stock. See also “—Anti-Takeover Effects of Delaware Law and Provisions of Our Amended and Restated Certificate of Incorporation and Bylaws—Provisions of our amended and restated certificate of incorporation and bylaws—Undesignated preferred stock” below.

Our board of directors will make any determination to issue such shares based on its judgment as to our best interests and the best interests of our stockholders. Upon the completion of this offering, we will have no shares of preferred stock outstanding and we have no current plans to issue any shares of preferred stock following completion of this offering.

## Options

As of \_\_\_\_\_, 2020, we had outstanding options to purchase \_\_\_\_\_ shares of our common stock, with a per share weighted-average exercise price of \$ \_\_\_\_\_ under the 2020 Plan.

## Registration Rights

Upon the completion of this offering, the holders of \_\_\_\_\_ shares of our common stock, including shares issuable upon the automatic conversion of our redeemable convertible preferred stock, or their permitted transferees, which we refer to as our registrable securities, are entitled to rights with respect to the registration of these securities under the Securities Act. These rights are provided under the terms of the Investors’ Rights Agreement. The Investors’ Rights Agreement includes demand registration rights, short-form registration rights and piggyback registration rights. All fees, costs and expenses incurred in connection with registrations under the Investors’ Rights Agreement, will be borne by us, and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

### *Demand registration rights*

Beginning 180 days after the effective date of this registration statement, the holders of our registrable securities are entitled to demand registration rights. Under the terms of the Investors’ Rights Agreement, we will be required, upon the request of holders of at least a majority of our outstanding registrable securities, to file a registration statement and effect the registration of these shares for public resale, unless our board of directors decides in good faith that such registration would be materially detrimental to us and our stockholders under the circumstances. We are required to effect up to two registrations pursuant to this provision of the Investors’ Rights Agreement.

### *Short form registration rights*

Upon the completion of this offering, the holders of our registrable securities are also entitled to short form registration rights. Pursuant to the Investors’ Rights Agreement, if we are eligible to file a registration statement on

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Form S-3, upon the request of holders of at least 20% of our outstanding registrable securities to sell registrable securities with an anticipated aggregate offering amount of at least \$5.0 million net of certain expenses related to the offering, we will be required to effect a registration of such shares, unless our board of directors decides in good faith that such registration would be materially detrimental to us and our stockholders under the circumstances. We are required to effect up to two registrations in any twelve-month period pursuant to this provision of the Investors' Rights Agreement.

### ***Piggyback registration rights***

The holders of our registrable securities are entitled to piggyback registration rights. If we register any of our securities either for our own account or for the account of other security holders, the holders of our outstanding registrable securities are entitled to include their shares in the registration. Subject to certain exceptions contained in the Investors' Rights Agreement, we and the underwriters may limit the number of shares included in the underwritten offering if the underwriters determine that marketing factors require a limitation of the number of shares to be underwritten.

### ***Indemnification***

The Investors' 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 of registration***

We will pay the registration expenses, subject to certain limited exceptions contained in the Investors' Rights Agreement, of the holders of the shares registered pursuant to the demand, short form and piggyback registration rights described above, including the expenses of one counsel for the selling holders.

### ***Expiration of registration rights***

The registration rights granted under the Investors' Rights Agreement will terminate upon the earlier of (i) a deemed liquidation event, as defined in our amended and restated certificate of incorporation (as in effect prior to the completion of this offering) or certain other events constituting our sale, (ii) at such time after our initial public offering when all registrable securities could be sold under Rule 144 of the Securities Act or a similar exemption without limitation during a three-month period without registration or (iii) the fifth anniversary of our initial public offering.

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

Certain provisions of the DGCL and of our amended and restated certificate of incorporation and bylaws that will become effective immediately prior to the completion of this offering could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and, as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions are also designed in part to encourage anyone seeking to acquire control of us to first negotiate with our board of directors. These provisions might also have the effect of preventing changes in our board of directors or management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests. However, we believe that the advantages gained by protecting our ability to negotiate with

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any unsolicited and potentially unfriendly acquirer outweigh the disadvantages of discouraging such proposals, including those priced above the then-current market value of our common stock, because, among other reasons, the negotiation of such proposals could improve their terms.

### ***Delaware takeover statute***

Upon completion of this offering, we will be subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge, exchange, mortgage or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

***Provisions of our amended and restated certificate of incorporation and bylaws***

Our amended and restated certificate of incorporation and bylaws to be in effect immediately prior to completion of this offering will include a number of provisions that may have the effect of delaying, deferring or discouraging another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

*Board composition and filling vacancies.* In accordance with our amended and restated certificate of incorporation, our board is divided into three classes serving staggered three-year terms, with one class being elected each year. Our amended and restated certificate of incorporation also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of \_\_\_\_\_ or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum.

*No written consent of stockholders.* Our amended and restated certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholder without holding a meeting of stockholders.

*Meetings of stockholders.* Our amended and restated bylaws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our amended and restated bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

*Advance notice requirements.* Our amended and restated bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days or more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. The notice must contain certain information specified in our amended and restated bylaws.

*Amendment to certificate of incorporation and bylaws.* As required by the DGCL, any amendment of our amended and restated certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our amended and restated certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment, and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, directors, limitation of liability and the amendment of our amended and restated certificate of incorporation must be approved by not less than \_\_\_\_\_ of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority vote of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of at least \_\_\_\_\_ of the outstanding shares entitled to vote on the amendment, voting together as a single class.

*Undesignated preferred stock.* Our amended and restated certificate of incorporation provides for \_\_\_\_\_ authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means

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of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of us or our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our amended and restated certificate of incorporation grants our board of directors' broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

*Exclusive forum.* Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any state law claims for: (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws, (iv) any action to interpret, apply, enforce, or determine the validity of our certificate of incorporation or bylaws, or (v) any action asserting a claim against us governed by the internal affairs doctrine. This exclusive forum provision will not apply to any causes of action arising under the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Unless we consent in writing to the selection of an alternate forum, the United States District Court for the Northern District of California shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, as our principal executive office is located in South San Francisco, California. Although our amended and restated bylaws contain the choice of forum provision described above, it is possible that a court could rule that such provisions are inapplicable for a particular claim or action or that such provisions are unenforceable.

### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is . The transfer agent and registrar's address is .

### **Listing**

We intend to apply to list our common stock on the Nasdaq Global Market under the symbol "GLTO."

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

For a discussion of liability and indemnification, see the section entitled "Management—Limitation on Liability and Indemnification Matters."

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, since only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale, sales of substantial amounts of common stock in the public market after the restrictions lapse could adversely affect the prevailing market price for our common stock as well as our ability to raise equity capital in the future. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

### Sale of Restricted Shares

Based on the number of shares of common stock outstanding as of \_\_\_\_\_, 2020, upon completion of this offering, \_\_\_\_\_ shares of common stock will be outstanding, assuming no exercise by the underwriters of their option to purchase additional shares and no exercise of options. All of the shares sold in this offering will be freely tradable. The remaining shares of common stock outstanding after this offering will be restricted as a result of securities laws or lock-up agreements as described below. Following the expiration of the lock-up period, all shares will be eligible for resale in compliance with Rule 144 or Rule 701 under the Securities Act. "Restricted securities" as defined under Rule 144 under the Securities Act were issued and sold by us in reliance on exemptions from the registration requirements of the Securities Act. These shares may be sold in the public market only if registered or qualified for an exemption from registration, such as under Rule 144 or Rule 701 under the Securities Act.

### Rule 144

In general, a person who has beneficially owned restricted stock for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned restricted shares for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares then outstanding, which will equal approximately \_\_\_\_\_ shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares, based on the number of shares outstanding as of \_\_\_\_\_; or
- the average weekly trading volume of our common stock on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

### Rule 701

Rule 701 under the Securities Act, or Rule 701, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased



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shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and under “Underwriting” included elsewhere in this prospectus and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

### **Lock-up Agreements**

In connection with this offering, we, each of our directors and executive officers, and holders of substantially all of our securities have agreed with the underwriters that for a period of 180 days following the date of this prospectus, subject to certain exceptions, we and they will not offer, sell, assign, transfer, pledge, contract to sell or otherwise dispose of or hedge any shares of our common stock or any securities convertible into or exchangeable for shares of our common stock. The representatives of the underwriters may, in their sole discretion, at any time, release all or any portion of the shares from the restrictions in this agreement.

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

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.

### **Registration Rights**

We are party to an investor rights agreement which provides that holders holding \_\_\_\_\_ shares of our common stock, including shares issuable upon the automatic conversion of our redeemable convertible preferred stock, have the right to demand that we file a registration statement or request that their shares of our common stock be covered by a registration statement that we are otherwise filing. See the section entitled “Description of Capital Stock—Registration Rights” in this prospectus. Except for shares purchased by affiliates, registration of their shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon effectiveness of the registration, subject to the expiration of the lock-up period described above and in the section entitled “Underwriting” in this prospectus, and to the extent such shares have been released from any repurchase option that we may hold.

### **Equity Incentive Plans**

As soon as practicable after the completion of this offering, we intend to file a Form S-8 registration statement under the Securities Act to register shares of our common stock subject to options and other equity awards outstanding or reserved for issuance under our equity incentive plans. This registration statement will become effective immediately upon filing, and shares covered by this registration statement will thereupon be eligible for sale in the public markets, subject to Rule 144 limitations applicable to affiliates and any lock-up agreements. For a more complete discussion of our equity incentive plans, see “Executive Compensation—Employee Benefits and Equity Compensation Plans.”

## **MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS TO NON-U.S. HOLDERS**

The following discussion is a summary of certain U.S. federal income tax considerations applicable to non-U.S. holders (as defined below) with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering. For purposes of this discussion, a non-U.S. holder means a beneficial owner of our common stock that is for U.S. federal income tax purposes:

- a non-resident alien individual;
- a foreign corporation or any other foreign organization taxable as a corporation for U.S. federal income tax purposes; or
- a foreign estate or trust, the income of which is not subject to U.S. federal income tax on a net income basis.

This discussion does not address the tax treatment of partnerships or other entities that are pass-through entities for U.S. federal income tax purposes or persons that hold their common stock through partnerships or other pass-through entities. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her or its tax advisor regarding the tax consequences of holding and disposing of our common stock through a partnership or other pass-through entity, as applicable.

This discussion is based on current provisions of the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any such change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus. There can be no assurance that the IRS will not challenge one or more of the tax consequences described herein. We assume in this discussion that a non-U.S. holder holds shares of our common stock as a capital asset within the meaning of Section 1221 of the Code, which is generally property held for investment.

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances including the alternative minimum tax, or the Medicare tax on net investment income, the timing of income accruals required under Section 451(b) of the Code, the rules regarding qualified small business stock within the meaning of Section 1202 of the Code and any election to apply Section 1400Z-2 of the Code to gains recognized with respect to shares of our common stock. This discussion also does not address any U.S. state, local or non-U.S. taxes or any other aspect of any U.S. federal tax other than the income tax. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- insurance companies;
- tax-exempt or governmental organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- pension plans;

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- “controlled foreign corporations,” “passive foreign investment companies,” and corporations that accumulate earnings to avoid U.S. federal income tax;
- “qualified foreign pension funds,” or entities wholly-owned by a “qualified foreign pension fund”;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and partners and investors therein);
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
- persons who have elected to mark securities to market;
- persons who have a functional currency other than the U.S. dollar;
- persons that own, or have owned, actually or constructively, more than 5% of our common stock;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation; and
- certain U.S. expatriates.

This discussion is for general information only and is not tax advice. Accordingly, all prospective non-U.S. holders of our common stock should consult their tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock.

### **Distributions on our common stock**

Distributions, if any, on our common stock 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. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder’s investment, up to such holder’s tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in “Gain on sale or other taxable disposition of our common stock.” Any such distributions will also be subject to the discussions below under the sections titled “Backup withholding and information reporting” and “Withholding and information reporting requirements—FATCA.”

Subject to the discussion in the following two paragraphs in this section, dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder’s country of residence. If we or another withholding agent apply over-withholding or if a non-U.S. holder does not timely provide us with the required certification, the non-U.S. holder may be entitled to a refund or credit of any excess tax withheld by timely filing an appropriate claim with the IRS.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income, net of specified deductions and

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credits, is taxed at the same graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional “branch profits tax” at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder’s country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder’s country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) to the applicable withholding agent and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing a U.S. tax return with the IRS.

### **Gain on sale or other taxable disposition of our common stock**

Subject to the discussions below under “Backup withholding and information reporting” and “Withholding and information reporting requirements—FATCA,” a non-U.S. holder generally will not be subject to any U.S. federal income tax on any gain realized upon such holder’s sale or other taxable disposition of shares of our common stock unless:

- the gain is effectively connected with the non-U.S. holder’s conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed-base maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on a net income basis at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in “Distributions on our common stock” also may apply;
- the non-U.S. holder is a nonresident alien individual who is present in the United States for a period or periods aggregating 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder’s country of residence) on the net gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses; or
- we are, or have been, at any time during the five-year period preceding such sale or other taxable disposition (or the non-U.S. holder’s holding period, if shorter) a “U.S. real property holding corporation,” unless our common stock is regularly traded on an established securities market and the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

## **Backup withholding and information reporting**

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above in “Distributions on our common stock,” generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them. Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder’s U.S. federal income tax liability, if any, provided that an appropriate claim is filed with the IRS in a timely manner.

## **Withholding and information reporting requirements—FATCA**

Provisions of the Code commonly referred to as the Foreign Account Tax Compliance Act, or FATCA, generally imposes a U.S. federal withholding tax at a rate of 30% on payments of dividends on our common stock paid to a foreign entity unless (i) if the foreign entity is a “foreign financial institution,” such foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a “foreign financial institution,” such foreign entity identifies certain of its U.S. investors, if any, or (iii) the foreign entity is otherwise exempt under FATCA. Under applicable U.S. Treasury regulations, withholding under FATCA currently applies to payments of dividends on our common stock. Currently proposed U.S. Treasury Regulations provide that FATCA withholding does not apply to gross proceeds from the disposition of property of a type that can produce U.S. source dividends or interest; however, prior versions of the rules would have made such gross proceeds subject to FATCA withholding. Taxpayers (including withholding agents) can generally rely on the proposed Treasury Regulations until final Treasury Regulations are issued. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of this withholding tax. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their tax advisors regarding the possible implications of this legislation on their investment in our common stock and the entities through which they hold our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

## UNDERWRITING

BofA Securities, Inc., SVB Leerink LLC and Credit Suisse Securities (USA) LLC 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.

Underwriter	Number of Shares
BofA Securities, Inc.	
SVB Leerink LLC.	
Credit Suisse Securities (USA) LLC	
Total	

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 officer's 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.

	Per Share	Total	
		Without Option	With Option
Public offering price	\$	\$	\$
Underwriting discount	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

The expenses of the offering, not including the underwriting discount, are estimated at \$ \_\_\_\_\_ and are payable by us.

### **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 \_\_\_\_\_ 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.

### **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 BofA Securities, Inc., SVB Leerink LLC and Credit Suisse Securities (USA) LLC. 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.

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, with certain exceptions, 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 Market Listing**

We expect the shares to be approved for listing on the Nasdaq Global Market, subject to notice of issuance, under the symbol "GLTO."

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,

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- the history of, and the prospects for, us 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, including the progress of our product candidates through clinical development 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 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 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.

## **EEA and the U.K.**

In relation to each member state of the EEA and the U.K., each referred to as a Relevant State, no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation), except that offers of shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

- a. to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- b. to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the underwriters for any such offer; or
- c. in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Relevant State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with us and the underwriters that it is a qualified investor within the meaning of the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in a Relevant State to qualified investors, in circumstances in which the prior consent of the underwriters has been obtained to each such proposed offer or resale.

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We, the underwriters and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

References to the Prospectus Regulation includes, in relation to the U.K., the Prospectus Regulation as it forms part of U.K. domestic law by virtue of the European Union (Withdrawal) Act 2018.

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

### **Notice to Prospective Investors in the U.K.**

This document is for distribution only to persons who (i) have professional experience in matters relating to investments and who qualify as investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended, the “Financial Promotion Order”), (ii) are persons falling within Article 49(2)(a) to (d), or high net worth companies, unincorporated associations etc., of the Financial Promotion Order, (iii) are outside the U.K., or (iv) are persons to whom an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000, as amended, or FSMA,) in connection with the issue or sale of any securities may otherwise lawfully be communicated or caused to be communicated (all such persons together being referred to as “relevant persons”). This document is directed only at relevant persons and must not be acted on or relied on by persons who are not relevant persons. Any investment or investment activity to which this document relates is available only to relevant persons and will be engaged in only 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 FINMA, or FINMA, 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

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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, or 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

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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, the shares were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or the SFA) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, 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) 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) 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,

securities or securities-based derivatives contracts (each term as defined in Section 2(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:

- (a) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4) (i)(B) of the SFA;
- (b) where no consideration is or will be given for the transfer;
- (c) where the transfer is by operation of law; or
- (d) as specified in Section 276(7) of the SFA.

### **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.

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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 common stock offered hereby will be passed upon for us by Goodwin Procter LLP, New York, NY. Certain legal matters in connection with our patents and intellectual property interests will be passed upon for us by Nex & Phister ApS, Copenhagen, Denmark. Legal matters in connection with the offering will be passed upon for the underwriters by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., Boston, MA.

## EXPERTS

The consolidated financial statements of Galecto, Inc. at December 31, 2019 and 2018, and for each of the two years in the period ended December 31, 2019, appearing in this prospectus and registration statement have been audited by EY Godkendt Revisionspartnerselskab, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about our ability to continue as a going concern as described in Note 1 to the consolidated financial statements) appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm 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 being offered by this prospectus, which constitutes a part of the registration statement. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at [www.sec.gov](http://www.sec.gov). Upon completion of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available via the SEC's website at [www.sec.gov](http://www.sec.gov). We also maintain a website at [www.galecto.com](http://www.galecto.com), at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. However, the information contained in or accessible through our website is not part of this prospectus or the registration statement of which this prospectus forms a part, and investors should not rely on such information in making a decision to purchase our common stock in this offering.

**GALECTO, INC.**

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Galecto, Inc.

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Galecto, Inc. (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit and cash flows for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

### The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has recurring losses from operations and an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Its ability to continue to operate is dependent upon obtaining additional financial support. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### 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 and in accordance with auditing standards generally accepted in the United States of America. 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 include 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/ EY Godkendt Revisionspartnerselskab

We have served as the Company's auditor since 2019.

Copenhagen, Denmark  
September 2, 2020



## GALECTO, INC.

## Consolidated Balance Sheets

(in thousands, except share and per share amounts)

	December 31,	
	2019	2018
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 11,294	\$ 30,987
Prepaid expenses and other current assets	5,117	3,973
Receivable on issuance of series C convertible preferred stock or Series C preferred stock	39,669	—
Total current assets	56,080	34,960
Restricted cash	231	144
Operating lease right-of-use asset	298	—
Total assets	<u>\$ 56,609</u>	<u>\$ 35,104</u>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 3,329	\$ 1,414
Accrued expenses and other current liabilities	4,598	1,286
Preferred stock tranche obligations	—	1,744
Total current liabilities	7,927	4,444
Operating lease liabilities, net of current portion	211	—
Total liabilities	8,138	4,444
<b>Commitments and contingencies (Note 9)</b>		
<b>Convertible preferred stock</b>		
Series B convertible preferred stock, or Series B preferred stock, \$0.00001 par value; 684,068 shares, authorized, issued and outstanding authorized at December 31, 2019 and 2018; liquidation value of \$15,608 at December 31, 2019	13,414	13,414
Series C preferred stock, \$0.00001 par value; 4,133,479 and 1,973,203 shares authorized at December 31, 2019 and 2018, respectively; 4,125,056 and 1,973,203 shares issued and outstanding at December 31, 2019 and 2018, respectively; liquidation value of \$114,786 at December 31, 2019	106,205	51,081
Total convertible preferred stock	119,619	64,495
<b>Stockholders' deficit</b>		
Common stock, par value of \$0.00001 per share; 5,350,404 shares authorized at December 31, 2019 and 2018, 100,000 shares issued and outstanding as of December 31, 2019 and 2018	—	—
Additional paid-in capital	826	826
Accumulated deficit	(69,523)	(33,017)
Accumulated other comprehensive loss	(2,451)	(1,644)
Total stockholders' deficit	(71,148)	(33,835)
Total liabilities, convertible preferred stock and stockholders' deficit	<u>\$ 56,609</u>	<u>\$ 35,104</u>

*See accompanying notes to the financial statements.*

## GALECTO, INC.

## Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2019	2018
Operating expenses		
Research and development	\$ 19,738	\$ 10,093
Purchased in-process research and development	16,788	—
General and administrative	2,445	2,814
Total operating expenses	<u>38,971</u>	<u>12,907</u>
Loss from operations	<u>(38,971)</u>	<u>(12,907)</u>
Other income (expense)		
Foreign exchange transaction gain, net	551	487
Fair value adjustments on preferred stock tranche obligations and note tranche and derivative obligations	1,913	(479)
Interest expense	—	(2,970)
Total other income (expense), net	<u>2,464</u>	<u>(2,962)</u>
Net loss	<u>(36,507)</u>	<u>(15,869)</u>
Cumulative dividends on convertible preferred stock	<u>(5,560)</u>	<u>(3,136)</u>
Net loss attributable to common stockholders	<u>(42,067)</u>	<u>(19,005)</u>
Net loss per common share, basic and diluted	<u>\$ (420.67)</u>	<u>\$ (190.05)</u>
Weighted-average number of shares used in computing net loss per common share, basic and diluted	<u>100,000</u>	<u>100,000</u>
Unaudited pro forma net loss per common share, basic and diluted	<u>\$ (13.21)</u>	
Unaudited pro forma weighted-average number of shares used in computing net loss per common share, basic and diluted	<u>2,763,166</u>	
Other comprehensive loss		
Net loss	(36,507)	(15,869)
Currency translation	(806)	(1,644)
Total comprehensive loss	<u>\$ (37,313)</u>	<u>\$ (17,513)</u>

*See accompanying notes to the financial statements.*

**GALECTO, INC.**
**Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit**

(in thousands, except share amounts)

	Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance, January 1, 2018	684,068	\$13,414	—	\$ —	100,000	\$ —	\$ 745	\$ —	\$ (17,148)	\$ (16,403)
Issuance of Series C preferred stock, net of issuance costs of \$150	—	—	1,284,795	32,535	—	—	—	—	—	—
Issuance of Series C preferred stock on conversion of convertible notes	—	—	688,408	18,546	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	81	—	—	81
Currency translation	—	—	—	—	—	—	—	(1,644)	—	(1,644)
Net loss	—	—	—	—	—	—	—	—	(15,869)	(15,869)
Balance, December 31, 2018	684,068	13,414	1,973,203	51,081	100,000	—	826	(1,644)	(33,017)	(33,835)
Issuance of series C preferred stock in connection with the purchase of PharmAkea	—	—	610,098	15,624	—	—	—	—	—	—
Commitment to the issuance of Series C preferred stock	—	—	1,541,755	39,500	—	—	—	—	—	—
Currency translation	—	—	—	—	—	—	—	(806)	—	(806)
Net loss	—	—	—	—	—	—	—	—	(36,507)	(36,507)
Balance, December 31, 2019	684,068	\$13,414	4,125,056	\$106,205	100,000	\$ —	\$ 826	\$ (2,451)	\$ (69,524)	\$ (71,149)

See accompanying notes to the financial statements.

**GALECTO, INC.**
**Consolidated Statements of Cash Flows**  
**(in thousands)**

	<b>Year Ended December 31,</b>	
	<b>2019</b>	<b>2018</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (36,507)	\$ (15,869)
Adjustment to reconcile net loss to net cash used in operating activities:		
Purchased in-process research and development	16,788	—
Stock-based compensation	—	81
Fair value adjustments on preferred stock tranche obligations and note tranche and derivative obligations	(1,913)	479
Noncash interest expense	—	2,551
Amortization of right of use lease asset	111	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,220)	(2,786)
Accounts payable	1,938	733
Accrued expenses and other current liabilities	1,606	1,120
Operating lease liabilities	(129)	—
Net cash used in operating activities	<u>(19,326)</u>	<u>(13,691)</u>
<b>Cash flows from investing activities</b>		
Merger acquisition costs, net of cash received	(326)	—
Net cash used in investing activities	<u>(326)</u>	<u>—</u>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of Series C preferred stock	—	34,511
Preferred stock issuance costs	—	(150)
Proceeds from issuance of long-term debts	—	8,513
Net cash provided by financing activities	<u>—</u>	<u>42,874</u>
Net (decrease) increase in cash and cash equivalents	<u>(19,652)</u>	<u>29,183</u>
Effect of exchange rate changes on cash and cash equivalents	46	23
Cash, cash equivalents and restricted cash, beginning of year	31,131	1,925
Cash, cash equivalents and restricted cash, end of year	<u>\$ 11,525</u>	<u>\$ 31,131</u>
<b>Components of cash, cash equivalents, and restricted cash</b>		
Cash and cash equivalents	11,294	30,987
Restricted cash	231	144
Total cash, cash equivalents, and restricted cash	<u>\$ 11,525</u>	<u>\$ 31,131</u>
<b>Supplemental disclosures of noncash activities</b>		
Issuance of Series C preferred stock in connection with acquisition	\$ 15,624	\$ —
Cumulative effect of change in accounting principle—adoption of ASC 842, <i>Leases</i>	\$ 15	\$ —
Exchange of convertible notes for Series C preferred stock	\$ —	\$ 16,322

*See accompanying notes to the financial statements.*

**GALECTO, INC.**

**Notes to the Consolidated Financial Statements**

**1. DESCRIPTION OF BUSINESS, ORGANIZATION AND LIQUIDITY**

***Business***

Galecto, Inc., together with its consolidated subsidiaries, the Company or Galecto, is clinical-stage biotechnology company developing therapeutics that are designed to target the biological processes that lie at the heart of fibrosis and fibrotic inflammation and impact a broad range of fibrotic and related diseases, including cancer. The Company's initial focus is on the development of small-molecule inhibitors of galectin-3 and lysyl oxidase-like 2, or LOXL2, which play key roles in regulating fibrosis.

***Reorganization and Purchase of PharmAkea, Inc.***

Galecto, Inc. was incorporated in Delaware in October 2019. On December 31, 2019, as part of an integrated transaction, Galecto, Inc., Galecto Biotech AB, a Swedish operating company, and PharmAkea, Inc., or PharmAkea, consummated a purchase agreement and plan of merger by and among Galecto, Inc., Galecto Biotech AB and PharmAkea, or the Purchase, whereby Galecto, Inc. (i) acquired the shareholdings of Galecto Biotech AB via a one-for-one exchange of equity between Galecto, Inc. and the shareholders of Galecto Biotech AB in a common control reorganization, and (ii) acquired PharmAkea in principally an all-stock transaction.

As of December 31, 2019, the Company's wholly-owned subsidiaries were PharmAkea and Galecto Biotech AB, and Galecto ApS, a Danish operating company, was Galecto Biotech AB's wholly-owned subsidiary. The consolidated balance sheet as of December 31, 2019 is that of Galecto, Inc. and as of December 31, 2018 is that of Galecto Biotech AB. The consolidated statements of operations and comprehensive loss, convertible preferred shares and stockholders' deficit and cash flows for the year ended December 31, 2019 are principally that of Galecto Biotech AB together with that of Galecto Inc. with respect to the Purchase of PharmAkea. The consolidated statements of operations and comprehensive loss, convertible preferred shares and stockholders' deficit and cash flows for the year ended December 31, 2018 are those of Galecto Biotech AB. As used in these consolidated financial statements, unless the context otherwise requires, references to Galecto or the Company, refers to the consolidated Galecto, Inc. group.

***Risks and uncertainties***

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance reporting capabilities.

The Company's product candidates are in development. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

## Liquidity and management plans

As of December 31, 2019, the Company had an accumulated deficit of \$69.5 million, from recurring losses since inception in 2011. The Company has incurred recurring losses and has no sales as no products have obtained the necessary regulatory approval in order to market products. The Company expects to continue to incur losses as a result of costs and expenses related to the Company's clinical development and corporate general and administrative activities.

The Company had negative cash flows from operating activities during the year ended December 31, 2019 of \$19.3 million, and current projections indicate that the Company will have continued negative cash flows for the foreseeable future. Net losses incurred for the year ended December 31, 2019 and 2018, amounted to \$36.5 million and \$15.9 million, respectively.

At December 31, 2019, the Company's cash and cash equivalents amounted to \$11.3 million, current assets amounted to \$56.1 million and current liabilities amounted to \$7.9 million. The Company achieved the two research and development milestones, as defined in the Series C preferred stock purchase agreement, prior to December 31, 2019, and therefore recorded a receivable on issuance of Series C preferred stock. The Company closed on the sale of Series C-4 and Series C-5 preferred stock in January 2020 resulting in the issuance of 1,541,755 shares of Series C convertible preferred stock for \$39.7 million in gross proceeds. The existing cash and cash equivalents will not be sufficient to enable the Company to meet its long-term plans, including commercialization of clinical pipeline products, if approved, or initiation or completion of future registration studies.

In the future, the Company will consider the following ways to fund its operations including: (1) raising additional capital through equity and/or debt financings; (2) new commercial relationships to help fund future clinical trial costs (i.e. licensing and partnerships); (3) reducing spending on one or more research and development programs by discontinuing development; and/or (4) restructuring operations to change its overhead structure. The Company's future liquidity needs, and ability to address those needs, will largely be determined by the success of its product candidates and key development and regulatory events and its decisions in the future.

The accompanying financial statements have been prepared in conformity with U.S. generally accepted accounting principles, or GAAP, which contemplate continuation of the Company as a going concern. The Company has not established a source of revenues sufficient to cover its operating costs, and as such, have been dependent on funding operations through the issuance of debt and sale of equity securities. Since inception, the Company has experienced significant losses and incurred negative cash flows from operations. The Company expects to incur further losses over the next several years as it develops its business. The Company has spent, and expects to continue to spend, a substantial amount of funds to implement its business strategy, including its planned product development efforts, preparation for its planned clinical trials, performance of clinical trials and its research and discovery efforts.

Management's plans include continuing to finance operations through the issuance of additional equity instruments and securities and continuing the development of the current pipeline or through the acquisition of a third party or license agreement. Any transactions which occur may contain covenants that restrict the ability of management to operate the business or may have rights, preferences or privileges senior to the Company's current shareholders and may dilute current shareholders of the Company. Engaging in a transaction with a third party is contingent on negotiations among the parties; therefore, there is no certainty that the Company will enter into such an agreement should the Company so desire.

There can be no assurance that the Company will achieve or sustain positive cash flows from operations or profitability. If the Company is unable to maintain adequate liquidity, future operations will need to be scaled back or discontinued. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### ***Coronavirus pandemic***

The coronavirus disease 2019, or COVID-19, pandemic, which began in December 2019 and has spread worldwide, has caused many governments to implement measures to slow the spread of the outbreak through quarantines, travel restrictions, heightened border scrutiny and other measures. The outbreak and government measures taken in response have also had a significant impact, both directly and indirectly, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the outbreak and its effects on the Company's business and operations are uncertain.

In response to the impact of COVID-19, the Company has implemented certain measures intended to help the Company manage its impact and position the Company to resume operations quickly and efficiently once these restrictions are lifted, such as executing a work-from-home strategy for administrative functions and operations.

Despite the Company's implementation of such measures, the actual and perceived impact of the COVID-19 pandemic is changing daily, and its ultimate effect on the Company cannot be predicted. As a result, there can be no assurance that the Company will not experience additional negative impacts associated with COVID-19, which could be significant. The COVID-19 pandemic may negatively impact the Company's business, financial condition and results of operations by decreasing or delaying the enrollment of patients in the Company's clinical trials or otherwise causing interruptions or delays in the Company's programs and services.

On March 27, 2020, the United States enacted the Coronavirus Aid, Relief and Economic Security Act, or CARES Act. The CARES Act is an emergency economic stimulus package that includes spending and tax breaks to strengthen the United States economy and fund a nationwide effort to curtail the effect of COVID-19. The CARES Act provides sweeping tax changes in response to the COVID-19 pandemic, some of the more significant provisions include removing certain limitations on the utilization of certain limitations on utilization of net operating losses, increasing the loss carryback period for certain losses to five years, increasing the ability to deduct interest expense, and deferring social security payments, as well as amending certain provisions of the previously enacted Tax Cuts and Jobs Act. The Company does not believe the CARES Act will have a material impact on its financial position and results of operations.

## **2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

### ***Basis of presentation***

The accompanying consolidated financial statements have been prepared in conformity with GAAP. Any reference in these notes to applicable guidance is meant to refer to GAAP, as found in the Accounting Standards Codification, or ASC, and Accounting Standards Update, or ASU, of the Financial Accounting Standards Board, or FASB.

### ***Principles of consolidation***

The Company's consolidated financial statements for 2019 and 2018 include the accounts of Galecto Inc. and its subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

### ***Use of estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect certain reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting periods. Significant items subject to such estimates and assumptions include contract research accruals,

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stock-based compensation expense, the fair value of the Company's common stock and valuation of the Company's deferred tax assets. The Company bases its estimates on historical experience and various other assumptions that management believes to be reasonable under the circumstances. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

### ***Currency and currency translation***

The consolidated financial statements are presented in U.S. dollars, the Company's reporting currency. Galecto Inc.'s and PharmAkea's functional currency is the U.S. dollar. The functional currency of the Company's subsidiary Galecto Biotech AB, and its subsidiary Galecto Biotech ApS, is the Euro. Adjustments that arise from exchange rate changes on transactions of each group entity denominated in a currency other than the functional currency are included in other income and expense in the consolidated statements of operations. Assets and liabilities of Galecto Biotech AB and Galecto Biotech ApS recorded in their Euro functional currency are translated into the U.S. dollar reporting currency of the Company at the exchange rate on the balance sheet date. Revenue and expenses of Galecto Biotech AB and Galecto Biotech ApS recorded in their Euro functional currency are translated into the U.S. dollar reporting currency of the Company at the average exchange rate prevailing during the year. Resulting translation adjustments are recorded to other comprehensive income (loss), or OCI.

### ***Restricted cash***

The Company is required to maintain cash collateral on deposit in a segregated money market bank account, as a condition of its security deposit with one of its banks for the use of corporate credit cards. As of December 31, 2019, and 2018, the Company presented restricted cash in the accompanying consolidated balance sheets of \$231,000 and \$144,000, respectively.

### ***Concentrations of credit risk and off-balance sheet risk***

The Company maintains its cash in bank deposit and checking accounts that at times exceed insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk.

### ***Fair value of financial instruments***

Fair value is defined as the price the Company would receive to sell an investment in a timely transaction or pay to transfer a liability in a timely transaction with an independent buyer in the principal market, or in the absence of a principal market, the most advantageous market for the investment or liability. A framework is used for measuring fair value utilizing a three-tier hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3).

The three levels of the fair value hierarchy are as follows:

**Level 1**—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

**Level 2**—Quoted prices in markets that are not considered to be active or financial instrument valuations for which all significant inputs are observable, either directly or indirectly; and

**Level 3**—Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

Financial instruments are categorized in their entirety based on the lowest level of input that is significant to the fair value measurement. The assessment of the significance of a particular input to the fair value



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measurement requires judgment and considers factors specific to the investment. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by us in determining fair value is greatest for instruments categorized in Level 3.

The Company monitors the availability of inputs that are significant to the measurement of fair value to assess the appropriate categorization of financial instruments within the fair value hierarchy. Changes in economic conditions or model-based valuation techniques may require the transfer of financial instruments from one fair value level to another. In such instances, our policy is to recognize significant transfers between levels at the end of the reporting period. The significance of transfers between levels is evaluated based upon the nature of the financial instrument and size of the transfer relative to total net assets available for benefits.

### ***Research and development expenses***

Research and development costs are expensed as incurred. The Company's research and development expenses consist primarily of costs incurred for the development of its product candidates and include expenses incurred under agreements with contract manufacturing organizations, or CMOs, CROs, investigative sites and consultants to conduct clinical trials and preclinical and non-clinical studies, costs to acquire, develop and manufacture supplies for clinical trials and other studies, salaries and related costs, including stock-based compensation, depreciation and other allocated facility-related and overhead expenses and licensing fees and milestone payments incurred under product license agreements where no alternative future use exists.

From time to time, Galecto obtains grants from public and private funds for its research and development projects. The grant income for a given period is recognized as a cost reimbursement and is typically based on the time and the costs that Galecto has spent on the specific project during that period. During the years ended December 31, 2019 and 2018, the Company had two active cost reimbursement grants with Tufts University and also with the Innovation Fund of Denmark. The grants provided reimbursement of direct research and development costs. For the years ended December 31, 2019 and 2018, research and development expenses in the consolidated statements of operations include \$388,000 and \$401,000, respectively, of grant income cost reimbursement.

The Company has historically met the requirements to receive a tax credit in Denmark for losses resulting from research and development costs of up to 25 million Danish Krone. The tax credit is reported as a reduction to research and development expense in the consolidated statements of operations. For the years ended December 31, 2019 and 2018, research and development expenses include refundable tax credits of \$824,000 and \$869,000 respectively.

### ***Accrued research and development costs***

Substantial portions of the Company's preclinical and clinical trials are performed by third-party laboratories, medical centers, CROs and other vendors, or collectively, CROs. These CROs generally bill monthly for services performed, or bill based upon milestone achievement. For preclinical studies, the Company accrues expenses based upon estimated percentage of work completed and the contract milestones remaining. For clinical studies, expenses are accrued based upon the number of patients enrolled and the duration of the study. The Company monitors patient enrollment, the progress of clinical studies and related activities to the extent possible through internal reviews of data reported to the Company by the CROs, correspondence with the CROs and clinical site visits. The Company's estimates depend on the timeliness and accuracy of the data provided by the CROs regarding the status of each program and total program spending. The Company periodically evaluates the estimates to determine if adjustments are necessary or appropriate based on information it receives.

### ***Acquired In-process research and development expenses***

The Company includes costs to acquire or in-license product candidates in acquired in-process research and development expenses. The Company has acquired the right to develop and commercialize its product

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candidate PAT-1251, which the Company now refers to as GB2064. These costs are immediately expensed provided that the payments do not also represent processes or activities that would constitute a business as defined under GAAP or provided that the product candidate has not achieved regulatory approval for marketing and absent obtaining such approval, has no alternative future use.

### ***Leases***

In February 2016, the FASB established Topic 842, Leases, by issuing ASU No. 2016-02, which supersedes ASC 840, Leases, and requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. Topic 842 was subsequently amended by ASU No. 2018-01, Land Easement Practical Expedient for Transition to Topic 842; ASU No. 2018-10, Codification Improvements to Topic 842, Leases; and ASU No. 2018-11, Targeted Improvements. Topic 842 as amended, or ASU 842, establishes a right-of-use, or ROU, model that requires a lessee to recognize a ROU asset and lease liability on the consolidated balance sheets for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the consolidated statements of operation.

The Company adopted ASU 842 on January 1, 2019 using the modified retrospective method, in which case the cumulative effect of applying the standard would be recognized at the date of initial application. Consequently, financial information will not be updated, and the disclosures required under ASU 842 will not be provided for dates and periods prior to the first quarter of fiscal year 2019.

The Company has completed a qualitative and quantitative assessment of its lease portfolio, in which the standard had a material impact on the consolidated balance sheets but did not have an impact on the consolidated statements of operations and comprehensive loss. Upon adoption, the Company recognized lease liabilities of \$379,000 based on the present value of the remaining minimum rental payments under current leasing standards for the Company's existing operating leases. The corresponding ROU assets of \$379,000 recognized upon adoption are net of deferred rent.

ASU 842 provides a number of optional practical expedients in transition. The Company elected the practical expedients that permit lessees not to reassess under ASU 842 prior conclusions about lease identification, lease classification and initial direct costs. The Company did not elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter not being applicable to the Company. The new standard also provides practical expedients for an entity's ongoing accounting. The Company elected the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, ROU assets or lease liabilities will not be recognized, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. The Company also elected the practical expedient to not separate lease and non-lease components for office leases.

At inception of a contract, the Company determines whether an arrangement is or contains a lease. For all leases, the Company determines the classification as either operating leases or finance leases. Operating leases are included in Operating lease right-of-use assets and Operating lease liabilities in the Company's consolidated balance sheets.

Lease recognition occurs at the commencement date and lease liability amounts are based on the present value of lease payments over the lease term. The lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. If a lease does not provide information to determine an implicit interest rate, the Company uses the Company's incremental borrowing rate in determining the present value of lease payments. ROU assets represent the right to use an underlying asset for the lease term, and lease liabilities represent the obligation to make lease payments under the lease. ROU assets also include any lease payments made prior to the commencement date and exclude lease incentives received. Operating lease expense is recognized on a straight-line basis over the lease term. The depreciable life of assets

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and leasehold improvements are limited by the expected lease term, unless there is a transfer of title or purchase option reasonably certain of exercise. Lease agreements with both lease and non-lease components, are generally accounted for together as a single lease component.

### ***Convertible preferred stock***

The Company classifies convertible preferred stock outside of stockholders' deficit on its consolidated balance sheet as the requirements of triggering a deemed liquidation event are not within the Company's control. In the event of a deemed liquidation event, the proceeds from the event are distributed in accordance with liquidation preferences (see Note 10). The Company records the issuance of convertible preferred stock at the issuance price less related issuance costs and less any discount arising on allocation of proceeds to one or more derivative features. The Company has not adjusted the carrying values of the convertible preferred stock to its liquidation preference because of the uncertainty as to whether a deemed liquidation event may occur.

### ***Equity-based compensation***

The Company accounts for stock options granted in accordance with ASC 718, Compensation-Stock Compensation (ASC 718). In accordance with ASC 718, compensation expense is measured at the estimated fair value of the stock options at grant date and is included as compensation expense over the vesting period during which an employee provides service in exchange for the award.

All share-based awards granted are measured based on the fair value on the date of the grant and compensation expense is recognized with respect to those awards over the requisite service period, which is generally the vesting period of the respective award. Forfeitures related to equity-based compensation awards are recognized as they occur, and the Company reverses any previously recognized compensation cost associated with forfeited awards in the period the forfeiture occurs.

Equity-based compensation expense is classified in the Company's consolidated statement of operations in the same manner in which the award recipients' payroll costs are classified or in which the award recipients' service payments are classified. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes model. The following summarizes the inputs used:

***Expected volatility***—Galacto is a private company and lacks company-specific historical and implied volatility information. Therefore, the Company estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until the Company has adequate historical data regarding the volatility of its own publicly traded stock price.

***Expected term***—The expected term of the Company's stock options has been determined based on the expected time to liquidity. Prior to January 1, 2019, the expected term of stock options issued was determined utilizing the simplified method for awards that qualified as plain-vanilla options.

***Risk-free interest rate***—The risk-free interest rate is based on the implied yield on a U.S. Treasury security at a constant maturity with a remaining term equal to the expected term of the option granted.

***Dividends***—Expected dividend yield is zero because the Company does not pay cash dividends on common shares and does not expect to pay any cash dividends in the foreseeable future.

### ***Income taxes***

Deferred income tax assets and liabilities arise from temporary differences associated with differences between the financial statements and tax basis of assets and liabilities, as measured by the enacted tax rates, which are expected to be in effect when these differences reverse. Deferred tax assets and liabilities are classified

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as current or non-current, depending upon the classification of the asset or liabilities to which they relate. Deferred tax assets and liabilities not related to an asset or liability are classified as current or non-current depending on the periods in which the temporary differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

The Company has generated net losses since inception and accordingly has not recorded a provision for income taxes.

The Company follows the provisions of ASC 740-10, *Uncertainty in Income Taxes*, or ASC 740-101. The Company has not recognized a liability as a result of the implementation of ASC 740-10. A reconciliation of the beginning and ending amount of unrecognized tax benefits has not been provided since there is no unrecognized benefit since the date of adoption. The Company has not recognized interest expense or penalties as a result of the implementation of ASC 740-10. If there were an unrecognized tax benefit, the Company would recognize interest accrued related to unrecognized tax benefits in interest expense and penalties in operating expenses.

The Company has identified the United States, Denmark and Sweden as its major tax jurisdictions.

### ***Net loss per share***

Basic and diluted net loss per share is calculated in conformity with the two-class method required for participating securities. Under the two-class method, basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the period, without consideration of potential dilutive securities. Diluted net loss per share is computed by dividing the net loss by the sum of the weighted average number of common shares outstanding during the period plus the dilutive effects of potentially dilutive securities outstanding during the period. Potentially dilutive securities include options for common stock and convertible preferred stock. The dilutive effect of options to purchase common stock and convertible preferred stock is computed using the treasury stock method and the dilutive effect of convertible preferred stock is calculated using the if-converted method. For all periods presented, diluted net loss per share is the same as basic net loss per share since the effect of including potential common shares is anti-dilutive.

### ***Unaudited pro forma financial information***

Unaudited pro forma basic and diluted net loss per share has been computed to give effect to the conversion of all outstanding convertible preferred stock into 4,809,124 shares of common stock immediately prior to the completion of the Company's planned initial public offering, or IPO. The unaudited pro forma net loss per share for the year ended December 31, 2019, was computed using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the conversion of all outstanding shares of convertible preferred stock into shares of common stock, as if such conversion had occurred at January 1, 2019, or their issuance dates, if later.

### ***Segments***

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the chief operating decision maker, or CODM, in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its chief executive officer. The Company has determined it operates in one segment.

### ***Other comprehensive income (loss)***

Other comprehensive income (loss), or OCI, is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The Company OCI includes currency translation.

**Emerging growth company status**

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act, until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

**Recently adopted accounting standards**

In July 2017, the FASB issued Accounting Standards Update 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features; and II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*, or ASU 2017-11. Part I of ASU 2017-11 addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of ASU 2017-11 addresses the difficulty of navigating Topic 480, *Distinguishing Liabilities from Equity*, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable non-controlling interests. The amendments in Part II of ASU 2017-11 do not have an accounting effect. The adoption of ASU No. 2017-11, during the year ended December 31, 2019, did not have any impact on the financial statements and related disclosures.

Prior to January 1, 2019, the Company accounted for leases under ASC 840, *Accounting for Leases*. Effective January 1, 2019, the Company adopted the guidance of ASC 842, *Leases*, or ASC 842, which requires an entity to recognize a right-of-use asset and a lease liability for virtually all leases. The Company adopted ASC 842 using a modified retrospective approach. The new standard provides a number of optional practical expedients in transition. The Company elected the 'package of practical expedients,' which permitted the Company not to reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs; and all of the new standard's available transition practical expedients. As a result, the comparative financial information has not been updated and the required disclosures prior to the date of adoption have not been updated and continue to be reported under the accounting standards in effect for those periods. The adoption of ASC 842 on January 1, 2019 did not have a material impact on the financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, or ASU 2018-07, which allows companies to account for nonemployee awards in the same manner as employee awards. The adoption of ASU No. 2018-07 on January 1, 2019 did not have a material impact on the financial statements.

**Recently issued accounting standards**

In June 2016, the FASB issued Accounting Standards Update No. 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*, or ASU 2016-13. ASU 2016-13 requires measurement and recognition of expected credit losses for financial assets. In April 2019, the FASB issued clarification to ASU 2016-13 within ASU 2019-04, *Codification Improvements to Topic 326, Financial Instruments-Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments*. The

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guidance will become effective as of January 1, 2020, and must be adopted using a modified retrospective approach, with certain exceptions. This guidance is effective for public business entities that meet the definition of a Securities and Exchange Commission filer, excluding eligible smaller reporting companies for fiscal years beginning after December 15, 2021. For all other entities, including emerging growth companies, it is effective for fiscal years beginning after December 15, 2022. The Company is currently assessing the potential impact of adopting ASU 2016-13 on its financial statements and financial statement disclosures.

During August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, or ASU 2018-13. ASU 2018-13 modifies the disclosure requirements for fair value measurements in *Topic 820, Fair Value Measurement*. The amendments are based on the concepts in the *FASB Concepts Statement, Conceptual Framework for Financial Reporting—Chapter 8: Notes to Financial Statements*, which the Board finalized on August 28, 2018. ASU 2018-13 is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2019. Early adoption is permitted. As of December 31, 2019, the Company had not elected to early adopt this guidance but did not expect that the adoption of this guidance would have a material effect on its financial statements.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*, or ASU 2019-12. ASU 2019-12 eliminates certain exceptions related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. It also clarifies and simplifies other aspects of the accounting for income taxes. This guidance is effective for public business entities for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. For all other entities, including emerging growth companies, it is effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. Early adoption is permitted. The Company is currently evaluating the impact that the new accounting standard will have on the financial statements and disclosures.

### 3. FAIR VALUE MEASUREMENTS

The Company had no financial assets or liabilities measured at fair value on a recurring basis as of December 31, 2019. The Company had a preferred stock tranche obligation (Note 10), or Preferred Stock Tranche Obligation, measured at (Level 3) fair value on a recurring basis of \$1.7 million as of December 31, 2018. There were no transfers among Level 1, Level 2 or Level 3 categories in the years ended December 31, 2019 or 2018.

The following table provides a reconciliation of the Company's liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) (in thousands):

	Preferred Stock Tranche Obligations	Note Derivative Obligation	Note Tranche Obligation	Total
Balance, January 1, 2018	\$ —	\$ 1,594	\$ 422	\$ 2,016
Addition on issuance of convertible notes	—	2,064	—	2,064
Addition on issuance of Series C preferred stock	1,826	—	—	1,826
Fair value adjustments	(82)	364	197	479
Foreign exchange transaction gain	—	(355)	(35)	(390)
Settlement on tranche issuance of convertible notes	—	—	(584)	(584)
Settlement on conversion of convertible notes	—	(3,667)	—	(3,667)
Balance, December 31, 2018	1,744	—	—	1,744
Fair value adjustments	(1,913)	—	—	(1,913)
Settlement on commitment to purchase Series C preferred stock	169	—	—	169
Balance, December 31, 2019	\$ —	\$ —	\$ —	\$ —

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### ***Preferred stock tranche obligation***

The Company's Preferred Stock Tranche Obligation (Note 10) is measured at fair value using an option pricing valuation methodology. The fair value of Preferred Stock Tranche Obligation includes inputs not observable in the market and thus represents a Level 3 measurement. The option methodology utilized requires inputs based on certain subjective assumptions, including (a) expected stock price volatility, (b) calculation of an expected term, (c) a risk-free interest rate, and (d) expected dividends. This approach results in the classification of these securities as Level 3 of the fair value hierarchy. The Company had no Preferred Stock Tranche Obligation as of December 31, 2019. The assumptions utilized to value the Preferred Stock Tranche Obligation as of December 31, 2018 were (a) expected stock price volatility of 77%; (b) expected term of 2.8 years; (c) a risk-free interest rate of 2.6%; and (d) an expectation of no dividends. For the years ended December 31, 2019 and 2018, the Company recognized a \$1.9 million gain and a \$115,000 loss, respectively, of nonoperating gain (loss) in the statement of operations as other expense –fair value adjustments on tranche liabilities and derivative obligations, with respect to changes to the fair value of the Preferred Stock Tranche Obligation.

### ***Note derivative obligation***

The Company's note derivative obligation (Note 8), or Note Derivative Obligation, was measured at fair value utilizing a scenario-based valuation method using a Monte Carlo simulation model. The fair value of the Note Derivative Obligation included inputs not observable in the market and thus represents a Level 3 measurement. The methodology utilized requires inputs based on certain subjective assumptions, including (a) the Company's expectations regarding each scenario at each valuation date, (b) drift calculations, (c) stock price volatility, (d) incremental time steps, (e) and a random component known as the Weiner process that introduces dynamic behavior in the asset price, and (f) a discount factor. The Company made a final fair value adjustment to the Note Derivative Obligation as described in Note 8 on conversion of the convertible notes to which the Note Derivative Obligation pertained.

### ***Note tranche obligation***

The Company's note tranche obligation (Note 8), or Note Tranche Obligation, was measured at fair value using a discounted cash flow methodology. The fair value of the Note Tranche Obligation included inputs not observable in the market and thus represents a Level 3 Measurement. The discounted cash flow methodology requires inputs based on certain subjective assumptions, including (a) the Company's incremental cost of borrowing, and (b) determination of the forecasted cash flow. The Company made a final fair value adjustment to the Note Tranche Obligation and the balance of the Note Tranche Obligation was included in the carrying value of the tranche closing of the convertible notes on the tranche closing of the convertible notes to which the Note Tranche Obligation pertained.

## **4. PURCHASE OF PHARMAKEA, INC.**

The Purchase was principally an all-stock transaction whereby the Company exchanged 610,098 shares of its Series C-3 preferred stock, or approximately 13% of the shares of the Company subsequently outstanding, for PharmAkea. The Company was determined to be the accounting acquirer, and the Purchase of PharmAkea has been accounted for as an asset acquisition pursuant to Topic 805, *Business Combinations*, as the principal asset acquired was PharmAkea's Phase 1 clinical development program of an orally delivered inhibitor of LOXL2 for the treatment of Myelofibrosis and other fibrotic indications, which the Company refers to as GB2064. At the time of the Purchase, PharmAkea had no facilities, employees, customers or assets other than the GB2064 program.

The following summarizes the purchase price of the Purchase (in thousands, except share and per share amounts):

Value of the shares of Series C preferred stock issued to former PharmAkea stockholders	\$15,625
Cash consideration to non-accredited former PharmAkea stockholders	216
Payments made and Company options issued to former PharmAkea executives pursuant to the terms of the Purchase	583
Transaction costs	978
Purchase price	<u>\$17,402</u>

The total purchase price has been allocated to the assets acquired and liabilities assumed as of December 31, 2019 as follows (in thousands):

Purchased in-process research and development—GB2064	\$16,788
Cash acquired	653
Trade liabilities assumed	(39)
Purchase price	<u>\$17,402</u>

Purchased in-process research and development with respect to GB2064 is charged directly to expense the consolidated statements of operations on the purchase date, December 31, 2019. The value of GB2064 consists primarily of technology associated with the drug compound that the Company plans to advance in clinical development but as of the date of the Purchase was in early stages of clinical development, had not received regulatory approval to commercialize and, thus, had no alternative future use.

The fair value of GB2064 was determined under a multi-period excess earnings method, or MPEEM, and income approach and a variation of the discounted cash flow method used to measure the fair value of intangible assets. The MPEEM fair value is a risk-adjusted assessment of the market potential of GB2064 for the treatment of Myelofibrosis, discounted using a calculated market participant weighted average cost of capital of 45%.

## 5. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2019</b>	<b>2018</b>
Contract research and development costs	\$3,344	\$2,970
Research and development tax credit receivable	827	844
Grant reimbursement receivable	379	—
Value-added tax refund receivable	253	145
Other	314	14
Total prepaid expenses and other current assets	<u>\$5,117</u>	<u>\$3,973</u>

## 6. LEASES

On January 1, 2019, the Company adopted ASC 842 using the modified retrospective transition approach allowed under ASU 2018-11 which releases companies from presenting comparative periods and related disclosures under ASC 842 and requires a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption (Note 2). The Company is party to three operating leases for office and laboratory space. The Company's finance leases are immaterial both individually and in the aggregate. The



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Company has elected to apply the short-term lease exception to all leases of one year or less. Rent expense for years ended December 31, 2019 and 2018 was \$222,000 and \$8,000 respectively.

The Company had an operating lease in Woburn Place, London for office space that expired in August 2020 and has a renewal option. The Company has an operating lease in Denmark for office space that expires in October 2021 and has a renewal option. The Company also had an operating lease for office space in Canada that expired in July 2020. Effective June 1, 2020, the Company added an additional 1,300 square feet of office space to its corporate headquarters in Copenhagen and amended the related lease agreement to include this additional space. The Company also entered into a new lease for 749 square feet of office space in London commencing September 1, 2020 and expiring August 31, 2022.

Quantitative information regarding the Company's leases for year ended December 31, 2019 is as follows (in thousands):

	<b>Year Ended December 31, 2019</b>
<b>Lease Cost</b>	
Operating lease cost	\$ 129
<b>Other Information</b>	
Operating cash flows paid for amounts included in the measurement of lease liabilities	\$ 129
Operating lease liabilities arising from obtaining right-of-use assets	\$ 391
Weighted average remaining lease term (years)	4.2
Weighted average discount rate	8.0%

Future lease payments under noncancelable leases are as follows at December 31, 2019 (in thousands):

<b>Future Lease Payments</b>	<b>Operating Leases</b>
2020	\$ 107
2021	64
2022	64
2023	64
2024	54
Total lease payments	353
Less: imputed interest	(55)
Total lease liabilities	\$ 298

As most of the Company's leases do not provide an implicit rate, the Company used its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The Company uses the incremental borrowing rate on January 1, 2019 for operating leases that commenced prior to that date.

## 7. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

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	<b>December 31,</b>	
	<b>2019</b>	<b>2018</b>
Contract research and development costs	\$3,493	\$1,119
Costs related to the Purchase of PharmAkea	838	—
Employee compensation costs	113	151
Lease liabilities	87	
Other liabilities	67	16
Total accrued expenses and other current liabilities	<u>\$4,598</u>	<u>\$1,286</u>

### **8. CONVERTIBLE NOTES**

The Company issued convertible notes with aggregate proceeds of \$14.2 million with initial closings in April 2017 and February 2018 and a tranche closing in May 2018, together the Notes. The Notes carried a stated interest rate of 8.0% per annum and were due and payable on June 30, 2018. The Notes contained a number of features, including a second tranche closing, automatic and optional conversion, and redemption provisions.

A portion of the proceeds of the April 2017 closing of the Notes were allocated to (i) a Note Derivative Obligation comprising certain of the redemption provisions, and (ii) a Note Tranche Obligation, resulting in a discount on the par value of the April 2017 closing of the Notes that was amortized using the effective interest method through the June 30, 2018 maturity date of the Notes. The Note Derivative and Tranche Obligations were recorded at fair value as discussed in Note 3.

The maturity date of the Notes was extended and, in October 2018, the Notes were converted into 688,408 shares of the Company's Series C-1 preferred stock according to the terms of the Notes at 80% of the subscription price in the sale and issuance of the Company's Series C-2 preferred stock to new investors (Note 10). On conversion, a final fair value adjustment was made to the Note Derivative and Tranche Obligations resulting in a carrying value for the Series C-1 preferred stock of \$18.3 million equal to the subscription price of the Series C-2 preferred stock (\$26.88 per share) concurrently sold and issued (Note 10).

Non-cash interest expense, comprised of the accrual of the stated 8% interest and amortization of the discount arising on the allocation of proceeds to the Derivative Obligation and Tranche obligations, was \$3.0 million in the year ended December 31, 2018.

### **9. COMMITMENTS AND CONTINGENCIES**

#### ***Lease commitments***

The Company's commitments related to lease agreements are disclosed in Note 5.

#### ***Legal proceedings***

From time to time, the Company may be party to litigation arising in the ordinary course of its business. The Company was not subject to any material legal proceedings during the years ended December 31, 2019 and 2018, and, to its knowledge, no material legal proceedings are currently pending or threatened.

#### ***Indemnification agreements***

The Company, as permitted under Delaware law and in accordance with its certification of incorporation and bylaws and pursuant to indemnification agreements with certain of its officers and directors, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, which the officer or director is or was serving at the Company's request in such capacity.

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The Company enters into certain types of contracts that contingently requires the Company to indemnify various parties against claims from third parties. These contracts primarily relate to (i) the Company's bylaws, under which the Company must indemnify directors and executive officers, and may indemnify other officers and employees, for liabilities arising out of their relationship, (ii) contracts under which the Company must indemnify directors and certain officers and consultants for liabilities arising out of their relationship, and (iii) procurement, service or license agreements under which the Company may be required to indemnify vendors, service providers or licensees for certain claims, including claims that may be brought against them arising from the Company's acts or omissions with respect to the Company's products, technology, intellectual property or services.

From time to time, the Company may receive indemnification claims under these contracts in the normal course of business. In the event that one or more of these matters were to result in a claim against the Company, an adverse outcome, including a judgment or settlement, may cause a material adverse effect on the Company's future business, operating results or financial condition. It is not possible to estimate the maximum amount potentially payable under these contracts since the Company has no history of prior indemnification claims and the unique facts and circumstances involved in each particular claim will be determinative.

### **10. CONVERTIBLE PREFERRED STOCK**

During the fiscal year ended December 31, 2018, Galecto Biotech AB concluded a Series C financing involving a combination of existing shareholders and new investors, or Series C Financing. At closing, Galecto Biotech AB issued 1,284,795 Series C-2 shares in exchange for \$34.5 million. Additionally, the conclusion of the Series C Financing triggered the conversion feature of the Notes, whereas additional 688,408 Series C-1 shares were issued in exchange for the conversion of the outstanding Notes (See Note 8).

The Series C Financing further allowed for milestone closings in the event of certain development milestones, whereby purchasers of Series C preferred stock had the option to purchase additional shares of Series C preferred stock, or the Preferred Stock Tranche Obligation. The milestones were achieved in 2019 and, in December 2019, Series C investors committed to the sale and issuance of 1,199,143 Series C-4 preferred shares and 342,612 Series C-5 preferred shares of the Company for a total of \$39.7 million. As a result of the issuance of the Series C-4 preferred stock and Series C-5 preferred, the Company issued a total of 198,770 additional Series C-3 preferred shares to former PharmAkea shareholders pursuant to the terms of the Purchase (See Note 4).

The sale and issuance of the Series C-4 preferred stock and Series C-5 preferred were committed to in December 2019 and are included in the consolidated balance sheet as of December 31, 2019 with a corresponding \$39.7 million receivable for the proceeds included within current assets in the consolidated balance sheet as of December 31, 2019. The issuance of additional Series C-3 preferred stock with respect to the Purchase of PharmAkea stemming from the sale and issuance of the Series C-4 preferred stock and Series C-5 preferred stock is also included in the consolidated balance sheet as of December 31, 2019 and comprises an element of the purchase price for the Purchase. The \$39.7 million proceeds were received, and shares issued in January 2020.

The Company concluded that the Preferred Stock Tranche Obligation met the definition of a freestanding financial instrument as the obligations were legally detachable and separately exercisable from the Series C-2 preferred stock issued. Therefore, the Company allocated the proceeds received from the issuance of the Series C-2 preferred stock between the Preferred Stock Tranche Obligation and the Series C-2 preferred stock. The fair value of the Preferred Stock Tranche Obligation of \$1.8 million on issuance was allocated from the \$34.5 million net proceeds of the Series C-2 preferred stock and is classified as a current liability on the consolidated balance sheet as of December 31, 2018 as the Series C Preferred would have become redeemable upon a deemed liquidation event, the occurrence of which is not within the Company's control.

#### ***Preferred stock***

The Company's amended and restated certificate of incorporation authorizes its board of directors, or Board, to issue up to 4,817,547 shares of preferred stock from time to time in one or more series. The rights,

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preferences restrictions, qualifications and limitations of such preferred stock are determined by the Board. The convertible preferred stock has the following rights, preferences, privileges and restrictions:

### ***Voting rights***

Each holder of outstanding shares of preferred stock is entitled to one vote for each share of common stock into which the shares of preferred stock held by such holder are convertible as of the record date.

### ***Dividends***

Each share of preferred stock is entitled to an accruing dividend, based on the original issue price of such share of preferred stock at a rate of eight percent per year, compounded annually on the basis of a 365-day year on each December 31<sup>st</sup>.

### ***Conversion of preferred stock***

Any holder of preferred stock is at any time entitled to request that its shares of preferred stock be converted into shares of common stock at a ratio 1:1. All shares of preferred stock shall convert automatically into shares of common stock at a ratio 1:1 in connection with: (a) an IPO meeting certain parameters, or Qualified IPO; (b) if a vote of the holders of preferred stock including a defined group of requisite holders; and (c) an IPO that is not qualified, or Nonqualified IPO. However, in the event of a Nonqualified IPO, in addition being converted into shares of common at a ratio of 1:1, holders will receive an aggregate number of additional shares of common stock based on the shortfall of the Nonqualified IPO from a Qualified IPO based upon the price per share of the common stock implied by the Nonqualified IPO valuation.

### ***Anti-dilution privileges***

In the event the Company issues any additional shares of common stock for a consideration per share that is less than the initial issuance price paid for the shares of preferred stock upon the initial issuance price of such shares of preferred stocks (as adjusted for stock splits and consolidation of stock), the conversion price (adjusted for stock splits and consolidations of stock) per share of preferred stock shall be adjusted on a narrow-based weighted average basis.

### ***Liquidation preference***

Cash and property shall be distributed to the shareholders, at such times and in such aggregate amounts as the Board may determine, as of the date of determination in the following priority:

- (i) First, the holders of share of Series C preferred stock shall receive an amount equal to the subscription price originally paid for the shares of Series C preferred stock paid plus interest of eight percent per annum (based on a 365-day year, compounded annually on December 31<sup>st</sup>) from the last date of payment of the subscription price of Series C preferred stock until distribution, reduced with any dividends paid with respect to the shares of Series C preferred stock prior to the distribution;
- (ii) Second, the holders of shares of Series B preferred stock shall receive an amount equal to the subscription price originally paid for the relevant shares of Series B preferred stock paid plus interest of eight percent per annum (based on a 365-day year, compounded annually on December 31<sup>st</sup>) from the last date of payment of the subscription price of Series B preferred stock until distribution, reduced with any dividends paid with respect to the Series B preferred stock prior to the distribution;
- (iii) Third, any remaining proceeds shall be distributed pro-rata among all holders of shares of preferred stock and common stock. To the extent the proceeds would not be sufficient to satisfy the entire

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preference amount for all shares of Series C preferred stock or Series B preferred stock (as the case may be), the distribution shall always be allocated among shares of Series C preferred stock of each sub-class so as to satisfy the same proportion of their respective preference amount and thereafter among shares of Series B preferred stock of each subclass so as to satisfy the same proportion of their respective preference amount.

### ***Redemption rights***

Upon the request of a defined group of requisite holders and following the occurrence of a deemed liquidation event in which the Company is not dissolved, the Company is required to redeem each share of preferred stock at a price per share equal to each series of preferred stock's initial issue price plus accrued and unpaid dividends as described above. In the event the proceeds from a sale, liquidation or deemed liquidation event are not sufficient to redeem all outstanding shares of preferred stock, the shares of preferred stock are required to be redeemed in accordance with their liquidation preferences.

## **11. COMMON STOCK**

The Company had 5,350,404 common shares authorized, of which 100,000 shares were issued and outstanding at December 31, 2019 and 2018. Common stockholders are entitled to one vote for each share of common stock held at all meetings of stockholders and written actions in lieu of meetings. Common stockholders are entitled to receive dividends, if and when declared by the Board. No dividends have been declared or paid by the Company through December 31, 2019.

## **12. EQUITY-BASED COMPENSATION**

### ***Employee equity plan***

On December 17, 2013, the Company adopted its 2013 Option Program, or Plan. The Plan initially allowed the Company to award up to 131,420 options, including 13,142 series A options, 52,568 series B options and 65,710 series C options. Each vested option will entitle the option holder to a single common share in the Company. Holders of stock options shall be entitled to exercise the vested portion of the stock option provided that a qualified exit, as defined in the plan, has occurred during the time period as determined by the Board. If a qualified exit, as defined in the Plan, occurs then all of the holders unvested options shall vest immediately. Options that are not exercised during the exercise period will automatically be forfeited. Stock options generally vest over a three-year period and expire December 31, 2023.

On August 5, 2017, an additional 17,000 options were made available under the Plan resulting in 148,420 options available for issuance. At December 31, 2019, the Company had 31,420 options available for future grant under the Plan.

The Company did not recognize any tax benefits for stock-based compensation during any of the periods presented.

The following table sets forth the activity for the Company's stock options during the periods presented:

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	<b>Number of Options</b>	<b>Weighted- average exercise price per share</b>	<b>Weighted- average remaining contractual term (in years)</b>	<b>Aggregate intrinsic value</b>
Outstanding at December 31, 2017	109,000	\$ 14.39	3.7	—
Granted	8,000	16.06		
Outstanding at December 31, 2018	117,000	14.50	4.3	—
Outstanding at December 31, 2019	117,000	\$ 14.50	3.3	—
Vested and expected to vest at December 31, 2019	117,000	\$ 14.50	3.3	—
Exercisable at December 31, 2019	117,000	\$ 14.50	3.3	—

The weighted-average grant date fair value of options granted during the year ended December 31, 2018 is \$9.79. No options were granted during the year ended December 31, 2019.

In June 2020, the Board of directors granted 471,500 new options to employees under the Plan with an exercise price of \$5.07.

**Equity-based compensation**

The Company recorded stock-based compensation expense of \$81,000 related to the issuance of stock options during the year ended December 31, 2018 that was recorded as research and development expense. As of December 31, 2019, there was no unrecognized compensation cost.

The fair values of the options granted were estimated based on the Black-Scholes model, using the following assumptions:

	<b>2018</b>
Dividend yield	—
Risk-free interest rate	2.75%
Volatility	80%
Expected term in years	5

**13. INCOME TAXES**

The Company had no income tax expense or benefit for the years ended December 31, 2019 and 2018. The Company has incurred net operating losses for all the periods presented. The Company has not reflected the benefit of any such net operating loss carryforwards in the accompanying financial statements. As of December 31, 2019, the domicile of the reporting entity has changed from Denmark to the United States resulting in a tax rate of 22% in 2018 and 21% in 2019. This is discussed further below.

The components of net loss are as follows (in thousands):

	<b>Year Ended December 31,</b>	
	<b>2019</b>	<b>2018</b>
Domestic	\$ (16,788)	\$ —
Foreign	(19,719)	(15,869)
<b>Total</b>	<b>\$ (36,507)</b>	<b>\$ (15,869)</b>

***Reconciliation of Effective Tax Rate***

The effective tax rate for the years ended December 31, 2019 and 2018 is different from the statutory rate primarily due to the valuation allowance against deferred tax assets as a result of insufficient sources of income. The reconciliation of the statutory income tax rate to the Company's effective income tax rate is as follows:

	<b>Year Ended December 31,</b>	
	<b>2019</b>	<b>2018</b>
Income tax benefit at the statutory rate	21.0%	22.0%
Permanent differences	0.7	(0.3)
Research and development tax credits	(1.8)	(4.3)
Purchased in-process research and development	(9.7)	—
Foreign rate differential	0.6	—
Other	0.2	0.1
Change in valuation allowance	(11.0)	(17.5)
<b>Total</b>	<b>—%</b>	<b>—%</b>

***Deferred taxes***

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The principal components of the Company's deferred tax assets consisted of the following (in thousands):

	<b>December 31,</b>	
	<b>2019</b>	<b>2018</b>
Deferred tax assets		
Net operating loss carryforwards	\$ 8,980	\$ 3,774
Research and development credits	2,019	—
Bonus compensation	156	—
<b>Total deferred tax assets</b>	<b>\$ 11,155</b>	<b>\$ 3,774</b>
Valuation allowance	(11,155)	(3,774)
<b>Net deferred tax assets</b>	<b>\$ —</b>	<b>\$ —</b>

In assessing the realizability of deferred tax assets, management considers whether it is more-likely-than-not that some portion or all of the deferred tax assets will not be realized. The Company regularly assesses the likelihood that the deferred tax assets will be recovered from future taxable income. The Company considers projected future taxable income and ongoing tax planning strategies, then records a valuation allowance to reduce the carrying value of the net deferred taxes to an amount that is more-likely-than-not able to be realized. Based upon the Company's assessment of all available evidence, including the previous three years of taxable income and loss after permanent items, estimates of future profitability, and the Company's overall prospects of future business, the Company determined that it is more-likely-than-not that the Company will not be able to realize a

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portion of the deferred tax assets in the future. The Company will continue to assess the potential realization of deferred tax assets on an annual basis, or an interim basis if circumstances warrant. If the Company's actual results and updated projections vary significantly from the projections used as a basis for this determination, the Company may need to change the valuation allowance against the gross deferred tax assets. On the basis of this evaluation, a full valuation allowance at December 31, 2019 and December 31, 2018 was recorded of \$11.2 million and \$3.8 million respectively to reduce the net deferred tax assets to their estimated realizable value. The change in valuation allowance was \$7.4 million.

The Company is subject to taxation in the United States and Denmark. The Company also files returns in certain other jurisdictions where it does not maintain a permanent establishment. As of December 31, 2019, tax years 2016 and forward were generally open to examination by the Danish tax authorities and tax year 2019 was open to examination by the United States tax authorities. The Company is not under examination by any taxing authorities.

As of December 31, 2019, the Company had gross U.S. federal net operating losses, or NOLs, of \$4.4 million and federal research and development credits, or R&D credits, of \$1.2 million to offset tax liabilities. The federal NOLs and federal R&D credit carryforwards begin to expire in 2036 and 2033, respectively. Of the federal NOLs, \$4.3 million have an infinite life. The Company also had gross state NOLs of \$4.4 million and state R&D credits of \$1.1 million which are available to offset state tax liabilities. The state NOLs begin to expire in 2036 and the state tax R&D credits have an indefinite life. The Company also had NOLs in Denmark of \$35.3 million which have an indefinite life. Federal and state NOLs and R&D credit carryforwards are also subject to annual limitations in the event that cumulative changes in the ownership interests of significant stockholders exceed 50% over a three-year period, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986. The Company has not completed an analysis to determine if the NOLs and R&D credits are limited due to a change in ownership.

The Company recognizes accrued interest related to unrecognized tax benefits and penalties as income tax expense. The Company does not have any material unrecognized tax benefits which would affect the effective tax rate if recognized. The Company does not have any unrecognized tax benefits which would reverse within the next twelve months.

The Company is eligible for the Danish enhanced research and development tax allowance, providing for an increase in the deductible value of the amount of certain R&D expenditures. For 2018 and 2019, the deduction is set at 101.5%. Furthermore, the deduction for R&D expenditures is set at 103% for 2020, 105% for 2021 through 2024, 108% for 2025, and 110% for 2026.

In addition, in 2013 the Folketinget, or Danish Parliament, introduced a tax credit policy that allows companies with losses resulting from research and development costs to receive payment of the tax base of losses of up to 25 million Danish Krone, or DKK. The Company has historically met the requirements to receive payment. The tax credit is reported as a reduction of research and development expense in the consolidated statements of operations. For the years ended December 31, 2019 and 2018, the Company applied for refundable tax credit of 25 million DKK for each year and a receivable was recorded for \$827,000 and \$844,000 respectively.

## **14. NET LOSS PER SHARE**

Basic and diluted net loss per share is calculated as follows (in thousands except share and per share amounts):



	<b>Year Ended December 31,</b>	
	<b>2019</b>	<b>2018</b>
Net loss	\$ (36,507)	\$ (15,869)
Cumulative dividends on convertible preferred stock	(5,560)	(3,136)
Net loss attributable to common stockholders	\$ (42,067)	\$ (19,005)
Net loss per common share, basic and diluted	\$ (420.67)	\$ (190.05)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	100,000	100,000

The following outstanding potentially dilutive securities have been excluded from the calculation of diluted net loss per share, as their effect is anti-dilutive:

	<b>December 31,</b>	
	<b>2019</b>	<b>2018</b>
Convertible preferred stock	4,809,124	2,657,271
Stock options to purchase common stock	117,000	117,000

## 15. UNAUDITED PRO FORMA NET LOSS PER SHARE

The unaudited pro forma net loss per share is computed using the weighted-average number of common shares outstanding after giving effect to the conversion of all the convertible preferred stock into shares of common stock as if such conversion had occurred on the later of January 1, 2019 or the issuance date of the convertible preferred shares. Pro forma basic and diluted net loss per share for the year ended December 31, 2019 is calculated as follows:

	<b>Year Ended</b>
	<b>December 31, 2019</b>
	<b>(unaudited)</b>
Net loss attributable to common stockholders	\$ (42,067)
Cumulative dividends on convertible preferred stock	5,560
Pro forma net loss attributable to common stockholders	\$ (36,507)
Weighted-average number of shares used in computing net loss per share, basic and diluted	100,000
Pro forma adjustment to reflect automatic conversion of convertible preferred stock to common stock upon the completion of the proposed initial public offering	2,663,166
Pro forma weighted average number of shares used in computing net loss per common shares, basic and diluted	2,763,166
Pro forma net loss per share, basic and diluted	\$ (13.21)

## 16. SUBSEQUENT EVENTS

The Company has evaluated subsequent events through September 2, 2020, which is the date on which the consolidated financial statements were available to be issued. The Company has concluded that no subsequent events have occurred that require disclosure, except for those disclosed in Notes 6, 10 and 12 to the consolidated financial statements.

Through and including \_\_\_\_\_, 2020, (the 25th day after the date of this prospectus), all dealers effecting transactions in the Common Stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

## Shares



## Common Stock

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PROSPECTUS

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**BofA Securities**

**SVB Leerink**

**Credit Suisse**

, 2020

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**Part II**

**Information Not Required in Prospectus**

**Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth the fees and expenses, other than underwriting discounts and commissions, payable in connection with the registration of the common stock hereunder. All amounts are estimates except the SEC registration fee, the FINRA filing fee and the Nasdaq Global Market listing fee.

	<b>Amount Paid or to Be Paid</b>
SEC registration fee	\$ *
FINRA filing fee	*
Nasdaq Global Market listing fee	*
Printing and mailing	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous	*
<b>Total</b>	<b>*****</b>

\* To be completed by amendment.

**Item 14. Indemnification of Directors and Officers.** Section 145 of the DGCL authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

We have adopted provisions in our amended and restated certificate of incorporation and amended and restated bylaws to be in effect immediately prior to the completion of this offering that limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for any breach of the director's duty of loyalty to us or our stockholders; any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law; any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and

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- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We intend to enter into indemnification agreements with each of our directors, executive officers, and other officers as determined from time to time by our board of directors or our remuneration committee. These agreements will provide that we will indemnify each of our directors, officers with whom we have entered into indemnification agreements, and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director, executive officer or affiliate in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for certain actions or proceedings arising out of that person's services as a director or officer brought on behalf of us or in furtherance of our rights. Additionally, certain of our directors or officers may have certain rights to indemnification, advancement of expenses or insurance provided by their affiliates or other third parties, which indemnification relates to and might apply to the same proceedings arising out of such director's or officer's services as a director referenced herein. Nonetheless, we will agree in the indemnification agreements that our obligations to those same directors or officers are primary and any obligation of such affiliates or other third parties to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

We will maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act of 1933, as amended, or the Securities Act.

The underwriting agreement filed as Exhibit 1.1 to this registration statement provides for indemnification of us and our directors and officers by the underwriters against certain liabilities under the Securities Act and the Securities Exchange Act of 1934.

### **Item 15. Recent Sales of Unregistered Securities.**

In the three years preceding the filing of this registration statement, we have issued the following securities that were not registered under the Securities Act. No underwriters were involved in the sales and the certificates representing the securities sold and issued contain legends restricting transfer of the securities without registration under the Securities Act or an applicable exemption from registration.

#### ***(a) Issuances of Capital Stock***

In October 2018, certain investors purchased an aggregate of 688,408 shares of our Series C-1 preferred stock for approximately £12,859,461.44 at \$22.58 per share, or \$15,544,690.74 at \$22.58 per share assuming a 1USD:1.1066 Euro exchange rate.

In October 2018, certain investors purchased an aggregate of 1,284,795 shares of our Series C-2 preferred stock for approximately £29,999,963.25 at \$26.88 per share, or \$36,241,428.92 at \$26.88 per share assuming a 1USD:1.1066 Euro exchange rate.

In December 2019, certain investors purchased an aggregate of 417,014 shares of our Series C-3 preferred stock for approximately £29,999,963.25 at \$25.61 per share, or \$10,678,432.49 at \$25.61 per share assuming a 1USD:1.1066 Euro exchange rate.

In January 2020, certain investors purchased an aggregate of 1,199,143 shares of our Series C-4 preferred stock for approximately £27,880,074.80 at £23.35 per share, or \$30,853,949.4 at \$25.73 per share assuming a 1USD:1.1019 Euro exchange rate.

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In January 2020, certain investors purchase an aggregate of 342,612 shares of our Series C-5 preferred stock for approximately £7,965,729 at £23.35 per share, or \$8,815,406.76 at \$25.73 per share assuming a 1USD:1.1019 Euro exchange rate.

The offers and sales of the securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, as transactions by an issuer not involving a public offering. All of the purchasers in these transactions represented to us in connection with their purchase that they were acquiring the securities for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. Such purchasers 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 or an available exemption from such registration. All of the foregoing securities are deemed restricted securities for the purposes of the Securities Act.

### ***(b) Grants and Exercises of Stock Options***

Since January 1, 2017, we have granted stock options to purchase an aggregate of 483,949 shares of our common stock, net of forfeitures, with an exercise price of \$5.07 per share, to certain employees, directors and consultants pursuant to the 2020 Stock Option and Grant Plan.

The issuances of the securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act or Rule 701 promulgated under the Securities Act as transactions pursuant to compensatory benefit plans. The shares of common stock issued upon the exercise of options are deemed to be restricted securities for purposes of the Securities Act.

## **Item 16. Exhibits and financial statement schedules.**

### **(a) Exhibits**

<b><u>Exhibit number</u></b>	<b><u>Description</u></b>
1.1*	Form of Underwriting Agreement.
3.1*	Amended and Restated Certificate of Incorporation of the Registrant as currently in effect.
3.2*	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant.
3.3*	Form of Amended and Restated Certificate of Incorporation of Registrant, to be in effect prior to the completion of this offering.
3.4*	Bylaws of the Registrant, as currently in effect.
3.5*	Form of Amended and Restated Bylaws of the Registrant, to be in effect prior to the completion of this offering.
4.1*	Specimen Common Stock Certificate.
4.2*	Investors' Rights Agreement among the Registrant and certain of its stockholders, dated December 31, 2019.
5.1*	Opinion of Goodwin Procter LLP.
10.1*#	2020 Stock Option and Grant Plan and form of award agreements thereunder.
10.2*#	2020 Incentive Equity Plan, and form of award agreements thereunder.
10.3*#	Senior Executive Cash Incentive Bonus Plan.

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<u>Exhibit number</u>	<u>Description</u>
10.4*#	Form of Indemnification Agreement between the Registrant and each of its executive officers.
10.5*#	Form of Indemnification Agreement between the Registrant and each of its directors.
10.6*#	Non-Employee Director Compensation Policy.
10.7*#	Service Agreement between Galecto Biotech ApS and Hans Schambye, dated April 25, 2013.
10.8*#	Employment Contract between Galecto Biotech ApS and Anders H. Pedersen, dated January 23, 2013, as amended on August 24, 2017.
10.9*#	Amendment to Employment Contract between Galecto Biotech ApS and Anders H. Pedersen, dated August 24, 2017.
10.10*#	Employment Contract between Galecto Biotech ApS and Bertil Lindmark, dated November 28, 2019.
10.11*#	Addendum to Employment Contract between Galecto Biotech ApS and Bertil Lindmark, dated January 15, 2020.
10.12*#	Employment Agreement between Galecto, Inc. and Jonathan Freve, dated March 11, 2020.
10.13*#	Amendment to Employment Agreement between Galecto, Inc. and Jonathan Freve, dated March 14, 2020.
10.14*	License for Use of Office Facilities, between Galecto, Inc and BE Offices Euston Limited, dated July 7, 2020.
10.15*	Lease Agreement between Galecto Biotech ApS and COBIS A/S, dated May 4, 2020.
21.1*	List of Subsidiaries of the Registrant.
23.1*	Consent of EY Godkendt Revisionspartnerselskab, independent registered public accounting firm.
23.2*	Consent of Goodwin Procter LLP (included in Exhibit 5.1).
24.1*	Power of Attorney (included on signature page to this registration statement).

\* To be filed by amendment.

# Indicates a management contract or any compensatory plan, contract or arrangement.

† Portions of this exhibit (indicated by asterisks) have been omitted in accordance with the rules of the SEC.

(b) Financial Statements Schedules:

None.

### **Item 17. Undertakings.**

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 Securities and Exchange Commission 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.

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The undersigned hereby undertakes that:

(1) The undersigned Registrant will provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

(2) 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.

(3) 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.

### Signatures

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Copenhagen, Country of Denmark, on the \_\_\_\_\_ day of \_\_\_\_\_, 2020.

#### GALECTO, INC.

By: \_\_\_\_\_  
Hans T. Schambye, M.D., Ph.D.  
Chief Executive Officer

### Power of Attorney

Each person whose individual signature appears below hereby authorizes and appoints \_\_\_\_\_ and \_\_\_\_\_ and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Registration Statement, including any and all post-effective amendments and amendments thereto, and any registration statement relating to the same offering as this Registration Statement that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys in fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys in fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the \_\_\_\_\_ day of \_\_\_\_\_, 2020.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
_____ Hans T. Schambye, M.D., Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	
_____ Jonathan Freve	Chief Financial Officer (Principal Financial and Accounting Officer)	
_____ Amit D. Munshi	Chairman	
_____ Karen Wagner, Ph.D.	Director	
_____ Chau Khuong	Director	
_____ Søren Lemonius	Director	



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<u>Signature</u>	<u>Title</u>	<u>Date</u>
_____ Chandra Leo, M.D.	Director	
_____ Erez Chimovitz	Director	
_____ Carl Goldfischer, M.D.	Director	
_____ Søren Møller, Ph.D.	Director	
_____ David Shapiro, M.D.	Director	