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As confidentially submitted to the Securities and Exchange Commission on March 15, 2019.

Registration No. 333-

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

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

Galera Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**2834**	**46-1454898**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

2 W Liberty Blvd #100
Malvern, PA 19355
(610) 725-1500
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

J. Mel Sorensen
Chief Executive Officer
2 W Liberty Blvd #100
Malvern, PA 19355
(610) 725-1500
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Peter N. Handrinos
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Latham & Watkins LLP
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Boston, MA 02116
(617) 948-6000

Ilir Mujalovic
Shearman & Sterling LLP
599 Lexington Avenue
New York, NY 10022
(212) 848-4000

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

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities To Be Registered	**Proposed Maximum Aggregate Offering Price(1)**	**Amount of Registration Fee(2)**
Common Stock, $0.001 par value per share	$	$

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes the aggregate offering price of additional shares that the underwriters have the option to purchase.

(2) Calculated pursuant to Rule 457(o) 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 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this 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 prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion
Preliminary Prospectus dated , 2019.

PROSPECTUS

Shares

Common Stock

This is Galera Therapeutics, Inc.'s initial public offering. We are selling shares of our common stock.

We expect the public offering price to be between $ and $ per share. Currently, no public market exists for the shares. We intend to apply to list our common stock on the Nasdaq Global Market under the symbol "GRTX."

We are an "emerging growth company" under the federal securities laws and are subject to reduced public company disclosure standards. See "Prospectus Summary—Implications of Being an Emerging Growth Company."

Investing in the common stock involves risks that are described in the "Risk Factors" section beginning on page 12 of this prospectus.

	Per Share	Total
Public offering price	$	$
Underwriting discount(1)	$	$
Proceeds, before expenses, to us	$	$

(1) We refer you to "Underwriting" beginning on page 164 for additional information regarding 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 discount, for 30 days after the date of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission 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 , 2019.

BofA Merrill Lynch **Citigroup** **Credit Suisse**

Canaccord Genuity

The date of this prospectus is , 2019.

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We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares of common stock offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

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

TRADEMARKS

This prospectus includes our trademarks and trade names, including, without limitation, GALERA, GALERA THERAPEUTICS and our logo, which are our property and are protected under applicable intellectual property laws. This prospectus also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this prospectus may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we or the applicable owner will not assert, to the fullest extent permitted under applicable law, our or its rights or the right of any applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, especially the "Risk Factors" section beginning on page 12 and our financial statements and the related notes appearing at the end of this prospectus, before making an investment decision.

Unless the context requires otherwise, references to "Galera," the "Company," "we," "us," and "our," refer to Galera Therapeutics, Inc. and its consolidated subsidiaries.

Overview

We are a clinical stage biopharmaceutical company focused on developing and commercializing a pipeline of novel, proprietary therapeutics that have the potential to transform radiotherapy in cancer. We leverage our expertise in superoxide dismutase mimetics to design drugs to reduce normal tissue toxicity from radiotherapy and to increase the anti-cancer efficacy of radiotherapy. Our lead product candidate, GC4419, is a potent and highly selective small molecule dismutase mimetic we are initially developing for the reduction of severe oral mucositis, or SOM. SOM is a common, debilitating complication of radiotherapy in patients with head and neck cancer, or HNC. The U.S. Food and Drug Administration, or FDA, has granted Breakthrough Therapy Designation to GC4419 for the reduction of the duration, incidence and severity of SOM induced by radiotherapy. In October 2018, we began evaluating GC4419 in a Phase 3 registrational trial and we expect to report top-line data in . We believe GC4419 can become the first FDA-approved drug and the standard of care for the reduction of SOM in patients with HNC receiving radiotherapy, and we plan to expand its use into other radiotherapy-induced toxicities.

We demonstrated proof-of-concept with GC4419 in SOM in a randomized, double-blinded, placebo-controlled 223-patient Phase 2b trial. In the trial, GC4419 met the primary endpoint by demonstrating a 92% reduction in the duration of SOM in the 90 mg treatment arm as compared to placebo, which was statistically significant and consistent with the results of our Phase 1b/2a SOM trial. Key secondary endpoints evaluating the incidence and severity of SOM also demonstrated substantial dose-dependent reductions of 34% and 47%, respectively, in the 90 mg treatment arm, and GC4419 was well tolerated in this trial. In addition, in this trial, the anti-cancer efficacy of radiotherapy was maintained through one year when combined with GC4419.

Radiotherapy-induced SOM can lead to devastating complications. A majority of patients will suffer severe pain which is often managed with the use of opioids. Patients with SOM are at risk of dehydration and malnutrition as a result of the inability to eat or drink, and often require nutrition through a feeding tube or intravenous line. SOM can also be dose-limiting, requiring a reduction or delay in subsequent radiotherapy, leading to poorer clinical outcomes. SOM is particularly common among patients with HNC receiving radiotherapy.

Each year in the United States, approximately 65,000 patients are diagnosed with HNC. We estimate that approximately 65% of patients diagnosed with HNC will be treated with radiotherapy. All patients with HNC treated with radiotherapy are at risk for developing SOM. We believe, if approved, GC4419 would be prescribed by physicians as standard-of-care treatment for patients with HNC receiving radiotherapy.

We plan to expand the evaluation of GC4419 into the reduction of radiotherapy-induced esophagitis, or mucositis of the esophagus, which is often seen in patients receiving radiotherapy for thoracic tumors. Esophagitis is a frequent and radiotherapy-limiting side effect in these patients. Symptoms can be life-threatening and include an inability to swallow, severe pain, ulceration, infection, bleeding and weight loss and may require hospitalization. Radiotherapy-induced esophagitis represents a significant unmet need. In our initial target

indication for esophagitis, lung cancer, there are approximately 230,000 new patients annually in the United States, of which approximately 50,000 are treated with radiotherapy.

Building upon extensive pre-clinical data showing that our dismutase mimetics also increased the anti-cancer efficacy of higher daily doses of radiotherapy, we are further developing our dismutase mimetics in this area. We plan to leverage the data from our ongoing pilot Phase 1b/2a trial of GC4419 in combination with stereotactic body radiation therapy, or SBRT, in locally advanced pancreatic cancer, or LAPC, to help develop GC4711, our second dismutase mimetic product candidate, to increase the anti-cancer efficacy of SBRT. We have successfully completed a Phase 1 trial of intravenous GC4711 in healthy volunteers and plan to commence a Phase 1b/2a trial of GC4711 in combination with SBRT in non-small cell lung cancer, or NSCLC, in .

We retain worldwide rights to our product candidate portfolio. Our product candidate portfolio is protected by issued patents with claims directed to composition of matter and method of use, which, when including patent term extensions, are projected to expire between 2027 and 2038 in the United States.

Our management team has extensive drug development and commercialization experience ranging from discovery through market registrational and commercial launches. Further, we are supported by a leading group of biotech investors including Adage Capital, Blackstone Life Sciences (formerly Clarus), HBM Healthcare, Nan Fung Life Sciences, New Enterprise Associates, Novartis Venture Fund, Novo Ventures, RA Capital, Rock Springs Capital, Sofinnova Ventures and Tekla Capital.

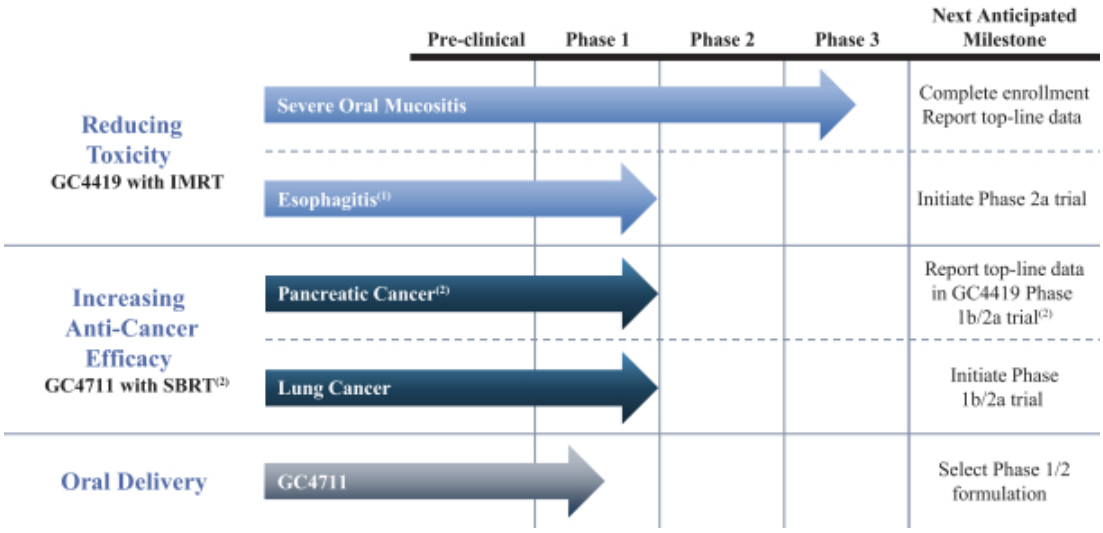
Background on Superoxide Dismutases and Our Dismutase Mimetics

Superoxide, a highly reactive molecule, is produced by every cell as a part of normal metabolism, but left uncontrolled it is highly toxic, leading to cell damage or cell death. To prevent this, the body produces superoxide dismutase enzymes, or SODs, which convert superoxide to hydrogen peroxide. Hydrogen peroxide is much less toxic than superoxide to normal tissue, but more toxic to cancer cells. Radiotherapy induces a large burst of superoxide in the irradiated tissues, which can overwhelm these SODs, damaging normal cells. Such damage to the oral mucosa, located in the mouth, is referred to as oral mucositis, or OM.

Low molecular weight drugs that mimic native SODs could address the inability of SODs to keep up with the superoxide bursts produced by radiotherapy. The challenge has been finding small molecule dismutase mimetics with similarly fast catalytic rates and high selectivity for superoxide that are also stable, safe and suitable for manufacturing. We are developing our dismutase mimetics with these essential features—***speed, selectivity, stability, safety and synthesis***.

Our Product Candidates

The following table summarizes our product candidates:



(1) Phase 2a trial to be based on GC4419 safety and tolerability findings in patients with HNC SOM studies.

(2) Phase 1b/2a pilot trial of GC4419 in combination with SBRT is ongoing in patients with LAPC whose tumor cannot be resected. We plan to leverage our observations from this trial in LAPC to help develop GC4711 to increase the anti-cancer efficacy of SBRT.

GC4419 for Radiotherapy-Induced Severe Oral Mucositis

No drug has been approved by the FDA for the treatment of SOM in patients with HNC. Current measures attempting to moderate SOM include basic oral care; anti-inflammatory agents; antimicrobials, coating agents, anesthetics and analgesics; laser and other light therapy, cryotherapy; and natural and other miscellaneous agents. The treatment guidelines developed by the Multinational Association of Supportive Care in Cancer and International Society of Oral Oncology, or MASCC / ISOO, indicate that there is a high unmet need for the treatment or prevention of OM in patients with HNC, and a lack of clear efficacy with existing treatment options.

We believe that GC4419 has the potential to be the first FDA-approved drug and the standard of care for the reduction of SOM in patients with HNC receiving radiotherapy, with the following benefits:

- ***Mechanism of action designed to address the root cause of OM:*** Unlike existing treatment options that are largely symptomatic and reactive in nature, we believe GC4419 has the potential to address and mitigate the root cause of OM. GC4419 is designed to rapidly convert superoxide to hydrogen peroxide, reducing mucosal damage and thereby the incidence and severity of mucositis.

- ***Compelling Randomized Phase 2b clinical data:*** Results from our Phase 2b trial demonstrate the potential benefits of GC4419, across all evaluated parameters of SOM. GC4419 has received Fast Track and Breakthrough Therapy Designation from the FDA.

- ***Maintenance of anti-cancer efficacy of radiotherapy:*** One year interim follow-up clinical data from our Phase 2b trial for GC4419 in patients with locally advanced HNC showed similar rates of tumor control and survival between GC4419 and placebo with no observed decrease in the anti-cancer efficacy of radiotherapy. We believe this is significant as maintenance of anti-cancer efficacy of radiotherapy is of key importance to physicians when considering new drugs to manage side effects of radiotherapy.

- ***Higher patient adherence:*** The intravenous formulation of GC4419, administered in a clinical setting by a health care provider, promotes higher patient adherence, optimizing clinical outcomes.

GC4419 for Radiotherapy-Induced Esophagitis

A second indication that we are evaluating for GC4419 is the treatment of radiotherapy-induced esophagitis. Similar to SOM in patients with HNC, there are also no drugs approved by the FDA for the treatment of radiotherapy-induced esophagitis, with treatment options focused on controlling the symptoms. By removing superoxide, GC4419 is designed to address the root cause of esophagitis and reduce the damage radiotherapy can cause to the patient's esophageal mucosa, and thereby reduce the incidence of radiotherapy-induced esophagitis. We believe GC4419 has the potential to become the standard of care for the reduction in the incidence of radiotherapy-induced esophagitis. We intend to initiate an open-label Phase 2a trial in for the reduction of the incidence of esophagitis in patients with lung cancer receiving intensity-modulated radiation therapy, or IMRT.

GC4711 for Increasing the Anti-Cancer Efficacy of Radiotherapy

Cancer cells have been observed to be more susceptible than normal cells to increased levels of hydrogen peroxide. In our pre-clinical studies, we have observed increased anti-cancer efficacy of higher daily doses of radiotherapy in combination with our dismutase mimetics. In a pre-clinical study, we demonstrated that this increase in anti-cancer efficacy was due to the conversion of superoxide to hydrogen peroxide by our dismutase mimetics. This increased efficacy could be particularly important in settings where the anti-cancer efficacy of radiotherapy alone is insufficient to achieve the desired outcome.

We are currently conducting a pilot, randomized, placebo-controlled Phase 1b/2a trial of GC4419 in combination with SBRT in patients with LAPC whose tumor cannot be resected. The primary objective of this trial is to determine the maximum tolerated daily dose of SBRT in conjunction with a dismutase mimetic, with secondary measures assessing progression-free survival, objective response rate and tumor resectability compared to placebo. We believe this combination therapy may lead to improved patient survival rates, which we will also track in our clinical development. We expect to report top-line data from this trial in .

We plan to leverage our observations from our GC4419 SBRT pilot Phase 1b/2a trial in LAPC to help develop GC4711 to increase the anti-cancer efficacy of SBRT. We have successfully completed a Phase 1 trial of intravenous GC4711 in healthy volunteers and plan to commence a Phase 1b/2a trial with GC4711 in combination with SBRT in patients with NSCLC in . In addition to this GC4711 Phase 1b/2a trial in NSCLC, we plan to conduct future trials in combination with SBRT with GC4711, including in LAPC if we are successful in our ongoing SBRT GC4419 pilot Phase 1b/2a trial in that indication. We are also currently evaluating several oral formulations of GC4711 in a Phase 1 trial in healthy volunteers, based on pre-clinical studies suggesting that GC4711 can be delivered orally.

Our Strategy

Our mission is to transform cancer therapy by reducing normal tissue toxicity induced by radiotherapy and to improve the lives of patients with cancer. We are also seeking to increase the anti-cancer efficacy of radiotherapy with the use of our dismutase mimetics. Key elements of our strategy are as follows:

- **Complete the development and obtain FDA approval for GC4419 for the reduction of radiotherapy-induced toxicities.** We are currently evaluating GC4419 in a Phase 3 registrational trial to reduce the incidence of SOM in patients receiving radiotherapy for locally advanced HNC. We expect to report top-line data from this trial by . We also plan to initiate a Phase 2a trial in to assess GC4419 in combination with radiotherapy to reduce the incidence of radiotherapy-induced esophagitis in patients with lung cancer. Based upon the outcomes of our ongoing and planned trials, we plan to initiate additional clinical trials for GC4419 to reduce radiotherapy-induced toxicities in other cancer indications.

- **Build a commercial infrastructure in the United States.** We intend to commercialize GC4419, if approved, by building a specialized sales and marketing organization in the United States focused on radiation oncologists. We believe a scientifically-oriented, customer-focused team of approximately 40 sales representatives would allow us to effectively reach the approximately 4,000 radiation oncologists in the United States. We also expect to leverage this sales organization to commercialize GC4711, if approved, and any of our future product candidates in the United States. Outside the United States, we may seek to establish collaborations for the commercialization of GC4419 and our other product candidates.

- **Advance the development of GC4711 in combination with SBRT to increase the anti-cancer efficacy of radiotherapy.** We successfully completed a Phase 1 trial with GC4711 in December 2017 in healthy volunteers, and plan to initiate a Phase 1b/2a trial with GC4711 in combination with SBRT in patients with NSCLC in . In addition, upon the successful completion of our ongoing pilot Phase 1b/2a trial of GC4419 in combination with SBRT in patients with LAPC, and based upon FDA feedback, we expect to pursue further development in patients with LAPC with GC4711 in combination with SBRT.

- **Develop additional novel dismutase mimetics and formulations.** We intend to leverage our expertise in superoxide dismutase mimetics to continue to develop novel compounds that are intended to reduce normal tissue toxicity from radiotherapy and increase the anti-cancer efficacy of radiotherapy. In addition, we intend to seek new applications for our dismutase mimetics, including potential combinations in cancer therapy.

- **Seek strategic collaborative relationships.** We intend to seek strategic collaborations to facilitate the capital-efficient development of our dismutase mimetics. We believe these collaborations could potentially provide significant funding to advance our dismutase mimetics candidate pipeline while allowing us to benefit from the development expertise of our collaborators.

Risks Associated with Our Business

Our business is subject to a number of risks that you should be aware of before making an investment decision. You should carefully consider all of the information set forth in this prospectus and, in particular, should evaluate the specific factors set forth under "Risk Factors" in deciding whether to invest in our common stock. Among these important risks are the following:

- We are a clinical stage biopharmaceutical company with a limited operating history and have not generated any revenue from product sales. We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.
- We are heavily dependent on the success of our lead product candidate, GC4419, and if GC4419 does not successfully complete clinical development or receive regulatory approval, or is not successfully commercialized, our business may be harmed.
- Even if this offering is successful, we may need substantial additional funding to meet our financial obligations and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy.
- The regulatory approval process is lengthy, expensive and uncertain, and we may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our ability to generate revenue, our business and our results of operations.
- We rely, and will continue to rely, on third parties to conduct our clinical trials for our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.
- If we are unable to or experience delays in establishing our own sales, marketing and distribution capabilities, or in entering into agreements with third parties to sell and market GC4419 or any future product candidates, we may not be successful in commercializing our product candidates if and when they are approved, and we may not be able to generate any revenue.
- We do not have our own manufacturing capabilities and will rely on third parties to produce additional clinical supplies, if needed, and commercial supplies of GC4419 and our other product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- The incidence and prevalence for target patient populations of our product candidates have not been established with precision. If the market opportunities for our product candidates are smaller than we estimate, or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability may be materially adversely affected.
- If we are unable to adequately protect our product candidates, or to secure and maintain freedom to operate, others could preclude us from commercializing our product candidates or compete against us more directly.
- The successful commercialization of GC4419 or any other product candidates will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate

reimbursement levels and pricing policies, which may depend in part on whether uses for our products are recommended in recognized drug compendia. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

- We face substantial competition, which may result in others discovering, developing or commercializing other therapies before or more successfully than we do, which could materially adversely affect our business and financial condition.

- Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, cause us to suspend or discontinue clinical trials, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Implications of Being an Emerging Growth Company

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we may take advantage of certain exemptions from various reporting requirements that are applicable to other publicly-traded entities that are not emerging growth companies. These exemptions include:

- the option to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;

- not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended;

- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (i.e., an auditor discussion and analysis);

- not being required to submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay," "say-on-frequency," and "say-on-golden parachutes;" and

- not being required to disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation.

As a result, we do not know if some investors will find our common stock less attractive. The result may be a less active trading market for our common stock, and the price of our common stock may become more volatile.

Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 13(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, as a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies. Section 107 of the JOBS Act provides that we can elect to opt out of the extended transition period at any time, which election is irrevocable.

We will remain an emerging growth company until the earliest of: (i) the last day of the first fiscal year in which our annual gross revenues exceed $1.07 billion; (ii) the last day of 2024; (iii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common equity held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter; or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during any three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements.

Corporate Information

We were incorporated in Delaware in November 2012. Our offices are located at 2 W Liberty Blvd #100, Malvern, Pennsylvania 19355. Our telephone number is (610) 725-1500. Our corporate website is *www.galeratx.com*. The information contained on or that can be accessed through our website is not incorporated by reference into this prospectus, and you should not consider information on our website to be part of this prospectus or in deciding to purchase our common stock.

The Offering

Common stock offered by us	shares
Common stock to be outstanding after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares in full)
Option to purchase additional shares	We have granted the underwriters a 30-day option to purchase up to additional shares of our common stock at the public offering price less estimated underwriting discounts and commissions.
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately $ million (or approximately $ million if the underwriters exercise in full their option to purchase additional shares of common stock), assuming an 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 the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with our existing cash resources, to fund the clinical development of GC4419 and GC4711. The remaining proceeds will be used for working capital and general corporate purposes. See "Use of Proceeds."
Risk factors	Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 12 and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
Proposed Nasdaq Global Market symbol	"GRTX"

The number of shares of our common stock to be outstanding after this offering is based on shares of our common stock outstanding as of December 31, 2018, and excludes:

- shares of our common stock issuable upon the exercise of options outstanding as of December 31, 2018, at a weighted-average exercise price of $ per share;
- shares of common stock reserved for future issuance pursuant to the Galera Therapeutics, Inc. Equity Incentive Plan, or the Existing Equity Incentive Plan; and
- shares of common stock reserved for future issuance pursuant to our 2019 Incentive Award Plan, or the 2019 Plan, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part.

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

- a -for- reverse stock split of our common stock to be effected on , 2019;
- the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into 96,385,795 shares of our common stock upon the closing of this offering;
- the filing of our amended and restated certificate of incorporation and the effectiveness of our amended and restated bylaws upon the closing of this offering;
- no exercise of the outstanding options referred to above; and
- no exercise by the underwriters of their option to purchase additional shares of our common stock.

Summary Consolidated Financial Data

The following tables set forth, for the periods and as of the dates indicated, our summary historical consolidated financial data. The consolidated statements of operations data for the years ended December 31, 2017 and 2018 and the consolidated balance sheet data as of December 31, 2018 are derived from our audited consolidated financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future. You should read the following information together with the more detailed information contained in "Selected Consolidated Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus.

	Year ended December 31,	
	2017	2018
	(in thousands, except share and per share amounts)	
Consolidated Statements of Operations Data:		
Operating expenses:		
Research and development	$ 20,594	$ 18,663
General and administrative	3,500	5,592
Loss from operations	(24,094)	(24,255)
Other income (expenses):		
Interest income	193	606
Interest expense	—	(220)
Foreign currency loss	(4)	(30)
Loss from operations before income tax benefit	(23,905)	(23,899)
Income tax benefit	360	223
Net loss	(23,545)	(23,676)
Accretion of redeemable convertible preferred stock to redemption value	(4,588)	(5,910)
Net loss attributable to common stockholders	$ (28,133)	$ (29,586)
Net loss per share of common stock, basic and diluted(1)	$ (18.51)	$ (19.46)
Weighted-average shares of common stock outstanding, basic and diluted(1)	1,520,000	1,520,000
Pro forma net loss per share of common stock, basic and diluted (unaudited)(1)		$ (0.31)
Pro forma weighted-average shares of common stock outstanding, basic and diluted (unaudited)(1)		76,977,463

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

	As of December 31, 2018		
	Actual	Pro Forma(1) (unaudited) (in thousands)	Pro Forma As Adjusted(2)(3) (unaudited)
Consolidated Balance Sheet Data:			
Cash, cash equivalents and short-term investments	$ 81,517	$ 81,517	$
Working capital(4)	77,408	77,408	
Total assets	88,056	88,056	
Royalty purchase liability	20,220	20,220	
Redeemable convertible preferred stock	165,902	—	
Total stockholders' (deficit) equity	(104,820)	61,082	

(1) Reflects the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 96,385,795 shares of common stock upon the closing of this offering.

(2) Reflects the pro forma adjustments described in footnote (1) and the sale by us of shares of common stock in this offering at 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, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(3) Pro forma as adjusted information is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each $1.00 increase or 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 or decrease pro forma as adjusted cash, cash equivalents and short-term investments, working capital, total assets and total stockholders' (deficit) equity 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, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A 1,000,000 share increase or decrease in the number of shares offered by us would increase or decrease pro forma as adjusted cash, cash equivalents and short-term investments, working capital, total assets and total stockholders' (deficit) equity by approximately $ million, assuming that the assumed initial price to public remains the same, and after deducting estimated underwriting discounts and commissions payable by us.

(4) We define working capital as current assets less current liabilities.

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 consolidated financial statements and the related notes and "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 adversely affect 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 Capital Needs

We are a clinical stage biopharmaceutical company with a limited operating history and have not generated any revenue from product sales. We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

We have incurred losses in each year since our inception in 2012 and anticipate incurring losses for the foreseeable future. To date, we have invested substantially all of our efforts and financial resources in identifying, acquiring, in-licensing and developing our product candidates, including commencing and conducting clinical trials and providing general and administrative support for these operations. Our future success is dependent on our ability to develop, obtain regulatory approval for and successfully commercialize one or more of our product candidates. We have not yet demonstrated our ability to successfully complete any Phase 3 or other pivotal clinical trials, obtain regulatory approvals, manufacture a drug at commercial scale, or conduct sales and marketing activities. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a marketable product. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. Typically, it takes many years to develop one new drug from the time it is discovered to when it is available for treating patients, and development may cease for a number of reasons.

We have incurred significant losses related to expenses for research and development and our ongoing operations. Our net losses for the years ended December 31, 2017 and 2018 were $23.5 million and $23.7 million, respectively. As of December 31, 2018, we had an accumulated deficit of $104.8 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we:

- continue our research and pre-clinical and clinical development of our product candidates, including our ongoing Phase 3 registrational trial for GC4419 for the reduction in the incidence of SOM in patients with locally advanced HNC receiving radiotherapy and our ongoing Phase 1b/2a pilot trial of GC4419 in patients with LAPC receiving SBRT, and commence our Phase 2a trial of GC4419 for the reduction in the incidence of esophagitis in patients with lung cancer receiving radiotherapy and our Phase 1b/2a trial of GC4711 in patients with NSCLC receiving radiotherapy;
- advance our programs into more expensive clinical trials;
- increase our manufacturing needs or add additional manufacturers or suppliers;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;

- seek to identify, assess, acquire or develop additional product candidates;
- make royalty or other payments under any royalty or purchase agreements, including our Royalty Agreement with Clarus;
- seek to maintain, protect and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company, our product development and our planned future commercialization efforts; and
- experience any delays or encounter issues with any of the above, including but not limited to failed trials, complex results, safety issues, other regulatory challenges that require longer follow-up of existing trials, additional major trials or additional supportive trials in order to pursue marketing approval.

To become and remain profitable, we must succeed in developing and eventually commercializing product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing pre-clinical studies and clinical trials of our product candidates, obtaining regulatory approval, and manufacturing, marketing and selling any product candidates for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

In cases where we are successful in obtaining regulatory approval to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

Because of the numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase.

Further, the net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period to period comparison of our results of operations may not be a good indication of our future performance. Once we are a public company, we will incur additional costs associated with operating as a public company. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Even if this offering is successful, we may need substantial additional funding to meet our financial obligations and to pursue our business objective. If we are unable to raise capital when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

Identifying potential product candidates and conducting pre-clinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the

necessary data or results required to obtain regulatory approval and achieve product sales. We expect our expenses to increase in connection with our ongoing activities as we continue enrolling patients in and complete our Phase 3 registrational trial of GC4419 for the reduction in the incidence of SOM in patients with locally advanced HNC, seek marketing approval for GC4419, pursue clinical trials and marketing approval of GC4419 in other indications, pursue clinical trials and marketing approval of GC4711 and advance any of our other product candidates we may develop or otherwise acquire. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to manufacturing, product sales, marketing and distribution. We may also need to raise additional funds sooner if we choose to pursue additional indications for our product candidates or otherwise expand more rapidly than we presently anticipate. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed on attractive terms, if at all, we will be forced to delay, reduce or eliminate certain of our clinical development plans, research and development programs or future commercialization efforts.

The development process for our product candidates is highly uncertain, and we cannot estimate with certainty the actual amounts necessary to successfully complete the development, regulatory approval process and commercialization of our product candidates. Based on our current operating plan, we believe that the net proceeds from this offering and our current cash and cash equivalents and short-term investments will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into . Our operating plans may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than expected, through public or private equity, debt financings or other sources. Our future capital requirements will depend on and could increase significantly as a result of many factors, including:

- the results, time and cost necessary for completing our Phase 3 registrational trial for GC4419 for the reduction in the incidence of SOM in patients with locally advanced HNC receiving radiotherapy and our ongoing Phase 1b/2a pilot trial of GC4419 in patients with LAPC receiving SBRT, and commencing our planned Phase 2a trial of GC4419 for the reduction in the incidence of esophagitis in patients with lung cancer receiving radiotherapy and our planned Phase 1b/2a trial of GC4711 in patients with NSCLC receiving radiotherapy;

- the number, size and type of any additional clinical trials;

- the costs, timing and outcomes of seeking and potentially obtaining approvals from the FDA or comparable foreign regulatory authorities, such as the European Medicines Agency, or EMA, or the Competent Authorities of the Member States of the European Economic Area, or EEA, including the potential for the FDA or comparable regulatory authorities to require that we conduct more studies and trials than those that we currently expect to conduct and the costs of post-marketing studies or risk evaluation and mitigation strategies, or REMS, that could be required by regulatory authorities;

- the costs and timing of transferring manufacturing technology to third-party manufacturers, producing product candidates to support clinical trials and preparing to manufacture our product candidates;

- our ability to successfully commercialize any of our product candidates, including the cost and timing of forming and expanding our sales organization and marketing capabilities;

- the amount of sales revenues from our product candidates, if approved, including the sales price and the availability of coverage and adequate third-party reimbursement;

- competitive and potentially competitive products and technologies and patients' receptivity to our product candidates and the technology underlying them in light of competitive products and technologies;

- the cash requirements of any future acquisitions, developments or discovery of additional product candidates, including any licensing or collaboration agreements;
- the time and cost necessary to respond to technological and market developments;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- any product liability or other lawsuits related to our product candidates or any products;
- the costs associated with being a public company;
- our need and ability to hire additional personnel; and
- the receptivity of the capital markets to financings by biotechnology companies generally and companies with product candidates and technologies such as ours specifically.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Dislocations in the financial markets may make equity and debt financing more difficult to obtain, and may have a material adverse effect on our ability to meet our fundraising needs when they arise. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our pre-clinical studies, clinical trials or other research or development programs, the commercialization of any product candidate. We may also be unable to expand our operations or otherwise capitalize on our business opportunities or may be required to relinquish rights to our product candidates or products. Any of these occurrences could materially affect our business, financial condition and results of operations.

Raising additional capital may cause dilution to our stockholders, including purchasers of shares of our common stock in this offering, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time as we can generate substantial product revenues, if ever, we expect to finance our cash needs through securities offerings or debt financings, or possibly, license and collaboration agreements or research grants. The terms of any financing may adversely affect the holdings or the rights of our stockholders and our issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our common stock to decline. The sale of additional equity or convertible securities would dilute all of our stockholders, including your ownership interest. The incurrence of indebtedness would result in increased fixed or variable payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies, product candidates or future revenue streams, or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. If we raise funds through research grants, we may be subject to certain requirements, which may limit our ability to use the funds or require us to share information from our research and development. Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our stockholders, and may cause the market price of our shares to decline.

Risks Related to the Discovery and Development of Our Product Candidates

We are heavily dependent on the success of our lead product candidate, GC4419, and if GC4419 does not successfully complete clinical development or receive regulatory approval, our business may be harmed.

We currently have no products that are approved for commercial sale. We have not completed the development of any product candidates and we may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to the advancement of GC4419, through clinical trials and the regulatory approval process, as well as the commercialization of GC4419 following regulatory approval, if received. Accordingly, our business currently depends heavily on the successful completion of our Phase 3 Reduction in Oral Mucositis with Avasopasem Manganese Trial, or ROMAN Trial, and subsequent regulatory approval and commercialization of GC4419.

We cannot be certain that GC4419 will receive regulatory approval, or be successfully commercialized even if we receive regulatory approval. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of products are, and will remain, subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market GC4419 in the United States until we receive approval of a New Drug Application, or NDA, or in any foreign country until we receive the requisite approvals from the appropriate authorities in such countries for marketing authorization.

We have not yet demonstrated our ability to complete later-stage or pivotal clinical trials, and there can be no assurance that our Phase 3 ROMAN Trial of GC4419 will produce results sufficient for us to submit an NDA or differentiate our product from currently available treatment options for the reduction of SOM in patients with HNC. Our ongoing Phase 3 ROMAN Trial may not demonstrate a statistically significant difference for the active 90 mg dose compared to placebo for the primary endpoint. Any failure to demonstrate a statistically significant difference compared to placebo would adversely impact the potential for regulatory approval, if any, of GC4419 in the United States. Furthermore, even if the statistical difference compared to placebo is achieved for the primary endpoint, we may not be able to demonstrate such differences for our secondary endpoints. As such, even if we were able to obtain approval for GC4419, these key secondary endpoints would not be mentioned in the U.S. label, which could potentially adversely affect product differentiation.

We have not submitted an NDA for GC4419 or any other marketing authorizing application for any other product candidates to the FDA or any comparable application to any other regulatory authority. Obtaining approval of an NDA or similar regulatory approval is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or other foreign regulatory authorities may delay, limit or deny approval of any of our current or future product candidates for many reasons, including:

- we may not be able to demonstrate that GC4419 is effective as treatments for any of our targeted indications to the satisfaction of the FDA or other relevant regulatory authorities;
- the relevant regulatory authorities may require additional pre-approval studies or clinical trials, which would increase our costs and prolong our development timelines;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or other relevant regulatory authorities for marketing approval;
- the FDA or other relevant regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the contract research organizations, or CROs, that we retain to conduct clinical trials may take actions outside of our control, or otherwise commit errors or breaches of protocols, that materially adversely impact our clinical trials and ability to obtain market approvals;

- the FDA or other relevant regulatory authorities may not find the data from pre-clinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of GC4419 outweigh their safety risks;
- the FDA or other relevant regulatory authorities may not be convinced that GC4419 has an acceptable safety profile;
- the FDA or other relevant regulatory authorities may disagree with our interpretation of data or significance of results from the pre-clinical studies and clinical trials of GC4419, or may require that we conduct additional studies;
- the FDA or other relevant regulatory authorities may not accept data generated from our clinical trial sites;
- if our NDA or other foreign application is reviewed by an advisory committee, the FDA or other relevant regulatory authority, as the case may be, may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA or other relevant regulatory authority, as the case may be, require, as a condition of approval, additional nonclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA or other relevant regulatory authorities may require additional post-marketing studies, which would be costly;
- the FDA or other relevant regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; and
- the FDA or other relevant regulatory authorities may change their approval policies or adopt new regulations.

Clinical drug development involves a lengthy and expensive process with uncertain timelines and outcomes, and results of earlier studies and trials may not be predictive of future trial results. If development of our product candidates is unsuccessful or delayed, we may be unable to obtain required regulatory approvals and be unable to commercialize our product candidates on a timely basis, if at all.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure or delay can occur at any time during the clinical trial process. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, even after promising results in earlier pre-clinical studies or clinical trials. These setbacks have been caused by, among other things, pre-clinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. The results of pre-clinical studies and clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. Notwithstanding any potential promising results in earlier studies, we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates.

In addition, interim, topline and preliminary data that we announce or publish from time to time may change as more patient data become available, and are subject to audit and verification procedures that could result in material changes in the final data. We may make assumptions, estimations, calculations and conclusions

as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim, topline, and preliminary data should be viewed with caution until final data are available. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general.

Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we have agreements with our CROs governing their committed activities, and the ability to audit their performance, we have limited influence over their actual performance. We rely on third-party vendors, such as CROs, scientists and collaborators to provide us with significant data and other information related to our pre-clinical studies or clinical trials and our business. If such third parties provide inaccurate, misleading or incomplete data, our business, prospects and results of operations could be materially adversely affected.

We may experience delays in initiating our clinical trials and we cannot be certain that the trials or any other future clinical trials for our product candidates will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delay or failure related to:

- the FDA or comparable foreign regulatory authorities, such as the Competent Authorities of the Member States of the EEA, disagreeing as to the design or implementation of our clinical trials;
- the size of the study population for further analysis of the study’s primary endpoints;
- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board, or IRB, or Ethics Committee approval at each site;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- addressing patient safety concerns that arise during the course of a trial;
- addressing any conflicts with new or existing laws or regulations;
- adding a sufficient number of clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or Ethics Committees of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities, such as the Competent Authorities of the Member States of the EEA. Such authorities may suspend or terminate a clinical trial due to a number of factors,

including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities, such as the Competent Authorities of the Member States of the EEA, resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Further, conducting clinical trials in foreign countries, as we plan to do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

If we experience delays in the completion, or termination, of any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenues from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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

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 study until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

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.

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

Success in pre-clinical studies or earlier clinical trials may not be indicative of results in future clinical trials.

Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Pre-clinical studies and Phase 1 and Phase 2 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in pre-clinical studies and early clinical trials does not ensure that later, large-scale efficacy trials will be successful nor does it predict final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in pre-clinical studies or having successfully advanced through initial clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in pre-clinical studies and earlier-stage clinical trials. Data obtained from pre-clinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

We plan to conduct clinical trials for our product candidates outside the United States and the FDA may not accept data from such trials.

We have conducted certain of our clinical trials outside the United States, and we plan to conduct additional clinical trials outside the United States. For example, we are currently conducting a Phase 1 dose escalation study of GC4711 in healthy volunteers in Australia. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of such study data by the FDA is subject to certain conditions. For example, the clinical trial must be conducted in accordance with good clinical practices, or GCP, requirements and the FDA must be able to validate the data from the clinical trial through an onsite inspection if it deems such inspection necessary.

Where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice, the clinical trials were performed by clinical investigators of recognized competence, and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, such clinical trials would be subject to the applicable local laws of the foreign jurisdictions where the clinical trials are conducted.

There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. There can also be no assurance that the comparable foreign regulatory authority in any jurisdiction in which we seek marketing approval for our product candidates will accept data from clinical trials conducted outside such jurisdiction. If the FDA or any such foreign regulatory authority does not accept any such data, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay aspects of our development plan. In addition, the conduct of clinical trials outside the United States could have a significant impact on us. Risks inherent in conducting international clinical trials include:

- foreign regulatory requirements that could burden or limit our ability to conduct our clinical trials;

- administrative burdens of conducting clinical trials under multiple foreign regulatory schemes;
- foreign exchange fluctuations;
- manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- diminished protection of intellectual property in some countries.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, cause us to suspend or discontinue clinical trials, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities, such as the EMA or the Competent Authorities of the Member States of the EEA. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. To date, patients treated with our product candidates have experienced drug-related side effects including lymphopenia, nausea, fatigue, oropharyngeal pain, constipation, radiation skin injury and vomiting.

If unacceptable side effects arise in the development of our product candidates, we, the FDA, the IRBs or Ethics Committees at the institutions in which our studies are conducted, or the DSMB could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Our clinical trials include cancer patients who are very sick and whose health may deteriorate, and we expect that additional clinical trials of our other product candidates will include similar patients with potentially deteriorating health. It is possible that some may die during our clinical trials for various reasons, including because the patient's underlying disease continues to advance despite treatment, or because the patient experiences medical problems that may not be related to our product candidate. For example, during our Phase 2b trial of GC4419, there was one non-treatment-related death in each of the placebo, 30 mg treatment and 90 mg treatment arms. Even if the deaths are not related to our product candidate, the deaths could affect perceptions regarding the safety of our product candidates.

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

- regulatory authorities may suspend, withdraw or limit their approval of the product, or seek an injunction against its manufacture or distribution;
- we may be required to recall a product or change the way such product is administered to patients;

- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to implement a REMS or create a Medication Guide outlining the risks of such side effects for distribution to patients, or implement other changes to how a product is distributed or administered;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and result in the loss of significant revenues to us, which would materially and adversely affect our results of operations and business.

The regulatory approval process is lengthy, expensive and uncertain, and we may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our ability to generate revenue, our business and our results of operations.

The development, research, testing, manufacturing, labeling, approval, selling, import, export, marketing, promotion and distribution of drug products are subject to extensive and evolving regulation by federal, state and local governmental authorities in the United States, principally the FDA, and by foreign regulatory authorities, such as the EMA or the Competent Authorities of the Member States of the EEA, which regulations differ from country to country. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States until we receive regulatory approval of an NDA from the FDA.

Obtaining regulatory approval of an NDA can be a lengthy, expensive and uncertain process. Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or other foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. The number of pre-clinical studies and clinical trials that will be required for FDA approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate.

Results from pre-clinical studies and clinical trials can be interpreted in different ways. Even if we believe the pre-clinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering product candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials and result in the FDA or other regulatory authorities denying approval of a drug candidate for any or all indications. The FDA may also require us to conduct additional studies or trials for our product candidates either prior to or post-approval, such as additional drug-drug interaction studies or safety or efficacy studies or trials, or it may object to elements of our clinical development program such as the number of subjects in our current clinical trials from the United States. For instance, the FDA has indicated that it could require us to conduct a drug-drug interaction study of GC4419 with cisplatin. We may experience difficulty in identifying and enrolling patients in such a trial, if one were to be required, which could interrupt, delay or halt the process of obtaining regulatory approval of GC4419.

The FDA or any foreign regulatory bodies can delay, limit or deny approval of our product candidates or require us to conduct additional pre-clinical studies or clinical testing or abandon a program for many reasons, including:

- the FDA or the applicable foreign regulatory agency's disagreement with the design or implementation of our clinical trials;
- negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory body that our product candidates are safe and effective for the proposed indication;
- the FDA's or the applicable foreign regulatory agency's disagreement with the interpretation of data from pre-clinical studies or clinical trials;
- our inability to demonstrate the clinical and other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA's or the applicable foreign regulatory agency's requirement for additional pre-clinical studies or clinical trials;
- the FDA's or the applicable foreign regulatory agency's disagreement regarding the formulation, labeling and/or the specifications of our product candidates;
- the FDA's or the applicable foreign regulatory agency's failure to approve the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

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

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

As product candidates proceed through pre-clinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these 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. Such changes may also require additional testing, FDA notification or FDA approval. 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 commence sales and generate revenue.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and management resources, we focus on development programs and product candidates that we identify for specific indications. As such, we are currently primarily focused on the development of GC4419 and GC4711. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications for GC4419 or GC4711 that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

While we have received Breakthrough Therapy Designation for GC4419, we may not receive such designation for our other product candidates, and such designation for GC4419 or any other product candidate may not lead to a faster development or regulatory review or approval process and will not increase the likelihood that our product candidates will receive marketing approval.

We have received Breakthrough Therapy Designation from the FDA for GC4419 for the reduction of the duration, incidence and severity of SOM induced by radiotherapy, with or without systemic therapy. We may also seek Breakthrough Therapy Designation for any other product candidates that we may develop. A breakthrough therapy is defined as a product that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that a product candidate meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification.

We have received Fast Track Designation for GC4419, and we may seek such designation for some or all of our other product candidates. We may not receive such designation, and even for those product candidates for which we do, it may not lead to a faster development or regulatory review or approval process, and will not increase the likelihood that product candidates will receive marketing approval.

We have received Fast Track Designation from the FDA for GC4419 for the reduction of the severity and incidence of radiation and chemotherapy-induced OM, and we may seek Fast Track Designation and review for some or all of our other product candidates. If a drug is intended for the treatment of a serious or life-threatening condition or disease, and pre-clinical or clinical data demonstrate the potential to address an unmet medical need, the product may qualify for Fast Track Designation, for which sponsors must apply. The FDA has broad discretion whether or not to grant this designation. Thus, even if we believe a particular product candidate is eligible for this designation, the FDA may decide not to grant it. Moreover, even if we do receive Fast Track Designation, we or our collaborators may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions, such as the EMA or the Competent Authorities of the Member States of the EEA, must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional pre-clinical studies or clinical trials, as studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market size will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing 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.

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 the conditions of approval, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing

regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practice-grade, or cGMP, requirements and GCP requirements for any clinical trials that we conduct post-approval. 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, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, 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 other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For

example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, 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.

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

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, as our product candidates would be, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. Physicians may nevertheless prescribe such drugs to their patients in a manner that is inconsistent with the approved label. For example, if we obtain approval for GC4419 for the reduction in the incidence of SOM in patients with locally advanced HNC receiving radiotherapy, we may pursue a strategy for GC4419 for the reduction of radiotherapy-induced esophagitis by presenting clinical data to entities like the National Comprehensive Cancer Network, or NCCN, to support use of GC4419 under these circumstances as a medically accepted indication in published drug compendia, notwithstanding the fact that we may not seek approval for GC4419 for radiotherapy-induced esophagitis by the FDA. Even if we are successful in obtaining Category 1 or Category 2A status from NCCN for GC4419 for the reduction of esophagitis, we will nevertheless be restricted from marketing and promoting the product for the reduction of esophagitis unless and until it is approved by the FDA for such indication.

If we are found to have promoted off-label uses, or if the government takes the position that our presenting clinical data related to off-label uses of GC4419 to NCCN or other drug compendia publishers to establish compendia-listed indications constitutes off-label promotion, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Risks Related to Our Dependence on Third Parties

We rely, and will continue to rely, on third parties to conduct our clinical trials for our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We have engaged a CRO to conduct our ongoing Phase 3 registrational trial for GC4419 for the reduction in the incidence of SOM in patients with locally advanced HNC receiving radiotherapy and our ongoing Phase 1b/2a pilot trial of GC4419 in patients with LAPC, and expect to engage a CRO for future clinical trials of GC4419, GC4711 and any other product candidates that we may progress to clinical development. We expect to continue to rely on third parties, such as clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials. If any of our relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. In addition, any third parties conducting our clinical trials will not be our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical programs. 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 clinical data they obtain is compromised due to the failure to adhere

to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

Switching or adding CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely on these parties for execution of our pre-clinical studies and clinical trials, and generally do not control their activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We are also required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. If we or any of our CROs or other third parties, including trial sites, fails to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP conditions. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of GC4419, GC4711 and any other product candidates.

We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential revenue.

We contract with third parties for the manufacture and supply of our product candidates for pre-clinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities or personnel. We do not have any long-term contractual arrangements with manufacturers and instead rely on third parties to manufacture our product candidates on a purchase-order or work-order basis. We currently have limited manufacturing arrangements, and we cannot be

certain that we will be able to establish redundancy in manufacturers for our product candidates, which could lead to reliance on a limited number of manufacturers for one or more of our product candidates. This reliance increases the risk that we will not have sufficient quantities of our drug candidates or products, if approved, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We also expect to rely on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of GC4419 and any other product candidates for which we obtain marketing approval. The facilities used by our contract manufacturing organizations, or CMOs, to manufacture our product candidates must be approved by the FDA or other regulatory authorities pursuant to inspections that will be conducted after we submit our NDA or comparable marketing application to the FDA or other regulatory authority. We do not have control over a supplier's or manufacturer's compliance with laws, regulations and applicable cGMP standards and other laws and regulations, such as those related to environmental health and safety matters. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. If our current or future suppliers are unable to supply us with sufficient raw materials for our pre-clinical studies and clinical trials, we may experience delays in our development efforts as we locate and qualify new raw material manufacturers.

We may be unable to establish any agreements with future third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, qualifying and validating such manufacturers may take a significant period of time and reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible increase in costs for the raw materials or drug substance in GC4419 or any of our other product candidates; and
- the possible termination or nonrenewal of any agreement by any third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with cGMP regulations or other regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Our product candidates and any drugs that we may develop may compete with other product candidates and drugs for access to manufacturing facilities. There are no assurances we would be able to enter into similar commercial arrangements with other manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval.

We may seek collaborations with third parties for the development or commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We may seek third-party collaborators for the development and commercialization of our product candidates, including for the commercialization of any of our product candidates that are approved for marketing outside the United States. Our likely collaborators for any collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. If we do enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates would pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected, including compliance with all applicable regulatory requirements;
- 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 based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that 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 product candidates if the collaborators believe that 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 drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator 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 products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination 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 or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such 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; and

- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

If we seek, but are not able to establish, collaborations, we may have to alter our development and commercialization plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional capital. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we 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. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such 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 capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate revenue.

Risks Related to Commercialization

Even if any of our product candidates 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.

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our

product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the timing of market introduction;
- the efficacy, safety and potential advantages compared to alternative treatments, including for GC4419;
- our ability to offer our products for sale at competitive prices;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- the perception by members of the healthcare community, including physicians or patients, that the process of administering our product candidates, including our intravenous infusion procedure, is not unduly cumbersome;
- the clinical indications for which our product candidates are approved;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities;
- the limited number of infusion sites where our product candidates can be administered;
- our ability to successfully develop, or make arrangements with third-party manufacturers for, commercial manufacturing processes for any of our product candidates that receive regulatory approval;
- our ability to hire and retain a sales force in the United States;
- the strength of marketing and distribution support;
- the recognition of uses for our products as medically accepted indications in recognized drug compendia;
- the availability of third-party coverage and adequate reimbursement for GC4419 and any other potential product candidates;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

If we are unable to establish our own sales, marketing and distribution capabilities, or enter into agreements with third parties to sell and market GC4419 or any other product candidates, we may not be successful in commercializing our product candidates if and when they are approved, and we may not be able to generate any revenue.

We do not currently have a sales, marketing or distribution infrastructure. We have never sold, marketed or distributed any therapeutic products. To achieve commercial success for any approved product candidate, we

will need to establish a sales and marketing organization. Under the Royalty Agreement with Clarus, we are required to establish a trained sales force sufficiently in advance of any anticipated commercial launch in a country where we seek to commercialize GC4419 or related product candidates. We expect to build a specialized sales and marketing organization of approximately 40 sales representatives to market our product candidates to the approximately 4,000 radiation oncologists in the United States. There are risks involved with establishing our own sales and marketing capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any drug launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- our inability to equip medical and sales personnel with effective materials, including medical and sales literature to help them educate physicians and other healthcare providers regarding applicable diseases and our future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- our inability to develop or obtain sufficient operational functions to support our commercial activities; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales, marketing and distribution capabilities and are forced to enter into arrangements with, and rely on, third parties to perform these services, our revenue and our profitability, if any, are likely to be lower than if we had developed such capabilities ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. 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 do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

The incidence and prevalence for target patient populations of our product candidates have not been established with precision. If the market opportunities for our product candidates are smaller than we estimate, or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability may be materially adversely affected.

The precise incidence and prevalence for all the conditions we aim to address with our programs are unknown and cannot be precisely determined. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new trials may change the estimated incidence or prevalence of these diseases.

The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates approved for sale for these indications, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Further, even if we obtain significant market share for our product candidates, because the potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

The successful commercialization of GC4419 or any other product candidates will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates, assuming FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement for our products or procedures using our products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates. Obtaining coverage and adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Separate reimbursement for the product itself or the treatment or procedure in which our product is used may not be available. A decision by a third-party payor not to cover or separately reimburse for our products or procedures using our products, could reduce physician utilization of our products once approved. Assuming there is coverage for our product candidates or procedures using our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future.

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

There is significant uncertainty related to the insurance coverage and reimbursement of newly-approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

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

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the prices we may set.

In the United States, the European Union and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the Affordable Care Act, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the Affordable Care Act, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;

- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting “transfers of value” made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;

- 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;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and

- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. For example, the Tax Cuts and Jobs Act of 2017, or the Tax Act, was enacted, which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. While the Trump administration and CMS have both stated that the ruling will have no immediate effect, it is unclear how this decision, and subsequent appeals, if any, and will impact the Affordable Care Act. Additionally, the current Trump administration and Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. It is uncertain the extent to which any such changes may impact our business or financial condition.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute will remain in effect through 2027 unless additional action is taken by Congress; and the American Taxpayer Relief Act of 2012, 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. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. 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. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing. We expect that additional U.S. healthcare reform measures will be adopted in the future, any of which could limit the amounts paid for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved.

In markets outside of the United States and the European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the European Union or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability may depend, in part, on our ability to commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties. We are evaluating the opportunities for the development and commercialization of our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;

- longer lead times for shipping;
- language barriers for technical training and the need for language translations;
- reduced protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

In some countries, particularly the countries in Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidates that we may develop.

We will face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any product candidates that we may develop. If we cannot successfully defend ourselves against claims that our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates that we may develop;
- injury to our reputation and significant negative media attention;
- regulatory investigations that could require costly recalls or product modifications;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of potential revenue;
- the diversion of management’s attention away from managing our business; and
- the inability to commercialize any product candidates that we may develop.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur and is subject to deductibles and coverage limitations. We anticipate that we will need to

increase our insurance coverage when and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If we are unable to obtain insurance at acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position. These liabilities could prevent or interfere with our commercialization efforts.

Risks Related to Competition, Retaining Key Employees and Managing Growth

We face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we do.

The development and commercialization of new drugs and biologics is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or biologics are pursuing the development of therapies in the fields in which we are interested. Some of these competitive products and therapies are based on entirely different scientific approaches to our approach. 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.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources, a more established presence in the market, and more expertise in research and development, manufacturing, pre-clinical studies and clinical trials, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining highly qualified scientific, sales, marketing 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, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we or our collaborators may develop. Because our product candidates are designed to reduce normal tissue toxicity from radiotherapy, our commercial opportunity could also be reduced or eliminated if radiotherapy methods are improved in a way that reduces normal tissue toxicity, or if new therapies are developed which effectively treat cancer with less or without normal tissue toxicity. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of companion diagnostics in guiding the use of related products, market acceptance by physicians and patients, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Many of our employees have become or will soon become vested in a substantial amount of our common stock or a number of common stock options. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock, particularly after the expiration of the lock-up agreements described herein.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We have a limited operating history and are highly dependent on the research and development, clinical, commercial and business development expertise of the principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The failure to recruit, or the loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel. If we are not able to continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or growth.

We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

In connection with becoming a public company, we expect to increase our number of employees and the scope of our operations. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, certain employees may need to perform activities that are beyond their regular scope of work, and we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

We may not be successful in executing our growth strategy to identify, discover, develop, in-license or acquire additional product candidates or our growth strategy may not deliver the anticipated results.

We plan to source new product candidates that are complementary to our existing product candidates through our internal discovery program, or in-licensing or acquiring them from other companies or academic

institutions. If we are unable to identify, discover, develop, in-license or acquire and integrate product candidates in accordance with this strategy, our ability to pursue this part of our growth strategy would be limited.

Research programs and business development efforts to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. In-licensing and acquisitions of technology often require significant payments, expenses and will consume additional resources. We will need to devote a substantial amount of time and personnel to research, develop and commercialize any acquired technology, in addition to our existing portfolio of programs. Our research programs, business development efforts or licensing attempts may fail to yield additional complementary or successful product candidates for clinical development and commercialization for a number of reasons, including, but not limited to, the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates with a high probability of success for development progression;
- we may not be able or willing to assemble sufficient resources or expertise to in-license, acquire or discover additional product candidates;
- for product candidates we seek to in-license or acquire, we may not be able to agree to acceptable terms with the licensor or owner of those product candidates;
- our product candidates may not succeed in pre-clinical studies or clinical trials;
- we may not succeed in formulation or process development;
- our product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive regulatory approval;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates that we develop may be covered by third parties' patents or other exclusive rights;
- product candidates that we develop may not allow us to leverage our expertise and our development and commercial infrastructure as currently expected;
- the market for a product candidate may change during our program so that such a product may become unreasonable to continue to develop;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If any of these events occurs, we may not be successful in executing our growth strategy or our growth strategy may not deliver the anticipated results.

Risks Related to Intellectual Property

If we are unable to adequately protect our proprietary technology and product candidates, if the scope of the patent protection obtained is not sufficiently broad, or if the terms of our patents are insufficient to protect our product candidates for an adequate amount of time, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our product candidates may be materially impaired.

We rely primarily upon a combination of patents, trademarks, trade secret protection, and other intellectual property rights as well as nondisclosure, confidentiality and other contractual agreements to protect the intellectual property related to our brands, product candidates, including GC4419 and GC4711, and other proprietary technologies. Our success depends on our ability to develop, manufacture, market and sell our product candidates, if approved, and use our proprietary technologies without alleged or actual infringement, misappropriation or other violation of the patents and other intellectual property rights of third parties. There have been many lawsuits and other proceedings asserting patents and other intellectual property rights in the pharmaceutical and biotechnology industries. We cannot assure you that our product candidates, including GC4419 and GC4711 will not infringe existing or future third-party patents. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be applications now pending of which we are unaware and which may later result in issued patents that we may infringe by commercializing our product candidates, including GC4419 and GC4711. There may also be issued patents or pending patent applications that we are aware of, but that we think are irrelevant to our product candidates, including GC4419 and GC4711, which may ultimately be found to be infringed by the manufacture, sale, or use of our product candidates, including GC4419 and GC4711. Moreover, we may face claims from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect. In addition, many of our product candidates, including GC4419 and GC4711 have a complex structure that makes it difficult to conduct a thorough search and review of all potentially relevant third-party patents. Because we have not yet conducted a formal freedom to operate analysis for patents related to our product candidates, we may not be aware of issued patents that a third party might assert are infringed by one of our current or future product candidates, which could materially impair our ability to commercialize our product candidates. Even if we diligently search third-party patents for potential infringement by our products or product candidates, including GC4419 or GC4711, we may not successfully find patents that our products or product candidates, including GC4419 or GC4711, may infringe. If we are unable to secure and maintain freedom to operate, others could preclude us from commercializing our product candidates.

The process of obtaining patent protection is expensive and time-consuming, and we may not be able to prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may choose not to seek patent protection for certain innovations or products and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope and, in any event, any patent protection we obtain may be limited. As a result, in some jurisdictions some of our products currently or in the future may not be, protected by patents. We generally apply for patents in those countries where we intend to make, have made, use, offer for sale, or sell products and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we may not accurately predict all the countries where patent protection would ultimately be desirable. If we fail to timely file a patent application in any such country or major market, we may be precluded from doing so at a later date. 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 in which we have patent protection that may not be sufficient to terminate infringing activities. In addition, the actual protection afforded by a patent varies on a product-by-product basis, from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Furthermore, we cannot guarantee that any patents will be issued from any pending or future owned or licensed patent applications, or that any current or future patents will provide us with any meaningful protection or competitive advantage. Even if issued, existing or future patents may be challenged, including with respect to ownership, narrowed, invalidated, held unenforceable or circumvented, any of which could limit our ability to prevent competitors and other third parties from developing and marketing similar products or limit the length of terms of patent protection we may have for our product candidates, including GC4419 and GC4711 and technologies. Moreover, should we be unable to obtain meaningful patent coverage for clinically relevant infusion rates for CG4419 and GC4711 in jurisdictions with commercially significant markets, our ability to extend and reinforce patent protection for these product candidates in those jurisdictions may be adversely impacted, which could limit our ability to prevent competitors and other third parties from developing and marketing similar products or limit the length of terms of patent protection we may have for those product candidates. Other companies may also design around technologies we have patented, licensed or developed. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our products or practicing our own patented technology.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights may be uncertain. The standards that the United States Patent and Trademark Office, or the USPTO, and its foreign counterparts use to grant patents are not always applied predictably or uniformly. Changes in either the patent laws, implementing regulations or the interpretation of patent laws may diminish the value of our rights. The legal systems of certain countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. For example, patent laws in various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than United States law does. In addition, many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to "work" the invention in that country, or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patent and other intellectual property protection, which makes it difficult to stop infringement.

Because patent applications in the United States, Europe and many other jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to conceive or reduce to practice the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or pending patent applications. We can give no assurance that all of the potentially relevant art relating to our patents and patent applications has been found; overlooked prior art could be used by a third party to challenge the validity, enforceability and scope of our patents or prevent a patent from issuing from a pending patent application. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the validity, enforceability and scope of our patents in the United States, Europe and in other countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against our competitors.

Third parties may challenge any existing patent or future patent we own or license through adversarial proceedings in the issuing offices or in court proceedings, including as a response to any assertion of our patents against them. In any of these proceedings, a court or agency with jurisdiction may find our patents invalid and/or unenforceable, or even if valid and enforceable, insufficient to provide protection against competing products and services sufficient to achieve our business objectives. We may be subject to a third-party pre-issuance submission

of prior art to the USPTO, or reexamination by the USPTO if a third party asserts a substantial question of patentability against any claim of a U.S. patent we own or license. The adoption of the Leahy-Smith America Invents Act, or the Leahy-Smith Act, in September 2011 established additional opportunities for third parties to invalidate U.S. patent claims, including inter partes review and post-grant review proceedings. Outside of the United States, patents we own or license may become subject to patent opposition or similar proceedings, which may result in loss of scope of some claims or the entire patent. In addition, such proceedings are very complex and expensive, and may divert our management's attention from our core business. If any of our patents are challenged, invalidated, circumvented by third parties or otherwise limited or expire prior to the commercialization of our products, and if we do not own or have exclusive rights to other enforceable patents protecting our products or other technologies, competitors and other third parties could market products and use processes that are substantially similar to, or superior to, ours and our business would suffer.

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 a competitive advantage. For example:

- others may be able to develop products that are similar to, or better than, ours in a way that is not covered by the claims of our patents;
- we might not have been the first to conceive or reduce to practice the inventions covered by our patents or pending patent applications;
- we might not have been the first to file patent applications for our inventions;
- any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or
- we may not develop additional proprietary technologies that are patentable.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own. We currently in-license certain intellectual property from third parties to be able to use such intellectual property in our products and product candidates and to aid in our research activities. In the future, we may in-license intellectual property from additional licensors. We may rely on certain of these licensors to file and prosecute patent applications and maintain, or assist us in the maintenance of, patents and otherwise protect the intellectual property we license from them. We may have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors have been or will be conducted diligently or in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate, or support our efforts to 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. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe, misappropriate or otherwise violate our patents, trademarks, copyrights, trade secrets or other intellectual property, or those of our licensors. To counter infringement, misappropriation, unauthorized use or other violations, we may be required to file legal claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

We may not be able to prevent, alone or with our licensees or any future licensors, infringement, misappropriation or other violations of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party or a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates, including GC4419 and GC4711. Such a loss of patent protection could harm our business. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from exploiting the claimed subject matter at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from exploiting its technology on the grounds that our patents do not cover such technology. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making, using, importing and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement, misappropriation or other intellectual property litigation, any award of monetary damages we receive may not be commercially valuable. 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 litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. We may not be able to detect or prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Our commercial success depends significantly on our ability to operate without infringing upon the intellectual property rights of third parties.

The biotechnology and pharmaceutical industries are subject to rapid technological change and substantial litigation regarding patent and other intellectual property rights. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for or obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates, including GC4419 and GC4711 and services. Numerous third-party patents exist in the fields relating to our products and services, and it is difficult for industry participants, including us, to identify all third-party patent rights relevant to our product candidates, including GC4419 and GC4711, services and technologies. As the biotechnology and pharmaceutical 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, because some patent applications are maintained as confidential for a certain period of time, we cannot be certain that third parties have not filed patent applications that cover our product candidates, including GC4419 and GC4711, services and technologies. Therefore, it is uncertain whether the issuance of any third-party patent would require

us to alter our development or commercial strategies for our product candidates, including GC4419 and GC4711 or processes, or to obtain licenses or cease certain activities.

Patents could be issued to third parties that we may ultimately be found to infringe. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing products using our technology. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtain a license under the applicable patents, or until such patents expire or they are determined to be held invalid or unenforceable. Our failure to obtain or maintain a license to any technology that we require to develop or commercialize our current and future product candidates, including GC4419 and GC4711 may materially harm our business, financial condition and results of operations. Furthermore, we would be exposed to a threat of litigation.

From time to time, we may be party to, or threatened with, litigation or other proceedings with third parties, including non-practicing entities, who allege that our product candidates, including GC4419 and GC4711, components of our product candidates, including GC4419 and GC4711, services, and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. The types of situations in which we may become a party to such litigation or proceedings include:

- we or our collaborators may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our product candidates, including GC4419 and GC4711 or processes do not infringe those third parties' patents;
- we or our collaborators may participate at substantial cost in International Trade Commission proceedings to abate importation of third party products that would compete unfairly with our products;
- if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference, derivation or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position;
- if third parties initiate litigation claiming that our processes or product candidates, including GC4419 and GC4711 infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings;
- if third parties initiate litigation or other proceedings, including inter partes reviews, oppositions or other similar agency proceedings, seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their products, services, or technologies do not infringe our patents or patents licensed to us, we will need to defend against such proceedings;
- we may be subject to ownership disputes relating to intellectual property, including disputes arising from conflicting obligations of consultants or others who are involved in developing our product candidates, including GC4419 and GC4711; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or product candidates, including GC4419 and GC4711 infringe or misappropriate its patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings.

These lawsuits and proceedings, regardless of merit, are time-consuming and expensive to initiate, maintain, defend or settle, and could divert the time and attention of managerial and technical personnel, which could materially adversely affect our business. Any such claim could also force use to do one or more of the following:

- incur substantial monetary liability for infringement or other violations of intellectual property rights, which we may have to pay if a court decides that the product candidate, service, or technology at issue infringes or violates the third party's rights, and if the court finds that the infringement was wilful, we could be ordered to pay up to treble damages and the third party's attorneys' fees;
- pay substantial damages to our customers or end users to discontinue use or replace infringing technology with non-infringing technology;
- stop manufacturing, offering for sale, selling, using, importing, exporting or licensing the product or technology incorporating the allegedly infringing technology or stop incorporating the allegedly infringing technology into such product, service, or technology;
- obtain from the owner of the infringed intellectual property right a license, which may require us to pay substantial upfront fees or royalties to sell or use the relevant technology and which may not be available on commercially reasonable terms, or at all;
- redesign our product candidates, including GC4419 and GC4711, services, and technology so they do not infringe or violate the third party's intellectual property rights, which may not be possible or may require substantial monetary expenditures and time;
- enter into cross-licenses with our competitors, which could weaken our overall intellectual property position;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property against others;
- find alternative suppliers for non-infringing products and technologies, which could be costly and create significant delay; or
- relinquish rights associated with one or more of our patent claims, if our claims are held invalid or otherwise unenforceable.

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us from manufacturing, marketing or otherwise commercializing our products, services and technology. Any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operation, financial condition or cash flows.

In addition, we may indemnify our customers and distributors against claims relating to the infringement of intellectual property rights of third parties related to our product candidates, including GC4419 and GC4711. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers or distributors, or may be required to obtain licenses for the product candidates, including GC4419 and GC4711 or services they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products or services.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a material adverse effect on the price of our common stock. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. The occurrence of any of these events may have a material adverse effect on our business, results of operation, financial condition or cash flows.

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

In addition to patent and trademark protection, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Because we expect to rely on third parties to manufacture our product candidates, including GC4419 and GC4711, and we expect to continue to collaborate with third parties on the development of our product candidates, including GC4419 and GC4711, we must, at times, share trade secrets with them. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them prior to disclosing our proprietary information, such as our consultants and vendors, or our former or current employees. These agreements typically limit the rights of third parties to use or disclose our confidential information, including our trade secrets. We also enter into confidentiality and invention assignment agreements with our employees and consultants. Despite these efforts, however, any of these parties may breach the agreements and disclose our trade secrets and other unpatented or unregistered proprietary information, and once disclosed, we are likely to lose trade secret protection. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to enforce trade secret protection. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business, operating results and financial condition. Additionally, we cannot be certain that competitors will not gain access to our trade secrets and other proprietary confidential information or independently develop substantially equivalent information and techniques.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future product candidates, including GC4419 and GC4711 and processes.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology and pharmaceutical industries involves both technological and legal complexity, and is therefore costly, time consuming, and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith Act was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switched the United States patent system from a "first-to-invent" system to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had conceived or reduced to practice the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications

and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and pending patent applications. 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. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

The United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act, or the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. We partner with a number of universities, including the University of Iowa and the University of Texas Southwestern Medical Center, with respect to certain of our research, development and manufacturing. While it is our policy to avoid engaging our university partners in projects in which there is a risk that federal funds may be commingled, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

If we do not obtain patent term extensions in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation with respect to our product candidates, including GC4419 and GC4711, thereby potentially extending the term of marketing exclusivity for such product candidates, including GC4419 and GC4711, our business may be harmed.

In the United States, a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, including GC4419 and GC4711, 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 Act of 1984, or the Hatch-Waxman Act, which permits a patent term extension of up to a maximum of five years beyond the normal expiration of the patent if the patent is eligible for such an extension under the Hatch-Waxman Act as compensation for patent term lost during development and the FDA regulatory review process, which is limited to the approved indication (and potentially additional indications approved during the period of extension) covered by the patent. This extension is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request.

We may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such extension, the duration of such extension may be less than our request and the patent term may still expire before

or shortly after we receive FDA marketing approval. If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and pre-clinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional 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. Non-compliance 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. If we fail to maintain the patents and patent applications covering our product candidates, including GC4419 and GC4711 or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our own, which would have a material adverse effect on our business.

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.

We have not yet registered trademarks for a commercial trade name for our product candidate(s), including GC4419 and GC4711 in the United States or elsewhere. During trademark registration proceedings, our trademark application(s) may be rejected. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties can oppose pending trademark applications and seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we propose to use with our product candidate(s), including GC4419 and GC4711 in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition with potential partners or customers in our markets of interest. In addition, third parties have used trademarks similar and identical to our trademarks in foreign jurisdictions, and have filed or may in the future file for registration of such trademarks. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in challenging such third-party rights, we may not be able to use these trademarks to market our products in those countries. In any case, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

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

Certain of our key patent families have been filed in the United States, as well as in numerous jurisdictions outside the United States. However, our intellectual property rights in certain jurisdictions outside the United States may be less robust. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. For example, the requirements for patentability may differ in certain countries, particularly developing countries, and we may be unable to obtain issued patents that contain claims that adequately cover or protect our current or future product candidates, including GC4419 and GC4711. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market current or future product candidates, including GC4419 and GC4711. Consequently, we may not be able to prevent third parties from practicing our technology in all countries outside the United States, or from selling or importing products made using our technology in and into those other jurisdictions where we do not have intellectual property rights. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export 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 product candidates, including GC4419 and GC4711, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain and enforce adequate intellectual property protection for our technology.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market our product candidates, including GC4419 and GC4711.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates, including GC4419 and GC4711 in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates, including GC4419 and GC4711 could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates, including GC4419 and GC4711 or the use of our products. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates,

including GC4419 and GC4711. We may incorrectly determine that our product candidates, including GC4419 and GC4711 are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates, including GC4419 and GC4711 and services. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates, including GC4419 and GC4711 and services.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates, including GC4419 and GC4711 that are held to be infringing. We might, if possible, also be forced to redesign products, product candidates, including GC4419 and GC4711 or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Patent terms may be inadequate to protect our competitive position on our product candidates, including GC4419 and GC4711 for an adequate amount of time.

Patents have a limited lifespan, and the protection patents afford is limited. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Even if patents covering our product candidates, including GC4419 and GC4711 are obtained, once the patent life has expired for patents covering a product or product candidate, we may be open to competition from competitive products and services. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

While we seek broad coverage under our existing patent applications, there is always a risk that an alteration to products or processes may provide sufficient basis for a competitor to avoid infringing our patent claims. In addition, patents, if granted, expire and we cannot provide any assurance that any potentially issued patents will adequately protect our product candidates, including GC4419 and GC4711. Once granted, patents may remain open to invalidity challenges including opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether.

In addition, the degree of future protection afforded by our intellectual property rights is uncertain because even granted intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology, but that are not covered by the claims of the patents that we own or control, assuming such patents have issued or do issue;

- we or our licensors or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;

- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our product candidates, including GC4419 and GC4711 or technologies could use the intellectual property of others without obtaining a proper license;
- parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not develop or in-license additional proprietary technologies that are patentable;
- we may not be able to obtain and maintain necessary licenses on commercially reasonable terms, or at all; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.

We do and may employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our licensors, competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, and we are not currently subject to any claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties, we may in the future be subject to such claims.

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. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or product candidates, including GC4419 and GC4711. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees, and could result in customers seeking other sources for the technology, or in ceasing from doing business with us.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect 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.

In addition, while we typically require our employees, consultants and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. To the extent that we fail to obtain such assignments, such assignments do not contain a self-executing assignment of intellectual property rights or such assignment agreements are breached, we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property and this may interfere with our ability to capture the commercial value of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. We may be subject to claims that former collaborators or other third parties have an ownership interest in our patents or other intellectual property. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time-consuming. If we are unsuccessful, we could lose valuable rights in intellectual property that we regard as our own.

We may not be successful in obtaining necessary intellectual property rights to future products through acquisitions and in-licenses.

Although we intend to develop products and technology through our own internal research, we may also seek to acquire or in-license technologies to grow our product offerings and technology portfolio. However, we may be unable to acquire or in-license intellectual property rights relating to, or necessary for, any such products or technology from third parties on commercially reasonable terms or at all. In that event, we may be unable to develop or commercialize such products or technology. We may also be unable to identify products or technology that we believe are an appropriate strategic fit for our Company and protect intellectual property relating to, or necessary for, such products and technology.

The in-licensing and acquisition of third-party intellectual property rights for product candidates, including GC4419 and GC4711 is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights for products that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to successfully obtain rights to additional technologies or products, our business, financial condition, results of operations and prospects for growth could suffer.

In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for products and technologies that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may be unable to

in-license or acquire the third-party intellectual property rights for products or technology on terms that would allow us to make an appropriate return on our investment.

Other Risks Related to Our Business

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain 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 for, 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 U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal civil and criminal false claims and civil monetary penalties laws, including the civil False Claims Act, which prohibit, among other things, including through civil whistleblower or qui tam actions, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes which prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as certain health plans, healthcare clearinghouses and healthcare providers as well as their business associates, independent contractors of a covered entity that perform certain services involving the use or disclosure of individually identifiable health information;

- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under

Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the government information related to certain payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private 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 U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state 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; and

- similar healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and requirements regarding the collection, distribution, use, security, and storage of personally identifiable information and other data relating to individuals (including the EU General Data Protection Regulation 2016/679, or GDPR).

As of May 25, 2018, the GDPR replaced the Data Protection Directive with respect to the processing of personal data in the European Union. The GDPR imposes many requirements for controllers and processors of personal data, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention and secondary use of information, increased requirements pertaining to health data and pseudonymised (i.e., key-coded) data and additional obligations when we contract third-party processors in connection with the processing of the personal data. The GDPR allows EU member states to make additional laws and regulations further limiting the processing of genetic, biometric or health data. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

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. For example, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws and export and import restrictions;
- employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism, political unrest, outbreak of disease and boycotts;
- curtailment of trade, and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions or its anti-bribery provisions.

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.

Our internal computer systems, or those of our third-party CMOs, CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product candidates' development programs.

Despite the implementation of security measures, our internal computer systems and those of our third-party CMOs, CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, theft, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure or accident, from time to time, we have been the target of cybersecurity breach attempts and expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and becoming more prevalent. While these cybersecurity breaches have not had a material impact on our operations, future breaches may do so. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for our product candidates 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 results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure or theft of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed.

We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us.

Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the HITECH. We are not currently classified as a covered entity or business associate under HIPAA and thus are not subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Our clinical trial programs outside the United States may implicate international data protection laws, including the EU Data Protection Directive and legislation of the EU member states implementing it.

Our activities outside the United States impose additional compliance requirements and generate additional risks of enforcement for noncompliance. Failure by our CROs and other third-party contractors to comply with the strict rules on the transfer of personal data outside of the European Union into the United States may result in the imposition of criminal and administrative sanctions on such collaborators, which could adversely affect our business. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. Moreover, patients about whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

If we or third-party CMOs, CROs or other contractors or consultants fail to comply with applicable federal, state or local regulatory requirements, we could be subject to a range of regulatory actions that could

affect our or our contractors' ability to develop and commercialize our product candidates and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability, breaches of data security or reputational damage.

Violations of or liabilities under environmental, health and safety laws and regulations could subject us to fines, penalties or other 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, the handling, use, storage, treatment and disposal of hazardous materials and wastes and the cleanup of contaminated sites. Our operations involve the use of potentially hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We could incur substantial costs as a result of violations of or liabilities under environmental requirements in connection with our operations or property, including fines, penalties and other sanctions, investigation and cleanup costs and third-party claims. Although we generally contract with third parties for the disposal of hazardous materials and wastes from our operations, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources.

Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of changes to applicable laws and regulations and cannot be certain of our future 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.

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, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Insurance policies are expensive and leave the Company exposed to uninsured liabilities.

Some of the insurance policies we currently maintain include general liability, employment practices liability, property, workers' compensation, umbrella, and directors' and officers' insurance. These policies may not adequately cover all categories of risk that our business may encounter.

Any additional product liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for GC4419, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the development and commercialization of any product candidates we develop. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

We also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally.

Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our product candidates or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property or result in public exposure of personal information of our employees, clinical trial patients, customers and others. Furthermore, negative posts or comments about us or our product candidates in social media could seriously damage our reputation, brand image and goodwill. Any of these events could have a material adverse effect on our business, prospects, operating results and financial condition and could adversely affect the price of our common stock.

Our employees and independent contractors, including consultants, vendors, and any third parties we may engage in connection with development and commercialization may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could harm our business.

Misconduct by our employees and independent contractors, including consultants, vendors, and any third parties we may engage in connection with development and commercialization, could include intentional, reckless or negligent conduct or unauthorized activities that violate: (i) the laws and regulations of the FDA, the EMA and other comparable regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) data privacy, security, fraud and abuse and other healthcare laws and regulations; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in pre-clinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

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

Natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities on which we rely, 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.

We may acquire businesses, or products or product candidates, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

We have acquired and in-licensed, and may acquire or in-license additional businesses or products, from other companies or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition or license, we will achieve the expected synergies to justify the transaction.

The impact of the Tax Act on our financial results is not entirely clear and could differ materially from the financial statements provided herein.

On December 22, 2017, the United States enacted the Tax Act, which significantly reformed the U.S. Internal Revenue Code of 1986, as amended, or the Code. Among a number of significant changes to the current U.S. federal income tax rules, the Tax Act reduced the marginal U.S. corporate income tax rate from 35% to 21%, limited the deduction for net interest expense, shifted the United States toward a more territorial tax system, and imposed new taxes to combat erosion of the U.S. federal income tax base. The financial statements contained herein reflect the effects of the Tax Act based on current guidance. However, there remain uncertainties and ambiguities in the application of certain provisions of the Tax Act, and, as a result, we made certain judgments and assumptions in the interpretation thereof. The U.S. Treasury Department and the Internal Revenue Service may issue further guidance on how the provisions of the Tax Act will be applied or otherwise administered that differs from our current interpretation. In addition, the Tax Act could be subject to potential amendments and technical corrections, any of which could materially lessen or increase certain adverse impacts of the legislation on us. As we further analyze the impact of the Tax Act and collect relevant information to complete our computations of the related accounting impact, we may make adjustments to the provisional amounts that could materially affect our provision.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.

In general, under Section 382 of the Code, a corporation that undergoes an “ownership change,” generally defined as a greater than 50% change by value in its equity ownership over a three year period, is subject to limitations on its ability to utilize its pre change net operating losses, or NOLs, to offset future taxable income. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs could be further limited by Section 382 of the Code. Future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Code. For these reasons, in the event we experience a change of control, we may not be able to utilize a material portion of the NOLs even if we attain profitability.

We are a multinational company that faces complex taxation regimes in various jurisdictions. Audits, investigations, and tax proceedings could have a material adverse effect on our business, results of operations, and financial condition.

We are subject to income and non-income taxes in multiple jurisdictions. Income tax accounting often involves complex issues, and judgment is required in determining our worldwide provision for income taxes and other tax liabilities. In particular, the jurisdictions in which we operate have detailed transfer pricing rules, which require that all transactions with non-resident related parties be priced using arm's length pricing principles within the meaning of such rules. We could be subject to tax audits involving transfer pricing issues. We believe that our tax positions are reasonable and our tax reserves are adequate to cover any potential liability. However, tax authorities in certain jurisdictions may disagree with our position, including the propriety of our related party arm's length transfer pricing policies and the tax treatment of corresponding expenses and income. If any of these tax authorities were successful in challenging our positions, we may be liable for additional income tax and penalties and interest related thereto in excess of any reserves established therefor, which may have a significant impact on our results and operations and future cash flow.

Risks Related to Our Common Stock and This Offering

An active trading market for our common stock may not develop, 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 our common stock. Although we intend to list our common stock on The Nasdaq Global Market, an active trading market for our common stock may never develop or be sustained following this offering. The initial public offering price of our common stock will be determined through negotiations between us and the underwriters. This initial public offering price may not be indicative of the market price of our common stock after this offering. In the absence of an active trading market for our common stock, investors may not be able to sell their common stock at or above the initial public offering price or at the time that they would like to sell.

The price of our common stock is likely to be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

Our share price is likely to be volatile. The shares market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the initial public offering price. The market price for our common stock may be influenced by many factors, including:

- the results of clinical trials for our product candidates;
- delays in the commencement, enrollment and the ultimate completion of clinical trials;
- the results and potential impact of competitive products or technologies;
- our ability to manufacture and successfully produce our product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- the level of expenses related to any of our product candidates or clinical development programs;
- variations in our financial results or those of companies that are perceived to be similar to us;

- financing or other corporate transactions, or inability to obtain additional funding;
- failure to meet or exceed expectations of the investment community;
- regulatory or legal developments in the United States and other countries;
- the recruitment or departure of key personnel;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions;
- changes in voting control of our executive officers and certain other members of our senior management or affiliates who hold our shares; and
- the other factors described in this “Risk Factors” section.

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

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. We do not currently have and may never obtain research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock after this offering, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our shares could decline if one or more equity research analysts downgrades our shares or issues other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause the price of our common stock or its trading volume to decline.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that these sales may occur, could result in a decrease in the market price of our common stock. Immediately after this offering, we will have outstanding shares of common stock, based on the number of shares common stock outstanding as of , 2019, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into shares of our common stock immediately prior to the closing of this offering. This includes the shares of our common stock that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates or existing stockholders. Of the remaining shares, shares are currently restricted as a result of securities laws or 180-day lock-up agreements (which may be waived, with or without notice, by Merrill Lynch, Pierce, Fenner & Smith Incorporated and Citigroup Global Markets Inc.) but will be able to be sold beginning 180 days after this offering, unless held by one of our affiliates, in which case

the resale of those securities will be subject to volume limitations under Rule 144 of the Securities Act of 1933, as amended. See "Shares Eligible for Future Sale." Moreover, after this offering, holders of an aggregate of up to shares of our common stock, including shares of our common stock issued upon the automatic conversion of all outstanding shares of our redeemable convertible preferred stock immediately prior to the closing of this offering, will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders as described in the section of this prospectus entitled "Description of Capital Stock—Registration Rights." We also intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market, subject to volume limitations applicable to affiliates and the lock-up agreements referred to above and described in the section of this prospectus entitled "Underwriting."

If you purchase shares of our common stock in this offering, you will suffer immediate dilution of your investment.

The initial public offering price of our common stock is substantially higher than the as adjusted net tangible book value per share of common stock. Therefore, if you purchase common stock in this offering, you will pay a price per share of our common stock that substantially exceeds our as adjusted net tangible book value per share of common stock after this offering. To the extent outstanding options are exercised, you will incur further dilution. Based on 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, you will experience immediate dilution of $ per share of common stock, representing the difference between our as adjusted net tangible book value per share of common stock after giving effect to this offering and the initial public offering price. In addition, purchasers of common stock in this offering will have contributed approximately % of the aggregate price paid by all purchasers of our common stock but will own only approximately % of our common stock outstanding after this offering. See "Dilution."

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our common stock price to fall.

We will need additional capital in the future to continue our planned operations. To the extent we raise additional capital by issuing additional common stock or other equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

After this offering, our officers, directors and principal stockholders each holding more than 5% of our common stock, collectively, will control approximately % of our outstanding common stock. As a result, these stockholders, if they act together, will be able to control the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could attempt to delay or prevent a change in control of us, even if such change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of us or our assets, and might affect the prevailing market price of our common stock due to investors' perceptions that conflicts of interest may exist or arise. As a result, this concentration of ownership may not be in the best interests of our other stockholders.

We have broad discretion in how we use the proceeds of this offering and may not use these proceeds effectively, which could affect our results of operations and cause our shares price to decline.

We will have considerable discretion in the application of the net proceeds of this offering. We intend to use the net proceeds from this offering, together with our existing cash resources, to fund our clinical development programs, working capital and other general corporate purposes. We may also use a portion of the net proceeds from this offering to in-license, acquire or invest in additional businesses, technologies, products or assets, although currently we have no specific agreements, commitments or understandings in this regard. As a result, investors will be relying upon management's judgment with only limited information about our specific intentions for the use of the balance of the net proceeds of this offering. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

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

We are an "emerging growth company," as defined in the JOBS Act. We will remain an emerging growth company until the earlier of (a) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (b) the last day of the fiscal year following the fifth anniversary of the date of the completion of this offering; (c) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (d) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404;
- an exemption from compliance with the requirement of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements;
- providing only two years of audited financial statements in addition to any required unaudited interim financial statements and a correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In this prospectus, we have not included all of the executive compensation-related information that would be required if we were not an emerging growth company.

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 provided only two years of audited financial statements and have not included all of the executive compensation information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our shares price may be more volatile.

We are a "smaller reporting company" and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are considered a "smaller reporting company." We are therefore entitled to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. We are also exempt from the requirement to obtain an external audit on the effectiveness of internal control over financial reporting provided in Section 404(b) of the Sarbanes-Oxley Act. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company mean our auditors do not review our internal control over financial reporting and may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock prices may be more volatile.

Because we have opted to take advantage of the JOBS Act provision which allows us to delay implementing new accounting standards, our consolidated financial statements may not be directly comparable to those of other public companies.

Pursuant to 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. 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. Because we have elected to take advantage of this provision of the JOBS Act, our consolidated financial statements and the reported results of operations contained therein may not be directly comparable to those of other public companies.

We will incur 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, and particularly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the Securities and Exchange Commission and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance.

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed

timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

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

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Moreover, 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, which prohibits a person who owns in excess of 15%

of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Furthermore, our amended and restated certificate of incorporation, which will become effective upon the closing of this offering, specifies that, 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 most legal actions involving claims brought against us by stockholders. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above.

We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. Additionally, the proposal to pay future dividends to stockholders will in addition effectively be at the sole discretion of our board of directors after taking into account various factors our board of directors deems relevant, including our business prospects, capital requirements, financial performance and new product development. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements concerning:

- our plans to develop and commercialize our product candidates;
- the timing of our ongoing or planned clinical trials for GC4419, GC4711 and our other product candidates;
- the timing of our NDA submission for GC4419 for the reduction of the incidence of SOM induced by radiotherapy with or without systemic therapy;
- the timing of and our ability to obtain and maintain regulatory approvals for GC4419, GC4711 and our other product candidates;
- the clinical utility of our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our expectations about the willingness of healthcare professionals to use GC4419, GC4711 and our other product candidates;
- our intellectual property position;
- our expected use of proceeds from this offering;
- our competitive position and the development of and projections relating to our competitors or our industry;
- our ability to identify, recruit and retain key personnel;
- the impact of laws and regulations;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- our plans to identify additional product candidates with significant commercial potential that are consistent with our commercial objectives; and
- our estimates regarding future revenue, expenses and needs for additional financing.

The forward-looking statements in this prospectus are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the sections in this prospectus entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. The forward-looking statements contained in this prospectus are excluded from the safe harbor protection provided by the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended.

MARKET AND INDUSTRY DATA

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations, market position and market opportunity, is based on our management's estimates and research, as well as industry and general publications and research, surveys and studies conducted by third parties. While we believe these publications, research surveys and studies to be reliable, we have not independently verified data from the third party sources. Management's estimates are derived from publicly available information, their knowledge of our industry and their assumptions based on such information and knowledge, which we believe to be reasonable. This data involves a number of assumptions and limitations which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates.

USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately $ million, assuming an 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 the estimated 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, we estimate that our net proceeds will be approximately $ million.

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share would increase or decrease 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 the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase or decrease of 1.0 million in the number of shares we are offering would increase or decrease the net proceeds to us from this offering by approximately $ million, assuming the assumed initial public offering price stays the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering, together with our existing cash resources, to fund the clinical development of GC4419 and GC4711. The remaining proceeds will be used for working capital and general corporate purposes.

As of the date of this prospectus, we cannot estimate with certainty the amount of net proceeds to be used for the purposes described above. This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. We may also use a portion of the net proceeds from this offering to acquire, in-license or invest in products, technologies or businesses that are complementary to our business. However, we currently have no agreements or commitments to complete any such transaction. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds.

We anticipate that our existing cash and cash equivalents and short-term investments, together with the anticipated net proceeds from this offering, will be sufficient to fund our operating expenses and capital expenditure requirements into . We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. Following this offering, we will require substantial capital to complete clinical development, seek regulatory approval of, and, if approved, commercialize our product candidates. We may satisfy our future cash needs through the sale of equity securities, debt financings, working capital lines of credit, corporate collaborations or license agreements, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources.

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

DIVIDEND POLICY

We have never declared or paid any dividends on our capital stock. We currently intend to retain all available funds and any future earnings, if any, for the operation and expansion of our business and, therefore, we do not anticipate declaring or paying cash dividends in the foreseeable future. The payment of dividends, if any, will be at the discretion of our board of directors and will depend on our results of operations, capital requirements, financial condition, prospects, contractual arrangements, any limitations on payment of dividends present in our future debt agreements, and other factors that our board of directors may deem relevant. Our ability to pay cash dividends on our capital stock in the future may also be limited by the terms of any preferred securities we may issue or agreements governing any additional indebtedness we may incur.

CAPITALIZATION

The following table sets forth our cash, cash equivalents and short-term investments and our capitalization as of December 31, 2018 on:

- an actual basis;
- a pro forma basis to reflect (1) the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 96,385,795 shares of common stock upon the completion of this offering, and (2) the effectiveness of our amended and restated certificate of incorporation; and
- a pro forma as adjusted basis to reflect the pro forma adjustments described above, and giving further effect to the sale of shares of our common stock in this offering at an 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, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this information in conjunction with our financial statements and the related notes appearing at the end of this prospectus, the information set forth under the headings “Use of Proceeds,” “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the other financial information contained in this prospectus.

	As of December 31, 2018		
	Actual	Pro Forma (unaudited)	Pro Forma As Adjusted(1) (unaudited)
	(in thousands, except share and per share data)		
Cash, cash equivalents and short-term investments	$ 81,517	$ 81,517	$
Royalty purchase liability	$ 20,220	$ 20,220	$
Redeemable convertible preferred stock, $0.001 par value per share; 96,385,795 shares authorized, issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	165,902	—	
Stockholders’ (deficit) equity:			
Preferred stock, $0.001 par value per share; no shares authorized, issued and outstanding, actual; shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	
Common stock, $0.001 par value per share; 115,000,000 shares authorized, 1,520,000 shares issued and outstanding, actual; shares authorized, 97,905,795 shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted	2	98	
Additional paid-in capital	—	165,806	
Accumulated other comprehensive income	3	3	
Accumulated deficit	(104,825)	(104,825)	
Total stockholders’ (deficit) equity	(104,820)	61,082	
Total capitalization	$ 81,302	$ 81,302	$

(1) The pro forma as adjusted information is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each $1.00 increase or 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 or decrease pro forma as adjusted cash, cash equivalents and short-term investments, 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, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. A 1,000,000 share increase or decrease in the number of shares offered by us would increase or decrease pro forma as adjusted cash, cash equivalents and short-term investments, additional paid-in capital, total stockholders' (deficit) equity and total capitalization by approximately $ million, assuming that the assumed initial price to public remains the same, and after deducting estimated underwriting discounts and commissions payable by us.

The number of shares of our common stock shown as issued and outstanding in the table above is based on shares of common stock outstanding as of December 31, 2018, and excludes:

- shares of common stock issuable upon the exercise of options outstanding as of December 31, 2018, at a weighted-average exercise price of $ per share;
- shares of common stock reserved for future issuance pursuant to our Existing Equity Incentive Plan; and
- shares of common stock reserved for future issuance pursuant to our 2019 Plan, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part.

DILUTION

If you invest in our common stock, your 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 per share of our common stock immediately after the completion of this offering.

Our historical net tangible book value (deficit) as of December 31, 2018 was $(108.0) million, or $(71.03) per share of common stock. Our historical net tangible book value (deficit) per share represents our total tangible assets (total assets less intangible assets and goodwill) less our total liabilities and redeemable convertible preferred stock (which is not included within stockholders' deficit), divided by the number of shares of common stock outstanding as of December 31, 2018.

Our pro forma net tangible book value as of December 31, 2018 was $57.9 million, or $0.59 per share of common stock. Pro forma net tangible book value per share represents our total tangible assets less our total liabilities, divided by the number of shares of common stock outstanding as of December 31, 2018, after giving effect to the automatic conversion of all of our outstanding shares of redeemable convertible preferred stock into 96,385,795 shares of common stock upon the completion of this offering.

Our pro forma as adjusted net tangible book value represents our pro forma net tangible book 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, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Our pro forma as adjusted net tangible book value as of December 31, 2018 was $ million, or $ per share of common stock. This amount represents an immediate increase in pro forma as adjusted net tangible book value of $ per share to our existing stockholders and an immediate dilution of $ per share to investors participating in this offering. We determine dilution per share to investors participating in this offering by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by investors participating in this offering.

The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share		$
Historical net tangible book value (deficit) per share as of December 31, 2018	$(71.03)	
Increase per share attributable to the pro forma transactions described above	71.62	
Pro forma net tangible book value per share as of December 31, 2018	0.59	
Increase in pro forma net tangible book value per share attributable to new investors purchasing shares from us in this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to new investors in this offering		$

Each $1.00 increase or 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 or decrease the pro forma as adjusted net tangible book value per share after this offering by $ per share and the dilution per share to investors participating in this offering by $ per share, 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. A 1,000,000 share increase in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase the pro forma as adjusted net tangible book value per share by $ and decrease the dilution per share to investors participating in this offering by $, assuming 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,

remains the same and after deducting estimated underwriting discounts and commissions payable by us. A 1,000,000 share decrease in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease the pro forma as adjusted net tangible book value per share after this offering by $ and increase the dilution per share to new investors participating in this offering by $, assuming 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, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information discussed above is illustrative only and will adjust based on the actual initial price to public and other terms of this offering determined at pricing.

If the underwriters exercise their option to purchase an additional shares of our common stock in this offering in full, the pro forma as adjusted net tangible book value of our common stock would increase to $ per share, representing an immediate increase to existing stockholders of $ per share and an immediate dilution of $ per share to new investors participating in this offering.

The following table summarizes as of December 31, 2018, on the pro forma as adjusted basis described above, the number of shares of our common stock, the total consideration and the average price per share (1) paid to us by our existing stockholders and (2) to be paid by investors purchasing our common stock in this offering at an 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, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders		%	$	%	$
New investors					
Total		100%	$	100%	

Each $1.00 increase or 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 or decrease the total consideration paid by new investors and the average price per share paid by new investors by $ million and $ per share, respectively. An increase or decrease of 1.0 million shares in the number of shares offered by us would increase or decrease the consideration paid by new investors and the average price per share paid by new investors by $ million and $ per share, respectively.

If the underwriters exercise their option to purchase additional shares of our common stock in full, the total consideration paid by new investors and the average price per share paid by new investors would be approximately $ million and $ per share, respectively, in each case assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

The tables and calculations above are based on shares of common stock outstanding as of December 31, 2018, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into shares of our common stock immediately prior to the closing of this offering, and excludes:

- shares of common stock issuable upon the exercise of options outstanding as of December 31, 2018, at a weighted-average exercise price of $ per share;
- shares of common stock reserved for future issuance pursuant to our Existing Equity Incentive Plan; and

- shares of common stock reserved for future issuance pursuant to our 2019 Plan, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part.

To the extent that any outstanding options are exercised, new options or other securities are issued under our equity incentive plans, or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

SELECTED CONSOLIDATED FINANCIAL DATA

We derived the selected consolidated statements of operations data for the years ended December 31, 2017 and 2018 and the selected consolidated balance sheet data as of December 31, 2017 and 2018 from our audited consolidated financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future.

When you read this selected consolidated financial data, it is important that you read it together with the historical audited consolidated financial statements and related notes, as well as the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," each as included elsewhere in this prospectus.

	Year ended December 31,	
	2017	2018
	(in thousands, except share and per share data)	
Consolidated Statements of Operations Data:		
Operating expenses:		
Research and development	$ 20,594	$ 18,663
General and administrative	3,500	5,592
Loss from operations	(24,094)	(24,255)
Other income (expenses):		
Interest income	193	606
Interest expense	—	(220)
Foreign currency loss	(4)	(30)
Loss from operations before income tax benefit	(23,905)	(23,889)
Income tax benefit	360	223
Net loss	(23,545)	(23,676)
Accretion of redeemable convertible preferred stock to redemption value	(4,588)	(5,910)
Net loss attributable to common stockholders	$ (28,133)	$ (29,586)
Net loss per share of common stock, basic and diluted(1)	$ (18.51)	$ (19.46)
Weighted-average shares of common stock outstanding, basic and diluted(1)	1,520,000	1,520,000
Pro forma net loss per share of common stock, basic and diluted (unaudited)(1)		$ (0.31)
Pro forma weighted-average shares of common stock outstanding, basic and diluted (unaudited)(1)		76,977,463

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

	As of December 31,	
	2017	2018
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 14,180	$ 81,517
Working capital(1)	10,872	77,408
Total assets	18,872	88,056
Royalty purchase liability	—	20,220
Redeemable convertible preferred stock	90,148	165,902
Accumulated deficit	(76,104)	(104,825)
Total stockholders' deficit	(76,105)	(104,820)

(1) We define working capital as current assets less current liabilities.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included elsewhere in this prospectus. Some of the information contained in this discussion and analysis contains forward-looking statements that involve risks and uncertainties. You should review the section titled "Risk Factors" in this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described below.

Overview

We are a clinical stage biopharmaceutical company focused on developing and commercializing a pipeline of novel, proprietary therapeutics that have the potential to transform radiotherapy in cancer. We leverage our expertise in superoxide dismutase mimetics to design drugs to reduce normal tissue toxicity from radiotherapy and to increase the anti-cancer efficacy of radiotherapy. Our lead product candidate, GC4419, is a potent and highly selective small molecule dismutase mimetic we are initially developing for the reduction of SOM. SOM is a common, debilitating complication of radiotherapy in patients with head and neck cancer, or HNC. In February 2018, the FDA granted Breakthrough Therapy Designation to GC4419 for the reduction of the duration, incidence and severity of SOM induced by radiotherapy with or without systemic therapy. In October 2018, we began evaluating GC4419 in a Phase 3 registrational trial and we expect to report top-line data in . We believe GC4419 can become the first FDA-approved drug and the standard of care for the reduction in the incidence of SOM in patients with HNC receiving radiotherapy, and we plan to expand its use into other radiotherapy-induced toxicities, including esophagitis.

Since our inception, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, acquiring and developing product and technology rights, and conducting research and development. We have incurred recurring losses and negative cash flows from operations and have funded our operations primarily through the sale and issuance of redeemable convertible preferred stock and proceeds received under the Royalty Agreement with Clarus, receiving aggregate gross proceeds of $167.8 million. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates. Our net loss was $23.5 million and $23.7 million for the years ended December 31, 2017 and 2018, respectively. As of December 31, 2018, we had $81.5 million in cash, cash equivalents and short-term investments and an accumulated deficit of $104.8 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through all stages of development and clinical trials and, ultimately, seek regulatory approval. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

As a result, we will need to raise substantial additional capital to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we plan to finance our operations through the sale of equity, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing as and when needed to finance our operations on terms acceptable to us or at all. If we are unable to secure adequate additional funding as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain

profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

We expect our existing cash, cash equivalents and short-term investments, together with the net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements into . See "Use of Proceeds."

Components of Results of Operations

Research and Development Expense

Research and development expenses consist primarily of costs incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred. These expenses include:

- expenses incurred to conduct the necessary pre-clinical studies and clinical trials required to obtain regulatory approval;
- personnel expenses, including salaries, benefits and share-based compensation expense for employees engaged in research and development functions;
- costs of funding research performed by third parties, including pursuant to agreements with CROs, as well as investigative sites and consultants that conduct our pre-clinical studies and clinical trials;
- expenses incurred under agreements with CMOs, including manufacturing scale-up expenses and the cost of acquiring and manufacturing pre-clinical study and clinical trial materials;
- consultant fees who assist with research and development activities;
- expenses related for regulatory activities, including filing fees paid to regulatory agencies; and
- allocated expenses for facility costs, including rent, utilities, depreciation and maintenance.

We track our external research and development expenses on a program-by-program basis, such as fees paid to CROs, CMOs and research laboratories in connection with our pre-clinical development, process development, manufacturing and clinical development activities. However, we do not track our internal research and development expenses on a program-by-program basis as they primarily relate to compensation, early research and other costs which are deployed across multiple projects under development.

The following table summarizes our research and development expenses by program for the years ended December 31, 2017 and 2018:

	Year ended December 31,	
	2017	2018
	(in thousands)	
GC4419	$12,610	$10,812
GC4711	2,670	2,696
Other research and development expense	1,830	765
Personnel related and share-based compensation expense	3,484	4,390
	$20,594	$18,663

Research and development activities are central to our business model. Product candidates in later stages of clinical development, such as GC4419, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase significantly over the next several years as we increase personnel costs, including stock-based compensation, conduct our later-stage clinical trials for GC4419 and GC4711 and conduct other clinical trials for current and future product candidates and prepare regulatory filings for our product candidates.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of our product candidates, or when, if ever, material net cash inflows may commence from our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- delays in regulators or institutional review boards authorizing us or our investigators to commence our clinical trials, or in our ability to negotiate agreements with clinical trial sites or CROs;
- our ability to secure adequate supply of our product candidates for our trials;
- the number of clinical sites included in the trials;
- the ability and the length of time required to enroll suitable patients;
- the number of patients that ultimately participate in the trials;
- the number of doses patients receive;
- any side effects associated with our product candidates;
- the duration of patient follow-up;
- the results of our clinical trials;
- significant and changing government regulations; and
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals. We may never succeed in achieving regulatory approval for our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of our product candidates. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Product commercialization will take several years, and we expect to spend a significant amount in development costs.

General and Administrative Expense

General and administrative expense consists primarily of personnel expenses, including salaries, benefits and share-based compensation expense, for employees in executive, finance, accounting, business

development and human resource functions. General and administrative expense also includes corporate facility costs, including rent, utilities, depreciation and maintenance, not otherwise included in research and development expense, as well as legal fees related to intellectual property and corporate matters and fees for accounting and consulting services.

We expect that our general and administrative expense will increase in the future to support our continued research and development activities, potential commercialization efforts and increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, lawyers and accountants, among other expenses. Additionally, we anticipate increased costs associated with being a public company, including expenses related to services associated with maintaining compliance with the requirements of Nasdaq and the SEC, insurance and investor relations costs. If any of our current or future product candidates obtains U.S. regulatory approval, we expect that we would incur significantly increased expenses associated with building a sales and marketing team.

Interest Income

Interest income consists of amounts earned on our cash, cash equivalents and short-term investments held with large institutional banks, U.S. Treasury obligations and a money market mutual fund invested in U.S. Treasury obligations, and our short-term investments in U.S. Treasury obligations.

Interest Expense

Interest expense consists of non-cash interest on proceeds received under the Royalty Agreement with Clarus.

Foreign Currency Losses

Foreign currency losses consist primarily of exchange rate fluctuations on transactions denominated in a currency other than the U.S. dollar.

Income Tax Benefit

Since inception, we have incurred significant net losses, and until 2017 we had not recorded any U.S. federal or state income tax benefits for the losses as they had been offset by valuation allowances. We recognized an income tax benefit for the revaluation of our deferred tax liability as a result of the Tax Act, which reduced our corporate tax rate to 21% during the year ended December 31, 2017. As a result of the change in the net operating loss carryforward period associated with the Tax Act, we recognized an income tax benefit to utilize indefinite deferred tax liabilities as a source of income against indefinite lived portions of our deferred tax assets during the year ended December 31, 2018.

Net Operating Loss and Research and Development Tax Credit Carryforwards

As of December 31, 2018, we had federal and state tax net operating loss carryforwards of $64.5 million and $81.8 million, respectively, which each begin to expire in 2032 unless previously utilized. We also had foreign net operating loss carryforwards of $0.8 million which begin to expire in 2032. As of December 31, 2018, we also had federal and state research and development tax credit carryforwards of $2.3 million. The federal research and development tax credit carryforwards will begin to expire in 2032 unless previously utilized.

Utilization of the federal and state net operating losses and credits may be subject to a substantial annual limitation. The annual limitation may result in the expiration of our net operating losses and credits before we can use them. We have recorded a valuation allowance on substantially all of our deferred tax assets, including our deferred tax assets related to our net operating loss and research and development tax credit carryforwards.

Results of Operations

The following table sets forth our results of operations for the years ended December 31, 2017 and 2018.

	Year ended December 31,	
	2017	2018
	(in thousands)	
Operating expenses:		
Research and development	$ 20,594	$ 18,663
General and administrative	3,500	5,592
Loss from operations	(24,094)	(24,255)
Other income (expenses):		
Interest income	193	606
Interest expense	—	(220)
Foreign currency loss	(4)	(30)
Loss from operations before income tax benefit	(23,905)	(23,899)
Income tax benefit	360	223
Net loss	$ (23,545)	$ (23,676)

Comparison of the Years Ended December 31, 2017 and 2018

Research and Development Expense

Research and development expense decreased by $1.9 million from $20.6 million for the year ended December 31, 2017 to $18.7 million for the year ended December 31, 2018. The decrease was primarily attributable to a $1.8 million decrease for GC4419 development costs as we substantially completed our Phase 2 clinical trial by the end of fiscal 2017. We also had $1.1 million in other research and development expenses in 2017 that did not recur in 2018 as we focused on preparing for our Phase 3 clinical trial for GC4419. These decreases were primarily offset by a $0.9 million increase in personnel related and share-based compensation expense due to increases in employee compensation and related costs and the increase in the number of consultants we engaged in 2018 as we increased our development activities.

General and Administrative Expense

General and administrative expense increased by $2.1 million from $3.5 million for the year ended December 31, 2017 to $5.6 million for the year ended December 31, 2018. The increase was primarily due to marketing studies for our product candidates, and an increase in professional fees.

Interest Income

Interest income increased by $0.4 million from $0.2 million for the year ended December 31, 2017 to $0.6 million for the year ended December 31, 2018. The increase was primarily due to higher average invested cash balances and higher interest rates on U.S. Treasury securities in 2018.

Interest Expense

We recognized $0.2 million in non-cash interest expense during the year ended December 31, 2018 in connection with the Royalty Agreement with Clarus.

Income Tax Benefit

As a result of the change in the corporate tax rate associated with the Tax Act, we recognized an income tax benefit of $0.4 million during the year ended December 31, 2017. We recorded an income tax benefit of $0.2 million during the year ended December 31, 2018 as a result of the change in the net operating loss carryforward period to reflect the adjustment allowed by the Tax Act to utilize indefinite deferred tax liabilities as a source of income against indefinite lived portions of our deferred tax assets.

Liquidity and Capital Resources

Since inception, we have funded our operations primarily through the sale and issuance of redeemable convertible preferred stock and proceeds received under the Royalty Agreement with Clarus, receiving aggregate gross proceeds of $167.8 million. As of December 31, 2018, we had $81.5 million in cash, cash equivalents and short-term investments and an accumulated deficit of $104.8 million. We have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years.

Cash Flows

The following table shows a summary of our cash flows for the periods indicated:

	Year ended December 31,	
	2017	2018
	(in thousands)	
Net cash used in operating activities	$ (23,406)	$ (22,166)
Net cash provided by (used in) investing activities	23,512	(59,036)
Net cash provided by financing activities	—	89,844
Net increase in cash and cash equivalents	$ 106	$ 8,642

Operating Activities

During the year ended December 31, 2017, we used $23.4 million of net cash in operating activities. Cash used in operating activities reflected our net loss of $23.5 million and a $0.7 million net increase in our operating assets and liabilities. The primary use of cash was to fund our operations related to the development of our product candidates. These activities were offset by non-cash charges of $0.8 million principally related to stock-based compensation expenses and depreciation expense.

During the year ended December 31, 2018, we used $22.2 million of net cash in operating activities. Cash used in operating activities reflected our net loss of $23.7 million and a $0.3 million net increase in our operating assets and liabilities. These activities were offset by non-cash charges of $1.2 million related to share-based compensation, interest expense on our Royalty Agreement with Clarus and depreciation expense.

Investing Activities

During the year ended December 31, 2017, investing activities provided $23.5 million in net cash proceeds and were primarily attributable to the $23.8 million in net cash proceeds received from the purchases and sales of our short-term investments that were offset by the $0.3 million for the purchase of property and equipment.

During the year ended December 31, 2018, we used $59.0 million of net cash in investing activities, primarily attributable to the $58.7 million in net purchases of our short-term investments and $0.3 million for the purchase of property and equipment.

Financing Activities

There were no cash flows from financing activities during the year ended December 31, 2017.

During the year ended December 31, 2018, financing activities provided $89.8 million in net cash proceeds, primarily attributable to $69.8 million in net proceeds from the sale of our Series C redeemable convertible preferred stock and $20.0 million in proceeds received in connection with the Royalty Agreement with Clarus.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue or initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, following the completion of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We anticipate that our expenses will increase substantially as we:

- complete clinical development of GC4419 for the reduction of SOM in patients with locally advanced HNC, including our ongoing Phase 3 clinical trial;
- prepare and file for regulatory approval of GC4419 for the reduction of SOM in patients with HNC;
- initiate and advance our planned Phase 2a clinical trial of GC4419 for the reduction in the incidence of radiotherapy-induced esophagitis;
- initiate and advance our planned Phase 1b/2a clinical trial for GC4711 to increase the anti-cancer efficacy of SBRT in patients with NSCLC;
- seek to discover and develop additional clinical and pre-clinical product candidates;
- scale up our clinical and regulatory capabilities;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional internal or external clinical, manufacturing and scientific personnel or consultants;
- add operational, financial and management information systems and personnel, including personnel to support our product development efforts; and
- incur additional legal, accounting and other expenses in operating as a public company.

We expect our existing cash, cash equivalents and short-term investments, together with the net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements into . See "Use of Proceeds."

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, results and costs of pre-clinical studies and clinical trials;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates.

Identifying potential product candidates and conducting pre-clinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available for the next couple of years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

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

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Royalty Agreement with Clarus

In November 2018, we entered into an Amended and Restated Purchase and Sale Agreement, or the Royalty Agreement, by and among us, Clarus IV Galera Royalty AIV, L.P., Clarus IV-A, L.P., Clarus IV-B, L.P., Clarus IV-C, L.P. and Clarus IV-D, L.P., or, collectively, Clarus. Pursuant to the Royalty Agreement, Clarus agreed to pay us, in the aggregate, up to $80 million, or the Royalty Purchase Price, in four tranches of $20 million each upon the achievement of specified clinical milestones in our ROMAN Trial. We agreed to apply the proceeds from such payments primarily to support clinical development and regulatory activities for GC4419, GC4711 and any pharmaceutical product comprising or containing GC4419 or GC4711, or, collectively, the Products, as well as to satisfy working capital obligations and for general corporate expenses. We achieved the first milestone under the Royalty Agreement and received the first tranche of the Royalty Purchase Price in November 2018.

In connection with the payment of each tranche of the Royalty Purchase Price, we have agreed to sell, convey, transfer and assign to Clarus all of our right, title and interest in a mid-single digit percentage of (i) the gross amount from the worldwide net sale of the Products and (ii) all amounts received by us or our affiliates, licensees and sublicensees (collectively, the Product Payments) during the Royalty Period. The Royalty Period means, on a Product-by-Product and country-by-country basis, the period of time commencing on the commercial launch of such Product in such country and ending on the latest to occur of (i) the 12th anniversary of such commercial launch, (ii) the expiration of all valid claims of our patents covering such Product in such country, and (iii) the expiration of regulatory data protection or market exclusivity or similar regulatory protection afforded by the health authorities in such country, to the extent such protection or exclusivity effectively prevents generic versions of such Product from entering the market in such country.

The Royalty Agreement will remain in effect until the date on which the aggregate amount of the Product Payments paid to Clarus exceeds a fixed single-digit multiple of the actual amount of the Royalty Purchase Price received by us, unless earlier terminated pursuant to the mutual written agreement of us and Clarus.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments at December 31, 2018:

	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
			(in thousands)		
Operating leases(1)	$ 440	$1,243	$ 65	$ —	$1,748
Total	$ 440	$1,243	$ 65	$ —	$1,748

(1) Reflects obligations pursuant to our office leases in Malvern, Pennsylvania and St. Louis, Missouri.

The commitment amounts in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, including fixed or minimum services to be used, fixed, minimum or variable price provisions, and the approximate timing of the actions under the contracts. Our contracts with CMOs, CROs and other third parties for the manufacture of our product candidates and to support clinical trials and pre-clinical research studies and testing are generally cancelable by us upon prior notice. Payments due upon cancellation consisting only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation are not included in the preceding table as the amount and timing of such payments are not known.

The contractual obligations table does not include any potential royalty payments that we may be required to make under our Royalty Agreement with Clarus. We excluded these royalty payments given that the timing of any such payments cannot be reasonably estimated at this time.

Off-Balance Sheet Arrangements

We do not have any relationships with unconsolidated entities or financial partnerships, including entities sometimes referred to as structured finance or special purpose entities that were established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. We do not engage in off-balance sheet financing arrangements. In addition, we do not engage in trading activities involving non-exchange traded contracts. We therefore believe that we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our audited consolidated financial statements included elsewhere in this prospectus, we believe the following accounting policies are the most critical to the judgments and estimates used in the preparation of our financial statements.

In-Process Research and Development and Goodwill

Intangible assets acquired in a business combination are recognized separately from goodwill and are initially recognized at their fair value at the acquisition date. Intangible assets related to in-process research and development, or IPR&D, are treated as indefinite lived intangible assets and not amortized until they are placed into service, typically upon regulatory approval. At that time, we will determine the useful life of the intangible asset and begin amortization. IPR&D assets are reviewed for impairment annually or more frequently if indicators of potential impairment exist. There were no impairments of IPR&D assets for the years ended December 31, 2017 and 2018.

Goodwill represents the excess of the purchase price over the estimated fair value of the identifiable assets acquired and liabilities assumed in a business combination. We evaluate goodwill for impairment annually or more frequently upon the occurrence of triggering events or substantive changes in circumstances that could indicate a potential impairment. An impairment loss is recognized when the fair value of the reporting unit to which the goodwill relates is below its carrying value for the difference between the fair value and its carrying amounts. There was no impairment of goodwill for the years ended December 31, 2017 and 2018.

Royalty Purchase Liability

Pursuant to our Royalty Agreement with Clarus, we received a cash payment of $20.0 million in November 2018 and are eligible to receive up to an additional $60.0 million from Clarus based upon the achievement of specific clinical milestones in our ROMAN Trial. We have accounted for the Royalty Agreement under Accounting Standards Codification Topic 470, *Debt*. The proceeds received are recorded as long-term debt obligations. Interest expense on such obligation is imputed by estimating risk adjusted future royalty payments over the term of the Royalty Agreement which takes into consideration the probability of obtaining FDA approval. Other significant assumptions include adjustments to estimated gross revenues to arrive at net product sales to which a royalty payment can be estimated. The non-cash interest expense recorded increases the balance of our royalty obligation. The royalty obligation will be reduced when royalty payments are made, if any.

However, actual royalty payments are highly uncertain and may change depending on a number of factors, including our ability to obtain FDA approval, successfully commercialize our product candidates and the timing of future royalty payments. We impute interest expense on our royalty purchase obligations based on such factors at each reporting period. As these factors change, we will adjust our estimate of the imputed interest expense accordingly. Given the amount and timing of proceeds received to date, changes in the assumptions used to impute interest expense would not have had a material impact to our consolidated financial statements as of and for the year ended December 31, 2018.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the development of our product candidates. We expense research and development costs as incurred.

We accrue an expense for pre-clinical studies and clinical trial activities performed by third parties based upon estimates of the proportion of work completed over the term of the individual trial and patient enrollment rates in accordance with agreements with CROs and clinical trial sites. We determine the estimates by reviewing contracts, vendor agreements and purchase orders, and through discussions with our internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services. However, actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending upon a number of factors, including our clinical development plan.

We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Nonrefundable advance payments for goods and services, including fees for process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Share-Based Compensation

We measure compensation expense for all share-based awards based on the estimated fair value of the share-based awards on the grant date. We use the Black-Scholes option pricing model to value our stock option awards. We recognize compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period of the award. We have not issued awards where vesting is subject to a market or performance condition.

The Black-Scholes option-pricing model requires the use of subjective assumptions that include the expected stock price volatility and the fair value of the underlying common stock on the date of grant. See Note 10 to our audited consolidated financial statements included elsewhere in this prospectus for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted during the years ended December 31, 2017 and 2018.

The following table summarizes by grant date the number of shares of common stock subject to stock options granted from January 1, 2017, as well as the associated per share exercise price and the estimated fair value per share of our common stock as of the grant date:

Grant date	Number of options granted	Exercise price per share	Estimated fair value per share of common stock
January 18, 2017	2,447,631	$ 0.53	$ 0.53
March 30, 2017	191,909	0.53	0.53
February 28, 2018	268,820	0.87	0.86
June 21, 2018	80,000	0.86	0.86
January 10, 2019	4,885,000	1.40	1.40

Based on an 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, the intrinsic value of vested and unvested stock options outstanding as of December 31, 2018 was $ million and $ million, respectively.

Estimating the Fair Value of Common Stock

We are required to estimate the fair value of the common stock underlying our share-based awards when performing the fair value calculations using the Black-Scholes option pricing model. Because our common stock is not currently publicly traded, the fair value of the common stock underlying our stock options has been determined on each grant date by our board of directors, with input from management, considering our most recently available third-party valuation of common shares. All options to purchase shares of our common stock are intended to be granted with an exercise price per share no less than the estimated fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant.

The third-party valuation of our common stock was performed using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants, or AICPA, *Audit and Accounting Practice Aid Series: Valuation of Privately Held Company Equity Securities Issued as Compensation*, or the AICPA Practice Guide. In addition, our board of directors considered various objective and subjective factors to estimate the estimated fair value of our common stock, including:

- the estimated value of each security both outstanding and anticipated;
- the anticipated capital structure that will directly impact the value of the currently outstanding securities;
- our results of operations and financial position;
- the status of our research and development efforts;
- the composition of, and changes to, our management team and board of directors;
- the lack of liquidity of our common stock as a private company;
- our stage of development and business strategy and the material risks related to our business and industry;
- external market conditions affecting the life sciences and biotechnology industry sectors;
- U.S. and global economic conditions;

- the likelihood of achieving a liquidity event for the holders of our common stock, such as an initial public offering, or IPO, or a sale of our company, given prevailing market conditions; and

- the market value and volatility of comparable companies.

Following the closing of this offering, the fair value of our common stock will be the closing price of our common stock on the Nasdaq Global Market as reported on the date of the grant.

Recent Accounting Pronouncements

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

Qualitative and Quantitative Disclosures About Market Risk

We are exposed to market risk related to changes in interest rates. As of December 31, 2018, we had cash, cash equivalents and short-term investments of $81.5 million consisting of bank deposits, U.S. Treasury securities, and a money market fund invested in U.S. Treasury securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in marketable debt securities. Our available-for-sale securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. We have the ability to hold our available-sale-securities until maturity, and therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments. We do not currently have any auction rate securities.

JOBS Act Transition Period

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from complying with new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, we may rely on certain of these exemptions, including without limitation, (1) providing an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (2) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier to occur of (a) the last day of the fiscal year (i) following the fifth anniversary of the completion of this offering, (ii) in which we have total annual gross revenues of at least $1.07 billion or (iii) in which we are deemed to be a “large accelerated filer” under the rules of the U.S. Securities and Exchange Commission, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (b) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

BUSINESS

Overview

We are a clinical stage biopharmaceutical company focused on developing and commercializing a pipeline of novel, proprietary therapeutics that have the potential to transform radiotherapy in cancer. We leverage our expertise in superoxide dismutase mimetics to design drugs to reduce normal tissue toxicity from radiotherapy and to increase the anti-cancer efficacy of radiotherapy. Our lead product candidate, GC4419, is a potent and highly selective small molecule dismutase mimetic we are initially developing for the reduction of severe oral mucositis, or SOM. SOM is a common, debilitating complication of radiotherapy in patients with head and neck cancer, or HNC. The U.S. Food and Drug Administration, or FDA, has granted Breakthrough Therapy Designation to GC4419 for the reduction of the duration, incidence and severity of SOM induced by radiotherapy. In October 2018, we began evaluating GC4419 in a Phase 3 registrational trial and we expect to report top-line data in . We believe GC4419 can become the first FDA-approved drug and the standard of care for the reduction of SOM in patients with HNC receiving radiotherapy, and we plan to expand its use into other radiotherapy-induced toxicities, including esophagitis.

GC4419, also known as avasopasem manganese, has successfully completed two clinical trials to reduce SOM in patients with HNC undergoing intensity-modulated radiation therapy, or IMRT, and also receiving cisplatin, a chemotherapy drug. SOM is commonly defined as Grade 3 or Grade 4 oral mucositis on the World Health Organization scale. We demonstrated proof-of-concept with GC4419 for this indication in a randomized, double-blinded, placebo-controlled 223-patient Phase 2b trial. In the trial, GC4419 met the primary endpoint by demonstrating a 92% reduction in the duration of SOM in the 90 mg treatment arm as compared to placebo, which was statistically significant and consistent with the results of our Phase 1b/2a SOM trial. Key secondary endpoints evaluating the incidence and severity of SOM also demonstrated substantial dose-dependent reductions of 34% and 47%, respectively, in the 90 mg treatment arm, and GC4419 was well tolerated in this trial. In addition, as in our other clinical trials and pre-clinical studies to date, in this trial, the anti-cancer efficacy of radiotherapy was maintained through one year when combined with GC4419. Following consultation with the FDA, we initiated a single confirmatory, randomized, placebo-controlled Phase 3 registrational trial of a 90 mg dose of GC4419 in patients with locally advanced HNC receiving radiotherapy, which we refer to as the ROMAN Trial. The primary endpoint of the ROMAN Trial is the reduction in the incidence of SOM through the completion of radiotherapy.

Superoxide, a highly reactive molecule, is produced by every cell as a part of normal metabolism, and at higher levels in certain diseases. Left uncontrolled it is highly toxic, leading to cell damage or cell death. To prevent this, the body produces superoxide dismutase enzymes, or SODs, which convert superoxide to hydrogen peroxide. Hydrogen peroxide is much less toxic than superoxide to normal tissue. Radiotherapy induces a large burst of superoxide in the irradiated tissues, which can overwhelm these SODs, damaging normal cells. Such damage to the oral mucosa, located in the mouth, is referred to as oral mucositis, or OM, and is particularly common among patients with HNC receiving radiotherapy.

Radiotherapy-induced SOM can lead to devastating complications. A majority of patients will suffer severe pain which is often managed with the use of opioids. Patients with SOM are at risk of dehydration and malnutrition as a result of the inability to eat or drink, and often require nutrition through a feeding tube or intravenous line. SOM can also be dose-limiting, requiring a reduction or delay in subsequent radiotherapy, leading to poorer clinical outcomes. Approximately 11% of patients receiving radiotherapy for HNC experience unplanned breaks of a week or more in radiotherapy due to SOM, with each week of treatment delay decreasing tumor control by over 10%. Additionally, it is estimated that patients with HNC who developed OM when treated with radiotherapy incurred, on average, approximately $32,000 in additional medical expenses compared to patients with HNC treated with radiotherapy who did not develop OM.

Each year in the United States, approximately 65,000 patients are diagnosed with HNC, according to the American Cancer Society. In the five largest European markets, approximately 68,000 patients are diagnosed

annually with HNC, and an additional 23,000 in Japan. We estimate that approximately 65% of patients diagnosed with HNC will be treated with radiotherapy. All patients with HNC treated with radiotherapy are at risk for developing SOM. We believe, if approved, GC4419 would be prescribed by physicians as standard-of-care treatment for patients with HNC receiving radiotherapy.

Based on observations from multiple studies, we estimate that approximately 70% of patients with HNC receiving radiotherapy will develop SOM. Despite this clear unmet need, no drug has been approved by the FDA for the treatment of SOM in patients with HNC. Current measures attempting to moderate SOM include basic oral care; anti-inflammatory agents; antimicrobials, coating agents, anesthetics and analgesics; laser and other light therapy, cryotherapy; and natural and other miscellaneous agents. The treatment guidelines developed by the Multinational Association of Supportive Care in Cancer and International Society of Oral Oncology, or MASCC / ISOO, demonstrate that there is a high unmet need for the treatment or prevention of OM in patients with HNC, and a lack of clear efficacy with existing treatment options.

We plan to expand the evaluation of GC4419 into the reduction of radiotherapy-induced esophagitis, or mucositis of the esophagus, which often develops in patients receiving radiotherapy for lung, esophageal, breast or head and neck cancers or for lymphoma. Esophagitis is a frequent and radiotherapy-limiting side effect in these patients. Symptoms can be life-threatening and include an inability to swallow, severe pain, ulceration, infection, bleeding and weight loss and may require hospitalization. There are also no drugs approved by the FDA for the prevention or treatment of radiotherapy-induced esophagitis, with treatment options focused on minimizing the symptoms of the problem. These do not address the underlying cause of esophagitis. We intend to initiate an open-label Phase 2a trial in for the reduction of the incidence of esophagitis in patients with lung cancer receiving IMRT.

Unlike existing treatment options that are largely palliative in nature, we believe GC4419 has the potential to address and mitigate the root cause of radiotherapy-induced mucositis, including OM and esophagitis. By removing superoxide, GC4419 is designed to reduce the damage radiotherapy causes to the patient's normal tissue, and thereby reduce the incidence and severity of mucositis.

In addition to developing GC4419 for the reduction of normal tissue toxicity from radiotherapy, we are developing our dismutase mimetics to increase the anti-cancer efficacy of higher daily doses of radiotherapy, including stereotactic body radiation therapy, or SBRT. Cancer cells have been observed to be more susceptible than normal cells to increased levels of hydrogen peroxide. In our pre-clinical studies, we have observed increased anti-cancer efficacy of higher daily doses of radiotherapy in combination with our dismutase mimetics. In a pre-clinical study, we demonstrated that this increase in anti-cancer efficacy was due to the conversion of superoxide to hydrogen peroxide by our dismutase mimetics. This increased efficacy could be particularly important in settings where the anti-cancer efficacy of radiotherapy alone is insufficient to achieve the desired outcome. Clinically, SBRT is increasingly used in patients with certain tumors, such as those seen in locally advanced pancreatic cancer, or LAPC, and non-small cell lung cancer, or NSCLC, that are less responsive to the small daily doses typical of IMRT. SBRT typically involves a patient receiving three to five large doses of radiotherapy, in contrast to the 30 to 35 small daily doses typical of IMRT. Even with the use of SBRT, the opportunity for improvement in treatment outcomes is substantial.

To explore this opportunity, we are currently conducting a pilot, randomized, placebo-controlled Phase 1b/2a trial of GC4419 in combination with SBRT in patients with LAPC whose tumor cannot be resected. The primary objective of this trial is to determine the maximum tolerated daily dose of SBRT in conjunction with our dismutase mimetic, with secondary measures assessing progression-free survival, objective response rate and tumor resectability compared to placebo. We believe this combination therapy may lead to improved patient survival rates, which we will also track in our clinical development. We expect to report top-line data from this trial in .

We plan to leverage our observations from our GC4419 SBRT pilot Phase 1b/2a trial in LAPC to help develop GC4711 to increase the anti-cancer efficacy of SBRT. We have successfully completed a Phase 1 trial of

intravenous GC4711 in healthy volunteers and plan to commence a Phase 1b/2a trial with GC4711 in combination with SBRT in patients with NSCLC in . In addition to this GC4711 Phase 1b/2a trial in NSCLC, we plan to conduct future trials with GC4711 in combination with SBRT, including in LAPC if we are successful in our ongoing SBRT GC4419 pilot Phase 1b/2a trial in that indication. We are also currently evaluating several oral formulations of GC4711 in a Phase 1 trial in healthy volunteers, based on pre-clinical studies suggesting that GC4711 can be delivered orally.

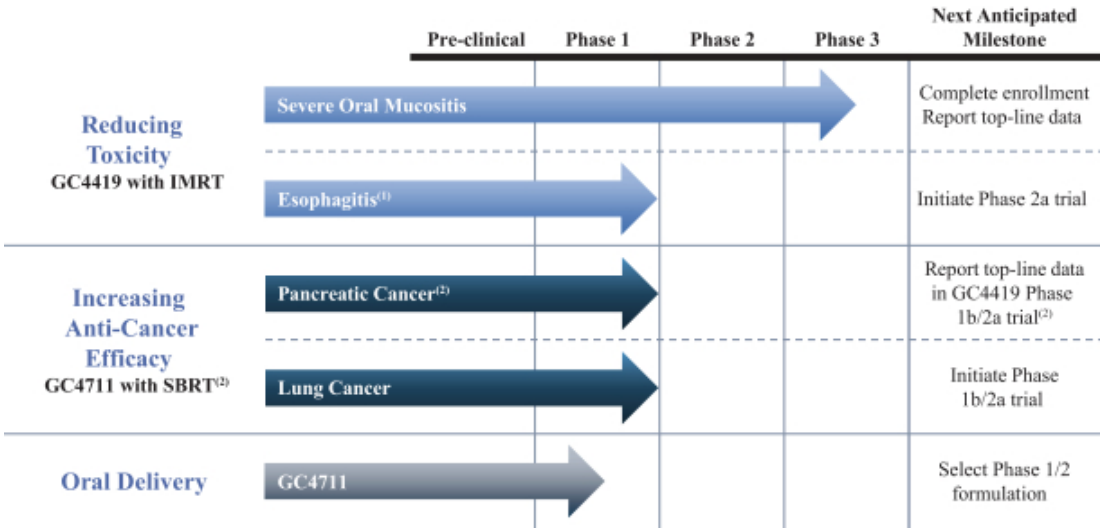
We retain worldwide rights to our product candidate portfolio. Our product candidate portfolio is protected by issued patents with claims directed to composition of matter and method of use, which, when including patent term extensions, are projected to expire between 2027 and 2038 in the United States.

We intend to commercialize GC4419 and our other current product candidates, if approved, by building a specialized sales and marketing organization of approximately 40 sales representatives focusing on radiation oncologists in the United States. We believe that this targeted sales organization would allow us to reach the concentrated prescribing base of approximately 4,000 U.S. radiation oncologists, who we believe are among the physicians most likely to use GC4419 and our other product candidates. Outside the United States, we may seek to establish collaborations to maximize the commercial opportunities for GC4419 and our other product candidates.

Our management team has extensive drug development and commercialization experience ranging from discovery through market registrational and commercial launches. Further, we are supported by a leading group of biotech investors including Adage Capital, Blackstone Life Sciences (formerly Clarus), HBM Healthcare, Nan Fung Life Sciences, New Enterprise Associates, Novartis Venture Fund, Novo Ventures, RA Capital, Rock Springs Capital, Sofinnova Ventures and Tekla Capital.

Our Pipeline

The following table summarizes our product candidates:



(1) Phase 2a trial to be based on GC4419 safety and tolerability findings in patients with HNC SOM studies.

(2) Phase 1b/2a pilot trial of GC4419 in combination with SBRT is ongoing in patients with LAPC whose tumor cannot be resected. We plan to leverage our observations from this trial in LAPC to help develop GC4711 to increase the anti-cancer efficacy of SBRT.

Our Strategy

Our mission is to transform cancer therapy by reducing normal tissue toxicity induced by radiotherapy and to improve the lives of patients with cancer. We are also seeking to increase the anti-cancer efficacy of radiotherapy with the use of our dismutase mimetics. Key elements of our strategy are as follows:

- **Complete the development and obtain FDA approval for GC4419 for the reduction of radiotherapy-induced toxicities.** GC4419 has received Breakthrough Therapy Designation from the FDA for the reduction of the duration, incidence and severity of SOM induced by radiotherapy, with or without systemic therapy. We are currently evaluating GC4419 in a Phase 3 registrational trial to reduce the incidence of SOM in patients receiving radiotherapy for locally advanced HNC. We expect to report top-line data from this trial by . We also plan to initiate a Phase 2a trial in to assess GC4419 in combination with radiotherapy to reduce the incidence of esophagitis in patients with lung cancer. Based upon the outcomes of our ongoing and planned trials, we plan to initiate additional clinical trials for GC4419 to reduce radiotherapy-induced toxicities in other cancer indications. We may also pursue a strategy for GC4419, if approved for reduction in the incidence of SOM, by presenting clinical data to entities like the National Comprehensive Cancer Network, or NCCN, to support the use of GC4419 to reduce esophagitis and/or other radiotherapy-induced toxicities as medically accepted indications in published drug compendia, notwithstanding that these indications may not be approved by the FDA.

- **Build a commercial infrastructure in the United States.** We intend to commercialize GC4419, if approved, by building a specialized sales and marketing organization in the United States focused on radiation oncologists. We believe a scientifically-oriented, customer-focused team of approximately 40 sales representatives would allow us to effectively reach the approximately 4,000 radiation oncologists in the United States. We also expect to leverage this sales organization to commercialize GC4711, if approved, and any of our future product candidates in the United States. Outside the United States, we may seek to establish collaborations for the commercialization of GC4419 and our other product candidates.

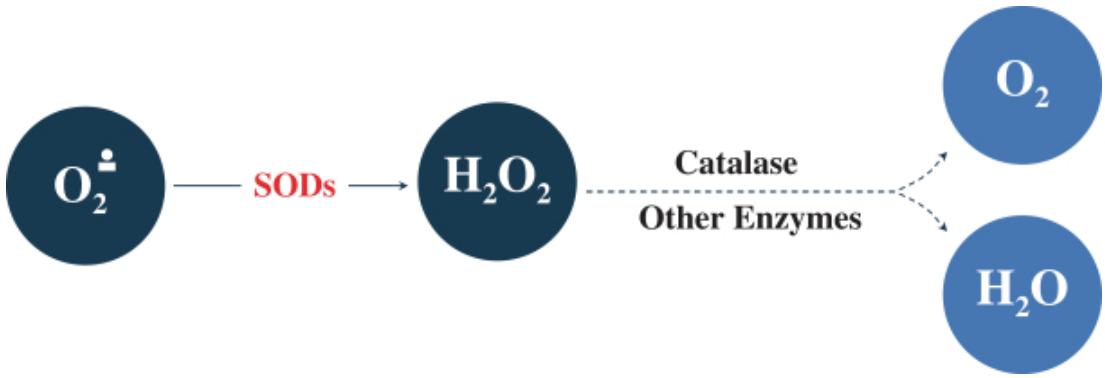
- **Advance the development of GC4711 in combination with SBRT to increase the anti-cancer efficacy of radiotherapy.** Based on extensive pre-clinical research results, we believe that GC4711 has the potential to increase the anti-cancer efficacy and safety profile of SBRT. We successfully completed a Phase 1 trial with GC4711 in healthy volunteers, and plan to initiate a Phase 1b/2a trial with GC4711 in combination with SBRT in patients with NSCLC in . In addition, upon the successful completion of our ongoing pilot Phase 1b/2a trial of GC4419 in combination with SBRT in patients with LAPC, and based upon FDA feedback, we expect to pursue further development in patients with LAPC with GC4711 in combination with SBRT. In part based on results from these trials, we also plan to evaluate GC4711's ability to increase the anti-cancer efficacy of SBRT in other cancer indications, including recurrent HNC.

- **Develop additional novel dismutase mimetics and formulations.** We intend to leverage our expertise in superoxide dismutase mimetics to continue to develop novel compounds that are intended to reduce normal tissue toxicity from radiotherapy and increase the anti-cancer efficacy of radiotherapy. Additionally, we believe we can broaden the utility of GC4711 or these novel compounds by formulating them for oral delivery. We are currently evaluating multiple oral formulations of GC4711 in a Phase 1 trial in healthy volunteers. In addition, we intend to seek new applications for our dismutase mimetics, including potential combinations in cancer therapy.

- **Seek strategic collaborative relationships.** We intend to seek strategic collaborations to facilitate the capital-efficient development of our dismutase mimetics. We believe these collaborations could potentially provide significant funding to advance our dismutase mimetics candidate pipeline while allowing us to benefit from the development expertise of our collaborators.

Background on Superoxide and Superoxide Dismutase

Superoxide is similar to the molecular oxygen, O_2, that is essential to breathing and life, except it carries one more electron. This extra electron, shown in the chemical formula O_2•-, makes superoxide a reactive oxygen species that can react with a variety of biological molecules. Superoxide is produced constantly in every living cell by normal activities such as mitochondrial respiration, and if not removed rapidly, it causes damage to lipids, proteins, DNA and other critical biological molecules. As a result, it can harm or kill cells and has been implicated in a variety of biological disorders, including cancer. As protection, human cells produce SODs to eliminate superoxide by rapidly and selectively converting it to hydrogen peroxide at rates of 10^7 molecules per second or higher. Hydrogen peroxide is much less toxic than superoxide to normal cells, and is subsequently broken down by various enzymes, such as catalase (the natural disposal enzyme for hydrogen peroxide), to molecular oxygen and water. The SOD pathway is depicted below.



Radiotherapy induces bursts of superoxide well in excess of normal amounts in the irradiated tissues, which can overwhelm native SOD activity. It generates superoxide directly, by splitting water molecules immediately, and indirectly, by activating enzymes that produce large amounts of superoxide following radiation. In addition, once tissue damage has begun, inflammatory cells attracted to the irradiated region also produce superoxide prodigiously. The resulting high levels of superoxide can induce significant damage in normal cells, and, depending on which organs fall within the irradiated field, can drive a variety of normal tissue toxicities. A condition referred to as mucositis occurs when the cells lining the gastro-intestinal tract, known as the mucosa, are damaged or killed.

Scientific literature suggests that metabolic differences make cancer cells much less sensitive than normal cells to elevated superoxide; elevated superoxide levels may even be typical of some cancers. As a result, the removal of the excess superoxide generated by radiotherapy does not decrease the anti-cancer efficacy of radiotherapy. Meanwhile, scientific literature also suggests that cancer cells are much more sensitive than normal cells to elevated hydrogen peroxide, so the conversion of excess superoxide to hydrogen peroxide by SODs may contribute to the anti-cancer efficacy of radiotherapy.

Artificially increasing SOD levels, by gene overexpression or administering recombinant SOD enzyme, has been shown in third-party pre-clinical and clinical studies to reduce radiotherapy-induced normal tissue toxicities, including mucositis. The pre-clinical studies have also suggested that increasing SOD levels can increase the anti-cancer efficacy of radiotherapy. Current therapeutic applications of the SODs themselves, however, have been limited by their following characteristics:

- large size and inability to enter cells and mitochondria, where superoxide is predominantly produced;
- immunogenicity, particularly when derived from non-human sources;

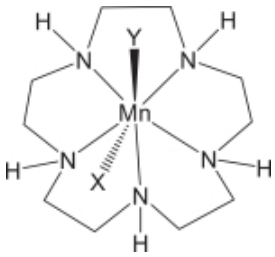
- short half-lives in circulation; and
- inactivation or inhibition by various reactive oxygen species, including hydrogen peroxide.

Our Superoxide Dismutase Mimetics

We believe low molecular weight drugs that can mimic native SODs can overcome the limitations of using the native enzymes therapeutically. The challenge has been finding small molecule dismutase mimetics with similarly fast catalytic rates and high selectivity for superoxide that are also stable, safe and suitable for manufacturing. We are developing our dismutase mimetics to address this challenge.

Our class of dismutase mimetics are based on a common core structure, where a macrocyclic ring positions five nitrogen atoms to tightly hold a manganese atom in the ring's center. These pentaaza macrocycles are manufactured with the manganese in the +2 oxidation state, or Mn^{+2}. In solution, this Mn^{+2} reacts rapidly with the protonated form of superoxide, which has the chemical formula HO_2• and is constantly in equilibrium with regular superoxide. In this reaction, Mn^{+2} gives up an electron and is oxidized to Mn^{+3}, making hydrogen peroxide. Then, as quickly as superoxide can reach the Mn^{+3}, it takes superoxide's extra electron, reducing back to Mn^{+2}, making molecular oxygen and bringing the dismutase mimetic full circle back to where it started.

Our Dismutase Mimetics Core Structure:
Pentaaza Macrocycles



The essential features of our dismutase mimetics are:

- **Speed.** Our dismutase mimetics catalyze the conversion of superoxide to hydrogen peroxide and molecular oxygen at a rapid rate of 2×10^7 molecules per second or more, comparable to native SODs. Their structures hold the manganese such that it can rapidly shift back and forth between Mn^{+2} and Mn^{+3}, meaning that their catalytic rate, or the speed that they convert superoxide, is mostly dependent on how fast superoxide can get to the manganese.
- **Selectivity.** Our dismutase mimetics are designed to interact only with superoxide. Central to this selectivity are three key attributes: (1) the Mn^{+2} will not react with reducing agents; (2) oxidizing Mn^{+2} requires a powerful oxidizing agent, so it will not react with nitric oxide and molecular oxygen; and (3) the Mn^{+2} oxidizes rapidly via a single-electron pathway, excluding many other biologically relevant reactive oxygen species, including peroxynitrite, hypochlorite and hydrogen peroxide, that operate as two-electron oxidizing agents.
- **Stability.** Our dismutase mimetics hold on tightly to the manganese at the center of the macrocyclic ring, allowing them to maintain their functionality as dismutase mimetics while they remain in the body.
- **Safety.** We have observed our dismutase mimetics to be well-tolerated in our pre-clinical studies and clinical trials in patients.
- **Synthesis.** We have developed an efficient and cost-effective manufacturing process.

In radiotherapy, we believe our dismutase mimetics have the potential to reduce normal tissue toxicity by removing excessive superoxide. We have demonstrated this in pre-clinical models not only of mucositis, but also radiotherapy damage to the lungs, liver and other organs. Importantly, our dismutase mimetics do not interfere with the anti-cancer efficacy of radiotherapy, as demonstrated in pre-clinical tumor models and in our placebo-controlled Phase 2b trial.

There is also the potential to increase the anti-cancer efficacy of SBRT, where our dismutase mimetics generate high daily doses of hydrogen peroxide. Pre-clinically we have shown this effect in a variety of cancer types, including head and neck, pancreatic, lung and breast cancer and, when SBRT is combined with immune checkpoint inhibitor therapy. Given the combination of reduced normal tissue toxicity and increased anti-cancer efficacy of radiotherapy, we believe that our dismutase mimetics can transform radiotherapy.

We currently have two dismutase mimetic candidates in clinical development, GC4419 and GC4711. Leveraging our expertise, we plan to continue to develop novel compounds and believe we can broaden the utility of our technology by formulating one or more candidates for oral delivery.

Radiotherapy-Induced Toxicities in Cancer Patients

A condition referred to as mucositis occurs when cells lining the gastro-intestinal tract, known as the mucosa, are damaged or killed. The oral mucosa is a common location for mucositis to occur, particularly for patients with HNC receiving radiotherapy. Another common location for mucositis to occur in patients receiving radiotherapy is the esophagus, referred to as esophagitis.

Oral Mucositis

OM occurs when radiotherapy induces the production of superoxide that attacks and breaks down the epithelial cells lining the mouth. The severity of OM is commonly measured using the WHO scale, which is also used by the FDA as a basis for product approvals. The scale consists of five Grades: Grade 0 through Grade 4. SOM is commonly defined as Grade 3 or Grade 4 OM.

Grade	WHO Scale Description
0	No OM
1	Erythema (redness) and soreness
2	Erythema and ulcers but patients can swallow solid food
3	Ulcers with extensive erythema and patients cannot swallow solid food
4	Oral alimentation (solid or liquid) is not possible

SOM can lead to devastating complications, including:

- **Pain.** A majority of patients experience severe pain, often requiring opioids to manage the pain. A publication describing 191 patients being treated for HNC noted that of the 157 patients reporting the greatest amount of mouth and throat soreness, 70% were taking opioids to alleviate their pain.

- **Dehydration and malnutrition.** Approximately 70% of patients with HNC receiving radiotherapy become unable to eat, drink, or both, often requiring nutrition through a gastrostomy tube or intravenous line.

- **Treatment interruption.** SOM can be dose-limiting, requiring a reduction or delay in radiotherapy, leading to poorer clinical outcomes. Approximately 11% of patients experience unplanned breaks of a week or more in radiotherapy, with each week of treatment delay decreasing tumor control by over 10%.

- **Increased economic burden.** Approximately 16% of patients receiving radiotherapy for HNC are hospitalized due to SOM. Based on a third-party analysis of medical insurance claims covering 40 million patient years, patients with HNC and treated with radiotherapy who developed OM incurred, on average, approximately $32,000 in additional medical expenses compared to such patients who did not develop OM.

Each year in the United States, approximately 65,000 patients are diagnosed with HNC, according to the American Cancer Society. In the five largest European markets, approximately 68,000 patients are diagnosed annually with HNC, and an additional 23,000 in Japan.

All of the patients with locally advanced HNC being treated with standard-of-care radiotherapy are at risk for developing SOM and, based on observations from multiple studies, we estimate that approximately 70% will develop SOM.

In a survey we conducted of 150 U.S. radiation oncologists, OM was identified as the most burdensome side effect caused by radiotherapy in patients being treated for HNC. OM was also characterized as the side effect most likely to cause treatment interruptions.

Current Treatment Landscape and Limitations

There are currently no FDA-approved drugs for the treatment of OM in patients with HNC. The MASCC / ISOO developed the leading clinical practice guidelines for management of OM. These guidelines, which are summarized below, indicate the inadequacy of clinical evidence to support the effectiveness of existing approaches for the management of OM in patients with HNC, and that these approaches have been largely palliative to date.

- **Basic oral care.** The guidelines suggest the use of basic oral care protocols to prevent OM across all cancer modalities; however, the guidelines indicate the clinical evidence is weak in supporting the effectiveness of this approach.

- **Anti-inflammatory agents.** The guidelines suggest the use of benzydamine mouthwash to prevent OM in patients with HNC, but only in patients receiving radiotherapy doses up to 50 gray without concomitant chemotherapy.

- **Antimicrobials, coating agents, anesthetics, and analgesics.** The guidelines suggest the use of 0.2% morphine mouthwash to treat pain associated with OM in patients with HNC.

- **Laser and other light therapy.** The guidelines suggest the use of low-level laser therapy to prevent OM in patients with HNC receiving radiotherapy, without concomitant chemotherapy. However, the guidelines indicate that the clinical evidence supporting the effectiveness of this approach is weak.

- **Cryotherapy.** The guidelines suggest the use of 30 minutes of oral cryotherapy to prevent OM in patients receiving bolus 5-fluorouracil chemotherapy (which is not applicable to standard-of-care radiotherapy for HNC).

- **Natural and other miscellaneous agents.** Due to inadequate clinical evidence, no guideline is possible for such agents.

These MASCC/ ISOO guidelines demonstrate that there is a high unmet need for the treatment or prevention of OM in patients with HNC, driven by the lack of clear efficacy of the existing treatment options. No therapies are recommended for the treatment or prevention of OM in patients with HNC receiving more than 50

gray of radiotherapy. The gray, or Gy, is the International System of Units unit of absorbed radiation dose. This unmet need is further demonstrated by the findings from our survey of 150 U.S. radiation oncologists, where only 19% and 21% of physicians, respectively, felt that existing treatment options are effective in preventing or reducing the incidence of SOM and in treating or reducing the duration of SOM in patients with HNC. The FDA has also acknowledged this unmet need and the lack of effective therapies for the reduction of the duration, incidence and severity of SOM induced by radiotherapy by granting GC4419 Fast Track and Breakthrough Therapy Designation.

Our Solution: GC4419 for Radiotherapy-Induced Severe Oral Mucositis

GC4419, also known as avasopasem manganese, is a potent and highly selective small molecule dismutase mimetic we are developing for the reduction of SOM in patients with HNC. We believe GC4419 has the potential to address shortcomings associated with current approaches and become the standard of care treatment for SOM in patients with locally advanced HNC.

Potential Benefits of GC4419 for Severe Oral Mucositis

We believe that GC4419 has the potential to be the first FDA-approved drug and the standard of care for the reduction of SOM in patients with HNC receiving radiotherapy, with the following benefits:

- ***Mechanism of action designed to address the root cause of OM:*** Unlike existing treatment options that are largely symptomatic and reactive in nature, we believe GC4419 has the potential to address and mitigate the root cause of OM. GC4419 is designed to rapidly convert superoxide to hydrogen peroxide, reducing mucosal damage and thereby the incidence and severity of mucositis.

- ***Compelling Randomized Phase 2b clinical data:*** Results from our Phase 2b trial demonstrate the potential benefits of GC4419 across all evaluated parameters of SOM. GC4419 has received Fast Track and Breakthrough Therapy Designation from the FDA.

- ***Maintenance of anti-cancer efficacy of radiotherapy:*** One year interim follow-up clinical data from our Phase 2b trial for GC4419 in patients with locally advanced HNC showed similar rates of tumor control and survival between GC4419 and placebo with no observed decrease in the anti-cancer efficacy of radiotherapy. We believe this is significant as maintenance of anti-cancer efficacy of radiotherapy is of key importance to physicians when considering new drugs to manage side effects of radiotherapy.

- ***Higher patient adherence:*** The intravenous formulation of GC4419, administered in a clinical setting by a health care provider, promotes higher patient adherence, optimizing clinical outcomes.

Clinical Development of GC4419 for Severe Oral Mucositis

Below is a summary of our clinical development of GC4419 for the reduction of SOM in patients with locally advanced HNC.

Trial and Status	Trial Design	Trial Objectives	Trial Milestones

Phase 3 registrational trial for SOM in patients with locally advanced HNC receiving radiotherapy (ROMAN Trial)
 	
Commenced in October 2018
	• Randomized, double-blinded, multi-center, placebo-controlled
	• Two arms: 90 mg and placebo
	• 335 patients
		• Primary objective: evaluate efficacy of GC4419 relative to placebo in reducing the incidence of SOM
		• Key secondary objectives: evaluate efficacy of GC4419 relative to placebo in reducing:
		  • the severity of SOM
		  • the number of days of SOM experienced by all patients
		• One-year tumor outcomes and two-year survival rates will be collected
			• Enrollment expected to be completed by .
			• Top-line data expected in .

Phase 2b trial for SOM in patients with locally advanced HNC receiving radiotherapy
 	
Completed
	• Randomized, double-blinded, multi-center, placebo-controlled
	• Three arms: 30 mg, 90 mg and placebo
	• 223 patients
		• Primary objective: assess efficacy of GC4419 relative to placebo in reducing the duration of SOM
		• Key secondary objectives: assess efficacy of GC4419 relative to placebo in reducing:
		  • the incidence of SOM
		  • the severity of SOM
		• Two-year tumor outcomes being collected
			• Primary endpoint met in 90 mg treatment arm:
			  • median duration reduced 92% compared to placebo arm (p* = 0.024)
			• Key secondary endpoints:
			  • incidence and severity of SOM in the 90 mg treatment arm reduced 34% and 47%, respectively

Trial and Status	Trial Design	Trial Objectives	Trial Milestones

Phase 1b/2a trial for SOM in patients with locally advanced HNC receiving radiotherapy
 	
Completed
	• Open-label, multi-center dose escalation trial
	• Doses ranged from 15 mg to 112 mg
	• 46 patients
		• Primary objectives:
		  • evaluate safety and tolerability of GC4419 in combination with IMRT and cisplatin
		  • determine a maximum tolerated dose
		• Key secondary objectives: assess potential of GC4419 to reduce the incidence, severity and duration of SOM
		• One-year tumor outcomes also collected
			• GC4419 was well tolerated
			• Maximum tolerated dose was not reached
			• One-year tumor outcomes consistent with historical control studies

* p-value represents the chance that the observed results occurred by chance alone. A p-value of less than 0.05 is considered statistically significant.

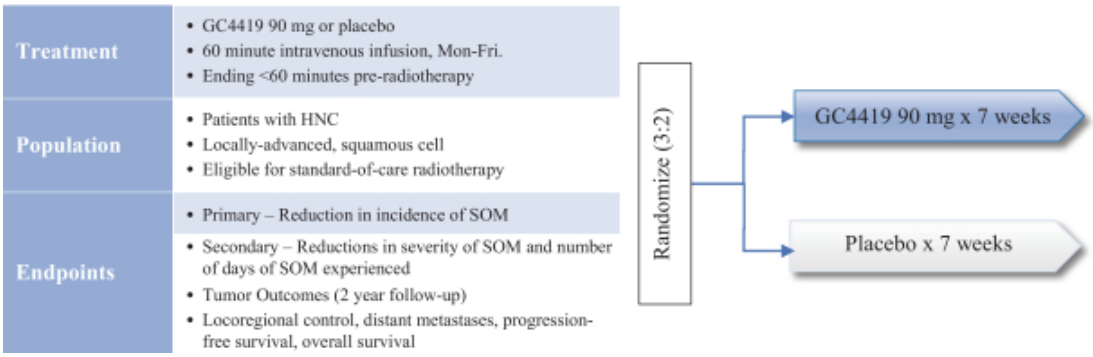
Ongoing ROMAN Trial (Phase 3)

In February 2018, GC4419 was granted Breakthrough Therapy Designation by the FDA for the reduction of the duration, incidence and severity of SOM induced by radiotherapy with or without systemic therapy. As part of our correspondence with the FDA, we received the following guidance:

- One pivotal trial is required to support a New Drug Application, NDA, filing;
- The Phase 2b trial will be considered supportive to the Phase 3 pivotal trial;
- Reduction in the incidence of SOM through the radiotherapy treatment period should be the primary endpoint of the Phase 3 registrational trial; and
- Two-year tumor outcomes from the Phase 2b trial and one-year tumor outcomes from the Phase 3 trial should be part of the NDA review.

In October 2018, we initiated a randomized, double-blinded, multicenter, placebo-controlled Phase 3 trial of GC4419 in patients with locally advanced HNC receiving radiotherapy, which we refer to as the Reduction in Oral Mucositis with Avasopasem Manganese Trial, or ROMAN Trial. We plan to enroll approximately 335 patients in a 3:2 randomization favoring the GC4419 90 mg treatment arm. Like our Phase 1b/2a and Phase 2b trials, the eligible population is patients with locally advanced, squamous cell HNC who are eligible for seven weeks of standard-of-care radiotherapy.

ROMAN Trial Design (n=335 patients)



The primary endpoint of the ROMAN Trial is the reduction in the incidence of SOM through the radiotherapy period for patients being treated with 90 mg of GC4419 as compared to placebo received as a 60-minute intravenous infusion less than 60 minutes before radiation, Monday to Friday, for seven weeks. All patients will be assessed twice weekly for OM by trained evaluators during the course of their radiotherapy treatment.

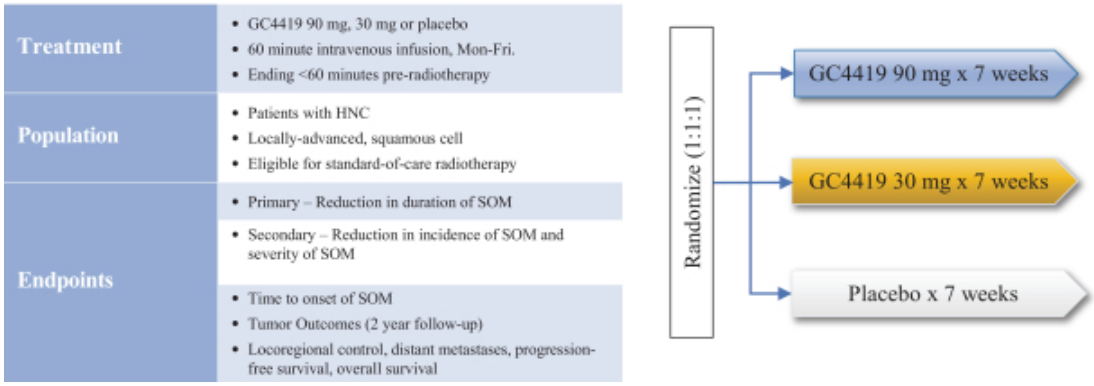
Secondary endpoints include, among others, reduction in the severity of SOM and reduction in the number of days of SOM experienced by all patients, as well as the effect of treatment on tumor outcomes measured by overall survival, or OS, progression-free survival, or PFS, locoregional control, or LRC, and distant metastasis-free, or DM-free, rates. For these purposes, we define the severity of SOM as the incidence of Grade 4 OM. Adverse events will be monitored during the trial period.

We expect to complete enrollment in the ROMAN Trial by and to report top-line data from this trial in . If these results are positive, we plan to submit an NDA to the FDA.

Phase 2b Trial in Patients with HNC

In November 2016, we initiated a Phase 2b trial in 223 patients with locally advanced HNC being treated with radiotherapy across multiple sites in the United States and Canada. The trial was a randomized, double-blinded, placebo-controlled trial assessing the effects of GC4419 on the duration, incidence and severity of SOM. Patients received 30 mg of GC4419, 90 mg of GC4419 or placebo as a 60-minute infusion less than 60 minutes before radiation, Monday to Friday, for seven weeks. All patients were assessed twice weekly for OM by trained evaluators during the course of their radiotherapy treatment. If SOM was present in a patient at the end of the course of his or her radiotherapy treatment, that patient continued to be evaluated weekly for up to eight additional weeks.

Phase 2b Trial Design (n=223 patients)



The primary endpoints of the trial were reduction in the duration of SOM in the 90 mg and 30 mg treatment arms. Duration was defined as the number of days from when a patient was first assessed with SOM until the first day that patient was assessed with Grade 2 or less OM, with no subsequent occurrences of SOM.

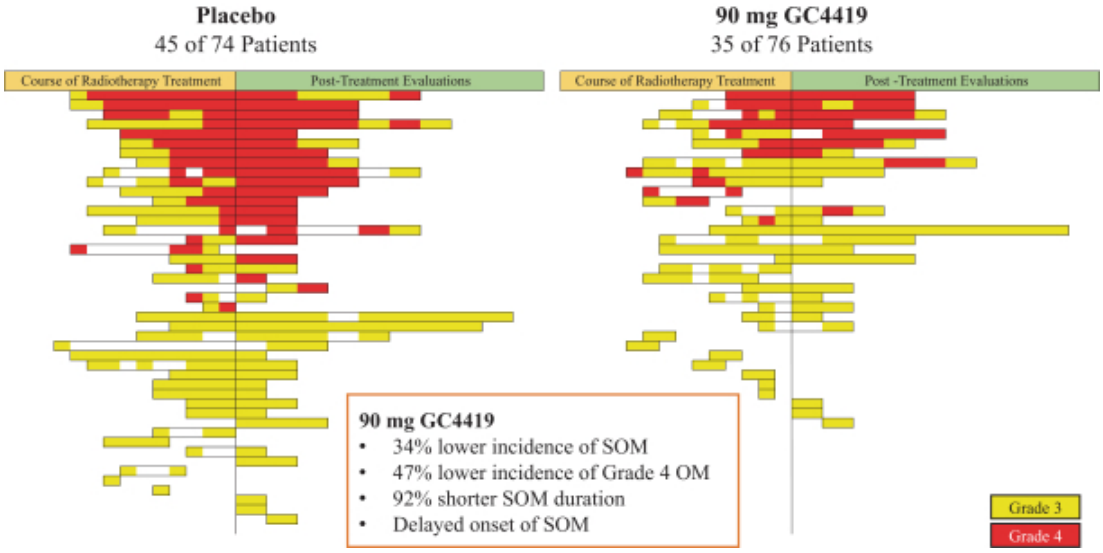
In this trial, the 90 mg treatment arm of GC4419 demonstrated statistically significant reductions compared to placebo on the primary endpoint. The median duration of SOM in this arm was 1.5 days, a 92% reduction compared to placebo (p=0.024).

Secondary endpoints included reduction in the incidence and severity of SOM in each of the 90 mg and 30 mg treatment arms. For these purposes, we define the severity of SOM as the incidence of Grade 4 OM. The incidence of SOM in the 90 mg treatment arm was reduced by 36% through 60 Gy and 34% through the full course of radiotherapy treatment compared to placebo and the severity of SOM in the 90 mg treatment arm was reduced by 47% through the full course of radiotherapy treatment compared to placebo.

In the 30 mg treatment arm, intermediate reductions compared to placebo were observed in median duration of SOM (58%), incidence of SOM through 60 Gy (31%) and through the full course of radiotherapy treatment (8%), and in severity of SOM (30%) through the full course of radiotherapy treatment.

In the trial, we also observed an apparent delay in the onset of SOM in the 90 mg treatment arm compared to placebo, reduced usage of opioids in both the 30 mg and 90 mg treatment arms compared to placebo, and reduced placement and use of gastrostomy tubes in the 90 mg treatment arm compared to placebo.

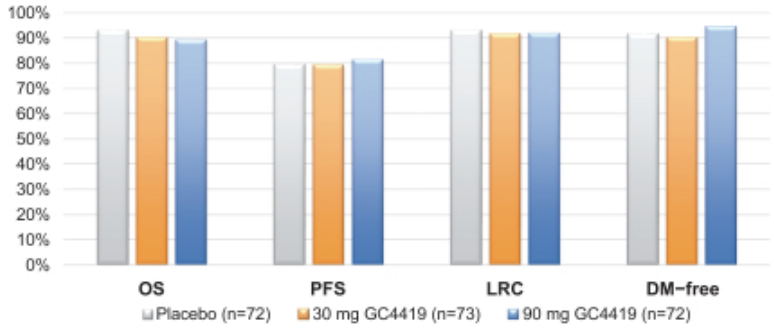
The following chart depicts the course of SOM in each patient in the 90 mg treatment arm or the placebo arm who experienced at least one episode of SOM during the course of his or her treatment and follow-up. Each bar represents a single patient and illustrates the length of time between that patient's first evaluated instance of SOM and his or her last evaluated instance of SOM, along with the severity of his or her SOM during that interval.



This chart demonstrates that (1) fewer patients in the 90 mg treatment arm developed SOM than in the placebo arm, (2) fewer patients in the 90 mg treatment arm developed Grade 4 OM than in the placebo arm, and (3) on average, SOM did not last as long for patients in the 90 mg treatment arm. This is consistent with the observed reductions in the individual numerical endpoints of duration, incidence and severity.

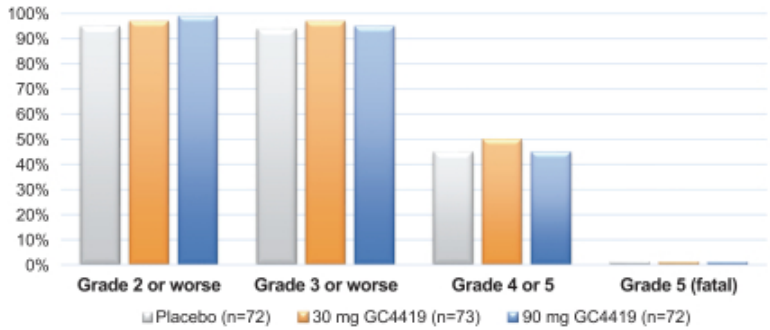
We are following patients from this trial for tumor outcomes out to two years following radiotherapy. In a one-year interim assessment of tumor outcomes, we observed similar outcomes among the three arms in OS, PFS, LRC and DM-free rates.

Tumor Outcomes Maintained through 1 Year
Interim Assessment



No difference was observed in the severity of adverse events among the three arms in the trial and the most frequent adverse events were similar among the three arms.

Safety Profile of Both GC4419 Doses was Comparable to Standard-of-Care Chemoradiotherapy (Placebo)



The percentage of patients with the most common adverse events in the Phase 2b trial are shown in the table below.

Most Frequent Adverse Events Similar Across Active and Placebo Arms

Most Frequent AEs (any grade)	Placebo (n=72)	30 mg GC4419 (n=73)	90 mg GC4419 (n=72)
Lymphopenia	89%	92%	88%
Nausea	75%	68%	82%
Fatigue	69%	60%	65%
Oropharyngeal pain	64%	63%	61%
Constipation	53%	59%	64%
Radiation skin injury	47%	51%	53%
Vomiting	47%	52%	49%
Dysgeusia (taste)	49%	55%	43%
Dysphagia	43%	42%	47%
Weight decreased	35%	40%	44%
Oral candidiasis	29%	45%	43%
Leukopenia	39%	37%	39%

Phase 1b/2a Trial in Patients with HNC

In August 2016, we completed a Phase 1b/2a, open-label, multi-center, dose escalation trial of the safety, tolerability, pharmacodynamic and pharmacokinetic properties of GC4419 in combination with radiotherapy and concurrent cisplatin in 46 patients with locally advanced HNC. The objectives of this trial were to evaluate the safety and tolerability of GC4419 and to assess the potential of GC4419 to reduce the duration, incidence and severity of SOM.

In this trial, patients were assigned to treatment duration groups based upon the dose and duration of dosing of GC4419 received and we observed that the incidence, duration, and severity of SOM through six weeks of radiotherapy (with patients receiving a cumulative radiotherapy dose of 60 Gy) decreased for patients who

received six to seven weeks of GC4419. In the group receiving six to seven weeks of GC4419, 29% of patients experienced SOM, with a median duration of 2.5 days, and no patients experienced Grade 4 OM. GC4419 was well tolerated and a maximum tolerated dose was not reached.

Patients in the trial were followed for tumor outcomes at one year post-radiotherapy. The observed LRC, DM-free, PFS, and OS rates in 44 patients evaluable for tumor outcome at one year were 93%, 93%, 84% and 93%, respectively. We believe these outcomes are similar to the outcomes observed in historical control studies, suggesting that GC4419 does not decrease the anti-cancer efficacy of radiotherapy.

Radiotherapy-Induced Esophagitis

Radiotherapy-induced esophagitis is a common and debilitating adverse effect that develops in patients receiving radiotherapy, most commonly for lung, esophageal, breast or head and neck cancers or for lymphoma. Radiotherapy-induced esophagitis is inflammation, edema, erythema, and erosion of the mucosal surface of the esophagus caused by radiotherapy. Symptoms can be life-threatening and include an inability to swallow, severe pain, ulceration, infection, bleeding and weight loss and may require hospitalization and. The severity of esophagitis is graded using the Common Terminology Criteria for Adverse Events, which is a five-point grading scale:

Grade	Description
1	Patients are asymptomatic with only clinical observations
2	Patients are symptomatic with altered eating or swallowing, with oral supplements indicated
3	Patients exhibit severely altered eating or swallowing requiring tube feeding, total parenteral nutrition or hospitalization
4	Patient requires urgent operative intervention; condition is life-threatening
5	Results in death

Radiotherapy-induced esophagitis potentially represents a larger market opportunity than OM. In lung cancer (our first target market for esophagitis), there are approximately 230,000 new patients annually in the United States, of which approximately 50,000 are treated with radiotherapy. The overall frequency of Grade 2 or higher esophagitis in patients receiving radiotherapy for the treatment of lung cancer is approximately 50%. The results of our survey of 150 U.S. radiation oncologists suggested that they view OM data as being representative of potential efficacy in esophagitis, which we believe supports the feasibility of exploring the use of GC4419 for the reduction of esophagitis.

Current Treatment Landscape and its Limitations

There are currently no FDA-approved drugs and no established guidelines for the treatment of radiotherapy-induced esophagitis. Treatment options are not only ineffective but also largely symptomatic in nature, with medications being administered in conjunction with a focus on adequate hydration and nutrition. These approaches, which include various analgesics such as topical lidocaine and opioids, and tube or intravenous feeding, do not treat the underlying cause of radiotherapy-induced esophagitis.

Our Solution: GC4419 for Radiotherapy-Induced Esophagitis

Unlike existing treatment options that are largely palliative in nature, we believe GC4419 has the potential to address and mitigate the root cause of radiotherapy-induced esophagitis. By removing superoxide, GC4419 is designed to reduce the damage radiotherapy ordinarily causes to the patient’s esophageal mucosa, and thereby reduce the incidence of radiotherapy-induced esophagitis. We believe GC4419 has the potential to become the standard of care for the reduction in the incidence of radiotherapy-induced esophagitis in patients with lung cancer.

Clinical Development of GC4419 for Esophagitis

Below is a summary of our clinical development of GC4419 for the treatment of esophagitis.

Trial and Status	Trial Design	Trial Objectives	Trial Milestones
Phase 2a trial for esophagitis in patients with lung cancer receiving IMRT Planned	• Open-label • 90 mg GC4419 given before each of typically 30 radiotherapy fractions • Approximately 60 patients	• Primary objective: assess efficacy of GC4419 in reducing the incidence of Grade 2 or higher esophagitis	• Trial expected to commence in .

Planned Phase 2a Trial in Patients with Lung Cancer

We plan to initiate a Phase 2a open-label trial of GC4419 in combination with radiotherapy with concurrent chemotherapy in approximately 60 patients with lung cancer.

The primary endpoint of the trial will be to assess the efficacy of GC4419 in reducing the incidence of Grade 2 or higher esophagitis in these patients. We expect to begin enrollment in the trial in .

Increasing Anti-Cancer Efficacy of Radiotherapy

As cancer cells are much more sensitive than normal cells to elevated hydrogen peroxide, we believe the conversion of excess superoxide to hydrogen peroxide by our dismutase mimetics has the potential to increase the anti-cancer efficacy of radiotherapy. We are evaluating our dismutase mimetics to determine their ability to increase the anti-cancer efficacy of high daily doses of radiotherapy, which we have demonstrated in our pre-clinical studies. This increased efficacy could be particularly important in settings where the current anti-cancer efficacy of radiotherapy alone is insufficient to achieve the desired outcome.

Locally Advanced Pancreatic Cancer Overview

Pancreatic cancer is a disease in which solid tumors form in the tissues of the pancreas. It is a particularly aggressive form of cancer and represents the third-leading cause of cancer deaths in the United States with approximately 57,000 new diagnoses and 46,000 deaths estimated in 2019. In the five largest European markets and Japan, there were approximately 109,000 new pancreatic cancer diagnoses in 2018. Approximately 30% of newly-diagnosed patients have non-metastatic disease that is unresectable due to the location of the primary tumor or its relationship to the surrounding vasculature. The first line of treatment for patients with unresectable tumors is chemotherapy. For those patients whose tumors remain unresectable following chemotherapy, SBRT is an emerging treatment option. Even with SBRT as an option, patients with pancreatic cancer often have a poor prognosis, with a five-year survival rate of only 7.7%. As a result, there remains a large unmet need to increase the effectiveness of disease management and ultimately improve outcomes for patients.

Non-Small Cell Lung Cancer Overview

According to the National Cancer Institute, or NCI, lung cancer is the leading cause of cancer-related mortality in the United States. The NCI estimates that in 2018 there were approximately 234,000 new cases of lung cancer (both NSCLC and small cell lung cancer) in the United States and approximately 154,000 deaths. Patients with NSCLC are typically treated with some combination of surgery, radiotherapy, chemotherapy and immunotherapy, depending on the severity of their disease, and SBRT is an established radiotherapy treatment for some forms of NSCLC. Even with all these current treatment options, the 5-year relative survival rate from 2008 to 2014 for patients with lung cancer was 18.6%. As such, improving the effectiveness of lung cancer treatment and improving patient outcomes represents a significant unmet need.

Our Solution: GC4711 for Increasing Anti-Cancer Efficacy in Patients Receiving SBRT

GC4711 is our second dismutase mimetic product candidate. We are specifically targeting GC4711, an analog of GC4419, to increase the anti-cancer efficacy of SBRT. It is currently in Phase 1 development both as a lyophilized product for intravenous administration given over 15 minutes and as an oral capsule. Based on our extensive pre-clinical data, we believe GC4711 has the potential to increase the anti-cancer efficacy of radiotherapy, and that it may also protect normal tissue during SBRT. By adding GC4711 to a SBRT regimen, we believe not only that our dismutase mimetics' conversion of superoxide to hydrogen peroxide may increase the anti-cancer efficacy of radiotherapy at current doses, but that patients may also be able to tolerate higher doses of radiotherapy.

In December 2017, we completed a Phase 1 single-dose trial of intravenously-administered GC4711 in Australia. The objectives of the trial were to assess the safety and tolerability of GC4711 and to characterize the pharmacokinetic profile of GC4711 in healthy volunteers. In the first stage of this trial, a sentinel cohort of four healthy volunteers received a single 30 mg intravenous dose of GC4711 over one hour, followed by a clinical safety review in which GC4711 was observed to be well tolerated with no serious adverse events. In the second stage of the trial, 32 healthy volunteers received a single 50 mg intravenous dose of GC4711 over one hour.

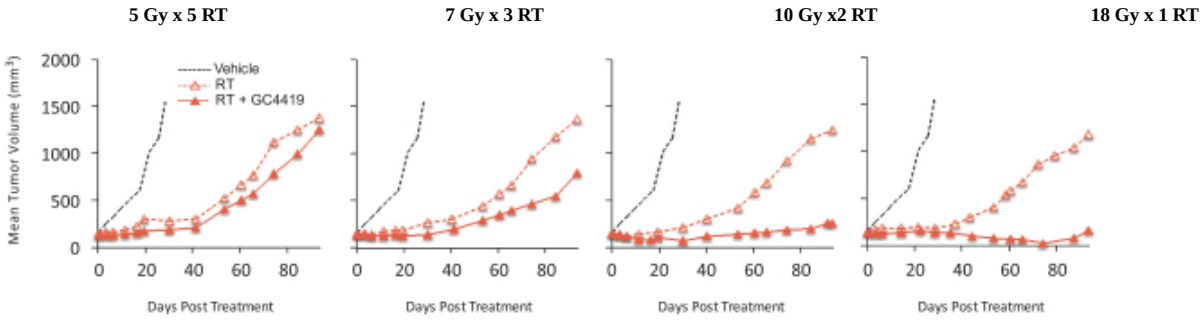
In this trial, GC4711 was observed to be well tolerated, with the most frequently reported adverse events being mild to moderate headache and infusion site pain. There were no Grade 3, 4, or 5 adverse events, and no adverse events led to withdrawal from the study.

We are currently assessing GC4711 in a second Australian Phase 1 study, examining dose escalation of 15-minute intravenous infusions in healthy volunteers. We plan to use the results of these studies to support an Investigative New Drug Application, or IND, filing for intravenous GC4711 delivered via 15-minute infusion in .

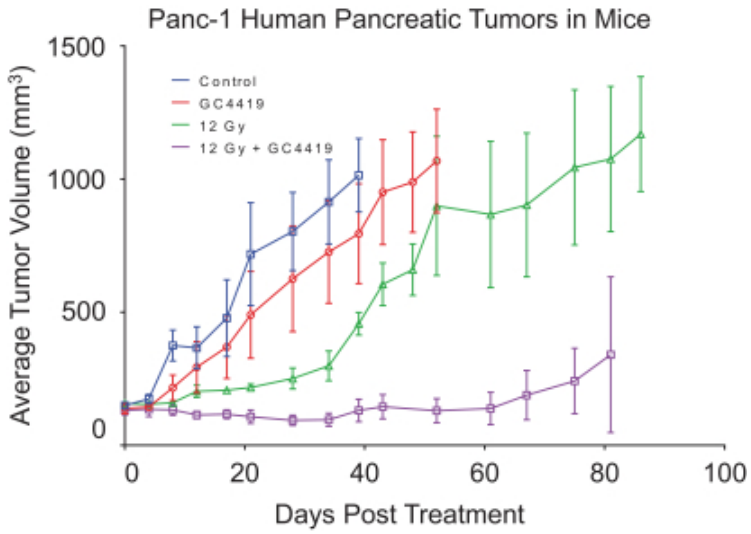
Pre-Clinical Results

We have observed in multiple xenograft and syngeneic tumor mouse models a strong correlation between the daily dose of radiation and the increase in anti-cancer efficacy with our dismutase mimetics. Notably, we observed that many of the mice at the highest daily dose of radiotherapy with a dismutase mimetic became tumor-free. The results of one such study, in which mice bearing NSCLC xenograft tumors received 24 mg/kg of GC4419 daily for five days concurrent with one of four different radiotherapy dosage regimens, are depicted below. For example, 5 Gy x 5 RT indicates that the mice received five daily doses of five Gy each. These radiotherapy regimens were selected because, without the addition of our dismutase mimetic, each should produce an equivalent reduction in tumor growth. The data reflects that expected result, but the increase in anti-cancer efficacy with addition of the dismutase mimetic increases significantly at the higher daily doses of radiotherapy.

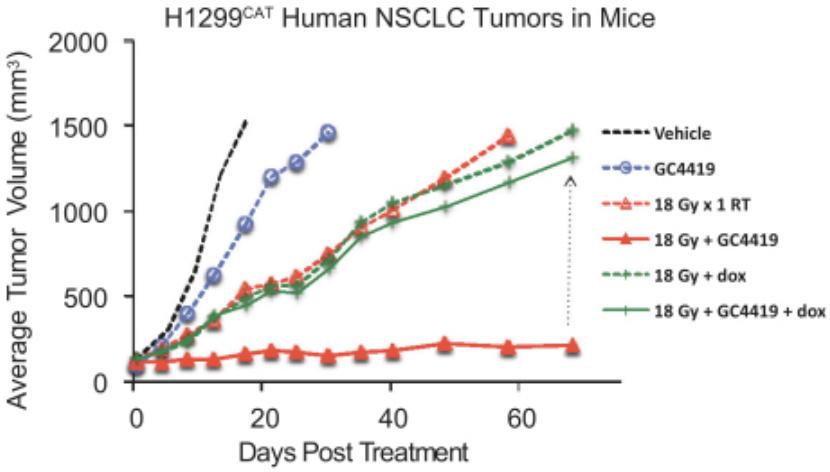
H1299 Human NSCLC Tumors in Mice



In another pre-clinical study, mice bearing pancreatic cancer xenograft tumors treated with a single 12 Gy dose demonstrated a meaningful decrease in tumor volume when GC4419 was added, as depicted below. We believe that this result shows that our dismutase mimetics have the potential to synergize with SBRT to rapidly convert superoxide to hydrogen peroxide and exploit cancer cells' increased sensitivity to hydrogen peroxide to promote cancer cell death.



Additional pre-clinical studies have provided further evidence supporting our dismutase mimetics' biological mechanism in combination with radiotherapy in solid tumors. To test the hypothesis that our dismutase mimetics' conversion of superoxide to hydrogen peroxide increases the anti-cancer efficacy of radiotherapy, we genetically engineered NSCLC tumors to overexpress catalase enzyme when triggered. This overexpression of catalase, a native enzyme that rapidly removes hydrogen peroxide, blocked the dismutase mimetic's synergy with radiotherapy in an experiment similar to the ones described above.



We believe the results of our studies represent significant potential in the treatment of cancer, particularly as recent advances in radiotherapy, such as SBRT, are capable of administering targeted, high daily doses of

radiotherapy to solid tumors. SBRT utilizes several beams of various intensities aimed at different angles to precisely target the tumor, with the goal of delivering the highest possible dose of radiotherapy to kill cancer cells while minimizing exposure to normal cells. For example, SBRT is an established radiotherapy treatment for NSCLC, used increasingly for small, peripheral lung tumors. Data to date suggest that SBRT could also increase the anti-cancer efficacy and safety of radiotherapy for many other patients with LAPC, NSCLC and other cancers. SBRT application for large or centrally located lung tumors, however, faces unique challenges, as lung and other toxicities limit the amount of radiotherapy patients can tolerate. As such, the most suitable patients for this procedure currently are those with smaller, well-defined tumors who are ineligible for or cannot tolerate surgery.

The increase in anti-cancer efficacy of SBRT with our dismutase mimetics has been shown in a variety of models of lung, pancreatic, head and neck, breast and other cancers. In addition, because low oxygen levels typically found deep in larger tumors can interfere with the anti-cancer efficacy of radiotherapy, it is important that our dismutase mimetics appear to also increase anti-cancer efficacy in hypoxic tumor models. Further, they may also reduce the normal tissue toxicities that restrict the patients now eligible for SBRT. Because of this we believe that the combination of GC4711 and SBRT has the potential to further increase the anti-cancer efficacy of and to broaden the group of patients who can benefit from SBRT.

The clinical research community is also exploring the possibility of increasing the anti-cancer efficacy of SBRT by combining it with checkpoint inhibitor immunotherapy, merging the targeted efficacy of radiotherapy with the demonstrated durability of checkpoint therapy. In pre-clinical models combining our dismutase mimetics with SBRT and anti-PD-1, anti-PD-L1 or anti-CTLA4 checkpoint therapy, this triple combination was more effective than combinations of SBRT combined with checkpoint therapy or SBRT combined with dismutase mimetic. The triple combination increased control of the irradiated primary tumors and also appeared to reduce the metastatic spread of the cancer and even controlled pre-existing tumors outside the radiation field. Based upon these data, we believe there is an opportunity to assess the combination of SBRT, checkpoint therapy and GC4711 as a novel approach to treating various cancers.

Clinical Development for Increasing Anti-Cancer Efficacy

Below is a summary of our clinical development of our dismutase mimetics for increasing the anti-cancer efficacy of radiotherapy.

Trial and Status	Trial Design	Trial Objectives	Trial Milestones
Phase 1b/2a pilot trial of GC4419 in patients with LAPC Ongoing Future trials in this indication planned to be conducted with GC4711	• Adaptive dose escalation trial • Three dose levels of SBRT being evaluated with each patient receiving five doses of SBRT • SBRT daily dose levels range from 10 Gy/dose to 12 Gy/dose • Two arms: 90 mg and placebo • 48 patients	• Primary objective: determine the maximum tolerated dose of SBRT when combined with GC4419 relative to placebo • Key secondary objectives: assess progression-free survival, objective response rate and tumor resectability with 90 mg GC4419 relative to placebo	• Top-line data expected in .

Phase 1b/2a trial of GC4711 in patients with NSCLC
 	
Planned
	• Open-label safety run-in of SBRT and GC4711 in approximately 15 patients
	• Followed by double-blind trial of SBRT, checkpoint inhibitor and GC4711
	  • Two arms: active and placebo
	  • 60 patients
		• Primary objective: safety and improvements in measures of pneumonitis
		• Key secondary objectives: objective response rate, progression-free survival and overall survival
			• Trial expected to commence in .

Phase 1b/2a Trial of GC4419 in Patients with LAPC

In February 2018, we initiated an adaptive dose escalation Phase 1b/2a pilot trial of GC4419 in combination with SBRT in patients with LAPC. We expect to enroll 48 patients in the trial. Three dose levels of SBRT are being evaluated and each patient is expected to receive a total of five doses of SBRT at daily dose levels ranging from 10 Gy/dose to 12 Gy/dose.

The primary endpoint of the trial is to determine the maximum tolerated dose of SBRT when combined with 90 mg of GC4419 or placebo.

Secondary endpoints in the trial include progression-free survival, objective response rate and tumor resectability in each of the arms.

We expect to report top-line data from the trial in .

Phase 1b/2a Trial of GC4711 in Patients with NSCLC

We plan to initiate a Phase 1b/2a trial of GC4711 in combination with radiotherapy and checkpoint inhibitor therapy in approximately 75 patients with NSCLC. Approximately 15 patients will be a part of the

open-label safety run-in and then approximately 30 patients will be randomized into each of the placebo and active treatment arms. The primary objective of the trial will be to assess safety and improvements in measures of pneumonitis. Key secondary objectives will include objective response rate, progression-free survival and overall survival. This study is being partially funded by NCI. We expect to begin enrollment in the trial in .

Oral Formulation of GC4711

Pre-clinical studies conducted by us suggest that GC4711 can also be delivered orally. We are currently evaluating candidate capsule formulations of GC4711 in a Phase 1 trial in healthy volunteers in Australia.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third party contract manufacturing organizations, or CMOs, for the supply of current good manufacturing practice-grade, or cGMP-grade, clinical trial materials and commercial quantities of our product candidates and products, if approved. We require all of our CMOs to conduct manufacturing activities in compliance with cGMP requirements. We have assembled a team of experienced employees and consultants to provide the necessary technical, quality and regulatory oversight of our CMOs.

We anticipate that these CMOs will have the capacity to support both clinical supply and commercial-scale production, but we do not have any formal agreements at this time with any of these CMOs to cover commercial production. We believe that we have or will have sufficient quantities of drug substance and drug product to supply our current Phase 3 trial of GC4419 for the reduction of SOM. We are in the process of implementing a redundant supply chain for GC4419 drug substance and drug product, with long-term agreements in place, to provide the drug substance and drug product prior to submission of an NDA.

We also may elect to pursue additional CMOs for manufacturing supplies of drug substance and finished drug product in the future. We believe that our standardized manufacturing process can be transferred to a number of other CMOs for the production of clinical and commercial supplies of our product candidates in the ordinary course of business.

Commercialization

Our aim is to become a fully integrated biopharmaceutical company. At this stage of the company, we have not yet established a commercial organization or distribution capabilities. We intend to commercialize GC4419, if approved, by building a specialized sales and marketing organization in the United States focused on radiation oncologists. We believe a scientifically oriented, customer-focused team of approximately 40 sales representatives would allow us to effectively reach the approximately 4,000 radiation oncologists in the United States, who treat patients using an even smaller number of radiation machines. Because of the limited number of physicians concentrated around a smaller number of radiation machines, we believe we can effectively commercialize GC4419, if approved, in the United States with a small, focused commercial organization. We also expect to leverage this sales organization to commercialize GC4711, if approved, and any of our future product candidates in the United States. Outside the United States, we may seek to establish collaborations for the commercialization of GC4419 and our other product candidates.

Competition

The biotechnology and pharmaceutical industries put significant emphasis and resources into the development of novel and proprietary therapies for cancer treatment. While we believe that our knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including large and specialty pharmaceutical and biotechnology companies, academic

research institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing treatment options and new therapies that may become available in the future.

Many of our potential competitors may have significantly greater financial resources, a more established presence in the market, and more expertise in research and development, manufacturing, pre-clinical and clinical testing, obtaining regulatory approvals and reimbursement, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These potential competitors may also compete with us in recruiting and retaining top qualified scientific, sales, marketing 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.

The key competitive factors affecting the success of GC4419, GC4711 and any of our other product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors. There are currently no FDA-approved drugs for the treatment of OM in patients with HNC and no FDA-approved drugs or established guidelines for the treatment of radiotherapy-induced esophagitis.

A number of large pharmaceutical and biotechnology companies that currently market and sell drugs or biologics are pursuing the development of therapies in the fields in which we are interested. Our commercial opportunity for any of our product candidates could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, less expensive, more convenient or easier to administer, or have fewer or less severe side effects, than any products that we may develop. Because our product candidates are designed to reduce the side effects of radiotherapy, our commercial opportunity could also be reduced or eliminated if radiotherapy methods are improved in a way that reduces the incidence of such side effects, or if new therapies are developed which effectively treat cancer without causing such side effects. Our competitors also may obtain FDA, EMA or other regulatory approval for their products 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.

License Agreements and Asset Acquisitions

In December 2003, Pfizer Inc, or Pfizer, granted Metaphore Pharmaceuticals, Inc., or Metaphore, an exclusive license, or the Pfizer License, to use its superoxide dismutase mimetic patents to develop and commercialize products, and Pfizer retained the non-exclusive, non-transferable right to use such patents for research purposes only. However, in March 2008, Metaphore’s parent company Activbiotics, Inc., or Activbiotics, became insolvent and an assignment for the benefit of creditors was made.

Pursuant to a bill of sale and sale agreement between Kereos, Inc., or Kereos, and Inotek Pharmaceuticals Corp., or Inotek, on the one hand, and Activbiotics and Metaphore on the other, Kereos and Inotek received joint rights on an “as is” basis to the Pfizer License, superoxide dismutase mimetic patents, and related clinical-stage compounds and small molecules, or the Purchased Assets. In accordance with the term sheet between Kereos and Inotek, dated March 2008, the purchasers divided the fields under which each party would use their interest in the Purchased Assets.

In May 2009, Kereos transferred to us their superoxide dismutase mimetic estate, which included their entire interest in the Purchased Assets and any other related intellectual property and their respective interests under the Pfizer License. Therefore, we are now the sole and exclusive licensee under the Pfizer License.

In May 2011, we entered into a property ownership and cross-license agreement with Inotek and an assignment agreement with Inotek, whereby we defined the terms of our collaboration going forward and divided the fields under which we would use our interest in the Purchased Assets as follows: (i) Inotek was granted an exclusive license to use the Purchased Assets for indications related to the treatment or prevention of acute and chronic ophthalmic diseases and conditions, other than those also related to oncology diseases, (ii) we were granted an exclusive license to use the Purchased Assets for indications related to the treatment, prevention or imaging of acute and chronic oncology diseases and related conditions, and (iii) we could both use the Purchased Assets for any other indications. In January 2012, Inotek assigned its interest in the superoxide dismutase mimetic estate to us, which included their entire interest in the Purchased Assets and all rights relating to clinical compounds, pre-clinical compounds and related patents developed during our collaboration.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for GC4419, GC4711 and any of our other product candidates, manufacturing methods and processes, novel discoveries, and other know-how; to operate without infringing on or otherwise violating the proprietary rights of others; and to prevent others from infringing or otherwise violating our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing or in-licensing U.S. and foreign patents and patent applications related to our product candidates and other proprietary technologies, inventions and improvements, including claims related to composition of matter and methods of use, that are important to the development and implementation of our business. We also rely on trademarks, trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position. For more information, please see “Risk Factors—Risks Related to Intellectual Property.”

Patents and Patent Applications

As of February 28, 2019, our owned and currently pending and/or in-force patent portfolio consisted of approximately 15 issued U.S. patents, five pending U.S. patent applications, 36 issued foreign patents including seven issued European patents that have been validated in many European countries, and 58 pending foreign applications.

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent’s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO, in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier expiring patent. In some instances, such a patent term adjustment may result in the term of a United States patent extending beyond 20 years from the earliest filing date of a non-provisional patent application. In the United States, the term of a patent that covers a drug product may also be eligible for patent term extension when regulatory approval is granted, provided the legal requirements are met. This permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to a maximum of five years beyond the expiration of the patent if the patent is eligible for such an extension under the Hatch-Waxman Act. The length of the patent term extension is related to the length of time the drug is under regulatory review; however, it cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and certain other jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our drug candidates receive approval by the FDA or foreign regulatory authorities, we expect to apply for patent term extensions on issued patents covering those drugs, depending upon the length of the clinical trials for each drug and other factors.

The two most advanced product candidates in our portfolio, GC4419 and GC4711, are protected by issued patents with claims directed to composition of matter and method of use. GC4419 is covered by a composition of

matter patent in the United States that has a natural expiration date in 2022. However, we believe GC4419 may be eligible for a patent term extension under the Hatch-Waxman Act of no more than four and a half years which, if granted, could result in an expiration date in 2027. GC4711 is covered by a composition of matter patent in the United States, which also covers oral viability of the product candidate, and has a natural expiration date in 2036. However, we believe GC4711 may be eligible for a patent term extension of at least about two years which, if granted, could result in an expiration date in 2038. The U.S. patent family covering the method of treating OM has a natural expiration date in late 2027, and if we are successful in obtaining a patent term extension of approximately two and a half years which we believe should be available, could result in an expiration date in early 2030. The U.S. patent family covering treating tissue damage resulting from radiation therapy, chemotherapy or a combination thereof by administering a high dose of GC4419 has a natural expiration date in 2032. When including patent term extensions, our product candidate portfolio is projected to expire between 2027 and 2038 in the United States.

However, there can be no assurance that any of our pending patent applications will issue or that we will benefit from any patent term extension or favorable adjustment to the term of any of our patents. The applicable authorities, including the FDA in the United States, may not agree with our assessment of whether such patent term extensions should be granted, and if granted, they may grant more limited extensions than we request.

We also have pending patent families in the United States that cover certain combinations of our product candidates with several oncology products that may provide protection for the use of our product candidates in connection with those oncology products, which, if granted, are projected to expire between 2037 and 2039.

Trademarks and Trade Secrets

As of February 28, 2019, our trademark portfolio contained two U.S. trademark registrations, for GALERA and GALERA THERAPEUTICS.

Furthermore, we rely upon trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality and invention assignment agreements with our commercial partners, collaborators, employees, and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with an employee or a third party. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees, and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Royalty Agreement with Clarus

In November 2018, we entered into an Amended and Restated Purchase and Sale Agreement, or the Royalty Agreement, by and among us, Clarus IV Galera Royalty AIV, L.P., Clarus IV-A, L.P., Clarus IV-B, L.P., Clarus IV-C, L.P. and Clarus IV-D, L.P., or, collectively, Clarus. Pursuant to the Royalty Agreement, Clarus agreed to pay us, in the aggregate, up to $80 million, or the Royalty Purchase Price, in four tranches of $20 million each upon the achievement of specified clinical milestones in our ROMAN Trial. We agreed to apply the proceeds from such payments primarily to support clinical development and regulatory activities for GC4419, GC4711 and any pharmaceutical product comprising or containing GC4419 or GC4711, or, collectively, the Products, as well as to satisfy working capital obligations and for general corporate expenses. We achieved the first milestone under the Royalty Agreement and received the first tranche of the Royalty Purchase Price in November 2018.

In connection with the payment of each tranche of the Royalty Purchase Price, we have agreed to sell, convey, transfer and assign to Clarus all of our right, title and interest in a mid-single digit percentage of (i) the

gross amount from the worldwide sale of the Products less certain items, including refunds, allowances, credits for recalls, customary discounts for purchase chargebacks, taxes in connection with transportation and/or delivery of Products, income-based taxes, customary distributor fees and commissions and customary distribution and transportation charges, and (ii) all recoveries, consideration, compensation, payments, collections, settlements and other amounts (including damages, awards, interest and penalties) of any kind or nature actually received by us or our affiliates, licensees and sublicensees in substitution or compensation for, or otherwise in lieu of, any net sales of the Products arising out of or resulting from any proceeding brought, or assertion made, by us against any third party relating to or arising out of any infringement, misuse or misappropriation by such third party of our intellectual property rights in the Products, less all out-of-pocket costs and expenses incurred by us or our affiliates, licensees and sublicensees in connection with such enforcement action, or, collectively, the Product Payments, during the Royalty Period. The Royalty Period means, on a Product-by-Product and country-by-country basis, the period of time commencing on the commercial launch of such Product in such country and ending on the latest to occur of (i) the 12th anniversary of such commercial launch, (ii) the expiration of all valid claims of our patents covering such Product in such country, and (iii) the expiration of regulatory data protection or market exclusivity or similar regulatory protection afforded by the health authorities in such country, to the extent such protection or exclusivity effectively prevents generic versions of such product from entering the market in such country.

If Clarus fails to fund the full amount of any remaining tranche of the Royalty Purchase Price within two business days of the conditions to the payment of such tranche having been satisfied, we may terminate our obligation to accept such tranche and any additional remaining tranches. In such event, Clarus's aggregate right, title and interest in the Product Payments shall be reduced to a low single-digit percentage.

Under the Royalty Agreement, if we commercialize our product candidates, we must establish a trained sales force sufficiently in advance of the anticipated commercial launch of our products. Along with other conditions, we may not grant any exclusive right or license under our patents and know-how related to our product candidates to any third party without the prior written consent of Clarus. In addition, we may not enter into any out-license that would expressly allow a third party to use our intellectual property to develop or commercialize a product that is competitive with the Products.

The Royalty Agreement will remain in effect until the date on which the aggregate amount of the Product Payments remitted to or otherwise received by Clarus exceeds a fixed single-digit multiple of the actual amount of the Royalty Purchase Price paid to and accepted by us in accordance with the terms of the Royalty Agreement, unless earlier terminated pursuant to the mutual written agreement of us and Clarus.

Government Regulation

The FDA and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome 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

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations 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 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 pre-clinical 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 Investigational New Drug application, or IND, 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 good clinical practice, or GCP, requirements to establish the safety and efficacy of the proposed drug product for each indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the 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 drug's identity, strength, quality and purity;
- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to commercial marketing or sale of the drug in the United States; and
- Compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, or to conduct a post-approval study.

Pre-Clinical Studies

Pre-clinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the pre-clinical studies, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some pre-clinical studies 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 commence.

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 at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution. 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 website.

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.

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. Phase 1, Phase 2 and Phase 3 clinical 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.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the pre-clinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and 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. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision.

In addition, under the Pediatric Research Equity Act of 2003, as amended and reauthorized, 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.

The FDA also may require submission of a REMS plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

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 to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA 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 trials or pre-clinical studies in order for FDA to reconsider 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.

Special FDA Expedited Review and Approval Programs

The FDA has various programs, including fast track designation, accelerated approval priority review, and breakthrough therapy designation, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential

to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. The FDA may review sections of the NDA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

The FDA may give a priority review designation to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the new PDUFA agreement, these six and ten month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures.

Moreover, under the provisions of the Food and Drug Administration Safety and Innovation Act, passed in July 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the 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. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

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

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 also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

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.

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 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 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. 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;
- safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warning or other safety information about the product;
- 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 revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- 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 only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Other Healthcare Laws

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such

laws include, without limitation, U.S. federal and state anti-kickback, fraud and abuse, false claims, consumer fraud, pricing reporting, data privacy and security, and transparency laws and regulations as well as similar foreign laws in the jurisdictions outside the U.S. Violations of such laws, or any other governmental regulations that apply, may result in penalties, including, without limitation, civil and criminal penalties, damages, fines, additional reporting and oversight obligations, the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs and individual imprisonment.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Significant uncertainty exists as to the coverage and reimbursement status of any newly approved product. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. With respect to off-label uses, third-party payors may provide coverage and reimbursement under certain circumstances. By way of example, Medicare covers off-label uses of FDA-approved drugs if the use is supported as a medically accepted indication by certain compendia and is not otherwise listed as unsupported, not indicated, not recommended, or equivalent terms, in any such compendia. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

In addition, third-party payors are increasingly reducing reimbursements for pharmaceutical products and services. The U.S. government and state legislatures have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. 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. Products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available or that the third-party payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect the pharmaceutical industry. In March 2010, the Affordable Care Act was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. The Affordable Care Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the Affordable Care Act

increases the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; requires collection of rebates for drugs paid by Medicaid managed care organizations; requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer 70 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs, implemented 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, expands of eligibility criteria for Medicaid programs, creates a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research and establishes of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of Medicare providers. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. Individual states in the United States have also become increasingly active in implementing 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, mechanisms to encourage importation from other countries and bulk purchasing.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials and approval of foreign countries or economic areas, such as the EU, before we may market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

In the European Economic Area, or EEA, which is comprised of the Member States of the European Union plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of MAs:

- Community MAs—These are issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA, and are valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA; for products that constitute a significant therapeutic, scientific or technical innovation; or for products that are in the interest of public health in the EU.

- National MAs—These are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, and are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure, an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State. The competent authority of the Reference Member State prepares a draft assessment report, a draft summary of the product characteristics, or SmPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SmPC, labeling or packaging proposed by the Reference Member State, the product is subsequently granted a National MA in all the Member States, i.e., in the Reference Member State and the Member States Concerned.

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA assess the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

As in the United States, it may be possible in foreign countries to obtain a period of market and/or data exclusivity that would have the effect of postponing the entry into the marketplace of a competitor's generic product. For example, if any of our products receive marketing approval in the EEA, we expect they will benefit from eight years of data exclusivity and 10 years of marketing exclusivity. An additional non-cumulative one-year period of marketing exclusivity is possible if during the data exclusivity period (the first eight years of the 10-year marketing exclusivity period), we obtain an authorization for one or more new therapeutic indications that are deemed to bring a significant clinical benefit compared to existing therapies. The data exclusivity period begins on the date of the product's first marketing authorization in the EEA and prevents generics from relying on the marketing authorization holder's pharmacological, toxicological and clinical data for a period of eight years. After eight years, a generic product application may be submitted and generic companies may rely on the marketing authorization holder's data. However, a generic cannot launch until two years later (or a total of 10 years after the first marketing authorization in the European Union of the innovator product), or three years later (or a total of 11 years after the first marketing authorization in the European Union of the innovator product) if the marketing authorization holder obtains marketing authorization for a new indication with significant clinical benefit within the eight-year data exclusivity period. In Japan, our products may be eligible for eight years of data exclusivity. There can be no assurance that we will qualify for such regulatory exclusivity, or that such exclusivity will prevent competitors from seeking approval solely on the basis of their own studies.

When conducting clinical trials in the European Union, we must adhere to the provisions of the European Union Clinical Trials Directive (Directive 2001/20/EC) and the laws and regulations of the EU Member States implementing them. These provisions require, among other things, that the prior authorization of an Ethics Committee and the competent Member State authority is obtained before commencing the clinical trial. In April 2014, the EU passed the Clinical Trials Regulation (Regulation 536/2014), which will replace the current Clinical Trials Directive. To ensure that the rules for clinical trials are identical throughout the European Union, the EU Clinical Trials Regulation was passed as a regulation that is directly applicable in all EU member states. All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive until the Clinical Trials Regulation becomes applicable. According to the current plans of the EMA, the Clinical Trials Regulation is expected to become applicable in 2019.

Employees

As of December 31, 2018, we had 18 employees. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

Facilities

Our principal office is located at 2 W Liberty Blvd #100, Malvern, Pennsylvania 19355, where we lease approximately 12,200 square feet of office space under a lease that terminates on February 28, 2023. We also occupy approximately 1,100 square feet of office space and approximately 1,125 square feet of laboratory space in St. Louis, Missouri under a lease that, by its terms, expired on January 31, 2019. We continue to occupy this space and are in the process of renewing the lease. We intend to add new facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Legal Proceedings

We are not subject to any material legal proceedings.

MANAGEMENT

Executive Officers and Directors

The following table sets forth information regarding our executive officers and directors as of the date of this prospectus.

Name	Age	Position
Executive Officers		
J. Mel Sorensen, M.D.	62	President, Chief Executive Officer and Director
Robert A. Beardsley, Ph.D.	58	Chief Operating Officer
Dennis P. Riley, Ph.D.	72	Chief Scientific Officer
Jon T. Holmlund, M.D.	62	Chief Medical Officer
Arthur Fratamico, R.Ph	53	Chief Business Officer
Non-Employee Directors		
Michael Powell, Ph.D.	64	Chairman of the Board
Emmett Cunningham, M.D., Ph.D., MPH	58	Director
Thomas Dyrberg, M.D., DMSc	64	Director
Jason Fuller, Ph.D.	41	Director
Campbell Murray, M.D.(1)	42	Director

(1) Dr. Murray is expected to resign from our board of directors effective immediately prior to, and contingent upon, the effectiveness of the registration statement of which this prospectus forms a part.

Executive Officers

J. Mel Sorensen, M.D. has served as Director, Chief Executive Officer and President of Galera since 2012. Dr. Sorensen serves on the board of several private biopharmaceutical companies, as director or Chairman, including Oncopia Therapeutics, OncoFusion Therapeutics, Esanik Therapeutics and Context Therapeutics. He is an advisor to the Biomarkers Consortium of the National Institutes of Health and to the Irish Cancer Society. Dr. Sorensen holds an M.B., B.Ch. and B.A.O. from University College, Dublin. Dr. Sorensen's postgraduate education and work has been in the United States, including an internal medicine residency in St. Louis and medical oncology fellowship at the Mayo Clinic, seven years at the National Cancer Institute as Senior Investigator in the Cancer Therapy Evaluation Program and four years each with Bayer and GlaxoSmithKline. Dr. Sorensen served as Director, Chief Executive Officer and President of Ascenta Therapeutics from 2004 until he joined Galera. We believe Dr. Sorensen's experience in the industry, his role as our Chief Executive Officer and President and his knowledge of the Company enable him to make valuable contributions to our board of directors.

Robert A. Beardsley, Ph.D. a co-founder of the Company, has served as our Chief Operating Officer since 2015, and from 2012 to 2017 as our Executive Chair. Prior to this, Dr. Beardsley was the Chief Executive Officer at Galera Therapeutics, LLC from 2010 to 2012, at Metabolic Solutions Development Corporation from 2009 until 2010, and at Kereos from 2003 until 2009, and the acting Chief Executive Officer at Metaphore Pharmaceuticals, Inc. in 2002. He has also served in various management roles at Confluence Life Sciences, bioStrategies Group, Vector Securities International, Enzyme Organics and Mobil Oil. Dr. Beardsley has served on a number of public and private boards including Euclises, Epigenetx, KemPharm, Kereos, CollaGenex Pharmaceuticals, Bioseek, and Metaphore Pharmaceuticals. Dr. Beardsley received a B.S. in Chemical Engineering, a Ph.D. in Biochemical Engineering from the University of Iowa and an M.B.A. in Finance from the University of Chicago.

Dennis P. Riley, Ph.D. a co-founder of the Company, has served as our Chief Scientific Officer since 2012. Prior to that, Dr. Riley served as Senior Vice President at Kereos from November, 2003 until April 2009

and was previously Vice President of Research at Metaphore Pharmaceuticals from April 1999 until May 2003. Dr. Riley received a B.S. in chemistry and mathematics from Heidelberg College and a Ph.D. from Ohio State University, followed by post-doctoral training at the University of Chicago. Dr. Riley was appointed an Adjunct Professor of Chemistry at Washington University in 1993, has authored or co-authored over 125 primary scientific publications and has been the recipient of numerous scientific awards including a Fellow of the American Association for the Advancement of Science.

Jon T. Holmlund, M.D. has served as our Chief Medical Officer since October 2012. Dr. Holmlund previously served as the Chief Medical Officer of Ascenta Therapeutics from April 2004 until November 2007 and at Isis (now lonis) Pharmaceuticals from August 1997 until March 2004, including as Vice President of Development from March 2003 until March 2004. Dr. Holmlund has also been an independent consultant on oncology drug development to the biopharmaceutical industry. He previously served as Medical Director of Aspire IRB, LLC, and as a senior investigator in the National Cancer lnstitute's Cancer Therapy Evaluation Program and Biological Response Modifiers Programs. Dr. Holmlund received his M.D. from SUNY Buffalo and completed postgraduate training in internal medicine and medical oncology at George Washington University Medical Center.

Arthur Fratamico, R.Ph has served as our Chief Business Officer since January 2017. Prior to joining us, Mr. Fratamico served as the Chief Business Officer of Vitae Pharmaceuticals from May 2014 until its sale to Allergan in October 2016. Prior to that, Mr. Fratamico was the Chief Business Officer for Flexion Therapeutics from June 2012 until January 2014. Mr. Fratamico received a B.S. in pharmacy from the Philadelphia College of Pharmacy and Science and an M.B.A. from Drexel University.

Non-Employee Directors

Michael Powell, Ph.D. has served as a member of our board of directors since November 2016 and as its Chair since July 2017. Dr. Powell is a General Partner at Sofinnova Ventures, where he has worked since 1997. Dr. Powell previously was Group Leader of Drug Delivery at Genentech from 1990 until 1997, and Director of Product Development at Cytel from 1987 until 1990. Dr. Powell currently serves as the Chair of Checkmate Pharma and Dauntless Pharmaceuticals and sits on the board of Pionyr Immunotherapeutics and Synlogic. He also serves on the Washington University Board of Trustees in St. Louis and is an Adjunct Professor of Pharmaceutical Chemistry at the University of Kansas. Dr. Powell holds a Ph.D. in Physical Chemistry from the University of Toronto and he completed post-doctoral studies in Bioorganic Chemistry at the University of California as a National Science and Engineering Research Council Scholar. We believe Dr. Powell is qualified to serve on our board of directors due to his extensive experience in investing in pharmaceutical companies.

Emmett Cunningham, M.D., Ph.D. has served as a member of our board of directors since September 2018. Dr. Cunningham is a Senior Managing Director in the Blackstone Life Sciences group, having joined Blackstone as part of its acquisition of Clarus in December 2018. He joined Clarus in 2006. From February 2004 to December 2005, he was Senior Vice President, Medical Strategy at Eyetech Pharmaceuticals, Inc., a pharmaceutical company. From April 2002 to February 2004, Dr. Cunningham was Vice President of Clinical Research Development and Licensing. Dr. Cunningham is also Adjunct Clinical Professor of Ophthalmology at Stanford University School of Medicine and the co-founder and Chair of the Ophthalmology Innovation Summit. Dr. Cunningham serves on the boards of directors of Annexon Biosciences, Graybug Vision, SFJ Pharmaceuticals Group and Lumos Pharma Inc. and he serves on the Scientific Advisory Board of Aerie Pharmaceuticals, Inc. He previously served as the Chair of the board of directors of Restoration Robotics. Dr. Cunningham received a B.S. from Drexel University, a B.A., M.D. and M.P.H. from Johns Hopkins University and a Ph.D. in neuroscience from the University of California at San Diego. We believe Dr. Cunningham is qualified to serve on our board of directors due to his experience in research and investing in medical companies.

Thomas Dyrberg, M.D., D.M.Sc. has served as a member of our board of directors since December 2015. In December 2000, Dr. Dyrberg joined Novo Holdings A/S, a limited liability company wholly owned by

the Novo Nordisk Foundation that is responsible for managing the Foundation's assets, where he serves as a managing partner of Novo Ventures. Prior to that, Dr. Dyrberg held positions at Novo Nordisk A/S. Dr. Dyrberg currently serves on the board of directors of Ophthotech Corporation, Nuvelution Pharma and Praxis Precision Medicines and previously served on the board of directors of PanOptica Inc., Veloxis Pharmaceuticals A/S and Entasis Therapetutics. Dr. Dyrberg received a D.M.Sc. and an M.D. from the University of Copenhagen. Dr. Dyrberg has held research positions at the Hagedorn Research Institute in Denmark and at the Scripps Research Institute in California. We believe that Dr. Dyrberg is qualified to serve on our board of directors due to his experience in research and investing in pharmaceutical companies.

Jason Fuller, Ph.D. has served as a member of our board of directors since September 2018. Dr. Fuller is a Principal at NEA where he focuses on investments in biopharmaceuticals, a position he has held since 2014. Prior to joining NEA, Dr. Fuller started at Third Rock Ventures in August 2008 and was a Principal there from 2010 until February 2013, where he helped manage several companies, including as the Director of Corporate Development at Jounce Therapeutics. Dr. Fuller received a B.S. in Chemical Engineering from Michigan State University and a Ph.D. from MIT. He received an MPhil from the University of Cambridge. We believe that Dr. Fuller is qualified to serve on our board of directors due to his experience in investing in biopharmaceutical companies.

Campbell Murray, M.D. has served as a member of our board of directors since December 2012. Dr. Murray has served as a Managing Director at the Novartis Venture Fund since August 2005. Previously, Dr. Murray served as the Director of Special Projects at the Novartis Institutes for BioMedical Research from July 2004 until July 2005. Currently, Dr. Murray serves as a member of the boards of directors of Annexon Biosciences, Expansion Therapeutics, Lemonaid Health and TScan Therapeutics. Dr. Murray received a bachelor of human biology from the University of Auckland Medical School, an M.B.A. from Harvard Business School, an M.P.P. from the John F. Kennedy School of Government, and an MBChB (M.D.) from the University of Auckland Medical School. We believe that Dr. Murray is qualified to serve on our board of directors due to his extensive investment experience in the biotechnology sector. Dr. Murray has notified us that he will resign from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. Dr. Murray's resignation is not due to any disagreement with the company or any matters relating to our operations, policies or practices

Board Composition and Election of Directors

Director Independence

Our board of directors currently consists of members. Our board of directors has determined that, of our directors, , , , and do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the rules of The Nasdaq Stock Market LLC, or Nasdaq. There are no family relationships among any of our directors or executive officers.

Classified Board of Directors

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

- the Class I directors will be and , and their terms will expire at our first annual meeting of stockholders following this offering;

- the Class II directors will be and , and their terms will expire at our second annual meeting of stockholders following this offering; and
- the Class III directors will be and , and their terms will expire at our third annual meeting of stockholders following this offering.

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

We expect that our board of directors will consist of members upon the effectiveness of the registration statement of which this prospectus forms a part. Dr. Powell is the chairman of our board of directors. Each director is currently elected to the board for a one-year term, to serve until the election and qualification of successor directors at the annual meeting of stockholders, or until the director's earlier removal, resignation or death.

Our directors were elected to and currently serve on the board pursuant to a voting agreement among us and several of our largest stockholders. See "Certain Relationships and Related Party Transactions—Voting Agreement." This agreement will terminate upon the closing of this offering, after which there will be no further contractual obligations regarding the election of our directors.

Board Leadership Structure

Our board of directors is currently chaired by Michael Powell. Our corporate governance guidelines will provide that, if the chairman of the board is a member of management or does not otherwise qualify as independent, the independent directors of the board may elect a lead director. The lead director's responsibilities would include, but would not be limited to: presiding over all meetings of the board of directors at which the chairman is not present, including any executive sessions of the independent directors; approving board meeting schedules and agendas; and acting as the liaison between the independent directors and the chief executive officer and chairman of the board. Our corporate governance guidelines will further provide the flexibility for our board of directors to modify our leadership structure in the future as it deems appropriate.

Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. Our audit committee also monitors compliance with legal and regulatory requirements. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, our entire board of directors is regularly informed through committee reports about such risks.

Board Committees

Our board of directors has an audit committee, a compensation committee and a nominating and corporate governance committee, each of which has the composition and the responsibilities described below. In addition, from time to time, special committees may be established under the direction of our board of directors when necessary to address specific issues.

Each of the audit committee, compensation committee and nominating and corporate governance committee operates under a charter that has been approved by our board of directors. Upon our listing on The Nasdaq Global Market, each committee's charter will be available under the Corporate Governance section of our website at *www.galeratx.com* immediately prior to the listing of our common stock on The Nasdaq Global Market. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

Audit Committee

Upon completion of this offering, our audit committee will consist of and , with serving as the chair of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable Nasdaq rules. Our board of directors has determined that each of these individuals meets the independence requirements of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, Rule 10A-3 under the Exchange Act and the applicable listing standards of Nasdaq. Each member of our audit committee can read and understand fundamental financial statements in accordance with Nasdaq audit committee requirements. In arriving at this determination, the board has examined each audit committee member's scope of experience and the nature of their prior and/or current employment.

Our board of directors has determined that qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the Nasdaq rules. In making this determination, our board has considered 's formal education and previous and current experience in financial and accounting roles. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

The audit committee's responsibilities include, among other things:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and the independent registered public accounting firm our annual and quarterly consolidated financial statements and related disclosures;
- coordinating our board of directors' oversight of our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- discussing our risk management policies;
- meeting independently with our internal auditing staff, if any, independent registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required by Securities Exchange Commission, or SEC, rules.

We believe that the composition and functioning of our audit committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Compensation Committee

Upon completion of this offering, our compensation committee will consist of , and , with serving as the chair of the committee. , and are non-employee directors, as defined in Rule 16b-3 promulgated under the Exchange Act and are "outside directors," as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended, or the Code. Our board of directors has determined that and are "independent" as defined under the applicable Nasdaq listing standards, including the standards specific to members of a compensation committee.

The compensation committee's responsibilities include, among other things:

- administering our equity incentive plan and reviewing and recommending to our board of directors approval of the grant of stock options and incentive stock pursuant to the equity incentive plan, including the terms and conditions of such grants;
- reviewing and recommending to our board of directors the establishment, modification and termination of bonus plans for officers and employees and the award of bonuses to our Chief Executive Officer;
- reviewing and recommending to our board of directors the approval of the hiring, firing and terms of compensation for our officers;
- in consultation with our board of directors, conducting a performance review of our Chief Executive Officer at least annually;
- periodically reviewing with our management our overall compensation and benefits plans with the goal of ensuring that such plans are competitive, soundly conceived and properly maintained and executed; and
- performing such other functions, duties or responsibilities as may be requested from time to time by our board of directors.

We believe that the composition and functioning of our compensation committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Nominating and Corporate Governance Committee

Upon completion of this offering, our nominating and corporate governance committee will consist of , and , with serving as chair of the committee. Our board of directors has determined that each of these individuals is "independent" as defined under the applicable listing standards of Nasdaq and SEC rules and regulations.

The nominating and corporate governance committee's responsibilities include, among other things:

- identifying and evaluating qualified candidates to serve on our board of directors;
- determining the criteria and policies for consideration and selection of directors to serve on our board of directors and our committees;

- considering the composition and size of our board of directors to ensure that it has the appropriate experience, expertise and perspective;
- evaluating, nominating and recommending individuals for membership on our board of directors;
- evaluating nominations by stockholders of candidates for election to our board of directors;
- retaining search firms and/or other consultants to identify and evaluate director nominees;
- advising our board of directors on corporate governance matters;
- reviewing and evaluating on an annual basis the performance of our board of directors and our committees;
- reviewing and making recommendations to the board of directors with respect to board succession planning;
- considering questions of possible conflicts of interest of directors as such questions arise;
- evaluating and considering the independence of members of our board of directors;
- reviewing and approving any related party transactions;
- developing and overseeing an orientation program for new directors and a continuing education program for all directors; and
- reviewing and evaluating on an annual basis the performance of the nominating and corporate governance committee and the nominating and corporate governance committee charter.

We believe that the composition and functioning of our nominating and corporate governance committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Our board of directors may from time to time establish other committees.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee is an officer or one of our employees. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee (or other committee performing equivalent functions or) of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Code of Ethics and Code of Conduct

We intend to adopt a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, executive officers and directors. Following the effectiveness of the registration statement of which this prospectus is a part, the Code of Conduct will be available on our website at *www.galeratx.com*. We intend to post on our website all disclosures that are required by law or the listing standards of The Nasdaq Global Market concerning any amendments to, or waivers from, any provision of the Code of Conduct. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

EXECUTIVE COMPENSATION

This section discusses the material components of the executive compensation program for our executive officers who are named in the "2018 Summary Compensation Table" below. In 2018, our "named executive officers" and their positions were as follows:

- J. Mel Sorensen, M.D., President and Chief Executive Officer;
- Robert A. Beardsley, Ph.D., Chief Operating Officer;
- Arthur J. Fratamico, Chief Business Officer; and
- Jon T. Holmlund, M.D., Chief Medical Officer.

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

2018 Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers for the year ended December 31, 2018.

Name and Principal Position	Salary ($)	Non-Equity Incentive Plan Compensation ($) (1)	Total
J. Mel Sorensen, M.D. *President and Chief Executive Officer*	$386,388	$ 135,236	$521,624
Robert A. Beardsley, Ph.D. *Chief Operating Officer*	$325,696	$ 97,709	$423,405
Arthur J. Fratamico *Chief Business Officer*	$314,150	$ 94,245	$408,395
Jon T. Holmlund, M.D. *Chief Medical Officer*	$323,568	$ 80,892	$404,460

(1) Represents amounts earned under our annual performance-based bonus program. For additional information, see "2018 Performance Bonuses" below.

Narrative to Summary Compensation Table

2018 Salaries

Our named executive officers receive a base salary to compensate them for services rendered to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role, and responsibilities. The base salaries of our named executive officers are reviewed from time to time and adjusted when our board of directors or compensation committee determines an adjustment is appropriate. The 2018 annual base salaries of our named executive officers are set forth in the 2018 Summary Compensation Table in the column entitled "Salary".

In January 2019, the compensation committee approved salary increases for each of our named executive officers, effective January 1, 2019, based on data provided by our independent compensation

consultant in order to more closely align the base salaries of these executives with market practice. The 2019 base salaries for our named executives officers are as follows: Dr. Sorensen, $405,707; Dr. Beardsley $341,981; Mr. Fratamico, $329,858; and Dr. Holmlund, $339,746.

2018 Performance Bonuses

We maintain a discretionary bonus plan that is designed to motivate and reward our executives, including our named executive officers, for achievements relative to our goals and expectations for each fiscal year. Each named executive officer has a target bonus opportunity, defined as a percentage of his annual base salary. Following the end of each year, our board of directors determines the bonuses for our executives, including our named executive officers, based on company performance against pre-established objectives and retains discretion to allow for individual adjustments based on such factors as it deems appropriate.

For 2018, the target bonuses for our named executive officers, expressed as a percentage of their respective base salaries, were 35% for Dr. Sorensen, 30% for Dr. Beardsley and Mr. Fratamico, and 25% for Dr. Holmlund. Our corporate performance objectives for 2018, as established by our board of directors, included certain accomplishments in clinical and non-clinical development, as well as financial and administrative goals. In January 2019, the board of directors assessed achievement against those previously established objectives and approved a 100% overall achievement level of our corporate goals and awarded bonuses to our named executive officers at 100% of their target bonus level. The actual annual cash bonuses awarded to each named executive officer for 2018 performance are set forth above in the 2018 Summary Compensation Table in the column entitled “Non-Equity Incentive Plan Compensation.”

For 2019, the board of directors approved bonus targets for our named executive officers, expressed as a percentage of their respective base salaries, as follows: 40% for Dr. Sorensen, 35% for Dr. Beardsley and Mr. Fratamico, and 30% for Dr. Holmlund.

Equity Compensation

We award stock options to our employees, including our named executive officers, as the long-term incentive component of our compensation program. We typically grant stock options to new hires upon their commencing employment with us. Additionally, we may grant stock options at such times as our board of directors determines appropriate. Generally, stock options vest over four years.

No stock options were granted to our named executive officers in 2018, though each named executive officer held stock options as of December 31, 2018 as shown in the table entitled “Outstanding Equity Awards at Fiscal Year-End” below.

We intend to adopt a 2019 Incentive Award Plan, referred to below as the 2019 Plan, in order to facilitate the grant of cash and equity incentives to directors, employees (including our named executive officers) and consultants of our company and certain of its affiliates and to enable our company and certain of its affiliates to obtain and retain services of these individuals, which we believe is essential to our long-term success. We expect that the 2019 Plan will be effective on the day prior to the first public trading date of our common stock. For additional information about the 2019 Plan, please see the section titled “Equity Incentive Plans” below.

Other Elements of Compensation

Retirement Plans

We currently maintain a 401(k) retirement savings plan for our employees, including our named executive officers, who satisfy certain eligibility requirements. Our named executive officers are eligible to participate in the 401(k) plan on the same terms as other full-time employees. Currently, we do not match contributions made by participants in the 401(k) plan.

Employee Benefits and Perquisites

All of our full-time employees, including our named executive officers, are eligible to participate in our health and welfare plans, including medical, dental, and vision benefits, short-term and long-term disability insurance, and accidental death and dismemberment insurance.

We do not provide any other perquisites or personal benefits to our named executive officers. None of our named executive officers participate in or have account balances in qualified or non-qualified defined benefit plans sponsored by us. Our board of directors may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our best interests.

Outstanding Equity Awards at Fiscal Year-End

The following table summarizes the number of shares of common stock underlying outstanding equity incentive plan awards for each named executive officer as of December 31, 2018.

		Option Awards			
Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable (1)	Number of Securities Underlying Unexercised Options (#) Unexercisable (1)(2)	Option Exercise Price ($)	Option Expiration Date
J. Mel Sorensen, M.D.	11/26/2012	860,000	—	0.21	11/26/2022
	9/17/2014	237,360	—	0.224	9/17/2024
	2/1/2016	1,247,845	463,485	0.48	3/2/2026
	1/18/2017	214,939	233,629	0.53	1/18/2027
Robert A. Beardsley, Ph.D.	11/26/2012	584,800	—	0.21	11/26/2022
	9/17/2014	161,405	—	0.224	9/17/2024
	2/1/2016	408,451	151,711	0.48	3/2/2026
	1/18/2017	83,310	90,554	0.53	1/18/2027
Arthur J. Fratamico	1/2/2017	442,228	480,683	0.53	1/18/2027
Jon T. Holmlund, M.D.	12/1/2012	103,200	—	0.21	1/23/2023
	9/17/2014	28,483	—	0.224	9/17/2024
	4/30/2016	386,374	175,624	0.48	4/1/2026
	1/18/2017	58,983	64,112	0.53	1/18/2027

(1) Pursuant to their employment agreements, all stock options held by Drs. Sorensen and Beardsley permit early exercise in exchange for shares of stock subject to a right of repurchase by the company and were, therefore, exercisable as of December 31, 2018. For Drs. Sorensen and Beardsley, the number of shares for which each option is shown as being exercisable and unexercisable represent, respectively, the number of shares for which each option was vested and unvested as of December 31, 2018.

(2) The unvested portion of the options vests in equal monthly installments until the fourth anniversary of the vesting commencement date, subject to the named executive officer's continued employment with the company through each applicable vesting date and accelerated vesting in the event the named executive officer's employment with the company is terminated by the company without cause or by the named executive officer for good reason, in either case, within 12 months following a change in control.

Executive Compensation Arrangements

We have entered into employment agreements with each of our named executive officers that sets forth the terms and conditions of each executive's employment with us. The employment agreements are for indefinite

terms and entitle the named executive officers to annual base salaries and eligibility to earn annual discretionary bonuses targeted at a percentage of their base salaries. See “2018 Salaries” and “2018 Performance Bonuses” above for additional information regarding the base salaries and annual bonuses of our named executive officers for 2018.

Pursuant to the employment agreements, regardless of the manner in which a named executive officer’s service terminates, each named executive officer is entitled to receive amounts previously earned during his term of service, including unpaid salary, any bonus awarded but not yet paid, payment for unused vacation and unreimbursed business expenses, and accrued benefits under the company’s employee benefit plans.

In addition, Drs. Sorensen and Beardsley and Mr. Fratamico are entitled to certain severance benefits under their employment agreements. If we terminate Drs. Sorensen or Beardsley or Mr. Fratamico without “cause” or he resigns for “good reason”, subject to his timely executing a release of claims, he is entitled to receive (i) base salary continuation for a period of six months and (ii) direct payment of or reimbursement for the same portion of the premiums for healthcare coverage paid by us while he was an employee for up to six months following termination.

Pursuant to the terms of their outstanding option agreements, if we terminate any of the named executive officers without cause, or a named executive officer resigns for good reason, in either case, within 12 months following a change in control of the company, the named executive officer will be entitled to accelerated vesting of all unvested option awards held by the named executive officer and, with respect to the options granted to Drs. Sorensen and Beardsley in 2012, pursuant to the terms of their employment agreements, the extension of the option exercise period to the standard expiration date of such options. Each employment agreement provides for a reduction in payments or benefits received under the agreement if we determine the payments would otherwise be subject to excise taxes under Section 4999 of the Code and the amount of the reduction does not exceed the amount of the applicable excise taxes.

Pursuant to their employment agreements, each of Drs. Sorensen and Beardsley and Mr. Fratamico has agreed to refrain from competing with us or soliciting our employees, consultants, partners or advisors, in each case, while employed and following his termination of employment for a period of 12 months. Dr. Holmlund has agreed to refrain from competing with us during while employed and from soliciting our employees while employed and following his termination of employment for a period of 12 months.

For purposes of the employment agreements, “cause” generally means, subject to certain cure rights, the executive’s (i) failure or inability to satisfy the material responsibilities and objectives reasonably assigned to the executive (other than due to a disability); (ii) material breach of the employment agreement or any other agreement between the company and the executive; (iii) commission of a felony or a crime involving moral turpitude, or any other act or omission involving dishonesty or fraud with respect to the company, its affiliates, or any of their customers or suppliers; (iv) behavior constituting sexual harassment, unlawful discrimination or similar behavior; (v) breach of any confidentiality or non-compete obligations; (vi) conduct that tends to bring the company or its affiliates into public disgrace or disrepute; or (vii) gross negligence or willful misconduct with respect to the company or any of its affiliates.

For purposes of the employment agreements, “good reason” generally means, subject to certain cure rights, (i) the company’s failure to comply with the material terms of the employment agreement; (ii) any request by the company that the executive perform an illegal act; (iii) a material reduction in the executive’s base salary, other than an across the board reduction based on the company’s financial condition or performance similarly affecting all or substantially all of senior management; or (iv) a material reduction in the executive’s responsibilities, positions, duties or authority which occurs within 12 months after a change in control.

In connection with this offering, we expect to enter into new employment agreements with our named executive officers. The material terms of those arrangements are not currently known and will be described in this prospectus once finally determined.

Director Compensation

Historically, we have not paid cash or equity compensation to any of our non-employee directors for service on our board of directors and no such amounts were paid to our non-employee directors during 2018. As of December 31, 2018, none of our non-employee directors held any option awards or unvested stock awards in us.

In connection with this offering, we intend to approve and implement a compensation program for our non-employee directors that consists of annual retainer fees and long-term equity awards. The material terms of this program are not yet known and will be described in this prospectus once they are determined.

Equity Incentive Plans

The following summarizes the material terms of the long-term incentive compensation plan in which our NEOs will be eligible to participate following the consummation of this offering and the Galera Therapeutics, Inc. Equity Incentive Plan, or the Existing Equity Incentive Plan, under which we have previously made periodic grants of equity and equity-based awards to our NEOs and other key employees.

Equity Incentive Plan

Our board of directors and stockholders approved the Existing Equity Incentive Plan under which we may grant stock options, stock appreciation rights and restricted stock. We had reserved a total of 15,748,833 shares of our common stock for issuance under the Existing Equity Incentive Plan as of December 31, 2018.

Following the effectiveness of the 2019 Plan, we will not make any further grants under the Existing Equity Incentive Plan. However, the Existing Equity Incentive Plan will continue to govern the terms and conditions of the outstanding awards granted under it. Shares of common stock subject to awards granted under the Existing Equity Incentive Plan that are forfeited, lapse unexercised or are settled in cash and which following the effective date of the 2019 Plan are not issued under the Existing Equity Incentive Plan will be available for issuance under the 2019 Plan.

Our board of directors, or a committee thereof, is authorized to administer the Existing Equity Incentive Plan and has the authority to take all actions and make all determinations under the Existing Equity Incentive Plan, and to establish such rules and regulations for the proper administration of the Existing Equity Incentive Plan as it deems appropriate. Following the effectiveness of this offering, we expect that the board of directors will delegate its general administrative authority under the Existing Equity Incentive Plan to its compensation committee.

The Existing Equity Incentive Plan provides for the grant of stock options, stock appreciation rights and restricted stock to employees, directors and consultants of the company or its subsidiaries. As of the date of this prospectus, awards of options are outstanding under the Existing Equity Incentive Plan.

In the event that any dividend or other distribution, recapitalization, stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of shares or other securities of the company, or other change in the corporate structure of the company affecting its shares of common stock occurs, the administrator will adjust outstanding awards under the Existing Equity Incentive Plan in order to prevent diminution or enlargement of the benefits or potential benefits intended to be made available under the Existing Equity Incentive Plan. In the event of a dissolution or liquidation of the company, each participant will be notified and unexercised awards will terminate immediately prior to such action. In connection with a change in control of the company, outstanding awards under the Existing Equity Incentive Plan may be cancelled for cash or an alternative award, have their vesting accelerated, or be assumed or substituted with awards by a successor entity.

The board of directors may amend, alter, suspend or terminate the Existing Equity Incentive Plan at any time; provided that no such action may impair the rights of any participant without the consent of the affected participant.

2019 Incentive Award Plan

Effective the day prior to the first public trading date of our common stock, we intend to adopt and ask our stockholders to approve the 2019 Plan under which we may grant cash and equity-based incentive awards to eligible service providers in order to attract, retain and motivate the persons who make important contributions to our company. The material terms of the 2019 Plan are summarized below.

Eligibility and Administration

Our employees, consultants and directors, and employees and consultants of our subsidiaries, will be eligible to receive awards under the 2019 Plan. The 2019 Plan will be administered by our board of directors, which may delegate its duties and responsibilities to one or more committees of our directors and/or officers (referred to collectively as the plan administrator below), subject to the limitations imposed under the 2019 Plan, Section 16 of the Exchange Act, stock exchange rules and other applicable laws. The plan administrator will have the authority to take all actions and make all determinations under the 2019 Plan, to interpret the 2019 Plan and award agreements and to adopt, amend and repeal rules for the administration of the 2019 Plan as it deems advisable. The plan administrator will also have the authority to determine which eligible service providers receive awards, grant awards and set the terms and conditions of all awards under the 2019 Plan, including any vesting and vesting acceleration provisions, subject to the conditions and limitations in the 2019 Plan.

Shares Available for Awards

An aggregate of shares of our common stock will initially be available for issuance under the 2019 Plan. The number of shares initially available for issuance will be increased by an annual increase on January 1 of each calendar year beginning in 2020 and ending in and including 2029, equal to the lesser of (A) and (B) a smaller number of shares determined by our board of directors. No more than shares of common stock may be issued under the 2019 Plan upon the exercise of incentive stock options. Shares available under the 2019 Plan may be authorized but unissued shares, shares purchased on the open market or treasury shares.

If an award under the 2019 Plan or the Galera Therapeutics, Inc. Equity Incentive Plan, which we refer to as our Existing Equity Incentive Plan, expires, lapses or is terminated, exchanged for cash, surrendered, repurchased, or canceled without having been fully exercised or forfeited, any unused shares subject to the award will, as applicable, become or again be available for new grants under the 2019 Plan. Awards granted under the 2019 Plan in substitution for any options or other stock or stock-based awards granted by an entity before the entity's merger or consolidation with us or our acquisition of the entity's property or stock will not reduce the shares available for grant under the 2019 Plan, but will count against the maximum number of shares that may be issued upon the exercise of incentive stock options.

In addition, the maximum aggregate grant date fair value as determined in accordance with FASB ASC Topic 718 (or any successor thereto), of awards granted to any non-employee director for services as a director pursuant to the 2019 Plan during any fiscal year may not exceed $ (or, in the fiscal year of any director's initial service, $). The plan administrator may, however, make exceptions to such limit on director compensation in extraordinary circumstances, subject to the limitations in the 2019 Plan.

Awards

The 2019 Plan provides for the grant of stock options, including incentive stock options, or ISOs, and nonqualified stock options, or NSOs, stock appreciation rights, or SARs, restricted stock, dividend equivalents,

restricted stock units, or RSUs, and other stock or cash based awards. Certain awards under the 2019 Plan may constitute or provide for payment of "nonqualified deferred compensation" under Section 409A of the Code. All awards under the 2019 Plan will be set forth in award agreements, which will detail the terms and conditions of awards, including any applicable vesting and payment terms and post-termination exercise limitations. A brief description of each award type follows.

- *Stock Options and SARs.* Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, by contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Code are satisfied. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The plan administrator will determine the number of shares covered by each option and SAR, the exercise price of each option and SAR and the conditions and limitations applicable to the exercise of each option and SAR. The exercise price of a stock option or SAR will not be less than 100% of the fair market value of the underlying share on the grant date (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute awards granted in connection with a corporate transaction. The term of a stock option or SAR may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders). The maximum aggregate number of shares of common stock with respect to one or more options or SARs that may be granted to any one person during any fiscal year of the company will be .

- *Restricted Stock and RSUs.* Restricted stock is an award of nontransferable shares of our common stock that remain forfeitable unless and until specified conditions are met and which may be subject to a purchase price. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met and may be accompanied by the right to receive the equivalent value of dividends paid on shares of our common stock prior to the delivery of the underlying shares. The plan administrator may provide that the delivery of the shares underlying RSUs will be deferred on a mandatory basis or at the election of the participant. The terms and conditions applicable to restricted stock and RSUs will be determined by the plan administrator, subject to the conditions and limitations contained in the 2019 Plan.

- *Other Stock or Cash Based Awards.* Other stock or cash based awards are awards of cash, fully vested shares of our common stock and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock or other property. Other stock or cash based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of compensation to which a participant is otherwise entitled. The plan administrator will determine the terms and conditions of other stock or cash based awards, which may include any purchase price, performance goal, transfer restrictions and vesting conditions.

Performance Criteria

The plan administrator may select performance criteria for an award to establish performance goals for a performance period. Performance criteria under the 2019 Plan may include, but are not limited to, the following: net earnings or losses (either before or after one or more of interest, taxes, depreciation, amortization, and non-cash equity-based compensation expense); gross or net sales or revenue or sales or revenue growth; net income (either before or after taxes) or adjusted net income; profits (including but not limited to gross profits, net profits, profit growth, net operation profit or economic profit), profit return ratios or operating margin; budget or operating earnings (either before or after taxes or before or after allocation of corporate overhead and bonus); cash flow (including operating cash flow and free cash flow or cash flow return on capital); return on assets;

return on capital or invested capital; cost of capital; return on stockholders' equity; total stockholder return; return on sales; costs, reductions in costs and cost control measures; expenses; working capital; earnings or loss per share; adjusted earnings or loss per share; price per share or dividends per share (or appreciation in or maintenance of such price or dividends); regulatory achievements or compliance; implementation, completion or attainment of objectives relating to research, development, regulatory, commercial, or strategic milestones or developments; market share; economic value or economic value added models; division, group or corporate financial goals; customer satisfaction/growth; customer service; employee satisfaction; recruitment and maintenance of personnel; human resources management; supervision of litigation and other legal matters; strategic partnerships and transactions; financial ratios (including those measuring liquidity, activity, profitability or leverage); debt levels or reductions; sales-related goals; financing and other capital raising transactions; cash on hand; acquisition activity; investment sourcing activity; and marketing initiatives, any of which may be measured in absolute terms or as compared to any incremental increase or decrease. Such performance goals also may be based solely by reference to the company's performance or the performance of a subsidiary, division, business segment or business unit of the company or a subsidiary, or based upon performance relative to performance of other companies or upon comparisons of any of the indicators of performance relative to performance of other companies. When determining performance goals, the plan administrator may provide for exclusion of the impact of an event or occurrence which the plan administrator determines should appropriately be excluded, including, without limitation, non-recurring charges or events, acquisitions or divestitures, changes in the corporate or capital structure, events unrelated to the business or outside of the control of management, foreign exchange considerations, and legal, regulatory, tax or accounting changes.

Certain Transactions

In connection with certain corporate transactions and events affecting our common stock, including a change in control, or change in any applicable laws or accounting principles, the plan administrator has broad discretion to take action under the 2019 Plan to prevent the dilution or enlargement of intended benefits, facilitate the transaction or event or give effect to the change in applicable laws or accounting principles. This includes canceling awards for cash or property, accelerating the vesting of awards, providing for the assumption or substitution of awards by a successor entity, adjusting the number and type of shares subject to outstanding awards and/or with respect to which awards may be granted under the 2019 Plan and replacing or terminating awards under the 2019 Plan. In addition, in the event of certain non-reciprocal transactions with our stockholders, the plan administrator will make equitable adjustments to the 2019 Plan and outstanding awards as it deems appropriate to reflect the transaction.

Plan Amendment and Termination

Our board of directors may amend or terminate the 2019 Plan at any time; however, no amendment, other than an amendment that increases the number of shares available under the 2019 Plan, may materially and adversely affect an award outstanding under the 2019 Plan without the consent of the affected participant and stockholder approval will be obtained for any amendment to the extent necessary to comply with applicable laws. Further, the plan administrator cannot, without the approval of our stockholders, amend any outstanding stock option or SAR to reduce its price per share. The 2019 Plan will remain in effect until the tenth anniversary of its effective date, unless earlier terminated by our board of directors. No awards may be granted under the 2019 Plan after its termination.

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

The plan administrator may modify awards granted to participants who are foreign nationals or employed outside the United States or establish subplans or procedures to address differences in laws, rules, regulations or customs of such foreign jurisdictions. All awards will be subject to any company claw-back policy as set forth in such claw-back policy or the applicable award agreement. Except as the plan administrator may determine or provide in an award agreement, awards under the 2019 Plan are generally non-transferrable, except

by will or the laws of descent and distribution, or, subject to the plan administrator's consent, pursuant to a domestic relations order, and are generally exercisable only by the participant. With regard to tax withholding obligations arising in connection with awards under the 2019 Plan, and exercise price obligations arising in connection with the exercise of stock options under the 2019 Plan, the plan administrator may, in its discretion, accept cash, wire transfer or check, shares of our common stock that meet specified conditions, a promissory note, a "market sell order," such other consideration as the plan administrator deems suitable or any combination of the foregoing.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2016, to which we have been a party in which the amount involved exceeded or will exceed $120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive Compensation." We also describe below certain other transactions with our directors, executive officers and stockholders.

Series B-1 Preferred Stock

In January 2016, we completed the sale of an aggregate of 3,636,363 shares of our Series B-1 Preferred Stock at a purchase price of $1.375 per share for an aggregate purchase price of $5.0 million. Each share of our Series B-1 Preferred Stock will convert into shares of our common stock upon the closing of this offering in accordance with our certificate of incorporation. The following table summarizes purchases of shares of our Series B-1 Preferred Stock by holders of more than 5% of our capital stock.

Participants	Total Shares Purchased	Aggregate Purchase Price (in thousands)
Greater than 5% Stockholders		
Enso Ventures 2 Limited(1)	3,636,363	$ 5,000

(1) Enso Ventures 2 Limited became a beneficial owner of more than 5% of our capital stock following its purchase of our Series B-1 Preferred Stock. Details regarding current beneficial owners of more than 5% of our capital stock are provided in this prospectus under the caption "Principal Stockholders."

Series B-2 Preferred Stock

In November 2016, we completed the sale of an aggregate of 9,090,909 shares of our Series B-2 Preferred Stock at a purchase price of $1.65 per share for an aggregate purchase price of $15.0 million. Each share of our Series B-2 Preferred Stock will convert into shares of our common stock upon the closing of this offering in accordance with our certificate of incorporation. The following table summarizes purchases of shares of our Series B-2 Preferred Stock by holders of more than 5% of our capital stock.

Participants	Total Shares Purchased	Aggregate Purchase Price (in thousands)
Greater than 5% Stockholders(1)		
Sofinnova Venture Partners IX, L.P.(2)	9,090,909	$ 15,000

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

(2) Dr. Michael Powell, a member of our board of directors, is affiliated with Sofinnova Venture Partners IX, L.P.

Series C Preferred Stock

In August 2018, we completed the sale of an aggregate of 31,696,436 shares of our Series C Preferred Stock at a purchase price of $2.2143 per share for an aggregate purchase price of $70.2 million. Each share of our Series C Preferred Stock will convert into shares of our common stock upon the closing of this offering in accordance with our certificate of incorporation. The following table summarizes purchases of shares of our Series C Preferred Stock by holders of more than 5% of our capital stock and one of our executive officers.

Participants	Total Shares Purchased	Aggregate Purchase Price (in thousands)
Greater than 5% Stockholders(1)		
New Enterprise Associates 14, L.P.(2)	1,354,829	$ 3,000
Novartis Bioventures Ltd.(3)	451,609	$ 1,000
Novo Holdings A/S(4)	2,709,659	$ 6,000
Sofinnova Venture Partners IX, L.P.(5)	2,709,659	$ 6,000
Clarus IV-A, L.P.(6)	2,334,966	$ 5,170
Clarus IV-B, L.P.(6)	1,522,035	$ 3,370
Clarus IV-C, L.P.(6)	2,807,372	$ 6,216
Clarus IV-D, L.P.(6)	561,385	$ 1,243
Executive Officers and Affiliates		
Robert A. Beardsley, Ph.D..	6,774	$ 15

(1) Additional details regarding these stockholders and their equity holdings are provided in this prospectus under the caption “Principal Stockholders.”

(2) Dr. Jason Fuller, a member of our board of directors, is affiliated with New Enterprise Associates 14, L.P.

(3) Dr. Campbell Murray, a member of our board of directors, is affiliated with Novartis Bioventures Ltd.

(4) Dr. Thomas Dyrberg, a member of our board of directors, is affiliated with Novo Holdings A/S.

(5) Dr. Michael Powell, a member of our board of directors, is affiliated with Sofinnova Venture Partners IX, L.P.

(6) Dr. Emmett Cunningham, a member of our board of directors, is affiliated with Clarus IV-A, L.P., Clarus IV-B, L.P., Clarus IV-C, L.P. and Clarus IV-D, L.P.

Royalty Agreement with Clarus

In November 2018, we entered into the Royalty Agreement with Clarus, a holder of more than 5% of our capital stock. Pursuant to the Royalty Agreement, Clarus agreed to pay us, in the aggregate, up to $80.0 million in four tranches of $20.0 million each, upon the achievement of specified clinical milestones in our ROMAN Trial, in exchange for all of our right, title and interest in a specified portion of the worldwide net sales of certain of our products during a specified period of time. We achieved the first milestone under the Royalty Agreement and received the first tranche of the Royalty Purchase Price in November 2018. For more information, please see “Business—Royalty Agreement with Clarus.”

Investors’ Rights Agreement

We are party to a second amended and restated investors’ rights agreement, or the Investors’ Rights Agreement, with each holder of our redeemable convertible preferred stock, which includes each holder of more than 5% of our capital stock and certain of our executive officers. The Investors’ Rights Agreement imposes certain affirmative obligations on us, and also grants certain rights to the holders, including certain information rights, rights to participate in future stock issuances and certain registration rights with respect to the registrable

securities held by them. See “Description of Capital Stock—Registration Rights” for additional information. Except for the registration rights described in the previous sentence, these rights will terminate and be of no further force or effect immediately before the consummation of this offering.

Voting Agreement

We are party to a second amended and restated voting agreement, or the Voting Agreement, pursuant to which each of Clarus, Sofinnova Venture Partners IX, L.P., Novo Holdings A/S, Novartis Bioventures Ltd. and New Enterprise Associates 14, L.P. has the right to designate one member to be elected to our board of directors. See “Management—Board Composition and Election of Directors.” The Voting Agreement will terminate by its terms in connection with the consummation of this offering and none of our stockholders will have any continuing rights pursuant to the Voting Agreement regarding the election or designation of members of our board of directors following this offering.

Right of First Refusal and Co-Sale Agreement

We are party to a second amended and restated right of first refusal and co-sale agreement with certain holders of our capital stock, or the Key Holders, and each holder of our redeemable convertible preferred stock, which includes each holder of more than 5% of our capital stock and certain of our executive officers, pursuant to which we have a right of first refusal in respect of certain sales of securities by our Key Holders. To the extent we do not exercise such right in full, the holders of redeemable convertible preferred stock are granted certain rights of first refusal and co-sale in respect of such sale. The right of first refusal and co-sale agreement will terminate immediately prior to the consummation of this offering.

Consulting Services from IntellectMap Corporation

Since February 2018, IntellectMap Corporation has provided advisory services to the Company on cybersecurity issues. The chief executive officer of IntellectMap is the brother of J. Mel Sorensen, our chief executive officer and a member of our board of directors. Fees paid to IntellectMap during the year ended December 31, 2018 were $0.2 million.

Employment Agreements

We have entered into employment agreements with each of our executive officers. See “Executive Compensation—Executive Compensation Arrangements” for a further discussion of these arrangements.

Director and Officer Indemnification and Insurance

We have agreed to indemnify each of our directors and executive officers against certain liabilities, costs and expenses, and have purchased directors’ and officers’ liability insurance. See “Description of Capital Stock—Limitations on Liability and Indemnification Matters.”

Stock Option Grants to Executive Officers and Directors

We have granted options to our executive officers and certain of our directors as more fully described in the section entitled “Executive Compensation.”

Policies and Procedures for Related Party Transactions

Our board of directors will adopt a written related person transaction policy, to be effective upon the closing of this offering, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of

Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds $120,000 in any fiscal year and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

PRINCIPAL STOCKHOLDERS

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

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

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, a person is deemed to be a "beneficial" owner of a security if that person has or shares voting power or investment power, which includes the power to dispose of or to direct the disposition of such security. Except as indicated in the footnotes below, we believe, based on the information furnished to us, that the individuals and entities named in the table below have sole voting and investment power with respect to all shares of common stock beneficially owned by them, subject to any applicable community property laws.

Percentage ownership of our common stock before this offering is based on 97,905,795 shares of our common stock outstanding as of December 31, 2018, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into shares of our common stock upon the closing of this offering. Percentage ownership of our common stock after this offering is based on shares of our common stock outstanding as of December 31, 2018, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock as described above and our issuance of shares of our common stock in this offering. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights held by such person that are currently exercisable or that will become exercisable within 60 days of December 31, 2018 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. Unless noted otherwise, the address of all listed stockholders is 2 W Liberty Blvd #100, Malvern, Pennsylvania 19355.

Name of beneficial owner	Shares of common stock beneficially owned	Percentage of common stock beneficially owned: Before this offering	Percentage of common stock beneficially owned: After this offering
5% stockholders:			
Entities affiliated with New Enterprise Associates(1)	19,954,829	20.4%	%
Novartis Bioventures Ltd.(2)	16,651,609	17.0	
Novo Holdings A/S(3)	14,709,659	15.0	
Sofinnova Venture Partners IX, L.P.(4)	11,800,568	12.1	
Entities affiliated with Blackstone(5)	7,225,758	7.4	
Named executive officers and directors:			
J. Mel Sorensen, M.D.(6)	2,763,639	2.7	
Robert A. Beardsley, Ph.D.(7)	1,637,330	1.7	
Dennis P. Riley, Ph.D.(8)	1,038,849	1.1	
Jon T. Holmlund, M.D.(9)	612,877	*	
Arthur Fratamico, R.Ph(10)	485,265	*	
Jason Fuller, Ph.D.(11)	19,954,829	20.4	
Campbell Murray, M.D.(2)	16,651,609	17.0	
Thomas Dyrberg, M.D.(12)	14,709,659	15.0	
Michael Powell, Ph.D.(13)	11,800,568	12.1	
Emmett Cunningham, M.D.(14)	7,225,758	7.4	
All executive officers and directors as a group (10 individuals)(15)	71,151,511	72.7	

* Less than 1%.

(1) Consists of (i) 19,929,829 shares of our redeemable convertible preferred stock held of record by New Enterprise Associates 14, L.P., or NEA 14, and (ii) 25,000 shares of our redeemable convertible preferred stock held of record by NEA Ventures 2012 Limited Partnership, or Ven 2012, which shares will convert into an aggregate of shares of our common stock upon, the closing of this offering. NEA Partners 14, L.P., or NEA Partners 14, is the general partner of NEA 14, and NEA 14 GP LTD, or NEA 14 LTD, is the general partner of NEA Partners 14. The directors of NEA 14 LTD are Peter J. Barris, Forest Baskett, Anthony A. Florence, Patrick J. Kerins, David M. Mott, Scott D. Sandell and Peter W. Sonsini. NEA Partners 14, NEA 14 LTD and the directors of NEA 14 LTD share voting and dispositive power with regard to the Company's securities held directly by NEA 14. The shares held by Ven 2012 are indirectly held by Karen P. Welsh, the general partner of Ven 2012. Karen P. Welsh has voting and dispositive power with regard to the Company's securities directly held by Ven 2012. All indirect holders disclaim beneficial ownership of all applicable shares, except to the extent of their pecuniary interest therein.

(2) The board of directors of Novartis Bioventures Ltd. has sole voting and investment control and power over such shares. None of the members of its board of directors has individual voting or investment power with respect to such shares and each disclaims beneficial ownership of such shares. Dr. Campbell Murray, a member of our board of directors, is also an employee of a corporation that is affiliated with Novartis Bioventures Ltd. Dr. Murray disclaims beneficial ownership of the shares held by Novartis Bioventures Ltd., except to the extent of his pecuniary interest arising as a result of his employment by such affiliate of Novartis Bioventures Ltd. Novartis Bioventures Ltd. is a Swiss corporation and an indirectly owned subsidiary of Novartis AG. The address for Novartis Bioventures Ltd is Lichtstrasse 35, CH-4056 Basel.

(3) Novo Holdings A/S, a Danish limited liability company, is wholly owned by Novo Nordisk Fonden (the "Foundation"), a Danish commercial foundation. Novo A/S changed its name to Novo Holdings A/S on June 23, 2017. Novo Holdings A/S is the holding company in the group of Novo companies (currently comprised of Novo Nordisk A/S, Novozymes A/S and NNIT A/S) and is responsible for managing the Foundation's assets, including its financial assets. Based on the governance structure of Novo Holdings A/S and the Foundation, the Foundation disclaims any beneficial ownership of the shares held by Novo Holdings A/S. Novo Holdings A/S, through its board of directors (the "Novo Board"), has the sole power to

vote and dispose of the shares. Sten Scheibye, Francis Michael Cyprian Cuss, Goran Ando, Jean-Luc Butel, Jeppe Christiansen, Steen Riisgaard, Per Wold-Olsen and Lars Rebien Sorensen serve on the Novo Board and may exercise voting and dispositive control over the shares only with the support of a majority of the Novo Board. As such, no individual member of the Novo Board is deemed to hold any beneficial ownership or reportable pecuniary interest in the shares. The business address of Novo Holdings A/S is Tuborg Havnevej 19, 2900 Hellerup, Denmark.

(4) Represents shares held directly by Sofinnova Venture Partners IX, L.P., or SVP IX. Dr. Michael F. Powell, a member of our board of directors, Dr. James Healy and Dr. Anand Mehra are the managing members of Sofinnova Management IX, L.L.C., the general partner of SVP IX, and as such, may be deemed to share voting and investment power with respect to such shares. Dr. Powell disclaims beneficial ownership. The mailing address of SVP IX is c/o Sofinnova Ventures, Inc., 3000 Sand Hill Road, Bldg. 4, Suite 250, Menlo Park, CA 94025.

(5)

(6) Includes (i) 76,000 shares of common stock and (ii) 2,687,639 shares of common stock underlying stock options exercisable within 60 days of December 31, 2018.

(7) Includes (i) 267,140 shares of common stock, (ii) 77,681 shares of our redeemable convertible preferred stock, which shares will convert into an aggregate of shares of our common stock upon the closing of this offering, and (iii) 1,292,509 shares of common stock underlying stock options exercisable within 60 days of December 31, 2018.

(8) Includes (i) 274,360 shares of common stock, (ii) 113,907 shares of our redeemable convertible preferred stock, which shares will convert into an aggregate of shares of our common stock upon the closing of this offering, and (iii) 650,582 shares of common stock underlying stock options exercisable within 60 days of December 31, 2018.

(9) Consists of 612,877 shares of common stock underlying stock options exercisable within 60 days of December 31, 2018.

(10) Consists of 485,265 shares of common stock underlying stock options exercisable within 60 days of December 31, 2018.

(11) Consists of (i) 19,929,829 shares of our redeemable convertible preferred stock held of record by New Enterprise Associates 14, L.P., or NEA 14, and (ii) 25,000 shares of our redeemable convertible preferred stock held of record directly by NEA Ventures 2012 Limited Partnership, or Ven 2012, which shares will convert into an aggregate of shares of our common stock upon the closing of this offering, which Dr. Fuller may be deemed to beneficially own. See footnote (1) above. Dr. Fuller disclaims beneficial ownership of such shares.

(12) Consists of 14,709,659 shares of our redeemable convertible preferred stock held of record by Novo Holdings A/S, which shares will convert into an aggregate of shares of our common stock upon the closing of this offering, which Dr. Dyrberg may be deemed to beneficially own. See footnote (3) above. Dr. Dyrberg disclaims beneficial ownership of such shares.

(13) Consists of 11,800,568 shares of our redeemable convertible preferred stock held by Sofinnova Venture Partners IX, L.P., which shares will convert into an aggregate of shares of our common stock upon the closing of this offering, which Dr. Powell may be deemed to beneficially own. See footnote (4) above. Dr. Powell disclaims beneficial ownership of such shares.

(14) Consists of 7,225,758 shares of our redeemable convertible preferred stock held by entities affiliated with Blackstone, which shares will convert into an aggregate of shares of our common stock upon the closing of this offering, which Dr. Cunningham may be deemed to beneficially own. See footnote (5) above. Dr. Cunningham disclaims beneficial ownership of such shares.

(15) Includes 5,728,872 shares of common stock underlying stock options exercisable within 60 days of December 31, 2018.

DESCRIPTION OF CAPITAL STOCK

Capital Structure

The following description of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the amended and restated bylaws that will be in effect upon the closing of this offering. Copies of these documents will be filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of our common stock and preferred stock reflect changes to our capital structure that will occur upon the closing of this offering.

General

Upon the closing of this offering, our authorized capital stock will consist of shares, all with a par value of $0.001 per share, of which:

- shares are designated as common stock; and
- shares are designated as preferred stock.

Common Stock

As of December 31, 2018, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into 96,385,795 shares of our common stock upon the closing of this offering, we had outstanding 97,905,795 shares of common stock held of record by 32 stockholders.

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue in the future.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. Our outstanding shares of common stock are, and the shares offered by us in this offering will be, when issued and paid for, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Redeemable Convertible Preferred Stock

As of December 31, 2018, there were 96,385,795 shares of our redeemable convertible preferred stock outstanding. Upon the closing of this offering, all outstanding shares of our redeemable convertible preferred stock will automatically convert into an aggregate of shares of our common stock.

Under the terms of our amended and restated certificate of incorporation that will become effective immediately prior to the closing of this offering, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from seeking to acquire, a majority of our outstanding voting stock. Upon the closing of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

Options

As of December 31, 2018, options to purchase 10,475,405 shares of our common stock were outstanding under our Existing Equity Incentive Plan, of which 7,571,290 options were vested of that date.

Registration Rights

The Investors' Rights Agreement grants the parties thereto certain registration rights in respect of the "Registrable Securities" held by them, which securities include (1) the shares of our common stock issuable or issued upon the conversion of shares of our redeemable convertible preferred stock, (2) any shares of our common stock, or any common stock issued or issuable upon conversion and/or exercise of any of our securities acquired by the parties after the date of the Investors' Rights Agreement, and (3) any shares of our common stock issued as a dividend or other distribution with respect to the shares described in the foregoing clauses (1) and (2). The registration of shares of our common stock pursuant to the exercise of these registration rights would enable the holders thereof to sell such shares without restriction under the Securities Act when the applicable registration statement is declared effective. Under the Investors' Rights Agreement, we will pay all expenses relating to such registrations, including the reasonable fees of one special counsel for the participating holders, and the holders will pay all underwriting discounts and commissions relating to the sale of their shares. The Investors' Rights Agreement also includes customary indemnification and procedural terms.

Holders of shares of our common stock (including shares issuable upon the conversion of our redeemable convertible preferred stock) are entitled to such registration rights pursuant to the Investors' Rights Agreement. These registration rights will expire on the earlier of (1) the date that is five years after the closing of this offering, (2) with respect to each stockholder, at such time as such stockholder can sell all of its shares pursuant to Rule 144 of the Securities Act or another similar exemption under the Securities Act during any three month period without registration, (3) the closing of a Deemed Liquidation Event, as defined in our certificate of incorporation.

Demand Registration Rights

At any time beginning 180 days after the effective date of the registration statement, the holders of not less than 30% of the Registrable Securities then outstanding may, on not more than two occasions, request that we prepare, file and maintain a registration statement on Form S-1 to register the Registrable Securities of such holders if the anticipated aggregate offering price, net of underwriting discounts and commissions, would be at least $10.0 million. Once we are eligible to use a registration statement on Form S-3, the stockholders party to the Investors' Rights Agreement may, on not more than two occasions in any 12-month period, request that we prepare, file and maintain a registration statement on Form S-3 covering the sale of their registrable securities, but only if the anticipated aggregate offering price, net of underwriting discounts and commissions, would exceed $1.0 million.

Piggyback Registration Rights

In the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the stockholders party to the Investors' Rights Agreement

will be entitled to certain "piggyback" registration rights allowing them to include their registrable securities in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act other than with respect to a demand registration or a registration statement on Form S-4 or S-8 or a registration in which the only common stock being registered is common stock issuable upon conversion of debt securities that are also being registered, these holders will be entitled to notice of the registration and will have the right to include their registrable securities in the registration subject to certain limitations.

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

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

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

Undesignated Preferred Stock

The ability of our board of directors, without action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Stockholder Meetings

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

Requirements for Advance Notification of Stockholder Nominations and Proposals

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

Elimination of Stockholder Action by Written Consent

Our fifth amended and restated certificate of incorporation will eliminate the right of stockholders to act by written consent without a meeting.

Staggered Board

Our board of directors will be divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. For more information on the classified

board, see "Management—Board Composition and Election of Directors." This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors

Our fifth amended and restated certificate of incorporation will provide 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 the holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote in the election of directors.

Stockholders Not Entitled to Cumulative Voting

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

Delaware Anti-Takeover Statute

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

Choice of Forum

Our fifth amended and restated certificate of incorporation will provide that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws; (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (5) any action asserting a claim governed by the internal affairs doctrine. Our fifth amended and restated certificate of incorporation will also provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. Our fifth amended and restated certificate of incorporation will further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. It is possible that a court of law could rule that the choice of forum provision contained in our restated certificate of incorporation is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock and the provision prohibiting cumulative voting, would require

approval by holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote thereon. The provisions of Delaware law, our fifth amended and restated certificate of incorporation and our restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Limitations on Liability and Indemnification Matters

Our fifth amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to the closing of this offering, will provide that we will indemnify each of our directors and executive officers to the fullest extent permitted by the DGCL. Prior to the consummation of this offering, we intend to enter into indemnification agreements with each of our directors and executive officers that may, in some cases, be broader than the specific indemnification provisions contained under Delaware law. Further, we agreed to indemnify each of our directors and executive officers against certain liabilities, costs and expenses, and we have purchased a policy of directors' and officers' liability insurance that insures our directors and executive officers against the cost of defense, settlement or payment of a judgment under certain circumstances. In addition, as permitted by Delaware law, our amended and restated certificate of incorporation will include provisions that eliminate the personal liability of our directors for monetary damages resulting from breaches of certain fiduciary duties as a director. The effect of this provision is to restrict our rights and the rights of our stockholders in derivative suits to recover monetary damages against a director for breach of fiduciary duties as a director.

These provisions may be held not to be enforceable for violations of the federal securities laws of the United States.

Listing

We intend to apply to list our common stock on The Nasdaq Global Market under the symbol "GRTX."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is .

SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our common stock, and no predictions can be made about the effect, if any, that market sales of our common stock or the availability of such shares for sale will have on the market price prevailing from time to time. Nevertheless, future sales of our common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock and could impair our ability to raise capital through future sales of our securities. See "Risk Factors—Risks Related to Our Common Stock and this Offering—A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well." Furthermore, although we intend to apply to have our common stock listed on The Nasdaq Global Market, we cannot assure you that there will be an active public trading market for our common stock.

Upon the closing of this offering, based on the number of shares of our common stock outstanding as of December 31, 2018 and after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into 96,385,795 shares of our common stock immediately prior to the closing of this offering, we will have an aggregate of shares of our common stock outstanding (or shares of our common stock if the underwriters exercise in full their option to purchase additional shares). Of these shares of our common stock, all of the shares sold in this offering (or shares if the underwriters exercise in full their option to purchase additional shares) will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act, whose sales would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining shares of our common stock will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below. Upon expiration of the lock-up period, we estimate that approximately shares of our common stock will be available for sale in the public market, subject in some cases to applicable volume limitations under Rule 144.

Lock-Up Agreements

We and each of our directors and executive officers and holders of substantially all of our outstanding capital stock have agreed that, without the prior written consent of Merrill Lynch, Pierce, Fenner & Smith Incorporated and Citigroup Global Markets Inc., we and they will not, subject to certain exceptions, during the period ending 180 days after the date of this prospectus, (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for common stock, whether now owned or hereafter acquired (including the power of disposition thereof); (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, directly or indirectly, any of the economic consequences of ownership of our common stock, whether any transaction described above is to be settled by delivery of our common stock or such other securities, in cash or otherwise; or (iii) publicly disclose the intention to do any of the foregoing described in (i) and (ii) above.

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above. These lock-up restrictions may be waived at any time by Merrill Lynch, Pierce, Fenner & Smith Incorporated and Citigroup Global Markets Inc. For a further description of these lock-up agreements, please see "Underwriting."

Rule 144

Affiliate Resales of Restricted Securities

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

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares of our common stock immediately after this offering; or
- the average weekly trading volume in shares 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 such sale.

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

Non-Affiliate Resales of Restricted Securities

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

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

Rule 701

In general, under Rule 701, any of an issuer's employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

The Securities and Exchange Commission has indicated that Rule 701 will apply to typical options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

Equity Plans

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

Registration Rights

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

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

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

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

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

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the

activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

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

Definition of a Non-U.S. Holder

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

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

Distributions

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

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

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S.

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

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

Sale or Other Taxable Disposition

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

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

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

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

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

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

Information Reporting and Backup Withholding

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

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

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

Additional Withholding Tax on Payments Made to Foreign Accounts

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

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock. While withholding under FATCA would also have applied to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, recently proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Although these recent Treasury Regulations are not final, taxpayers generally may rely on them until final Treasury Regulations are issued.

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

UNDERWRITING

Merrill Lynch, Pierce, Fenner & Smith Incorporated, Citigroup Global Markets Inc. 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
Merrill Lynch, Pierce, Fenner & Smith Incorporated	
Citigroup Global Markets Inc.	
Credit Suisse Securities (USA) LLC	
Canaccord Genuity 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 several 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	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. We have also agreed to reimburse the underwriters for their expenses relating to clearance of this offering with the Financial Industry Regulatory Authority in an amount up to $.

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 Merrill Lynch, Pierce, Fenner & Smith Incorporated and Citigroup Global Markets Inc. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly

- offer, pledge, sell or contract to sell any common stock,
- sell any option or contract to purchase any common stock,
- purchase any option or contract to sell any common stock,
- grant any option, right or warrant for the sale of any common stock,
- lend or otherwise dispose of or transfer any common stock,
- request or demand that we file or make a confidential submission of a registration statement related to the common stock,
- 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, or
- publicly disclose the intention to do any of the foregoing.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition. Merrill Lynch, Pierce, Fenner & Smith Incorporated and Citigroup Global Markets Inc., in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time with or without notice. In addition, in the event that one or more stockholders is granted an early release from any restriction on transfer described in the lock-up agreements during the lock-up period described therein with respect to our securities in an aggregate amount in excess of certain percentages of our issued and outstanding shares of common stock on an as-converted to common stock basis (whether in one or multiple releases), then each stockholder holding in excess of one percent of the outstanding shares of our securities on an as-converted to common stock basis, or a Major Holder, will automatically be granted an early release on the same terms from the lock-up restrictions on transfer under the lock-up agreement on a pro-rata basis. In the event of an underwritten primary or secondary public offering or sale of our common stock during the period ending 180 days after the date of this prospectus, such early release shall only apply with respect to such Major Holder's participation in such offering.

Nasdaq Global Market Listing

We intend to apply to list our common stock on The Nasdaq Global Market under the symbol "GRTX."

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

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us,
- our financial information,
- the history of, and the prospects for, our company and the industry in which we compete,
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,
- the present state of our development, 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

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. 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.

Notice to Prospective Investors in the European Economic Area

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

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

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Article 3(2) of the Prospectus Directive,

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

Each person located in a Member State to whom any offer of ordinary shares is made or who receives any communication in respect of an offer of ordinary shares, or who initially acquires any ordinary shares will be

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

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

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

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

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

Notice to Prospective Investors in the United Kingdom

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

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("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, or 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 (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("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 ("DFSA"). This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission ("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 (the "Corporations Act"), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

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

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

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap.

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

Notice to Prospective Investors in Japan

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

Notice to Prospective Investors in Singapore

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

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

(a) 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

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

(a) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(b) where no consideration is or will be given for the transfer;

(c) where the transfer is by operation of law;

(d) as specified in Section 276(7) of the SFA; or

(e) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Notice to Prospective Investors in Canada

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

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

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

LEGAL MATTERS

The validity of the shares of our common stock offered hereby will be passed upon for us by Latham & Watkins LLP. Certain legal matters will be passed upon for the underwriters by Shearman & Sterling LLP, New York, New York.

EXPERTS

The consolidated financial statements of Galera Therapeutics, Inc. as of December 31, 2017 and 2018, and for the years then ended have been included herein and in the registration statement in reliance on the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said 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 offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the shares of common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. You may read and copy the registration statement, the related exhibits and other material we file with the SEC at the SEC's Public Reference Room, 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can also request copies of those documents, upon Payment of a duplicating fee, by writing to the SEC. You may obtain information on the operation of the public reference rooms by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the SEC. The address of that site is *www.sec.gov*.

Upon the effectiveness of the registration statement, we will be subject to the informational requirements of the Exchange Act, and, in accordance with the Exchange Act, will file reports, proxy and information statements and other information with the SEC. Such annual, quarterly and special reports, proxy and information statements and other information can be inspected and copied at the locations set forth above. We intend to make this information available on the investor relations section of our website, which is located at *www.galeratx.com*. Information on, or accessible through, our website is not part of this prospectus.

GALERA THERAPEUTICS, INC.

Index to consolidated financial statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors
Galera Therapeutics, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Galera Therapeutics, Inc. and its subsidiaries (the Company) as of December 31, 2017 and 2018, the related consolidated statements of operations, comprehensive loss, changes in redeemable convertible preferred stock and stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2018, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2014.

Philadelphia, Pennsylvania
March 15, 2019

GALERA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS EXCEPT SHARE AND PER-SHARE AMOUNTS)

	December 31,		December 31, 2018
	2017	2018	Pro forma (unaudited)
Assets			
Current assets:			
Cash and cash equivalents	$ 6,169	$ 14,811	$ 14,811
Short-term investments	8,011	66,706	66,706
Tax incentive receivable	507	870	870
Prepaid expenses and other current assets	479	1,465	1,465
Total current assets	15,166	83,852	83,852
Property and equipment, net	325	568	568
Acquired intangible asset	2,258	2,258	2,258
Goodwill	881	881	881
Other assets	242	497	497
Total assets	$ 18,872	$ 88,056	$ 88,056
Liabilities, redeemable convertible preferred stock and stockholders' (deficit) equity			
Current liabilities:			
Accounts payable	$ 2,257	$ 3,867	$ 3,867
Accrued expenses	2,037	2,577	2,577
Total current liabilities	4,294	6,444	6,444
Royalty purchase liability	—	20,220	20,220
Deferred rent	14	12	12
Deferred tax liability	521	298	298
Total liabilities	4,829	26,974	26,974
Commitments (Note 7)			
Redeemable convertible preferred stock, $0.001 par value:			
96,385,795 shares authorized, 64,689,359 and 96,385,795 shares issued and outstanding at December 31, 2017 and 2018, respectively (liquidation value of $168,045 at December 31, 2018)	90,148	165,902	—
Stockholders' (deficit) equity:			
Common stock, $0.001 par value: 115,000,000 shares authorized; 1,520,000 shares issued and outstanding at December 31, 2017 and 2018; 97,905,795 shares issued and outstanding at December 31, 2018 pro forma	2	2	98
Additional paid-in capital	—	—	165,806
Accumulated other comprehensive (loss) income	(3)	3	3
Accumulated deficit	(76,104)	(104,825)	(104,825)
Total stockholders' (deficit) equity	(76,105)	(104,820)	61,082
Total liabilities, redeemable convertible preferred stock and stockholders' (deficit) equity	$ 18,872	$ 88,056	$ 88,056

See accompanying notes to consolidated financial statements

GALERA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS EXCEPT SHARE AND PER-SHARE AMOUNTS)

	Year ended December 31,	
	2017	2018
Operating expenses:		
Research and development	$ 20,594	$ 18,663
General and administrative	3,500	5,592
Loss from operations	(24,094)	(24,255)
Other income (expenses):		
Interest income	193	606
Interest expense	—	(220)
Foreign currency loss	(4)	(30)
Loss from operations before income tax benefit	(23,905)	(23,899)
Income tax benefit	360	223
Net loss	(23,545)	(23,676)
Accretion of redeemable convertible preferred stock to redemption value	(4,588)	(5,910)
Net loss attributable to common stockholders	$ (28,133)	$ (29,586)
Net loss per share of common stock, basic and diluted	$ (18.51)	$ (19.46)
Weighted-average shares of common stock outstanding, basic and diluted	1,520,000	1,520,000
Pro forma net loss per share of common stock, basic and diluted (unaudited)		$ (0.31)
Pro forma weighted-average shares of common stock outstanding, basic and diluted (unaudited)		76,977,463

See accompanying notes to consolidated financial statements

GALERA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(IN THOUSANDS)

	Year ended December 31,	
	2017	2018
Net loss	$ (23,545)	$ (23,676)
Unrealized (loss) gain on short-term investments	(4)	6
Comprehensive loss	$ (23,549)	$ (23,670)

See accompanying notes to consolidated financial statements

GALERA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(IN THOUSANDS EXCEPT SHARE AMOUNTS)

	Redeemable convertible preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive (loss) income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at January 1, 2017	64,689,359	$ 85,560	1,520,000	$ 2	$ —	$ 1	$ (48,697)	$ (48,694)
Share-based compensation expense	—	—	—	—	726	—	—	726
Accretion of redeemable convertible preferred stock to redemption value	—	4,588	—	—	(726)	—	(3,862)	(4,588)
Unrealized loss on short-term investments	—	—	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	—	—	(23,545)	(23,545)
Balance at December 31, 2017	64,689,359	90,148	1,520,000	2	—	(3)	(76,104)	(76,105)
Sale of Series C redeemable convertible preferred stock, net of issuance costs of $342	31,696,436	69,844	—	—	—	—	—	—
Share-based compensation expense	—	—	—	—	865	—	—	865
Accretion of redeemable convertible preferred stock to redemption value	—	5,910	—	—	(865)	—	(5,045)	(5,910)
Unrealized gain on short-term investments	—	—	—	—	—	6	—	6
Net loss	—	—	—	—	—	—	(23,676)	(23,676)
Balance at December 31, 2018	96,385,795	$165,902	1,520,000	$ 2	$ —	$ 3	$ (104,825)	$ (104,820)

See accompanying notes to consolidated financial statements

GALERA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)

	Year ended December 31, 2017	2018
Operating activities:		
Net loss	$ (23,545)	$ (23,676)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	84	127
Noncash interest expense	—	220
Share-based compensation expense	726	865
Changes in operating assets and liabilities:		
Tax incentive receivable	(63)	(363)
Prepaid expenses and other current assets	(38)	(986)
Other assets	—	(255)
Accounts payable	(652)	1,587
Accrued expense	440	540
Deferred rent	2	(2)
Deferred tax liability	(360)	(223)
Cash used in operating activities	(23,406)	(22,166)
Investing activities:		
Purchases of short-term investments	(9,919)	(71,190)
Proceeds from sales of short-term investments	33,750	12,501
Purchase of property and equipment	(319)	(347)
Cash provided by (used in) investing activities	23,512	(59,036)
Financing activities:		
Proceeds from royalty purchase agreement	—	20,000
Proceeds from the sale of Series C redeemable convertible preferred stock, net of issuance costs	—	69,844
Cash provided by financing activities	—	89,844
Net increase in cash and cash equivalents	106	8,642
Cash and cash equivalents at beginning of year	6,063	6,169
Cash and cash equivalents at end of year	$ 6,169	$ 14,811
Supplemental schedule of non-cash financing activities:		
Accretion of redeemable convertible preferred stock to redemption value	$ 4,588	$ 5,910
Purchase of property and equipment included in accounts payable	$ —	$ 23

See accompanying notes to consolidated financial statements

GALERA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and description of business

Galera Therapeutics, Inc. was incorporated as a Delaware corporation on November 19, 2012 (inception) and together with its subsidiaries, (the Company or Galera) is a clinical stage biopharmaceutical company focused on developing and commercializing a pipeline of novel, proprietary therapeutics that have the potential to transform radiotherapy in cancer. The Company's lead product candidate, GC4419, is a potent and highly selective small molecule dismutase mimetic being developed for the reduction of severe oral mucositis, or SOM. In February 2018, the U.S. Food and Drug Administration, or FDA, granted Breakthrough Therapy Designation to GC4419 for the reduction of the duration, incidence and severity of SOM induced by radiotherapy with or without systemic therapy. The Company is currently evaluating GC4419 in a Phase 3 registrational trial. In addition to developing GC4419 for the reduction of normal tissue toxicity from radiotherapy, the Company is developing its dismutase mimetics to increase the anti-cancer efficacy of higher daily doses of radiotherapy, including stereotactic body radiation therapy, or SBRT. The Company's second dismutase mimetic product candidate, GC4711, is being developed to increase the anti-cancer efficacy of SBRT and has successfully completed a Phase 1 trial of intravenous GC4711 in healthy volunteers. The Company plans to leverage its observations from the GC4419 SBRT pilot Phase 1b/2a trial in LAPC to prepare a GC4711 SBRT combination Phase 1b/2a trial in NSCLC.

Liquidity

The Company has incurred recurring losses and negative cash flows from operations since inception and has an accumulated deficit of $104.8 million as of December 31, 2018. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its product candidates currently in development. Management believes that the Company's cash and cash equivalents and short-term investments as of December 31, 2018 are sufficient to fund the projected operations of the Company into the second quarter of 2020. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates.

Operations since inception have consisted primarily of organizing the Company, securing financing, developing licensed technologies, performing research, and conducting pre-clinical studies and clinical trials. The Company faces risks associated with companies whose products are in development. These risks include the need for additional financing to complete its research and development, achieving its research and development objectives, defending its intellectual property rights, recruiting and retaining skilled personnel, and dependence on key members of management.

2. Basis of presentation and significant accounting policies

Basis of presentation and consolidation

The accompanying consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles (U.S. GAAP). The consolidated financial statements include the accounts of Galera Therapeutics, Inc. and its wholly owned subsidiaries, Galera Therapeutics Australia Pty Ltd (Galera Australia) and Galera Labs, LLC. All intercompany accounts and transactions have been eliminated in consolidation.

The Company has determined the functional currency of Galera Australia to be the U.S. dollar. The Company records remeasurement gains and losses on monetary assets and liabilities, such as tax incentive receivables and accounts payable, which are not denominated in U.S. dollars in the statements of operations.

GALERA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Use of estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Estimates and assumptions are periodically reviewed and the effects of revisions are reflected in the consolidated financial statements in the period they are determined to be necessary. Significant areas that require management's estimates include the fair value of common stock, share-based compensation assumptions, and accrued clinical trial expense.

Unaudited pro forma financial information

Immediately prior to the closing of a qualified initial public offering, all of the Company's outstanding redeemable convertible preferred stock will automatically convert into common stock. The accompanying unaudited pro forma consolidated balance sheet as of December 31, 2018 assumes the conversion of all outstanding shares of redeemable convertible preferred stock into 96,385,795 shares of common stock. In the accompanying consolidated statements of operations, unaudited pro forma basic and diluted net loss per share of common stock has been prepared to give effect to the automatic conversion of all outstanding shares of redeemable convertible preferred stock as if they had been converted at the later of the beginning of the reporting period or the issuance date of the redeemable convertible preferred stock. Accordingly, the unaudited pro forma net loss attributable to common stockholders used in the calculation of unaudited basic and diluted pro forma net loss per share of common stock excludes the effects of accretion on redeemable convertible preferred stock.

Segment information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one segment.

Fair value of financial instruments

Management believes that the carrying amounts of the Company's financial instruments, including accounts payable and accrued expenses, approximate fair value due to the short-term nature of those instruments. Short-term investments are recorded at their estimated fair value. The royalty purchase liability is accounted for as debt and interest is accreted over the expected repayment period which approximates fair value.

Concentration of credit risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents and short-term investments. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash and cash equivalents.

Cash and cash equivalents

The Company considers all highly liquid investments that have maturities of three months or less when acquired to be cash equivalents. Cash and cash equivalents as of December 31, 2017 and 2018 consisted of bank deposits, U.S. Treasury obligations and a money market mutual fund invested in U.S. Treasury obligations.

GALERA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Short-term investments

Short-term investments consist of debt securities with a maturity of greater than three months when acquired. The Company classifies its short-term investments at the time of purchase as available-for-sale securities. Available-for-sale securities are carried at fair value. Unrealized gains and losses on available-for-sale securities are reported in accumulated other comprehensive income (loss), a component of stockholders' equity (deficit), until realized. Short-term investments at December 31, 2017 and 2018 consisted of U.S. Treasury obligations with fair values of $8.0 million and $66.7 million, respectively and unrealized (losses) gains of ($4,000) and $6,000, respectively.

Tax incentive receivable

Galera Australia is eligible to participate in an Australian research and development tax incentive program under which the Company is eligible to receive a cash refund from the Australian Taxation Office for a percentage of the research and development costs expended by Galera Australia in Australia. The cash refund is available to companies with an annual aggregate revenue of less than $20.0 million (Australian) during the reimbursable period. The Company's estimate of the amount of cash refund it expects to receive related to the Australian research and development tax incentive program is included in tax incentive receivable in the accompanying consolidated balance sheets and such amounts are recorded as reduction of research and development expense in the statements of operations. During the years ended December 31, 2017 and 2018, the Company recorded reductions to research and development expenses of $0.5 million and $0.4 million, respectively. The Company's estimate of the amount of cash refund it expects to receive as part of this incentive program from July 1, 2017 through December 31, 2018 based on eligible spending was $0.9 million. During the year ended December 31, 2017, the Company received $0.7 million in research and development tax incentive refunds related to qualified Australian expenses incurred through June 30, 2017.

In addition, Galera Australia incurs Goods and Services Tax (GST) on services provided by Australian vendors. As an Australian entity, it is entitled to a refund of the GST paid. The Company's estimate of the amount of cash refund it expects to receive related to GST was $44,000 as of December 31, 2018, which is included in prepaid expenses and other current assets in the accompanying consolidated balance sheet.

Property and equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over their estimated useful lives ranging from three to five years. Leasehold improvements are amortized over the shorter of their economic lives or the remaining lease term. The costs of maintenance and repairs are expensed as incurred. Improvements and betterments that add new functionality or extend the useful life of the asset are capitalized.

Impairment of long-lived assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated undiscounted future cash flows, then an impairment charge is recognized for the amount by which the carrying value of the asset exceeds the estimated fair value of the asset. As of December 31, 2018, the Company believes that no revision of the remaining useful lives or write-down of long-lived assets is required.

GALERA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Goodwill and acquired intangible asset

In November 2012, the Company completed a Series A redeemable convertible preferred stock (Series A) financing with venture capital investors and simultaneously acquired Galera Therapeutics, LLC (LLC), a limited liability company incorporated in Missouri in 2009. LLC was renamed Galera Labs, LLC, in January 2013 and operates as a wholly owned subsidiary of the Company. The Company applied the purchase method of accounting under which the consideration given to the LLC members and noteholders was allocated to the fair value of the net assets assumed from the LLC at the date of the acquisition. The sole intangible asset acquired represented the fair value of in-process research and development (IPR&D) which has been recorded on the accompanying consolidated balance sheet as an indefinite life intangible asset. A deferred tax liability was recorded for the difference between the fair value of the acquired IPR&D and its tax basis of zero which was recognized as goodwill in applying the purchase method of accounting.

Intangible assets related to IPR&D are considered indefinite-lived intangible assets and, along with goodwill, are not amortized, but are assessed for impairment annually or more frequently if impairment indicators exist. For those compounds that reach commercialization, the IPR&D assets will be amortized over their estimated useful lives. If the associated research and development effort related to IPR&D is abandoned, the related assets will be written-off and the Company will record a noncash impairment loss on its consolidated statements of operations. For the years ended December 31, 2017 and 2018, the Company determined that there was no impairment to goodwill or IPR&D.

Research and development expenses

Research and development costs are expensed as incurred and consist primarily of funds paid to third parties for the provision of services for product candidate development, clinical and preclinical development and related supply and manufacturing costs, and regulatory compliance costs. The Company accrues and expenses preclinical studies and clinical trial activities performed by third parties based upon estimates of the proportion of work completed over the term of the individual trial and patient enrollment rates in accordance with agreements with clinical research organizations and clinical trial sites. The Company determines the estimates by reviewing contracts, vendor agreements and purchase orders, and through discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services. However, actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending upon a number of factors, including the Company's clinical development plan.

Management makes estimates of the Company's accrued expenses as of each balance sheet date in the Company's consolidated financial statements based on facts and circumstances known to the Company at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Nonrefundable advance payments for goods and services, including fees for process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Share-based compensation

The Company measures employee and nonemployee director share-based awards at their grant-date fair value and records compensation expense on a straight-line basis over the vesting period of the awards.

Estimating the fair value of share-based awards requires the input of subjective assumptions, including the estimated fair value of the Company's common stock, and, for stock options, the expected life of the options

and stock price volatility. The Company uses the Black-Scholes option pricing model to value its stock option awards. The assumptions used in estimating the fair value of share-based awards represent management's estimate and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and management uses different assumptions, share-based compensation expense could be materially different for future awards.

The expected life of the stock options is estimated using the "simplified method," as the Company has no historical information from which to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock option grants. The simplified method is the midpoint between the vesting period and the contractual term of the option. For stock price volatility, the Company uses comparable public companies as a basis for its expected volatility to calculate the fair value of option grants. The risk-free rate is based on the U.S. Treasury yield curve commensurate with the expected life of the option.

Income taxes

The Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss and credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The Company recognizes the benefit of an uncertain tax position that it has taken or expects to take on its income tax return if such a position is more likely than not to be sustained.

Accretion of redeemable convertible preferred stock

The Company's redeemable convertible preferred stock is classified as temporary equity in the accompanying consolidated balance sheets. The carrying values of the redeemable convertible preferred stock are being accreted to their respective redemption values for accruing dividends and issuance costs, using the effective interest method, from the date of issuance to the earliest date the holders can demand redemption. The redemption value is accreted through a charge to additional paid-in-capital, if available, or to accumulated deficit.

Net loss per share

Basic loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during each period. Diluted loss per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as redeemable convertible preferred stock and stock options, which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic net loss per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares of common stock outstanding, as they would be anti-dilutive:

	Year ended December 31,	
	2017	2018
Stock options	10,241,585	10,475,405
Redeemable convertible preferred stock	64,689,359	96,385,795
	74,930,944	106,861,200

GALERA THERAPEUTICS, INC.
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Recent accounting pronouncements

In February 2016, the Financial Accounting Standards Board, (FASB), issued Accounting Standards Update, (ASU), 2016-02, *Leases*, which requires that lease arrangements longer than 12 months result in an entity recognizing an asset and liability on the balance sheet. Additionally, certain qualitative and quantitative disclosures will be required in the financial statements. The updated guidance is effective for annual and interim periods beginning after December 15, 2018. The Company is in the process of evaluating the impact of this updated guidance will have on its consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Classification of Certain Cash Receipts and Cash Payments (Topic 230)*, which provides specific guidance related to eight cash flow classification issues with the objective of reducing the existing diversity in practice for certain cash receipts and cash payments. The standard is effective for annual reporting periods beginning after December 15, 2018 and interim periods reporting within fiscal years beginning after December 15, 2019. The adoption of this ASU is not expected to have a material impact on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting (Topic 718)*, which simplifies the accounting for nonemployee share-based transactions. The amendments specify that Topic 718 applies to all share-based transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based awards. The standard will be effective for fiscal years beginning after December 15, 2018, although early adoption is permitted (but no sooner than the adoption of Topic 606). The Company early adopted this guidance effective January 1, 2018 and it did not have a material impact on the Company's consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, which removes and modifies some existing disclosure requirements and adds others. The ASU is effective for all entities for fiscal years beginning after December 15, 2019, including interim periods therein. Early adoption is permitted for any eliminated or modified disclosures upon issuance of this ASU. The adoption of this ASU is not expected to have a material impact on the Company's consolidated financial statements.

3. Fair value measurements

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines fair value based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

- Level 1 Inputs: Unadjusted quoted prices in active markets for identical assets or liabilities accessible to the reporting entity at the measurement date.

- Level 2 Inputs: Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability.

- Level 3 Inputs: Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at measurement date.

GALERA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The following table presents the Company's assets and liabilities that are measured at fair value on a recurring basis (amounts in thousands):

	December 31, 2017		
	(Level 1)	(Level 2)	(Level 3)
Assets			
Money market funds and U.S. Treasury obligations (included in cash equivalents)	$ 5,722	$ —	$ —
Short-term investments	$ 8,011	$ —	$ —

	December 31, 2018		
	(Level 1)	(Level 2)	(Level 3)
Assets			
Money market funds and U.S. Treasury obligations (included in cash equivalents)	$13,770	$ —	$ —
Short-term investments	$66,706	$ —	$ —

There were no changes in valuation techniques during the years ended December 31, 2017 and 2018. The Company's short-term investment instruments are classified using Level 1 inputs within the fair value hierarchy because they are valued using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency.

4. Property and equipment

Property and equipment consist of (amounts in thousands):

	December 31,	
	2017	2018
Laboratory equipment	$ 302	$ 507
Computer hardware and software	78	109
Furniture and fixtures	128	159
Property and equipment, gross	508	775
Less: Accumulated depreciation	(183)	(207)
Property and equipment, net	$ 325	$ 568

Depreciation expense was $84,000 and $0.1 million for the years ended December 31, 2017 and 2018, respectively.

5. Accrued expenses

Accrued expenses consist of (amounts in thousands):

	December 31,	
	2017	2018
Compensation and related benefits	$ 658	$ 776
Research and development expenses	1,288	1,665
Professional fees	91	136
	$2,037	$2,577

GALERA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

6. Royalty purchase liability

In November 2018, the Company entered into an Amended and Restated Purchase and Sale Agreement (Royalty Agreement), with Clarus IV Galera Royalty AIV, L.P., Clarus IV-A, L.P., Clarus IV-B, L.P., Clarus IV-C, L.P. and Clarus IV-D, L.P. (collectively, Clarus). Pursuant to the Royalty Agreement, Clarus agreed to pay up to $80.0 million (the Royalty Purchase Price) in four tranches of $20.0 million each upon the achievement of specific Phase 3 clinical trial patient enrollment milestones. The Company received the first tranche of the Royalty Purchase Price in November 2018.

The Company accounts for the Royalty Agreement as a debt instrument. The $20.0 million proceeds from the first tranche under the Royalty Agreement have been recorded as a liability on the Company's consolidated balance sheet. Interest expense is imputed based on the estimated royalty repayment period described below which results in a corresponding increase in the liability balance. The Company recognized $0.2 million in noncash interest expense during the year ended December 31, 2018. As of December 31, 2018, the effective interest rate was 8.7%.

Clarus is entitled to a mid single-digit percentage royalty based on the worldwide net sales of the GC4419 and GC4711 (the Products). The royalty period will continue until the earlier of (i) the 12th anniversary of commercial launch of the Products, (ii) the expiration of the patents covering such Products, and (iii) the expiration of regulatory data protection or market exclusivity or similar regulatory protection afforded by the health authorities in such country, to the extent such protection or exclusivity effectively prevents generic versions of such Products from entering the market in such country.

If Clarus fails to fund the remaining $60.0 million Royalty Purchase Price within two days of the conditions to the payment of such tranche having been satisfied, the Company may terminate its obligation to accept such tranche and any additional remaining tranches. In such an event, the Company's royalty obligations to Clarus shall be reduced to a low single-digit percentage.

The Royalty Agreement will remain in effect until the aggregate amount of the royalty payments paid to Clarus exceeds a fixed single-digit multiple of the actual amount of the Royalty Purchase Price received by the Company, unless earlier terminated pursuant to the mutual written agreement of the Company and Clarus.

7. Commitments

Operating leases

The Company leases office space in Malvern, Pennsylvania and office and laboratory space in St. Louis, Missouri. The Malvern office lease extends through February 2023. Rent expense related to the Malvern office lease was $0.2 million and $0.3 million for the years ended December 31, 2017 and 2018, respectively. The St. Louis lease extends through January 2021. Rent expense related to the St. Louis lease was $41,000 and $44,000 for the years ended December 31, 2017 and 2018, respectively.

The Company also leases certain office equipment under an operating lease. Future minimum lease payments under noncancelable operating leases are as follows (in thousands):

2019	$ 440
2020	460
2021	392
2022	391
2023	65
	$1,748

GALERA THERAPEUTICS, INC.
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Employment benefit plan

In September 2013, the Company implemented the Galera Therapeutics, Inc. 401(k) Plan (the Plan) covering all qualified employees. Under the Plan, participating employees may defer up to the Internal Revenue Service's annual contribution limit. The Company at its discretion may match each employee's contributions. The Company made no matching contributions for the years ended December 31, 2017 and 2018.

Employment contracts

The Company has entered into employment contracts with its officers and certain employees that provide for severance and continuation of benefits in the event of termination of employment either by the Company without cause or by the employee for good reason, both as defined in the agreement. In addition, in the event of termination of employment following a change in control, as defined, either by the Company without cause or by the employee for good reason, any unvested portion of the employee's initial stock option grant becomes immediately vested.

Litigation

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties, and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. There are no matters currently outstanding.

8. License agreement

In May 2009, Kereos, Inc. (Kereos) transferred to the Company its superoxide dismutase mimetic patents and related clinical stage compounds and small molecules in exchange for a cash payment of $80,000 and a future payment of up to $0.2 million, contingent upon the Company entering into a non-equity funding arrangement, as defined in the agreement.

9. Redeemable convertible preferred stock and stockholders' (deficit) equity

Redeemable convertible preferred stock

In August 2018, the Company sold 31,696,436 shares of Series C redeemable convertible preferred stock (Series C) to investors for $2.2143 per share for proceeds of $69.8 million, net of issuance costs of $0.3 million.

As of December 31, 2018, the authorized, issued and outstanding shares of redeemable convertible preferred stock and their principal terms were as follows (in thousands except share amounts):

	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Liquidation Value
Series A	22,280,087	22,280,087	$ 28,685	$ 29,301
Series B	29,682,000	29,682,000	43,710	44,342
Series B-1	3,636,363	3,636,363	5,777	5,884
Series B-2	9,090,909	9,090,909	16,649	16,913
Series C	31,696,436	31,696,436	71,081	71,605
	96,385,795	96,385,795	$ 165,902	$ 168,045

GALERA THERAPEUTICS, INC.
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The following is a summary of the amended rights, preferences, and terms of the Series A, Series B, Series B-1, Series B-2 and Series C, collectively, the Preferred Stock:

Rank

The Preferred Stock ranks senior to common stock as to payment of dividends, distributions of assets upon a liquidation event, or otherwise.

Dividends

The holders of the Preferred Stock are entitled to receive cash dividends at the rate of 6% per year as and when declared by the Board of Directors. Preferred Stock dividends accrue cumulatively, and no dividends have been declared through December 31, 2018. Any cumulative but unpaid dividends are payable upon a liquidation event or conversion of the Preferred Stock into common stock. As of December 31, 2017 and 2018, there were $12.3 million and $18.5 million of cumulative unpaid Preferred Stock dividends, respectively.

Voting rights

The holders of the Preferred Stock are entitled to a number of votes equal to the number of shares of common stock into which their shares can be converted. The holders of the Preferred are entitled to elect five members of the Board of Directors.

Liquidation preference

In the event of a liquidation, dissolution, or winding up of the Company, or in the event the Company merges with or is acquired by another entity, the holders of the Preferred Stock are entitled to be paid an amount equal to $1.00 per share of Series A, $1.25 per share of Series B, $1.375 per share of Series B-1, $1.65 per share of Series B-2 and $2.2143 per share of Series C, plus any cumulative unpaid dividends. Once the preceding liquidation preference has been paid, any remaining assets would be distributed pro rata among the holders of the Preferred Stock and common stock.

Conversion

At any time, at the option of the holder, each share of Preferred Stock is convertible into one share of common stock, subject to certain antidilution adjustments. The Preferred Stock is automatically converted into common stock in the event of an initial public offering of specified characteristics, or upon the agreement of holders of a majority of the outstanding Preferred Stock, including at least three of the five largest holders.

Redemption

At any time after August 30, 2024, the holders of a majority of the outstanding Preferred Stock, including at least three of the five largest holders, may require the Company to redeem all of the then outstanding shares of Preferred Stock for an amount equal to $1.00 per share of Series A, $1.25 per share of Series B, $1.375 per share of Series B-1, $1.65 per share of Series B-2 and $2.2143 per share of Series C, plus any cumulative unpaid dividends. The carrying value of the Preferred Stock is being accreted to its redemption value by a charge to additional paid-in capital, if any, then accumulated deficit.

Protective provisions

Approval of holders of a majority of the Preferred Stock, including at least three of the five largest holders, is required for certain significant corporate actions.

GALERA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Common stock

The holders of the common stock are entitled to elect one member of the Board of Directors.

10. Share-based compensation

In November 2012, the Company adopted the Equity Incentive Plan (the Plan). The total number of shares authorized under the Plan as of December 31, 2018 was 15,748,833. Of this amount, 5,273,428 shares are available for future grants as of December 31, 2018. Eligible participants include employees, directors, and consultants. The Plan permits the granting of incentive stock options, non-statutory stock options, stock awards, and stock purchase rights. The terms of the agreements are determined by the Company's Board of Directors. The Company's awards vest based on the terms in the agreements and generally vest over 4 years and have a term of 10 years.

Share-based compensation expense was as follows for the years ended December 31, 2017 and 2018 (amounts in thousands):

	Year ended December 31,	
	2017	2018
Research and development	$ 390	$ 434
General and administrative	336	431
	$ 726	$ 865

The following table summarizes the activity related to stock option grants for the years ended December 31, 2017 and 2018:

	Shares	Weighted average exercise price per share	Weighted-average remaining contractual life (years)
Outstanding at January 1, 2017	7,602,045	$0.38	
Granted	2,639,540	0.53	
Outstanding at December 31, 2017	10,241,585	0.42	
Granted	348,820	0.87	
Forfeited	(115,000)	0.87	
Outstanding at December 31, 2018	10,475,405	$0.43	6.7
Vested and exercisable at December 31, 2018	7,571,290	$0.39	6.3
Vested and expected to vest at December 31, 2018	10,475,405	$0.43	6.7

As of December 31, 2018, the unrecognized compensation cost was $1.2 million and will be recognized over an estimated weighted-average amortization period of 1.6 years. The aggregate intrinsic value of options outstanding and options exercisable as of December 31, 2018 was $10.2 million and $7.6 million, respectively. Options granted during the year ended December 31, 2017 and 2018 had weighted-average grant-date fair values of $0.42 and $0.69 per share, respectively.

The fair value of options is estimated using the Black-Scholes option pricing model, which takes into account inputs such as the exercise price, the estimated fair value of the underlying common stock at the grant

date, expected term, expected stock price volatility, risk-free interest rate and dividend yield. The fair value of stock options during the years ended December 31, 2017 and 2018 was determined using the methods and assumptions discussed below.

- The expected term of employee stock options with service-based vesting is determined using the "simplified" method, as prescribed in SEC's Staff Accounting Bulletin (SAB) No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to the Company's lack of sufficient historical data. The expected term of nonemployee options is equal to the contractual term.

- The expected stock price volatility is based on historical volatilities of comparable public entities within the Company's industry which were commensurate with the expected term assumption as described in SAB No. 107.

- The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the expected term.

- The expected dividend yield is 0% because the Company has not historically paid, and does not expect, for the foreseeable future, to pay a dividend on its common stock.

- As the Company's common stock has not been publicly traded, its board of directors periodically estimated the fair value of the Company's common stock considering, among other things, contemporaneous valuations of its common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation.*

The grant date fair value of each option grant was estimated throughout the year using the Black-Scholes option-pricing model using the following weighted-average assumptions:

	Year ended December 31,	
	2017	2018
Expected term (in years)	6.2	7.8
Expected stock price volatility	90.7%	88.0%
Risk-free interest rate	2.1%	2.79%
Expected dividend yield	0%	0%
Fair value of common stock	$ 0.53	$ 0.86

11. Income taxes

The Company's loss before income taxes for the years ended December 31, 2017 and 2018 is summarized as follows (in thousands):

	Year ended December 31,	
	2017	2018
Domestic	$ (21,917)	$ (22,779)
Foreign	(1,988)	(1,120)
	$ (23,905)	$ (23,899)

GALERA THERAPEUTICS, INC.
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The Company's tax provision (benefit) for the years ended December 31, 2017 and 2018 is summarized as follows (in thousands):

	Year ended December 31, 2017	2018
Current:		
Federal	$ —	$ —
State	—	—
Foreign	—	—
	—	—
Deferred:		
Federal	(294)	$ (379)
State	(66)	156
Foreign	—	—
	(360)	(223)
Total income tax benefit	$ (360)	$ (223)

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

	Year ended December 31, 2017	2018
Federal tax benefit at statutory rate	34.0%	21.0%
State tax, net of federal benefit	1.9	0.7
Net operating loss carryforwards	—	10.6
Change in tax rate	(31.9)	(0.4)
Sale of royalty interest	—	(17.6)
Difference in foreign tax rate	(0.2)	0.4
Research and development	(1.6)	3.3
Change in valuation allowance	0.7	(16.2)
Share-based compensation	(0.9)	(0.6)
Other	(0.5)	(0.3)
	1.5%	0.9%

GALERA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The tax effects of temporary differences that gave rise to significant portions of the deferred tax assets and liabilities were as follows (in thousands):

	December 31, 2017	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 16,564	$ 19,733
Share-based compensation	53	118
Research and development credits	1,253	2,317
Accrued expenses and other	154	119
Gross deferred tax asset	18,024	22,287
Valuation allowance	(18,024)	(21,908)
Net deferred tax asset	—	379
Deferred tax liabilities		
Acquired in-process research and development	(521)	(677)
Deferred tax liabilities	$ (521)	$ (298)

In assessing the need for a valuation allowance, the Company may utilize indefinite-lived deferred tax liabilities from an intangible asset as a future source of income. The Company's acquired IPR&D intangible asset can be utilized as a source of income arising from the future reversal of temporary difference that can be offset against post 2017 indefinite-lived net operating losses (NOLs). Therefore, the Company is permitted to offset the indefinite-lived deferred tax liability up to the 80 percent limitation for NOLs generated subsequent to January 1, 2018. As such, a reduction to the valuation allowance related to deferred tax assets was recorded and the Company recognized an income tax benefit of $0.2 million. The valuation allowance decreased by $0.2 million and $3.9 million for the years ended December 31, 2017 and 2018, respectively.

The following table summarizes carryforwards of federal NOLs and tax credits as of December 31, 2017 and 2018 (in thousands):

	December 31, 2017	2018
Federal	$64,203	$64,520
State	44,681	81,807
Foreign	210	812

The NOL carryforwards begin expiring in 2032 for federal income tax purposes, and in 2032 for state purposes. Utilization of the NOLs and general business tax credits carryforwards may be subject to a substantial limitation under Sections 382 and 383 of the Internal Revenue Code of 1986 as amended, if changes in ownership of the Company have occur previously or occur in the future. As of December 31, 2018, the Company also had federal and state research and development tax credit carryforwards of $2.3 million that will begin to expire in 2032, unless previously utilized.

The NOL and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50 percent, as defined under Sections 382 and 383 of the Internal Revenue Code,

respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has not done an analysis to determine whether or not ownership changes have occurred since inception. Certain state NOLs may also be limited, including Pennsylvania, which limits NOL utilization as a percentage of apportioned taxable income.

The Company will recognize interest and penalties related to uncertain tax positions as income tax expense. As of December 31, 2018, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statements of operations. Due to NOL and tax credit carry forwards that remain unutilized, income tax returns for tax years from 2015 through 2017 remain subject to examination by the taxing jurisdictions. The NOLs remain subject to review until utilized.

In December 2017, the Tax Cuts and Jobs Act (the "2017 Tax Act") was enacted. The 2017 Tax Act includes a number of changes to existing U.S. tax laws that impact the Company, most notably a reduction of the U.S. corporate income tax rate from 34 percent to 21 percent for tax years beginning after December 31, 2017. The 2017 Tax Act also provides for a one-time transition tax on certain foreign earnings and the acceleration of depreciation for certain assets placed into service after September 27, 2017 as well as prospective changes beginning in 2018, including repeal of the domestic manufacturing deduction, additional limitations on executive compensation and limitations on the deductibility of interest.

In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118"), which provided guidance on accounting for the federal tax rate change and other tax effects of the Tax Act. SAB 118 provided a measurement period that should not extend beyond one year from the 2017 Tax Act enactment date for companies to complete the accounting under Accounting Standards Codification Topic 740, *Income Taxes*. In connection with the Company's adoption of the 2017 Tax Act and in consideration of SAB 118, there were no changes made to the provisional amounts recognized in 2017 in connection with the enactment of the 2017 Tax Act. The accounting for the income tax effects of the 2017 Tax Act is complete as of December 31, 2018.

12. Related party transactions

In 2018, IntellectMap provided advisory services to the Company. The chief executive officer of IntellectMap is the brother of the Company's chief executive officer. Fees paid to IntellectMap during the year ended December 31, 2018 were $0.2 million.

13. Subsequent events

The Company has evaluated subsequent events from the balance sheet date through March 15, 2019, the date at which the consolidated financial statements were available to be issued, and determine that there are no other item to disclose.

Through and including , 2019 (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

PROSPECTUS

BofA Merrill Lynch

Citigroup

Credit Suisse

Canaccord Genuity

, 2019

Part II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and the Nasdaq listing fee.

	Amount
Securities and Exchange Commission registration fee	$ *
FINRA filing fee	*
Initial Nasdaq listing fee	*
Accountants' fees and expenses	*
Legal fees and expenses	*
Blue Sky fees and expenses	*
Transfer Agent's fees and expenses	*
Printing and engraving expenses	*
Miscellaneous	*
Total expenses	$ *

* To be filed by amendment.

Item 14. Indemnification of Directors and Officers.

The Registrant is governed by the Delaware General Corporation Law, or DGCL. Section 145 of the DGCL provides that a corporation may indemnify any person, including an officer or director, who was or is, or is threatened to be made, a party to any threatened, pending or completed legal action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person was or is an officer, director, employee or agent of such corporation or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided such officer, director, employee or agent acted in good faith and in a manner such person reasonably believed to be in, or not opposed to, the corporation's best interest and, for criminal proceedings, had no reasonable cause to believe that such person's conduct was unlawful. A Delaware corporation may indemnify any person, including an officer or director, who was or is, or is threatened to be made, a party to any threatened, pending or contemplated action or suit by or in the right of such corporation, under the same conditions, except that such indemnification is limited to expenses (including attorneys' fees) actually and reasonably incurred by such person, and except that no indemnification is permitted without judicial approval if such person is adjudged to be liable to such corporation. Where an officer or director of a corporation is successful, on the merits or otherwise, in the defense of any action, suit or proceeding referred to above, or any claim, issue or matter therein, the corporation must indemnify that person against the expenses (including attorneys' fees) which such officer or director actually and reasonably incurred in connection therewith.

The Registrant's amended and restated certificate of incorporation will authorize the indemnification of its officers and directors, consistent with Section 145 of the DGCL.

Reference is made to Section 102(b)(7) of the DGCL, which enables a corporation in its original certificate of incorporation or an amendment thereto to eliminate or limit the personal liability of a director for

violations of the director's fiduciary duty, except (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) pursuant to Section 174 of the DGCL, which provides for liability of directors for unlawful payments of dividends of unlawful stock purchase or redemptions or (iv) for any transaction from which a director derived an improper personal benefit.

We have entered into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request.

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act against certain liabilities.

Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding all unregistered securities sold by us since January 1, 2016. Also included is the consideration received by us for such shares and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

(a) Issuance of Capital Stock.

1. In January 2016, we issued an aggregate of 3,636,363 shares of our Series B-1 Preferred Stock to investors at a price per share of $1.375. These shares will automatically convert into shares of our common stock upon the closing of this offering.
2. In November 2016, we issued an aggregate of 9,090,909 shares of our Series B-2 Preferred Stock to investors at a price per share of $1.65. These shares will automatically convert into shares of our common stock upon the closing of this offering.
3. In August 2018, we issued an aggregate of 31,696,436 shares of our Series C Preferred Stock to investors at a price per share of $2.2143. These shares will automatically convert into shares of our common stock upon the closing of this offering.

(b) Equity Awards.

1. Since January 1, 2016, we have granted stock options to employees, directors and consultants, covering an aggregate of 12,609,584 shares of our common stock, having exercise prices ranging from $0.47 to $1.40 per share, in connection with services provided to us by such parties.

Unless otherwise stated, the issuances of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder, or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. Individuals who purchased securities as described above represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the share certificates issued in such transactions.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions or any public offering.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

The following documents are filed as exhibits to this registration statement.

Exhibit Number	Description of Exhibit
1.1*	Form of Underwriting Agreement
3.1	Fourth Amended and Restated Certificate of Incorporation of Galera Therapeutics, Inc. (currently in effect)
3.2	Bylaws of Galera Therapeutics, Inc. (currently in effect)
3.3*	Form of Fifth Amended and Restated Certificate of Incorporation of Galera Therapeutics, Inc. (to be effective upon the closing of this offering)
3.4*	Form of Amended and Restated Bylaws of Galera Therapeutics, Inc. (to be effective upon the closing of this offering)
4.1*	Form of Certificate of Common Stock
4.2	Second Amended and Restated Investors' Rights Agreement, dated as of August 30, 2018, by and among Galera Therapeutics, Inc. and the investors party thereto
5.1*	Opinion of Latham & Watkins LLP
10.1*	Dismutase Mimetics Transfer Agreement, dated as of May 22, 2009, by and between Galera Therapeutics, LLC and Kereos, Inc.
10.2*	Property Ownership and Cross-License Agreement dated as of May 20, 2011, by and between Galera Therapeutics, LLC and Inotek Pharmaceuticals Corporation
10.3*	Assignment Agreement, dated as of January 1, 2012, by and between Galera Therapeutics, LLC and Inotek Pharmaceuticals Corporation
10.4*†	Amended and Restated Purchase and Sale Agreement, dated as of November 14, 2018, by and among Galera Therapeutics, Inc. and Clarus IV Galera Royalty AIV, L.P., Clarus IV-A, L.P., Clarus IV-B, L.P., Clarus IV-C, L.P., and Clarus IV-D, L.P.
10.5#*	Employment Agreement, dated November 26, 2012, by and between Galera Therapeutics, Inc. and J. Mel Sorensen, M.D.
10.6#*	Employment Agreement, as amended on October 1, 2015, by and between Galera Therapeutics, Inc. and Robert A. Beardsley, Ph.D.
10.7#*	Employment Agreement, as amended February 1, 2014, by and between Galera Therapeutics, Inc. and Dennis P. Riley, Ph.D.
10.8#*	Employment Agreement, dated April 1, 2016, by and between Galera Therapeutics, Inc. and Jon T. Holmlund, M.D.
10.9#*	Employment Agreement, dated January 2, 2017, by and between Galera Therapeutics, Inc. and Arthur J. Fratamico, R.Ph.
10.10#*	Form of Indemnification Agreement between Galera Therapeutics, Inc. and its directors and officers
10.11#	Galera Therapeutics, Inc. Equity Incentive Plan, as amended
10.12#*	Galera Therapeutics, Inc. 2019 Incentive Award Plan
10.13#*	Form of Stock Option Award Agreement under the Galera Therapeutics, Inc. 2019 Incentive Award Plan
10.14#*	Galera Therapeutics, Inc. Non-Employee Director Compensation Policy
21.1	Subsidiaries of Galera Therapeutics, Inc.
23.1*	Consent of KPMG LLP
23.2*	Consent of Latham & Watkins LLP (included in Exhibit 5.1)
24.1*	Power of Attorney (included on signature page)

* To be filed by amendment.

\# Indicates management contract or compensatory plan.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately with the SEC.

(b) Financial Statement Schedules. Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriter, at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the 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.

The undersigned hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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SIGNATURES

Pursuant to the requirements of the Securities Act, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Malvern, Pennsylvania, on this day of , 2019.

GALERA THERAPEUTICS, INC.
By: _____
J. Mel Sorensen, M.D.
Chief Executive Officer and President

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SIGNATURES AND POWER OF ATTORNEY

We, the undersigned officers and directors of Galera Therapeutics, Inc., hereby severally constitute and appoint J. Mel Sorensen and , and each of them singly (with full power to each of them to act alone), our true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution in each of them for him and in his name, place and stead, and in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement (or any other registration statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), 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 requisite or necessary to be done in and about the premises, as full to all intents and purposes as he might or could do in person, hereby 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 hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities held on the dates indicated.

Signature	Title	Date
J. Mel Sorensen, M.D.	Chief Executive Officer, President and Director (principal executive officer)	, 2019
	Chief Financial Officer (principal financial and accounting officer)	, 2019
Michael Powell, Ph.D.	Chairman of the Board of Directors	, 2019
Emmett Cunningham, M.D., Ph.D., MPH	Director	, 2019
Thomas Dyrberg, M.D., DMSc	Director	, 2019
Jason Fuller, Ph.D.	Director	, 2019
Campbell Murray, M.D.	Director	, 2019

Exhibit 3.1

FOURTH AMENDED AND RESTATED

CERTIFICATE OF INCORPORATION
OF
GALERA THERAPEUTICS, INC.

Pursuant to §§ 228, 242 and 245(c) of the General Corporation Law

of the State of Delaware

An original Certificate of Incorporation of Galera Therapeutics, Inc., was filed with the Secretary of State on November 19, 2012, and was amended by a Certificate of Amendment filed with the Secretary of State on July 25, 2014, and was amended and restated by a First Amended and Restated Certificate of Incorporation filed with the Secretary of State on October 1, 2015, and was amended and restated by a Second Amended and Restated Certificate of Incorporation filed with the Secretary of State on January 21, 2016, and was amended and restated by a Third Amended and Restated Certificate of Incorporation filed with the Secretary of State on November 15, 2016. This Fourth Amended and Restated Certificate of Incorporation (the "**Certificate of Incorporation**") has been duly adopted by Galera Therapeutics, Inc. in accordance with §§228, 242 and 245(c) of the General Corporation Law of the State of Delaware.

The text of the Certificate of Incorporation is hereby amended and restated to read in its entirety as follows:

Galera Therapeutics, Inc., a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "**General Corporation Law**"),

DOES HEREBY CERTIFY:

1. That the name of this corporation is Galera Therapeutics, Inc.

2. That the Certificate of Incorporation of this corporation is to read as follows:

FIRST: The name of this corporation is Galera Therapeutics, Inc. (the "**Corporation**").

SECOND: The address of the registered office of the Corporation in the State of Delaware is 251 Little Falls Drive, Wilmington, County of New Castle, 19808. The name of its registered agent at such address is Corporation Service Company.

THIRD: The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law.

FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 115,000,000 shares of Common Stock, $0.001 par value per share ("**Common Stock**"), and (ii) 96,385,795 shares of Preferred Stock, $0.001 par value per share ("**Preferred Stock**"), of which 22,280,087 shall be designated as Series A Preferred Stock, 29,682,000 shall be designated as Series B Preferred Stock, 3,636,363 shall be designated as Series B-1 Preferred Stock, 9,090,909 shall be designated as Series B-2 Preferred Stock, and 31,696,436 shall be designated Series C Preferred Stock.

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.

A. COMMON STOCK

1. General. The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth herein.

2. Voting. The holders of the Common Stock are entitled to one vote for each share of Common Stock held at all meetings of stockholders (and written actions in lieu of meetings). There shall be no cumulative voting. The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by (in addition to any vote of the holders of one or more series of Preferred Stock that may be required by the terms of the Certificate of Incorporation) the affirmative vote of the holders of shares of capital stock of the Corporation representing a majority of the votes represented by all outstanding shares of capital stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law.

B. PREFERRED STOCK

The following rights, preferences, powers, privileges and restrictions, qualifications and limitations of the Preferred Stock are set forth herein. Unless otherwise indicated, references to "Sections" or "Subsections" in this Part B of this Article Fourth refer to sections and subsections of Part B of this Article Fourth.

1. Dividends. From and after the date of the issuance of any shares of Series A Preferred Stock, Series B Preferred Stock, Series B-1 Preferred Stock, Series B-2 Preferred Stock or Series C Preferred Stock, respectively, dividends at the rate per annum of 6% of the Preferred Stock Original Issue Price per share shall accrue on such shares of Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Preferred Stock) (the "**Accruing Dividends**"). Accruing Dividends shall accrue from day to day, whether or not declared, and shall be cumulative; provided however, that except as set forth in the following sentence of this Section 1 or in Subsection 2.1 and Section B.6, the Corporation shall be under no obligation to pay such Accruing Dividends. The Corporation shall not declare, pay or set aside any dividends on shares of Common Stock (other than dividends payable in shares of Common Stock) unless (in addition to the obtaining of any consents required elsewhere in the Certificate of Incorporation) the holders of each series of the Preferred Stock then outstanding shall first receive, or simultaneously receive, a dividend on each outstanding share of Preferred Stock in an amount at least equal to the greater of (a) the amount of the aggregate Accruing Dividends then

accrued on such share of Preferred Stock and not previously paid and (b) that dividend per share of Preferred Stock as would equal the product of (1) the dividend payable on each share of Common Stock, and (2) the number of shares of Common Stock issuable upon conversion of a share of Preferred Stock, in each case calculated on the record date for determination of holders entitled to receive such dividend. The Corporation shall not declare, pay or set aside any dividends on any shares of Preferred Stock unless (in addition to the obtaining of any consents required elsewhere in the Certificate of Incorporation) the Corporation shall simultaneously declare, pay or set aside, as the case may be, a dividend on each other outstanding share of Preferred Stock in a pro rata amount to such dividend based on the aggregate Accrued Dividends. The "**Series A Original Issue Price**" shall mean $1.00 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to Series A Preferred Stock occurring on or after the Filing Date. The "**Series B Original Issue Price**" shall mean $1.25 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B Preferred Stock occurring on or after the Filing Date. The "**Series B-1 Original Issue Price**" shall mean $1.375 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B-1 Preferred Stock occurring on or after the Filing Date. The "**Series B-2 Original Issue Price**" shall mean $1.65 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B-2 Preferred Stock occurring on or after the Filing Date. The "**Series C Original Issue Price**" shall mean $2.2143 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series C Preferred Stock occurring on or after the Filing Date. The "**Preferred Stock Original Issue Price**" shall mean, with respect to the Series A Preferred Stock, the Series A Original Issue Price, with respect to the Series B Preferred Stock, the Series B Original Issue Price, with respect to the Series B-1 Preferred Stock, the Series B-1 Original Issue Price, with respect to the Series B-2 Preferred Stock, the Series B-2 Original Issue Price, and with respect to the Series C Preferred Stock, the Series C Original Issue Price. The "**Filing Date**" shall mean the date of the filing and effectiveness of this Fourth Amended and Restated Certificate of Incorporation.

2. Liquidation, Dissolution or Winding Up; Certain Mergers, Consolidations and Asset Sales.

2.1 Preferential Payments to Holders of Preferred Stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation, the holders of shares of Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Corporation available for distribution to its stockholders, and in the event of a Deemed Liquidation Event (as defined below), the holders of shares of Preferred Stock then outstanding shall be entitled to be paid out of the consideration payable to stockholders in such Deemed Liquidation Event or out of the Available Proceeds (as defined below), as applicable, before any payment shall be made to the holders of Common Stock by reason of their ownership thereof, an amount per share equal to the Preferred Stock Original Issue Price, plus any Accruing Dividends accrued but unpaid thereon, whether or not declared, together with any other dividends declared but unpaid thereon. If upon any such liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, the assets of the Corporation available for distribution to its

stockholders shall be insufficient to pay the holders of shares of Preferred Stock the full amount to which they shall be entitled under this Subsection 2.1, the holders of shares of Preferred Stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

2.2 Distribution of Remaining Assets. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, after the payment of all preferential amounts required to be paid to the holders of shares of Preferred Stock the remaining assets of the Corporation available for distribution to its stockholders shall be distributed among the holders of the shares of Preferred Stock and Common Stock, pro rata based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been converted to Common Stock pursuant to the terms of the Certificate of Incorporation immediately prior to such dissolution, liquidation or winding up of the Corporation or Deemed Liquidation Event. The aggregate amount which a holder of a share of Preferred Stock is entitled to receive under Subsections 2.1 and 2.2 is hereinafter referred to as the "**Preferred Liquidation Amount**."

2.3 Deemed Liquidation Events.

2.3.1 Definition. Each of the following events shall be considered a "**Deemed Liquidation Event**" unless the Requisite Holders elect otherwise by written notice sent to the Corporation at least 20 days prior to the effective date of any such event:

(a) a merger or consolidation in which

(i) the Corporation is a constituent party or

(ii) a subsidiary of the Corporation is a constituent party and the Corporation issues shares of its capital stock pursuant to such merger or consolidation,

except any such merger or consolidation involving the Corporation or a subsidiary in which the shares of capital stock of the Corporation outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such merger or consolidation, at least a majority, by voting power, of the capital stock of (1) the surviving or resulting corporation or (2) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such surviving or resulting corporation; or

(b) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Corporation or any subsidiary of the Corporation of all or substantially all the assets of the Corporation and its subsidiaries taken as a whole, or the sale or disposition (whether by merger or otherwise) of one or more subsidiaries of the Corporation if substantially all of the assets of the Corporation and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the Corporation.

2.3.2 Effecting a Deemed Liquidation Event.

(a) The Corporation shall not have the power to effect a Deemed Liquidation Event referred to in Subsection 2.3.1(a)(i) unless the agreement or plan of merger or consolidation for such transaction (the "**Merger Agreement**") provides that the consideration payable to the stockholders of the Corporation shall be allocated among the holders of capital stock of the Corporation in accordance with Subsections 2.1 and 2.2.

(b) In the event of a Deemed Liquidation Event referred to in Subsection 2.3.1(a)(ii) or 2.3.1(b), if the Corporation does not effect a dissolution of the Corporation under the General Corporation Law within 90 days after such Deemed Liquidation Event, then (i) the Corporation shall send a written notice to each holder of Preferred Stock no later than the 90th day after the Deemed Liquidation Event advising such holders of their right (and the requirements to be met to secure such right) pursuant to the terms of the following clause (ii) to require the redemption of such shares of Preferred Stock, and (ii) if the Requisite Holders so request in a written instrument delivered to the Corporation not later than 120 days after such Deemed Liquidation Event, the Corporation shall use the consideration received by the Corporation for such Deemed Liquidation Event (net of any retained liabilities associated with the assets sold or technology licensed, as determined in good faith by the Board of Directors of the Corporation), together with any other assets of the Corporation available for distribution to its stockholders, all to the extent permitted by Delaware law governing distributions to stockholders (the "**Available Proceeds**"), on the 150th day after such Deemed Liquidation Event, to redeem all outstanding shares of Preferred Stock at a price per share equal to the applicable Preferred Liquidation Amount.

Notwithstanding the foregoing, in the event of a redemption pursuant to the preceding sentence, if the Available Proceeds are not sufficient to redeem all outstanding shares of Preferred Stock, the Corporation shall ratably redeem each holder's shares of Preferred Stock to the fullest extent of such Available Proceeds, and shall redeem the remaining shares as soon as it may lawfully do so under Delaware law governing distributions to stockholders. The provisions of Section 6 shall apply, with such necessary changes in the details thereof as are necessitated by the context, to the redemption of the Preferred Stock pursuant to this Subsection 2.3.2. Prior to the distribution or redemption provided for in this Subsection 2.3.2, the Corporation shall not expend or dissipate the consideration received for such Deemed Liquidation Event, except to discharge expenses incurred in connection with such Deemed Liquidation Event.

2.3.3 Amount Deemed Paid or Distributed. If the amount deemed paid or distributed to the holders of capital stock of the Corporation upon any such merger, consolidation, sale, transfer, exclusive license, other disposition or redemption is made in property other than in cash, the value of such distribution shall be the fair market value of such property, determined in good faith by the Board of Directors; provided, however, that if the value of such non-cash property is established in the definitive documentation entered into in connection with such transaction (the "**Acquisition Agreement**"), then value thereof for purposes of this Subsection 2.3.3 shall be established using the method set forth in the Acquisition Agreement. If the methodology for valuing any securities is not established in the Acquisition Agreement, then the value of such securities shall be determined as follows:

(a) For securities not subject to investment letters or other similar restrictions on free marketability,

(i) if traded on a securities exchange or the Nasdaq Stock Market, the value shall be deemed to be the average of the closing prices of the securities on such exchange or market over the 30-day period ending three days prior to the closing of such transaction;

(ii) if actively traded over-the-counter, the value shall be deemed to be the average of the closing bid prices over the 30-day period ending three days prior to the closing of such transaction; or

(iii) if there is no active public market, the value shall be the fair market value thereof, as determined in good faith by the Board of Directors of the Corporation.

(b) If the methodology for valuing any securities is not established in the Acquisition Agreement, then the method of valuation of securities subject to investment letters or other similar restrictions on free marketability (other than restrictions arising solely by virtue of a stockholder's status as an affiliate or former affiliate) shall take into account an appropriate discount (as determined in good faith by the Board of Directors of the Corporation) from the market value as determined pursuant to clause (a) above so as to reflect the approximate fair market value thereof.

2.3.4 Allocation of Escrow. In the event of a Deemed Liquidation Event pursuant to Subsection 2.3.1(a)(i), if any portion of the consideration payable to the stockholders of the Corporation is placed into escrow and/or is payable to the stockholders of the Corporation subject to contingencies (including consideration to be available for satisfaction of indemnification or similar obligations) (the "**Additional Consideration**"), the Merger Agreement shall provide that (a) the portion of such consideration that is not placed in escrow and not subject to any contingencies (the "**Initial Consideration**") shall be allocated among the holders of capital stock of the Corporation in accordance with Subsections 2.1 and 2.2 as if the Initial Consideration were the only consideration payable in connection with such Deemed Liquidation Event and (b) at each time in which any Additional Consideration becomes payable to the stockholders of the Corporation upon release from escrow or satisfaction of contingencies, such additional consideration shall be allocated among the holders of capital stock of the Corporation in accordance with Subsections 2.1 and 2.2 after taking into account the previous payment of the Initial Consideration and any previous payment of Additional Consideration as part of the same transaction.

3. Voting.

3.1 General. On any matter presented to the stockholders of the Corporation for their action or consideration at any meeting of stockholders of the Corporation (or by written consent of stockholders in lieu of meeting), each holder of outstanding shares of Preferred Stock shall be entitled to cast the number of votes equal to the number of whole shares of Common Stock into which the shares of Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of the Certificate of Incorporation, holders of Preferred Stock shall vote together with the holders of Common Stock as a single class.

3.2 Election of Directors. The holders of record of the shares of Series A Preferred Stock, exclusively and as a separate class, shall be entitled to elect two (2) directors of the Corporation (the "**Series A Directors**"); the holders of record of the shares of Series B Preferred Stock, exclusively and as a separate class, shall be entitled to elect one (1) director of the Corporation (the "**Series B Director**"); the holders of record of the shares of Series B-2 Preferred Stock, exclusively and as a separate class, shall be entitled to elect one (1) director of the Corporation (the "**Series B-2 Director**"); and the holders of record of the shares of Series C Preferred Stock, exclusively and as a separate class, shall be entitled to elect one (1) director of the Corporation (the "**Series C Director**" and, together with the Series A Directors, Series B Director, and Series B-2 Director, the "**Preferred Directors**"), and the holders of record of the shares of Common Stock, exclusively and as a separate class, shall be entitled to elect one (1) director of the Corporation. Any director elected as provided in the preceding sentence may be removed without cause by, and only by, the affirmative vote of the holders of the shares of the class or series of capital stock entitled to elect such director or directors, given either at a special meeting of such stockholders duly called for that purpose or pursuant to a written consent of stockholders. If the holders of shares of Preferred Stock or Common Stock, as the case may be, fail to elect a sufficient number of directors to fill all directorships for which they are entitled to elect directors, voting exclusively and as a separate class, pursuant to the first sentence of this Subsection 3.2, then any directorship not so filled shall remain vacant until such time as the holders of the Preferred Stock or Common Stock, as the case may be, elect a person to fill such directorship by vote or written consent in lieu of a meeting; and no such directorship may be filled by stockholders of the Corporation other than by the stockholders of the Corporation that are entitled to elect a person to fill such directorship, voting exclusively and as a separate class. The holders of record of the shares of Common Stock and of any other class or series of voting stock (including the Preferred Stock), exclusively and voting together as a single class, shall be entitled to elect the balance of the total number of directors of the Corporation. At any meeting held for the purpose of electing a director, the presence in person or by proxy of the holders of a majority of the outstanding shares of the class or series entitled to elect such director shall constitute a quorum for the purpose of electing such director. Except as otherwise provided in this Subsection 3.2, a vacancy in any directorship filled by the holders of any class or series shall be filled only by vote or written consent in lieu of a meeting of the holders of such class or series or by any remaining director or directors elected by the holders of such class or series pursuant to this Subsection 3.2. The rights of the holders of the Preferred Stock and the rights of the holders of the Common Stock under the first sentence of this Subsection 3.2 shall terminate on the first date following the Series C Original Issue Date (as defined below) on which the holders of each applicable class or series of Preferred Stock or Common Stock, beneficially hold less than 2,500,000 shares of such class or series of Preferred Stock or Common Stock, as applicable (subject in each case to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Preferred Stock).

3.3 Preferred Stock Protective Provisions. At any time when at least 5,000,000 shares of Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Preferred Stock) are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, do any of the following without (in addition to any other vote required by law or the Certificate of Incorporation) the written consent or affirmative vote of the "**Requisite Holders**", which shall be (a) the holders of a majority of the then outstanding shares of Preferred Stock voting together as a single class, and (b) at least three of Clarus IV GP, LLC (on behalf of Clarus IV-A, L.P., Clarus IV-B, L.P., Clarus IV-C, L.P., Clarus IV-D, L.P. or any of their successors or assigns, collectively, the "**Clarus Funds**")), New Enterprise Associates 14, L.P., Novartis Bioventures Ltd., Novo Holdings A/S, and Sofinnova Venture Partners IX, L.P. so long as each of such holders owns at least 2,500,000 shares of Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Preferred Stock) (such holders, the "**Major Holders**"); provided that if one or more of the Clarus Funds, New Enterprise Associates 14, L.P., Novartis Bioventures Ltd., Novo Holdings A/S, or Sofinnova Venture Partners IX, L.P. shall cease to be a Major Holder, then the written consent or affirmative vote of a majority of the remaining Major Holders shall be required pursuant to clause (b) of the definition of "Requisite Holders", and any such act or transaction entered into without such consent or vote shall be null and void ab initio, and of no force or effect:

3.3.1 liquidate, dissolve or wind-up the business and affairs of the Corporation or any subsidiary of the Corporation, effect any merger or consolidation or any other Deemed Liquidation Event, or consent to any of the foregoing;

3.3.2 amend, alter or repeal any provision of (a) the Certificate of Incorporation or Bylaws of the Corporation or (b) any similar organizational document of any subsidiary of the Corporation;

3.3.3 create, or authorize the creation of, or issue or obligate itself to issue shares of, any additional class or series of capital stock unless the same ranks junior to the Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends and rights of redemption, or increase the authorized number of shares of Common Stock, Series A Preferred Stock, Series B Preferred Stock, Series B-1 Preferred Stock, Series B-2 Preferred Stock, Series C Preferred Stock, or any additional class or series of capital stock;

3.3.4 (i) reclassify, alter or amend any existing security of the Corporation that is pari passu with the Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to the Preferred Stock in respect of any such right, preference or privilege, or (ii) reclassify, alter or amend any existing security of the Corporation that is junior to the

Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to or pari passu with the Preferred Stock in respect of any such right, preference or privilege;

3.3.5 purchase or redeem (or permit any subsidiary to purchase or redeem) or pay or declare any dividend or make any distribution on, any shares of capital stock of the Corporation other than (i) redemptions of or dividends or distributions on the Preferred Stock as expressly authorized herein, (ii) dividends or other distributions payable on the Common Stock solely in the form of additional shares of Common Stock and (iii) repurchases of stock from former employees, officers, directors, consultants or other persons who performed services for the Corporation or any subsidiary in connection with the cessation of such employment or service at the lower of the original purchase price or the then-current fair market value thereof;

3.3.6 create, or authorize the creation of, or issue, or authorize the issuance of any debt security, or guarantee any indebtedness, or permit any subsidiary to take any such action with respect to any debt security or indebtedness, if the aggregate indebtedness of the Corporation and its subsidiaries for borrowed money following such action would exceed $100,000 other than trade debt incurred in the ordinary course of business or included as part of an annual budget approved by the Board of Directors, including a majority of the members of the Board of Directors elected by the holders of the Preferred Stock;

3.3.7 create, or hold capital stock in, any subsidiary that is not wholly owned (either directly or through one or more other subsidiaries) by the Corporation, or sell, transfer or otherwise dispose of any capital stock of any direct or indirect subsidiary of the Corporation, or permit any direct or indirect subsidiary to sell, lease, transfer, exclusively license or otherwise dispose (in a single transaction or series of related transactions) of all or substantially all of the assets of such subsidiary;

3.3.8 increase or decrease (a) the authorized number of directors constituting the Board of Directors of the Corporation or (b) the authorized number of directors or managers constituting the Board of Directors, Board of Managers or similar governing body of any subsidiary of the Corporation;

3.3.9 enter into any acquisition, transfer, license, sale or other disposition of intellectual property rights or other assets outside the ordinary course of business that involves (a) royalty obligations, or (b) payments to or from the Company in excess of $500,000 in the aggregate or amend, modify or waive any terms of any of the foregoing, or cause any subsidiary of the Corporation to do any of the foregoing;

3.3.10 create or authorize the creation of any stock option or other equity incentive plan or arrangement, or increase the number of shares available for issuance under any such plan or arrangement, or cause any subsidiary of the Corporation to do any of the foregoing with respect to any equity interests in such subsidiary; or

3.3.11 enter into any transfer, sale or other disposition of royalty interests in the sale of Corporation products or services or amend, modify or waive any terms of any of the foregoing, or cause any subsidiary of the Corporation to do any of the foregoing.

3.4 Series A Preferred Stock Protective Provisions. At any time when at least 2,500,000 shares of Series A Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Preferred Stock) are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, without (in addition to any other vote required by law or the Certificate of Incorporation) the written consent or affirmative vote of the holders of at least 65% of the then outstanding shares of Series A Preferred Stock, given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void ab initio, and of no force or effect, (i) modify any of the terms of the Series A Preferred Stock set forth in this Certificate or (ii) (a) reclassify, alter or amend any existing security of the Corporation that is pari passu with the Series A Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to the Series A Preferred Stock in respect of any such right, preference or privilege, or (b) reclassify, alter or amend any existing security of the Corporation that is junior to the Series A Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to or pari passu with the Series A Preferred Stock in respect of any such right, preference or privilege.

3.5 Series B Preferred Stock, Series B-1 Preferred Stock and Series B-2 Preferred Stock Protective Provisions. At any time when at least 2,500,000 shares of Series B Preferred Stock, Series B-1 Preferred Stock and Series B-2 Preferred Stock (in the aggregate and subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B Preferred Stock, Series B-1 Preferred Stock and Series B-2 Preferred Stock) are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, without (in addition to any other vote required by law or the Certificate of Incorporation) the written consent or affirmative vote of the holders of at least 84% of the then outstanding shares of Series B Preferred Stock, Series B-1 Preferred Stock and Series B-2 Preferred Stock, given in writing or by vote at a meeting, consenting or voting (as the case may be) together as a separate class, and any such act or transaction entered into without such consent or vote shall be null and void ab initio, and of no force or effect, (i) modify any of the terms of the Series B Preferred Stock, Series B-1 Preferred Stock and Series B-2 Preferred Stock (collectively, the "**B Subseries**") set forth in this Certificate or (ii) (a) reclassify, alter or amend any existing security of the Corporation that is pari passu with any series of Preferred Stock in the B Subseries in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to any series of Preferred Stock in the B Subseries in respect of any such right, preference or privilege, or (b) reclassify, alter or amend any existing security of the Corporation that is junior to any series of Preferred Stock in the B Subseries in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends

or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to or pari passu with any series of Preferred Stock in the B Subseries in respect of any such right, preference or privilege; provided, however, that (x) any modification of any of the terms of any series of Preferred Stock in the B Subseries set forth in this Certificate made in compliance with subsection (i) above must also be made to each other series of Preferred Stock in the B Subseries in the same manner, and (b) any reclassification, alteration or amendment of any existing security of the Corporation in compliance with subsection (ii) above, must affect each series of Preferred Stock in the B Subseries in the same manner; *unless* the holders of at least 76% of the outstanding shares of the Series B Preferred Stock or a majority of the outstanding shares of the Series B-1 Preferred Stock or Series B-2 Preferred Stock, in each case as applicable, and voting as a separate class, consent or affirm in writing or by vote at a meeting that any such modification of any of the terms of such series of B Subseries set forth in this Certificate may be modified in a manner different from such other series of B Subseries.

3.6 Series C Preferred Stock Protective Provisions. The Corporation shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, without (in addition to any other vote required by law or the Certificate of Incorporation) the written consent or affirmative vote of the holders of at least a majority of the then outstanding shares of Series C Preferred Stock (including the Clarus Funds), given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void ab initio, and of no force or effect, (i) modify any of the terms of the Series C Preferred Stock set forth in this Certificate; or (ii) (a) reclassify, alter or amend any existing security of the Corporation that is junior to or pari passu with the Series C Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to the Series C Preferred Stock in respect of any such right, preference or privilege, or (b) reclassify, alter or amend any existing security of the Corporation that is junior to the Series C Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to or pari passu with the Series C Preferred Stock in respect of any such right, preference or privilege.

4. Optional Conversion.

The holders of the Preferred Stock shall have conversion rights as follows (the "**Conversion Rights**"):

4.1 Right to Convert.

4.1.1 Conversion Ratio. Each share of Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and nonassessable shares of Common Stock as is determined by dividing the Preferred Original Issue Price by the Preferred Conversion Price (as defined below) in effect at the time of conversion. As of the Filing Date, the "**Series A Conversion Price**" is $1.00. As of the Filing Date, the "**Series B Conversion Price**" is $1.25. As of the Filing Date, the "**Series B-1 Conversion**

Price" is $1.375. As of the Filing Date, the "**Series B-2 Conversion Price**" is $1.65. As of the Filing Date, the "**Series C Conversion Price**" is $2.2143. The "**Preferred Conversion Price**" shall mean, with respect to the Series A Preferred Stock, the Series A Conversion Price, with respect to the Series B Preferred Stock, the Series B Conversion Price, with respect to the Series B-1 Preferred Stock, the Series B-1 Conversion Price, with respect to the Series B-2 Preferred Stock, the Series B-2 Conversion Price and, with respect to the Series C Preferred Stock, the Series C Conversion Price. Such initial Preferred Conversion Price, and the rate at which shares of Preferred Stock may be converted into shares of Common Stock, shall be subject to adjustment as provided below.

4.1.2 Termination of Conversion Rights. In the event of a notice of redemption of any shares of Preferred Stock pursuant to Section 6, the Conversion Rights of the shares designated for redemption shall terminate at the close of business on the last full day preceding the date fixed for redemption, unless the redemption price is not fully paid on such redemption date, in which case the Conversion Rights for such shares shall continue until such price is paid in full. In the event of a liquidation, dissolution or winding up of the Corporation or a Deemed Liquidation Event, the Conversion Rights shall terminate at the close of business on the last full day preceding the date fixed for the payment of any such amounts distributable on such event to the holders of Preferred Stock.

4.2 Fractional Shares. No fractional shares of Common Stock shall be issued upon conversion of the Preferred Stock. In lieu of any fractional shares to which the holder would otherwise be entitled, the Corporation shall pay cash equal to such fraction multiplied by the fair market value of a share of Common Stock as determined in good faith by the Board of Directors of the Corporation. Whether or not fractional shares would be issuable upon such conversion shall be determined on the basis of the total number of shares of Preferred Stock the holder is at the time converting into Common Stock and the aggregate number of shares of Common Stock issuable upon such conversion.

4.3 Mechanics of Conversion.

4.3.1 Notice of Conversion. In order for a holder of Preferred Stock to voluntarily convert shares of Preferred Stock into shares of Common Stock, such holder shall surrender the certificate or certificates for such shares of Preferred Stock (or, if such registered holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate), at the office of the transfer agent for the Preferred Stock (or at the principal office of the Corporation if the Corporation serves as its own transfer agent), together with written notice that such holder elects to convert all or any number of the shares of the Preferred Stock represented by such certificate or certificates and, if applicable, any event on which such conversion is contingent. Such notice shall state such holder's name or the names of the nominees in which such holder wishes the certificate or certificates for shares of Common Stock to be issued. If required by the Corporation, certificates surrendered for conversion shall be endorsed or accompanied by a written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or his, her or its attorney duly authorized in writing. The close of business on the date of receipt by the transfer agent (or

by the Corporation if the Corporation serves as its own transfer agent) of such certificates (or lost certificate affidavit and agreement) and notice shall be the time of conversion (the "**Conversion Time**"), and the shares of Common Stock issuable upon conversion of the shares represented by such certificate shall be deemed to be outstanding of record as of such date. The Corporation shall, as soon as practicable after the Conversion Time, (i) issue and deliver to such holder of Preferred Stock, or to his, her or its nominees, a certificate or certificates for the number of full shares of Common Stock issuable upon such conversion in accordance with the provisions hereof and a certificate for the number (if any) of the shares of Preferred Stock represented by the surrendered certificate that were not converted into Common Stock, (ii) pay in cash such amount as provided in Subsection 4.2 in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion and (iii) pay all declared but unpaid dividends on the shares of Preferred Stock converted.

4.3.2 Reservation of Shares. The Corporation shall at all times when the Preferred Stock shall be outstanding, reserve and keep available out of its authorized but unissued capital stock, for the purpose of effecting the conversion of the Preferred Stock, such number of its duly authorized shares of Common Stock as shall from time to time be sufficient to effect the conversion of all outstanding Preferred Stock; and if at any time the number of authorized but unissued shares of Common Stock shall not be sufficient to effect the conversion of all then outstanding shares of the Preferred Stock, the Corporation shall take such corporate action as may be necessary to increase its authorized but unissued shares of Common Stock to such number of shares as shall be sufficient for such purposes, including, without limitation, engaging in best efforts to obtain the requisite stockholder approval of any necessary amendment to the Certificate of Incorporation. Before taking any action which would cause an adjustment reducing the Preferred Conversion Price below the then par value of the shares of Common Stock issuable upon conversion of the Preferred Stock, the Corporation will take any corporate action which may, in the opinion of its counsel, be necessary in order that the Corporation may validly and legally issue fully paid and nonassessable shares of Common Stock at such adjusted Preferred Conversion Price.

4.3.3 Effect of Conversion. All shares of Preferred Stock which shall have been surrendered for conversion as herein provided shall no longer be deemed to be outstanding and all rights with respect to such shares shall immediately cease and terminate at the Conversion Time, except only the right of the holders thereof to receive shares of Common Stock in exchange therefor, to receive payment in lieu of any fraction of a share otherwise issuable upon such conversion as provided in Subsection 4.2 and to receive payment of any dividends declared but unpaid thereon. Any shares of Preferred Stock so converted shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Preferred Stock accordingly.

4.3.4 No Further Adjustment. Upon any such conversion, no adjustment to the Preferred Conversion Price shall be made for any declared but unpaid dividends on the Preferred Stock surrendered for conversion or on the Common Stock delivered upon conversion.

4.3.5 Taxes. The Corporation shall pay any and all issue and other similar taxes that may be payable in respect of any issuance or delivery of shares of Common Stock upon conversion of shares of Preferred Stock pursuant to this Section 4. The Corporation shall not, however, be required to pay any tax which may be payable in respect of any transfer involved in the issuance and delivery of shares of Common Stock in a name other than that in which the shares of Preferred Stock so converted were registered, and no such issuance or delivery shall be made unless and until the person or entity requesting such issuance has paid to the Corporation the amount of any such tax or has established, to the satisfaction of the Corporation, that such tax has been paid.

4.4 Adjustments to Preferred Conversion Price for Diluting Issues.

4.4.1 Special Definitions. For purposes of this Article Fourth, the following definitions shall apply:

(a) "**Option**" shall mean rights, options or warrants to subscribe for, purchase or otherwise acquire Common Stock or Convertible Securities.

(b) "**Series C Original Issue Date**" shall mean the date on which the first share of Series C Preferred Stock was issued.

(c) "**Convertible Securities**" shall mean any evidences of indebtedness, shares or other securities directly or indirectly convertible into or exchangeable for Common Stock, but excluding Options.

(d) "**Additional Shares of Common Stock**" shall mean all shares of Common Stock issued (or, pursuant to Subsection 4.4.3 below, deemed to be issued) by the Corporation after the Series C Original Issue Date, other than (1) the following shares of Common Stock and (2) shares of Common Stock deemed issued pursuant to the following Options and Convertible Securities (clauses (1) and (2), collectively, "**Exempted Securities**"):

(i) shares of Common Stock, Options or Convertible Securities issued as a dividend or distribution on Preferred Stock;

(ii) shares of Common Stock, Options or Convertible Securities issued by reason of a dividend, stock split, split-up or other distribution on shares of Common Stock that is covered by Subsection 4.5, 4.6, 4.7 or 4.8;

(iii) shares of Common Stock or Options issued to employees or directors of, or consultants or advisors to, the Corporation or any of its subsidiaries pursuant to a plan, agreement or arrangement approved by the Board of Directors of the Corporation, including a majority of the Preferred Directors, and by the Corporation's stockholders to the extent required under the Certificate of Incorporation; or

(iv) shares of Common Stock or Convertible Securities actually issued upon the exercise of Options or shares of Common Stock actually issued upon the conversion or exchange of Convertible Securities, in each case provided such issuance is pursuant to the terms of such Option or Convertible Security.

4.4.2 No Adjustment of Preferred Conversion Price. No adjustment in the Preferred Conversion Price shall be made as the result of the issuance or deemed issuance of Additional Shares of Common Stock if the Corporation receives written notice from the Requisite Holders agreeing that no such adjustment shall be made as the result of the issuance or deemed issuance of such Additional Shares of Common Stock.

4.4.3 Deemed Issue of Additional Shares of Common Stock.

(a) If the Corporation at any time or from time to time after the Series C Original Issue Date shall issue any Options or Convertible Securities (excluding Options or Convertible Securities which are themselves Exempted Securities) or shall fix a record date for the determination of holders of any class of securities entitled to receive any such Options or Convertible Securities, then the maximum number of shares of Common Stock (as set forth in the instrument relating thereto, assuming the satisfaction of any conditions to exercisability, convertibility or exchangeability but without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or, in the case of Convertible Securities and Options therefor, the conversion or exchange of such Convertible Securities, shall be deemed to be Additional Shares of Common Stock issued as of the time of such issue or, in case such a record date shall have been fixed, as of the close of business on such record date.

(b) If the terms of any Option or Convertible Security, the issuance of which resulted in an adjustment to the Preferred Conversion Price pursuant to the terms of Subsection 4.4.4, are revised as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security (but excluding automatic adjustments to such terms pursuant to anti-dilution or similar provisions of such Option or Convertible Security) to provide for either (1) any increase or decrease in the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any such Option or Convertible Security or (2) any increase or decrease in the consideration payable to the Corporation upon such exercise, conversion and/or exchange, then, effective upon such increase or decrease becoming effective, the Preferred Conversion Price computed upon the original issue of such Option or Convertible Security (or upon the occurrence of a record date with respect thereto) shall be readjusted to such Preferred Conversion Price as would have obtained had such revised terms been in effect upon the original date of issuance of such Option or Convertible Security. Notwithstanding the foregoing, no readjustment pursuant to this clause (b) shall have the effect of increasing the Preferred Conversion Price to an amount which exceeds the lower of (i) the Preferred Conversion Price in effect immediately prior to the original adjustment made as

a result of the issuance of such Option or Convertible Security, or (ii) the Preferred Conversion Price that would have resulted from any issuances of Additional Shares of Common Stock (other than deemed issuances of Additional Shares of Common Stock as a result of the issuance of such Option or Convertible Security) between the original adjustment date and such readjustment date.

(c) If the terms of any Option or Convertible Security (excluding Options or Convertible Securities which are themselves Exempted Securities), the issuance of which did not result in an adjustment to the Preferred Conversion Price pursuant to the terms of Subsection 4.4.4 (either because the consideration per share (determined pursuant to Subsection 4.4.5) of the Additional Shares of Common Stock subject thereto was equal to or greater than the Preferred Conversion Price then in effect, or because such Option or Convertible Security was issued before the Series C Original Issue Date), are revised after the Series C Original Issue Date as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security (but excluding automatic adjustments to such terms pursuant to anti-dilution or similar provisions of such Option or Convertible Security) to provide for either (1) any increase in the number of shares of Common Stock issuable upon the exercise, conversion or exchange of any such Option or Convertible Security or (2) any decrease in the consideration payable to the Corporation upon such exercise, conversion or exchange, then such Option or Convertible Security, as so amended or adjusted, and the Additional Shares of Common Stock subject thereto (determined in the manner provided in Subsection 4.4.3(a)) shall be deemed to have been issued effective upon such increase or decrease becoming effective.

(d) Upon the expiration or termination of any unexercised Option or unconverted or unexchanged Convertible Security (or portion thereof) which resulted (either upon its original issuance or upon a revision of its terms) in an adjustment to the Preferred Conversion Price pursuant to the terms of Subsection 4.4.4, the Preferred Conversion Price shall be readjusted to such Preferred Conversion Price as would have obtained had such Option or Convertible Security (or portion thereof) never been issued.

(e) If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the Corporation upon such exercise, conversion and/or exchange, is calculable at the time such Option or Convertible Security is issued or amended but is subject to adjustment based upon subsequent events, any adjustment to the Preferred Conversion Price provided for in this Subsection 4.4.3 shall be effected at the time of such issuance or amendment based on such number of shares or amount of consideration without regard to any provisions for subsequent adjustments (and any subsequent adjustments shall be treated as provided in clauses (b) and (c) of this Subsection 4.4.3). If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the Corporation upon such exercise, conversion and/or exchange, cannot be calculated at all at the time such Option or Convertible Security is issued or amended, any adjustment to the Preferred Conversion Price that would result under the terms of this Subsection 4.4.3 at the time of such issuance or amendment shall instead be effected at the time such number of shares and/or amount of consideration is first calculable (even if subject to subsequent adjustments), assuming for purposes of calculating such adjustment to the Preferred Conversion Price that such issuance or amendment took place at the time such calculation can first be made.

4.4.4 Adjustment of Preferred Conversion Price Upon Issuance of Additional Shares of Common Stock. In the event the Corporation shall at any time after the Series C Original Issue Date issue Additional Shares of Common Stock (including Additional Shares of Common Stock deemed to be issued pursuant to Subsection 4.4.3), without consideration or for a consideration per share less than the Preferred Conversion Price in effect immediately prior to such issue, then the Preferred Conversion Price shall be reduced, concurrently with such issue, to a price (calculated to the nearest one-hundredth of a cent) determined in accordance with the following formula:

$$CP2 = CP1* (A + B) \div (A + C).$$

For purposes of the foregoing formula, the following definitions shall apply:

(a) "CP_2" shall mean the Preferred Conversion Price in effect immediately after such issue of Additional Shares of Common Stock;

(b) "CP_1" shall mean the Preferred Conversion Price in effect immediately prior to such issue of Additional Shares of Common Stock;

(c) "A" shall mean the number of shares of Common Stock outstanding immediately prior to such issue of Additional Shares of Common Stock (treating for this purpose as outstanding all shares of Common Stock issuable upon exercise of Options outstanding immediately prior to such issue or upon conversion or exchange of Convertible Securities (including the Preferred Stock) outstanding (assuming exercise of any outstanding Options therefor) immediately prior to such issue);

(d) "B" shall mean the number of shares of Common Stock that would have been issued if such Additional Shares of Common Stock had been issued at a price per share equal to CP1 (determined by dividing the aggregate consideration received by the Corporation in respect of such issue by CP1); and

(e) "C" shall mean the number of such Additional Shares of Common Stock issued in such transaction.

4.4.5 Determination of Consideration. For purposes of this Subsection 4.4, the consideration received by the Corporation for the issue of any Additional Shares of Common Stock shall be computed as follows:

(a) Cash and Property: Such consideration shall:

(i) insofar as it consists of cash, be computed at the aggregate amount of cash received by the Corporation, excluding amounts paid or payable for accrued interest;

(ii) insofar as it consists of property other than cash, be computed at the fair market value thereof at the time of such issue, as determined in good faith by the Board of Directors of the Corporation; and

(iii) in the event Additional Shares of Common Stock are issued together with other shares or securities or other assets of the Corporation for consideration which covers both, be the proportion of such consideration so received, computed as provided in clauses (i) and (ii) above, as determined in good faith by the Board of Directors of the Corporation.

(b) Options and Convertible Securities. The consideration per share received by the Corporation for Additional Shares of Common Stock deemed to have been issued pursuant to Subsection 4.4.3, relating to Options and Convertible Securities, shall be determined by dividing

(i) the total amount, if any, received or receivable by the Corporation as consideration for the issue of such Options or Convertible Securities, plus the minimum aggregate amount of additional consideration (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such consideration) payable to the Corporation upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities, by

(ii) the maximum number of shares of Common Stock (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities.

4.4.6 Multiple Closing Dates. In the event the Corporation shall issue on more than one date Additional Shares of Common Stock that are a part of one transaction or a series of related transactions and that would result in an adjustment to the Preferred Conversion Price pursuant to the terms of Subsection 4.4.4, then, upon the final such issuance, the Preferred Conversion Price shall be readjusted to give effect to all such issuances as if they occurred on the date of the first such issuance (and without giving effect to any additional adjustments as a result of any such subsequent issuances within such period).

4.5 Adjustment for Stock Splits and Combinations. If the Corporation shall at any time or from time to time after the Series C Original Issue Date effect a subdivision of the outstanding Common Stock, the Preferred Conversion Price in effect immediately before that subdivision shall be proportionately decreased so that the number of shares of Common Stock issuable on conversion of each share of such series shall be increased in proportion to such increase in the aggregate number of shares of Common Stock outstanding. If the Corporation shall at any time or from time to time after the Series C Original Issue Date combine the outstanding shares of Common Stock, the Preferred Conversion Price in effect immediately before the combination shall be proportionately increased so that the number of shares of Common Stock issuable on conversion of each share of such series shall be decreased in proportion to such decrease in the aggregate number of shares of Common Stock outstanding. Any adjustment under this subsection shall become effective at the close of business on the date the subdivision or combination becomes effective.

4.6 Adjustment for Certain Dividends and Distributions. In the event the Corporation at any time or from time to time after the Series C Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable on the Common Stock in additional shares of Common Stock, then and in each such event the Preferred Conversion Price in effect immediately before such event shall be decreased as of the time of such issuance or, in the event such a record date shall have been fixed, as of the close of business on such record date, by multiplying the Preferred Conversion Price then in effect by a fraction:

(1) the numerator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date, and

(2) the denominator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date plus the number of shares of Common Stock issuable in payment of such dividend or distribution.

Notwithstanding the foregoing, (a) if such record date shall have been fixed and such dividend is not fully paid or if such distribution is not fully made on the date fixed therefor, the Preferred Conversion Price shall be recomputed accordingly as of the close of business on such record date and thereafter the Preferred Conversion Price shall be adjusted pursuant to this subsection as of the time of actual payment of such dividends or distributions; and (b) no such adjustment shall be made if the holders of Preferred Stock simultaneously receive a dividend or other distribution of shares of Common Stock in a number equal to the number of shares of Common Stock as they would have received if all outstanding shares of Preferred Stock had been converted into Common Stock on the date of such event.

4.7 Adjustments for Other Dividends and Distributions. In the event the Corporation at any time or from time to time after the Series C Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable in securities of the Corporation (other than a distribution of shares of Common Stock in respect of outstanding shares of Common Stock) or in other property and the provisions of Section 1 do not apply to such dividend or distribution, then and in each such event the holders of Preferred Stock shall receive, simultaneously with the distribution to the holders of Common Stock, a dividend or other distribution of such securities or other property in an amount equal to the amount of such securities or other property as they would have received if all outstanding shares of Preferred Stock had been converted into Common Stock on the date of such event.

4.8 Adjustment for Merger or Reorganization, etc. Subject to the provisions of Subsection 2.3, if there shall occur any reorganization, recapitalization, reclassification, consolidation or merger involving the Corporation in which the Common Stock (but not the Preferred Stock) is converted into or exchanged for securities, cash or other property (other than a transaction covered by Subsections 4.4, 4.6 or 4.7), then, following any such reorganization, recapitalization, reclassification, consolidation or merger, each share of Preferred Stock shall thereafter be convertible in lieu of the Common Stock into which it was convertible prior to such event into the kind and amount of securities, cash or other property which a holder of the number of shares of Common Stock of the Corporation issuable upon conversion of one share of Preferred Stock immediately prior to such reorganization, recapitalization, reclassification, consolidation or merger would have been entitled to receive pursuant to such transaction; and, in such case, appropriate adjustment (as determined in good faith by the Board of Directors of the Corporation) shall be made in the application of the provisions in this Section 4 with respect to the rights and interests thereafter of the holders of the Preferred Stock, to the end that the provisions set forth in this Section 4 (including provisions with respect to changes in and other adjustments of the Preferred Conversion Price) shall thereafter be applicable, as nearly as reasonably may be, in relation to any securities or other property thereafter deliverable upon the conversion of the Preferred Stock. For the avoidance of doubt, nothing in this Subsection 4.8 shall be construed as preventing the holders of Preferred Stock from seeking any appraisal rights to which they are otherwise entitled under the DGCL in connection with a merger triggering an adjustment hereunder, nor shall this Subsection 4.8 be deemed conclusive evidence of the fair value of the shares of Preferred Stock in any such appraisal proceeding.

4.9 Certificate as to Adjustments. Upon the occurrence of each adjustment or readjustment of the Preferred Conversion Price pursuant to this Section 4, the Corporation at its expense shall, as promptly as reasonably practicable but in any event not later than 10 days thereafter, compute such adjustment or readjustment in accordance with the terms hereof and furnish to each holder of Preferred Stock a certificate setting forth such adjustment or readjustment (including the kind and amount of securities, cash or other property into which the Preferred Stock is convertible) and showing in detail the facts upon which such adjustment or readjustment is based. The Corporation shall, as promptly as reasonably practicable after the written request at any time of any holder of Preferred Stock (but in any event not later than 10 days thereafter), furnish or cause to be furnished to such holder a certificate setting forth (i) the Preferred Conversion Price then in effect, and (ii) the number of shares of Common Stock and the amount, if any, of other securities, cash or property which then would be received upon the conversion of Preferred Stock.

4.10 Notice of Record Date. In the event:

(a) the Corporation shall take a record of the holders of its Common Stock (or other capital stock or securities at the time issuable upon conversion of the Preferred Stock) for the purpose of entitling or enabling them to receive any dividend or other distribution, or to receive any right to subscribe for or purchase any shares of capital stock of any class or any other securities, or to receive any other security; or

(b) of any capital reorganization of the Corporation, any reclassification of the Common Stock of the Corporation, or any Deemed Liquidation Event; or

(c) of the voluntary or involuntary dissolution, liquidation or winding-up of the Corporation,

then, and in each such case, the Corporation will send or cause to be sent to the holders of the Preferred Stock a notice specifying, as the case may be, (i) the record date for such dividend, distribution or right, and the amount and character of such dividend, distribution or right, or (ii) the effective date on which such reorganization, reclassification, consolidation, merger, transfer, Deemed Liquidation Event, dissolution, liquidation or winding-up is proposed to take place, and the time, if any is to be fixed, as of which the holders of record of Common Stock (or such other capital stock or securities at the time issuable upon the conversion of the Preferred Stock) shall be entitled to exchange their shares of Common Stock (or such other capital stock or securities) for securities or other property deliverable upon such reorganization, reclassification, consolidation, merger, transfer, Deemed Liquidation Event, dissolution, liquidation or winding-up, and the amount per share and character of such exchange applicable to the Preferred Stock and the Common Stock. Such notice shall be sent at least 10 days prior to the record date or effective date for the event specified in such notice.

5. Mandatory Conversion.

5.1 Trigger Events. Upon either (a) the closing of the sale of shares of Common Stock to the public at a price of at least $3.30 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Common Stock), in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $30.0 million of gross proceeds to the Corporation or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the Requisite Holders (the time of such closing or the date and time specified or the time of the event specified in such vote or written consent is referred to herein as the "**Mandatory Conversion Time**"), (i) all outstanding shares of Preferred Stock shall automatically be converted into shares of Common Stock, at the then effective conversion rate and (ii) such shares may not be reissued by the Corporation.

5.2 Procedural Requirements. All holders of record of shares of Preferred Stock shall be sent written notice of the Mandatory Conversion Time and the place designated for mandatory conversion of all such shares of Preferred Stock pursuant to this Section 5. Such notice need not be sent in advance of the occurrence of the Mandatory Conversion Time. Upon receipt of such notice, each holder of shares of Preferred Stock shall surrender his, her or its certificate or certificates for all such shares (or, if such holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate) to the Corporation at the place designated in such notice. If so required by the Corporation, certificates surrendered for conversion shall be endorsed or accompanied by written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or by his, her or its attorney duly authorized in writing. All rights with respect to the Preferred Stock converted pursuant to Subsection 5.1, including the rights, if any, to receive notices and vote (other than as a holder of Common Stock), will terminate at the Mandatory Conversion Time (notwithstanding the failure of the holder or holders thereof to surrender the certificates at or prior to such time), except only the rights of the holders thereof, upon surrender of their certificate or certificates (or lost certificate affidavit and agreement) therefor, to receive the items provided for in the next sentence of this Subsection 5.2. As soon as practicable after the Mandatory Conversion Time and the surrender of the certificate or certificates (or lost certificate affidavit and agreement) for Preferred Stock, the Corporation shall issue and deliver to such holder, or to his, her or its nominees, a certificate or certificates for the number of full shares of Common Stock issuable on such conversion in accordance with the provisions hereof, together with cash as provided in Subsection 4.2 in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion and the payment of any declared but unpaid dividends on the shares of Preferred Stock converted. Such converted Preferred Stock shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Preferred Stock accordingly.

6. Redemption.

6.1 General. Unless prohibited by Delaware law governing distributions to stockholders, shares of Preferred Stock shall be redeemed by the Corporation at a price equal to the Preferred Original Issue Price per share, plus all Accruing Dividends accrued but unpaid thereon, whether or not declared, together with any other dividends declared but unpaid thereon (the "**Redemption Price**"), in three annual installments commencing not more than 60 days after receipt by the Corporation at any time on or after the date six (6) years after the Series C Original Issue Date, from the Requisite Holders, of written notice requesting redemption of all shares of Preferred Stock (the "**Redemption Request**"). Upon receipt of a Redemption Request, the Corporation shall apply all of its assets to any such redemption, and to no other corporate purpose, except to the extent prohibited by Delaware law governing distributions to stockholders. The date of each such installment shall be referred to as a "**Redemption Date**". On each Redemption Date, the Corporation shall redeem, on a pro rata basis in accordance with the number of shares of Preferred Stock owned by each holder, that number of outstanding shares of Preferred Stock determined by dividing (i) the total number of shares of Preferred Stock outstanding immediately prior to such Redemption Date by (ii) the number of remaining Redemption Dates (including the Redemption Date to which such

calculation applies). If on any Redemption Date Delaware law governing distributions to stockholders prevents the Corporation from redeeming all shares of Preferred Stock to be redeemed, the Corporation shall ratably redeem the maximum number of shares that it may redeem consistent with such law, and shall redeem the remaining shares as soon as it may lawfully do so under such law.

6.2 Redemption Notice. The Corporation shall send written notice of the mandatory redemption (the "**Redemption Notice**") to each holder of record of Preferred Stock not less than 40 days prior to each Redemption Date. Each Redemption Notice shall state:

(a) the number of shares of Preferred Stock held by the holder that the Corporation shall redeem on the Redemption Date specified in the Redemption Notice;

(b) the Redemption Date and the Redemption Price;

(c) the date upon which the holder's right to convert such shares terminates (as determined in accordance with Subsection 4.1); and

(d) that the holder is to surrender to the Corporation, in the manner and at the place designated, his, her or its certificate or certificates representing the shares of Preferred Stock to be redeemed.

If the Corporation receives, on or prior to the 20th day after the date of delivery of the Redemption Notice to a holder of Preferred Stock, written notice from such holder that such holder elects to be excluded from the redemption provided in this Section 6, then the shares of Preferred Stock registered on the books of the Corporation in the name of such holder at the time of the Corporation's receipt of such notice shall thereafter be "**Excluded Shares**." Excluded Shares shall not be redeemed or redeemable pursuant to this Section 6, whether on such Redemption Date or thereafter.

6.3 Surrender of Certificates; Payment. On or before the applicable Redemption Date, each holder of shares of Preferred Stock to be redeemed on such Redemption Date, unless such holder has exercised his, her or its right to convert such shares as provided in Section 4, shall surrender the certificate or certificates representing such shares (or, if such registered holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate) to the Corporation, in the manner and at the place designated in the Redemption Notice, and thereupon the Redemption Price for such shares shall be payable to the order of the person whose name appears on such certificate or certificates as the owner thereof. In the event less than all of the shares of Preferred Stock represented by a certificate are redeemed, a new certificate representing the unredeemed shares of Preferred Stock shall promptly be issued to such holder.

6.4 Rights Subsequent to Redemption. If the Redemption Notice shall have been duly given, and if on the applicable Redemption Date the Redemption Price payable upon redemption of the shares of Preferred Stock to be redeemed on such Redemption Date is paid or tendered for payment or deposited with an independent payment agent so as to be

available therefor in a timely manner, then notwithstanding that the certificates evidencing any of the shares of Preferred Stock so called for redemption shall not have been surrendered, dividends with respect to such shares of Preferred Stock shall cease to accrue after such Redemption Date and all rights with respect to such shares shall forthwith after the Redemption Date terminate, except only the right of the holders to receive the Redemption Price without interest upon surrender of their certificate or certificates therefor.

7. Redeemed or Otherwise Acquired Shares. Any shares of Preferred Stock that are redeemed or otherwise acquired by the Corporation or any of its subsidiaries shall be automatically and immediately cancelled and retired and shall not be reissued, sold or transferred. Neither the Corporation nor any of its subsidiaries may exercise any voting or other rights granted to the holders of Preferred Stock following redemption.

8. Waiver. Any of the rights, powers, preferences and other terms of the Preferred Stock set forth herein may be waived on behalf of all holders of Preferred Stock by the affirmative written consent or vote of the Requisite Holders, subject to the provisions of Section 3 of this Article Fourth.

9. Notices. Any notice required or permitted by the provisions of this Article Fourth to be given to a holder of shares of Preferred Stock shall be mailed, postage prepaid, to the post office address last shown on the records of the Corporation, or given by electronic communication in compliance with the provisions of the General Corporation Law, and shall be deemed sent upon such mailing or electronic transmission.

FIFTH: Subject to any additional vote required by the Certificate of Incorporation or Bylaws, in furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to make, repeal, alter, amend and rescind any or all of the Bylaws of the Corporation.

SIXTH: Subject to any additional vote required by the Certificate of Incorporation, the number of directors of the Corporation shall be determined in the manner set forth in the Bylaws of the Corporation.

SEVENTH: Elections of directors need not be by written ballot unless the Bylaws of the Corporation shall so provide.

EIGHTH: Meetings of stockholders may be held within or without the State of Delaware, as the Bylaws of the Corporation may provide. The books of the Corporation may be kept outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or in the Bylaws of the Corporation.

NINTH: To the fullest extent permitted by law, a director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. If the General Corporation Law or any other law of the State of Delaware is amended after approval by the stockholders of this Article Ninth to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law as so amended.

Any repeal or modification of the foregoing provisions of this Article Ninth by the stockholders of the Corporation shall not adversely affect any right or protection of a director of the Corporation existing at the time of, or increase the liability of any director of the Corporation with respect to any acts or omissions of such director occurring prior to, such repeal or modification.

TENTH: The following indemnification provisions shall apply to the persons enumerated below.

1. Right to Indemnification of Directors and Officers. The Corporation shall indemnify and hold harmless, to the fullest extent permitted by applicable law as it presently exists or may hereafter be amended, any person (an "**Indemnified Person**") who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (a "**Proceeding**"), by reason of the fact that such person, or a person for whom such person is the legal representative, is or was a director or officer of the Corporation or, while a director or officer of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, limited liability company, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such Indemnified Person in such Proceeding. Notwithstanding the preceding sentence, except as otherwise provided in Section 3 of this Article Tenth, the Corporation shall be required to indemnify an Indemnified Person in connection with a Proceeding (or part thereof) commenced by such Indemnified Person only if the commencement of such Proceeding (or part thereof) by the Indemnified Person was authorized in advance by the Board of Directors.

2. Prepayment of Expenses of Directors and Officers. The Corporation shall pay the expenses (including attorneys' fees) incurred by an Indemnified Person in defending any Proceeding in advance of its final disposition, provided, however, that, to the extent required by law, such payment of expenses in advance of the final disposition of the Proceeding shall be made only upon receipt of an undertaking by the Indemnified Person to repay all amounts advanced if it should be ultimately determined that the Indemnified Person is not entitled to be indemnified under this Article Tenth or otherwise.

3. Claims by Directors and Officers. If a claim for indemnification or advancement of expenses under this Article Tenth is not paid in full within 30 days after a written claim therefor by the Indemnified Person has been received by the Corporation, the Indemnified Person may file suit to recover the unpaid amount of such claim and, if successful in whole or in part, shall be entitled to be paid the expense of prosecuting such claim. In any such action the Corporation shall have the burden of proving that the Indemnified Person is not entitled to the requested indemnification or advancement of expenses under applicable law.

4. Indemnification of Employees and Agents. The Corporation may indemnify and advance expenses to any person who was or is made or is threatened to be made or is otherwise involved in any Proceeding by reason of the fact that such person, or a person for whom such person is the legal representative, is or was an employee or agent of the Corporation or, while an employee or agent of the Corporation, is or was serving at the request of the

Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, limited liability company, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorney's fees) reasonably incurred by such person in connection with such Proceeding. The ultimate determination of entitlement to indemnification of persons who are non-director or officer employees or agents shall be made in such manner as is determined by the Board of Directors in its sole discretion. Notwithstanding the foregoing sentence, the Corporation shall not be required to indemnify a person in connection with a Proceeding initiated by such person if the Proceeding was not authorized in advance by the Board of Directors.

5. Advancement of Expenses of Employees and Agents. The Corporation may pay the expenses (including attorney's fees) incurred by an employee or agent in defending any Proceeding in advance of its final disposition on such terms and conditions as may be determined by the Board of Directors.

6. Non-Exclusivity of Rights. The rights conferred on any person by this Article Tenth shall not be exclusive of any other rights which such person may have or hereafter acquire under any statute, provision of the Certificate of Incorporation, the by-laws, agreement, vote of stockholders or disinterested directors or otherwise.

7. Other Indemnification. The Corporation's obligation, if any, to indemnify any person who was or is serving at its request as a director, officer or employee of another Corporation, partnership, limited liability company, joint venture, trust, organization or other enterprise shall be reduced by any amount such person may collect as indemnification from such other Corporation, partnership, limited liability company, joint venture, trust, organization or other enterprise.

8. Insurance. The Board of Directors may, to the full extent permitted by applicable law as it presently exists, or may hereafter be amended from time to time, authorize an appropriate officer or officers to purchase and maintain at the Corporation's expense insurance: (a) to indemnify the Corporation for any obligation which it incurs as a result of the indemnification of directors, officers and employees under the provisions of this Article Tenth; and (b) to indemnify or insure directors, officers and employees against liability in instances in which they may not otherwise be indemnified by the Corporation under the provisions of this Article Tenth.

9. Amendment or Repeal. Any repeal or modification of the foregoing provisions of this Article Tenth shall not adversely affect any right or protection hereunder of any person in respect of any act or omission occurring prior to the time of such repeal or modification. The rights provided hereunder shall inure to the benefit of any Indemnified Person and such person's heirs, executors and administrators.

ELEVENTH: The Corporation renounces, to the fullest extent permitted by law, any interest or expectancy of the Corporation in, or in being offered an opportunity to participate in, any Excluded Opportunity. An "**Excluded Opportunity**" is any matter, transaction or interest that is presented to, or acquired, created or developed by, or which otherwise comes into the possession of, (i) any director of the Corporation who is not an employee of the Corporation or

any of its subsidiaries, or (ii) any holder of Preferred Stock or any partner, member, director, stockholder, employee or agent of any such holder, other than someone who is an employee of the Corporation or any of its subsidiaries (collectively, "**Covered Persons**"), unless such matter, transaction or interest is presented to, or acquired, created or developed by, or otherwise comes into the possession of, a Covered Person expressly and solely in such Covered Person's capacity as a director of the Corporation.

TWELFTH: Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery in the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of fiduciary duty owed by any director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or the Corporation's certificate of incorporation or bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine.

* * *

IN WITNESS WHEREOF, this Certificate of Incorporation has been executed on this30th day of August.

Galera Therapeutics, Inc.

By: /s/ Mel Sorensen
Name: Mel Sorensen
Title: President and Chief Executive Officer

[Signature Page to Fourth Amended and Restated Certificate of Incorporation]

BYLAWS

OF

GALERA THERAPEUTICS, INC.
(a Delaware corporation)

TABLE OF CONTENTS

ARTICLE 1
Offices

1.1 Principal Office. The Board of Directors (the "Board") shall fix the location of the principal executive office of the corporation at any place within or outside the State of Delaware.

1.2 Additional Offices. The Board or the Chief Executive Officer may at any time establish branch or subordinate offices at any place or places.

ARTICLE 2
Meeting of Stockholders

2.1 Place of Meeting. All meetings of the stockholders for the election of directors shall be held at the principal office of the Corporation, at such place as may be fixed from time to time by the Board, or at such other place either within or without the State of Delaware, as shall be designated from time to time by the Board and stated in the notice of the meeting. Meetings of stockholders for any purpose may be held at such time and place within or without the State of Delaware as the Board may fix from time to time, and as shall be stated in the notice of the meeting or in a duly executed waiver of notice thereof.

2.2 Action Without Meeting by Written Consent. All actions required to be taken at any annual or special meeting may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing, setting forth the action so taken, shall be signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted, and shall be delivered to the Corporation by delivery to its registered office, its principal place of business, or an officer or agent of the Corporation having custody of the book in which proceedings of meetings or stockholders are recorded.

2.3 Annual Meeting. Annual meetings of stockholders shall be held at such date and time as shall be designated from time to time by the Board and stated in the notice of the meeting. At such annual meetings, the stockholders shall elect a Board and transact such other business as may properly be brought before the meetings.

2.4 Special Meetings. Special meetings of the stockholders may be called for any purpose or purposes, unless otherwise prescribed by the statute or by the Certificate of Incorporation, at the request of the Board, the Chairman of the Board, the President or the holders of shares entitled to cast not less than 10 percent (10%) of the votes at the meeting, or such additional persons as may be provided in the certificate of incorporation or bylaws. Such request shall state the purpose or purposes of the proposed meeting. Upon request in writing that a special meeting of stockholders be called for any proper purpose, directed to the Chairman of the Board, the President, the Chief Executive Officer, the Vice President or the Secretary, by any person (other than the board of directors) entitled to call a special meeting of stockholders, the person forthwith shall cause notice to be given to the stockholders entitled to vote that a meeting will be held at a time requested by the person or persons calling the meeting, such time not to be

less than fifteen (15), nor more than sixty (60), days after receipt of the request. Such request shall state the purpose or purposes of the proposed meeting.

2.5 Notice of Meetings. Written notice of stockholders' meetings, stating the place, date and time of the meeting, and the purpose or purposes for which the meeting is called, shall be given to each stockholder entitled to vote at such meeting not less than ten (10), nor more than sixty (60), days prior to the meeting. When a meeting is adjourned to another place, date or time, written notice need not be given of the adjourned meeting if the place, date and time thereof are announced at the meeting at which the adjournment is taken; provided, however, that if the date of any adjourned meeting is more than thirty (30) days after the date for which the meeting was originally noticed, or if a new record date is fixed for the adjourned meeting, written notice of the place, date and time of the adjourned meeting shall be given in conformity herewith. At any adjourned meeting, any business may be transacted which might have been transacted at the original meeting.

2.6 Business Matter of a Special Meeting. Business transacted at any special meeting of stockholders shall be limited to the purposes stated in the notice.

2.7 List of Stockholders. The officer in charge of the stock ledger of the Corporation or the transfer agent shall prepare and make, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, during ordinary business hours, for a period of at least ten (10) days prior to the meeting: (i) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (ii) during ordinary business hours, at the principal place of business of the Corporation. In the event that the Corporation determines to make the list available on an electronic network, the Corporation may take reasonable steps to ensure that such information is available only to stockholders of the Corporation. If the meeting is to be held at a place, then the list shall be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting.

2.8 Organization and Conduct of Business. The Chairman of the Board or, in his or her absence, the President of the Corporation or, in their absence, such person as the Board may have designated or, in the absence of such a person, such person as may be chosen by the holders of a majority of the shares entitled to vote who are present, in person or by proxy, shall call to order any meeting of the stockholders and act as Chairman of the meeting. In the absence of the Secretary of the Corporation, the Secretary of the meeting shall be such person as the Chairman appoints.

The Chairman of any meeting of stockholders shall determine the order of business and the procedure at the meeting, including such regulation of the manner of voting and the conduct of discussion as seems to him or her in order.

2.9 Quorum and Adjournments. Except where otherwise provided by law or in the Certificate of Incorporation or these Bylaws, the holders of a majority of the stock issued and outstanding and entitled to vote, present in person or represented in proxy, shall constitute a quorum at all meetings of the stockholders. The stockholders present at a duly called or held meeting at which a quorum is present may continue to do business until adjournment, notwithstanding the withdrawal of enough stockholders to have less than a quorum if any action taken (other than adjournment) is approved by at least a majority of the shares required to constitute a quorum. At such adjourned meeting at which a quorum is present or represented, any business may be transacted which might have been transacted at the meeting as originally noticed. If, however, a quorum shall not be present or represented at any meeting of the stockholders, the stockholders entitled to vote thereat who are present in person or represented by proxy shall have the power to adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum shall be present or represented.

2.10 Voting Rights. Unless otherwise provided in the Certificate of Incorporation, each stockholder shall at every meeting of the stockholders be entitled to one vote in person or by proxy for each share of the capital stock having voting power held by such stockholder.

2.11 Majority Vote. When a quorum is present at any meeting, the vote of the holders of a majority of the stock having voting power present in person or represented by proxy shall decide any question brought before such meeting, unless the question is one upon which, by express provision of the statutes or of the Certificate of Incorporation or of these Bylaws, a different vote is required, in which case such express provision shall govern and control the decision of such question.

2.12 Record Date for Stockholder Notice and Voting. For purposes of determining the stockholders entitled to notice of any meeting or to vote, or entitled to receive payment of any dividend or other distribution, or entitled to exercise any right in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the Board may fix, in advance, a record date, which shall not be more than sixty (60) days, nor less than ten (10) days before the date of any such meeting, nor more than sixty (60) days before any other action. If the Board does not so fix a record date, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the business day next preceding the day on which notice is given or, if notice is waived, at the close of business on the business day next preceding the day on which the meeting is held.

2.13 Proxies. Every person entitled to vote for directors or on any other matter shall have the right to do so either in person or by one or more agents authorized by a written proxy signed by the person and filed with the Secretary of the Corporation. A proxy shall be deemed signed if the stockholder’s name is placed on the proxy (whether by manual signature, typewriting, telegraphic transmission, electronic transmission or otherwise) by the stockholder or the stockholder’s attorney-in-fact. A validly executed proxy which does not state that it is irrevocable shall continue in full force and effect unless (a) revoked by the person executing it,

before the vote pursuant to that proxy, by a writing delivered to the Corporation stating that the proxy is revoked or by a subsequent proxy executed by the maker of the proxy, or by that person's attendance and vote at the meeting; or (b) written notice of the death or incapacity of the maker of that proxy is received by the Corporation before the vote pursuant to that proxy is counted; provided, however, that no proxy shall be valid after the expiration of eleven months from the date of the proxy, unless otherwise provided in the proxy.

2.14 Inspectors of Election. Before any meeting of stockholders, the Board may appoint any person other than nominees for office to act as inspectors of election at the meeting or its adjournment. If no inspectors of election are so appointed, the Chairman of the meeting may, and on the request of any stockholder or a stockholder's proxy shall, appoint inspectors of election at the meeting. The number of inspectors shall be either one (1) or three (3). If inspectors are appointed at a meeting on the request of one or more stockholders or proxies, the holders of a majority of shares or their proxies present at the meeting shall determine whether one (1) or three (3) inspectors are to be appointed. If any person appointed as inspector fails to appear or fails or refuses to act, the Chairman of the meeting may, and upon the request of any Stockholder or a stockholder's proxy shall, appoint a person to fill that vacancy.

ARTICLE 3
Directors

3.1 Number: Qualifications. The authorized number of directors shall be between five (5) and seven (7), and shall initially be six (6), such number to be changed from time to time by resolution of the Board and in accordance with any stockholder approval requirements contained in the Certificate of Incorporation. All directors shall be elected at the annual meeting or at any special meeting of the stockholders, except as provided in Section 3.2 hereof, and each director so elected shall hold office until the next annual meeting or any special meeting, or until his successor is elected and qualified, or until his earlier resignation or removal. Directors need not be stockholders. All elections of directors shall be by written ballot, unless otherwise provided in the certificate of incorporation; if authorized by the Board, such requirement of a written ballot shall be satisfied by a ballot submitted by electronic transmission, provided that any such electronic transmission must either set forth or be submitted with information from which it can be determined that the electronic transmission was authorized by the stockholder or proxy holder.

3.2 Resignation and Vacancies. A vacancy or vacancies in the Board shall be deemed to exist in the case of the death, resignation or removal of any director, or if the authorized number of directors be increased. Vacancies may be filled by a majority of the remaining directors, though less than a quorum, or by a sole remaining director, unless otherwise provided in the Certificate of Incorporation. The stockholders may elect a director or directors at any time to fill any vacancy or vacancies not filled by the directors. If the Board accepts the resignation of a director tendered to take effect at a future time, the Board shall have power to elect a successor to take office when the resignation is to become effective. If there are no directors in office, then an election of directors may be held in the manner provided by statute.

3.3 Removal of Directors. Unless otherwise restricted by statute, or by the Certificate of Incorporation or these Bylaws, any director or the entire Board may be removed, with or

without cause, by the holders of at least a majority of the shares entitled to vote at an election of directors.

3.4 Powers. The business of the Corporation shall be managed by or under the direction of the Board which may exercise all such powers of the Corporation and do all such lawful acts and things which are not by statute or by the Certificate of Incorporation or by these Bylaws directed or required to be exercised or done by the stockholders.

3.5 Place of Meetings. The Board may hold meetings, both regular and special, either within or without the State of Delaware.

3.6 Regular Meetings. Regular meetings of the Board may be held without notice at such time and place as may be determined from time to time by the Board.

3.7 Special Meetings. Special meetings of the Board of Directors may be called by the Chairman of the Board, the President or a Vice President, and shall be called by the President or Secretary at the written request of any one director. Except as otherwise required by statute, notice of each special meeting shall be given to each director, if by mail, when addressed to him or her at his or her residence or usual place of business, unless he or she shall have filed with the Secretary a written request that notices intended for him or her be mailed to some other address, in which case it shall be mailed to the address designated in such request, on at least two (2) days' notice prior to the time of the meeting, or shall be sent to him or her at such place by e-mail or other electronic means, or delivered to him or her personally, not later than four (4) hours before the time the meeting is to be held. Such notice shall state the time and place of such meeting, but need not state the purposes thereof, unless otherwise required by statute, the Certificate of Incorporation of the Corporation or these Bylaws.

3.8 Quorum and Adjournments. At all meetings of the Board, a majority of the directors then in office shall constitute a quorum for the transaction of business, and the act of a majority of the directors present at any meeting at which there is a quorum shall be the act of the Board, except as may otherwise be specifically provided by law or by the Certificate of Incorporation. If a quorum is not present at any meeting of the Board, the directors present may adjourn the meeting from time to time, without notice other than announcement at the meeting at which the adjournment is taken, until a quorum shall be present. A meeting at which a quorum is initially present may continue to transact business notwithstanding the withdrawal of directors, if any action taken is approved of by at least a majority of the required quorum for that meeting.

3.9 Action Without Meeting. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, any action required or permitted to be taken at any meeting of the Board or of any committee thereof may be taken without a meeting, if all members of the Board or committee, as the case may be, consent thereto in writing or by electronic transmission, and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the Board or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

3.10 Teleconference and Videoconferences. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, any member of the Board or of any committee may participate in a meeting by means of videoconference, teleconference or similar communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting shall constitute presence in person at the meeting.

3.11 Waiver of Notice. Notice of a meeting need not be given to any director who signs a waiver of notice or provides a waiver by electronic transmission or a consent to holding the meeting or an approval of the minutes thereof, whether before or after the meeting, or who attends the meeting without protesting, either prior thereto or at its commencement, the lack of notice to such director. All such waivers, consents and approvals or any waiver by electronic transmission shall be filed with the corporate records or made a part of the minutes of the meeting.

3.12 Fees and Compensation of Directors. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, the Board shall have the authority to fix the compensation of directors. The directors may be paid their expenses, if any, of attendance at each meeting of the Board, and may be paid a fixed sum for attendance at each meeting of the Board or a stated salary as director. No such payment shall preclude any director from serving the Corporation in any other capacity and receiving compensation therefor. Members of special or standing committees may be allowed like compensation for attending committee meetings.

3.13 Rights of Inspection. Every director shall have the absolute right at any reasonable time to inspect and copy all books, records and documents of every kind, and to inspect the physical properties of the Corporation and also of its subsidiary corporations, domestic or foreign. Such inspection by a director may be made in person or by agent or attorney, and includes the right to copy and obtain extracts.

ARTICLE 4
Committees of Directors

4.1 Selection. The Board may, by resolution passed by a majority of the entire Board, designate one or more committees, each committee to consist of one or more of the directors of the Corporation. The Board may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not he or she or they constitute a quorum, may unanimously appoint another member of the Board to act at the meeting in the place of any such absent or disqualified member.

4.2 Power. Any such committee, to the extent provided in the resolution of the Board, shall have and may exercise all the powers and authority of the Board in the management of the business and affairs of the Corporation, and may authorize the seal of the Corporation to be affixed to all papers which may require it; but no such committee shall have the power or authority in reference to amending the Certificate of Incorporation (except that a committee may, to the extent authorized in the resolution or resolutions providing for the issuance of shares of stock adopted by the Board as provided in section 151(a) of the General Corporation Law of

Delaware, fix any of the preferences or rights of such shares relating to dividends, redemption, dissolution, any distribution of assets of the Corporation or the conversion into, or the exchange of such shares for, shares of any other class or classes or any other series of the same or any other class or classes of stock of the Corporation), adopting an agreement of merger or consolidation, recommending to the stockholders the sale, lease or exchange of all or substantially all of the Corporation's property and assets, recommending to the stockholders a dissolution of the Corporation or a revocation of dissolution, removing or indemnifying directors or amending the Bylaws of the Corporation; and, unless the resolution or the Certificate of Incorporation expressly so provides, no such committee shall have the power or authority to declare a dividend or to authorize the issuance of stock or to adopt a certificate of ownership and merger. Such committee or committees shall have such name or names as may be determined from time to time by resolution adopted by the Board.

4.3 Committee Minutes. Each committee shall keep regular minutes of its meetings and report the same to the Board when required.

ARTICLE 5
Officers

5.1 Officers Designated. The officers of the Corporation shall be chosen by the Board and shall be a President, a Secretary and a Treasurer. The Board may also choose a Chairman of the Board and one or more assistant Secretaries and assistant Treasurers. The Board or any duly authorized committee may also choose one or more Vice Presidents. Any number of offices may be held by the same person, unless the Certificate of Incorporation or these Bylaws otherwise provide.

5.2 Appointment of Officers. The officers of the Corporation, except such officers as may be appointed in accordance with the provisions of Section 5.3 or 5.5 hereof, shall be appointed by the Board, and each shall serve at the pleasure of the Board, subject to the rights, if any, of an officer under any contract of employment.

5.3 Subordinate Officers. The Board or any duly authorized committee may appoint, and may empower the President to appoint, such other officers and agents as the business of the Corporation may require, each of whom shall hold office for such period, have such authority and perform such duties as are provided in the Bylaws or as the Board or duly authorized committee may from time to time determine.

5.4 Removal and Resignation of Officers. Subject to the rights, if any, of an officer under any contract of employment, any officer may be removed, either with or without cause, by an affirmative vote of the majority of the Board or authorized committee, at any regular or special meeting of the Board or such committee, or, except in case of an officer chosen by the Board or authorized committee, by any officer upon whom such power of removal may be conferred by the Board or authorized committee. Any officer may resign at any time by giving written notice to the Corporation. Any resignation shall take effect at the date of the receipt of that notice or at any later time specified in that notice; and, unless otherwise specified in that notice, the acceptance of the resignation shall not be necessary to make it effective. Any

resignation is without prejudice to the rights, if any, of the Corporation under any contract to which the officer is a party.

5.5 Vacancies in Offices. A vacancy in any office because of death, resignation, removal, disqualification or any other cause shall be filled in the manner prescribed in these Bylaws for regular appointment to that office.

5.6 Compensation. The salaries of all officers of the Corporation shall be fixed from time to time by the Board, and no officer shall be prevented from receiving a salary because he is also a director of the Corporation.

5.7 The Chairman of the Board. The Chairman of the Board, if such an officer be elected, shall, if present, perform such other powers and duties as may be assigned to him from time to time by the Board. If there is no President, the Chairman of the Board shall also be the Chief Executive Officer of the Corporation and shall have the powers and duties prescribed in Section 5.8 hereof.

5.8 The President. Subject to such supervisory powers, if any, as may be given by the Board to the Chairman of the Board, if there be such an officer, the President shall be the Chief Executive Officer of the Corporation, shall preside at all meetings of the stockholders and in the absence of the Chairman of the Board, or if there be none, at all meetings of the Board, shall have general and active management of the business of the Corporation, and shall see that all orders and resolutions of the Board are carried into effect. He or she shall execute bonds, mortgages and other contracts requiring a seal, under the seal of the Corporation, except where required or permitted by law to be otherwise signed and executed, and except where the signing and execution thereof shall be expressly delegated by the Board to some other officer or agent of the Corporation.

5.9 The Vice President. The Vice President (or in the event there be more than one, the Vice Presidents in the order designated by the directors, or in the absence of any designation, in the order of their election), shall, in the absence of the President or in the event of his disability or refusal to act, perform the duties of the President, and when so acting, shall have the powers of and be subject to all the restrictions upon the President. The Vice President(s) shall perform such other duties and have such other powers as may from time to time be prescribed for them by the Board, the President, the Chairman of the Board or these Bylaws.

5.10 The Secretary. The Secretary shall attend all meetings of the Board and the stockholders and record all votes and the proceedings of the meetings in a book to be kept for that purpose, and shall perform like duties for the standing committees, when required. The Secretary shall give, or cause to be given, notice of all meetings of stockholders and special meetings of the Board, and shall perform such other duties as may from time to time be prescribed by the Board, the Chairman of the Board or the President, under whose supervision he or she shall act. The Secretary shall have custody of the seal of the Corporation, and the Secretary, or an Assistant Secretary, shall have authority to affix the same to any instrument requiring it, and, when so affixed, the seal may be attested by his or her signature or by the signature of such Assistant Secretary. The Board may give general authority to any other officer to affix the seal of the Corporation and to attest the affixing thereof by his or her signature. The

Secretary shall keep, or cause to be kept, at the principal executive office or at the office of the Corporation's transfer agent or registrar, as determined by resolution of the Board, a share register, or a duplicate share register, showing the names of all stockholders and their addresses, the number and classes of shares held by each, the number and date of certificates issued for the same, and the number and date of cancellation of every certificate surrendered for cancellation.

5.11 The Assistant Secretary. The Assistant Secretary, or if there be more than one, the Assistant Secretaries in the order designated by the Board (or in the absence of any designation, in the order of their election) shall, in the absence of the Secretary, or in the event of his or her inability or refusal to act, perform the duties and exercise the powers of the Secretary and shall perform such other duties and have such other powers as may from time to time be prescribed by the Board.

5.12 The Treasurer. The Treasurer shall have the custody of the Corporate funds and securities and shall keep full and accurate accounts of receipts and disbursements in books belonging to the Corporation, and shall deposit all moneys and other valuable effects in the name and to the credit of the Corporation in such depositories as may be designated by the Board. The Treasurer shall disburse the funds of the Corporation as may be ordered by the Board, taking proper vouchers for such disbursements, and shall render to the President and the Board, at its regular meetings, or when the Board so requires, an account of all his or her transactions as Treasurer and of the financial condition of the Corporation. The Treasurer may also be known as the Chief Financial Officer.

5.13 The Assistant Treasurer. The Assistant Treasurer, or if there shall be more than one, the Assistant Treasurers in the order designated by the Board (or in the absence of any designation, in the order of their election) shall, in the absence of the Treasurer or in the event of his or her inability or refusal to act, perform the duties and exercise the powers of the Treasurer, and shall perform such other duties and have such other powers as may from time to time be prescribed by the Board.

ARTICLE 6
Indemnification of Directors, Officers, Employees and Other Agents

6.1 Indemnification of Directors and Officers. The Corporation shall indemnify and hold harmless, to the fullest extent permitted by applicable law as it presently exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Corporation to provide broader indemnification rights than such law permitted the Corporation to provide prior to such amendment), any person (an "Indemnified Person") who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative, arbitrative or investigative (a "Proceeding"), by reason of the fact that such person, or a person for whom such person is the legal representative, is or was a director or officer of the Corporation or, while a director or officer of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, limited liability company, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such Indemnified Person in such Proceeding. Notwithstanding the

preceding sentence, except as otherwise provided in this Section 6.1, the Corporation shall be required to indemnify an Indemnified Person in connection with a Proceeding (or part thereof) commenced by such Indemnified Person only if the commencement of such Proceeding (or part thereof) by the Indemnified Person was authorized in advance by the Board of Directors, unless such Proceeding was brought to enforce a director's or officer's rights to indemnification under these Bylaws in accordance with the provisions set forth herein.

6.2 Claims by Directors and Officers. If a claim for indemnification or advancement of expenses under this Article Six is not paid in full within 30 days after a written claim therefor by the Indemnified Person has been received by the Corporation, the Indemnified Person may file suit to recover the unpaid amount of such claim and, if successful in whole or in part, shall be entitled to be paid the expense of prosecuting such claim. In any such action the Corporation shall have the burden of proving that the Indemnified Person is not entitled to the requested indemnification or advancement of expenses under applicable law.

6.3 Prepayment of Expenses of Directors and Officers. The Corporation shall pay the expenses (including attorneys' fees) incurred by an Indemnified Person in defending any Proceeding in advance of its final disposition, provided, however, that, to the extent required by law, such payment of expenses in advance of the final disposition of the Proceeding shall be made only upon receipt of an undertaking by the Indemnified Person to repay all amounts advanced if it should be ultimately determined that the Indemnified Person is not entitled to be indemnified under this Article 6 or otherwise.

6.4 Indemnification of Employees and Agents. The Corporation may indemnify and advance expenses to any person who was or is made or is threatened to be made or is otherwise involved in any Proceeding by reason of the fact that such person, or a person for whom such person is the legal representative, is or was an employee or agent of the Corporation or, while an employee or agent of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, limited liability company, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorney's fees) reasonably incurred by such person in connection with such Proceeding. The ultimate determination of entitlement to indemnification of persons who are non-director or officer employees or agents shall be made in such manner as is determined by the Board of Directors in its sole discretion. Notwithstanding the foregoing sentence, the Corporation shall not be required to indemnify a person in connection with a Proceeding initiated by such person if the Proceeding was not authorized in advance by the Board of Directors.

6.5 Advancement of Expenses of Employees and Agents. The Corporation may pay the expenses (including attorney's fees) incurred by an employee or agent in defending any Proceeding in advance of its final disposition on such terms and conditions as may be determined by the Board of Directors.

6.6 Non-Exclusivity of Rights. The rights conferred on any person by this Article Six shall not be exclusive of any other rights which such person may have or hereafter acquire under any statute, provision of the certificate of incorporation, these Bylaws, agreement, vote of stockholders or disinterested directors or otherwise.

6.7 Other Indemnification. The Corporation's obligation, if any, to indemnify any person who was or is serving at its request as a director, officer or employee of another Corporation, partnership, limited liability company, joint venture, trust, organization or other enterprise shall be reduced by any amount such person may collect as indemnification from such other Corporation, partnership, limited liability company, joint venture, trust, organization or other enterprise.

6.8 Insurance. The Board of Directors may, to the full extent permitted by applicable law as it presently exists, or may hereafter be amended from time to time, authorize an appropriate officer or officers to purchase and maintain at the Corporation's expense insurance: (a) to indemnify the Corporation for any obligation which it incurs as a result of the indemnification of directors, officers and employees under the provisions of this Article Six; and (b) to indemnify or insure directors, officers and employees against liability in instances in which they may not otherwise be indemnified by the Corporation under the provisions of this Article Six.

6.9 Amendment or Repeal. Any repeal or modification of the foregoing provisions of this Article Six shall not adversely affect any right or protection hereunder of any person in respect of any act or omission occurring prior to the time of such repeal or modification. The rights provided hereunder shall inure to the benefit of any Indemnified Person and such person's heirs, executors and administrators.

ARTICLE 7
Stock Certificates

7.1 Certificates for Shares. The shares of the Corporation shall be represented by certificates or shall be uncertificated. Certificates shall be signed by, or be in the name of the Corporation by, the Chairman of the Board, or the President or a Vice President and by the Treasurer or an Assistant Treasurer, or the Secretary or an Assistant Secretary of the Corporation. Within a reasonable time after the issuance or transfer of uncertified stock, the Corporation shall send to the registered owner thereof a written notice containing the information required by the General Corporation Law of the State of Delaware or a statement that the Corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative participating, optional or other special rights of each class of stock or series thereof, and the qualifications, limitations or restrictions of such preferences and/or rights.

7.2 Signatures on Certificates. Any or all of the signatures on a certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if he were such officer, transfer agent or registrar at the date of issue.

7.3 Transfer of Stock. Upon surrender to the Corporation or the transfer agent of the Corporation of a certificate of shares duly endorsed or accompanied by proper evidence of succession, assignation or authority to transfer, it shall be the duty of the Corporation to issue a new certificate to the person entitled thereto, to cancel the old certificate and record the

transaction upon its books. Upon receipt of proper transfer instructions from the registered owner of uncertificated shares, such uncertificated shares shall be canceled, and issuance of new equivalent uncertificated shares or certificated shares shall be made to the person entitled thereto, and the transaction shall be recorded upon the books of the Corporation.

7.4 Registered Stockholders. The Corporation shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends, and to vote as such owner, and to hold liable for calls and assessments a percent registered on its books as the owner of shares, and shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of any other person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.

7.5 Record Date. In order that the Corporation may determine the stockholders of record who are entitled to receive notice of, or to vote at, any meeting of stockholders or any adjournment thereof, or to express consent to corporate action in writing without a meeting, or entitled to receive payment of any dividend or other distribution or allotment of any rights, or to exercise any rights in respect of any change, conversion, or exchange of stock or for the purpose of any lawful action, the Board may fix, in advance, a record date which shall not be more than sixty (60), nor less than ten (10), days prior to the date of such meeting, nor more than sixty (60) days prior to the date of any other action. A determination of stockholders of record entitled to notice or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board may fix a new record date for the adjourned meeting.

7.6 Lost, Stolen or Destroyed Certificates. The Board may direct that a new certificate or certificates be issued to replace any certificate or certificates theretofore issued by the Corporation alleged to have been lost, stolen or destroyed, upon the making of an affidavit of that fact by the person claiming the certificate of stock to be lost, stolen or destroyed. When authorizing the issue of a new certificate or certificates, the Board may, in its discretion and as a condition precedent to the issuance thereof, require the owner of the lost, stolen or destroyed certificate or certificates, or his or her legal representative, to advertise the same in such manner as it shall require, and/or to give the Corporation a bond in such sum as it may direct as indemnity against any claim that may be made against the Corporation with respect to the certificate alleged to have been lost, stolen or destroyed.

ARTICLE 8
Notices

8.1 Notice. Whenever, under the provisions of the statutes or of the Certificate of Incorporation or of these Bylaws, notice is required to be given to any director or stockholder, it shall not be construed to mean personal notice, but such notice may be given in writing, by mail, addressed to such director or stockholder, at his or her address as it appears on the records of the Corporation, with postage thereon prepaid, and such notice shall be deemed to be given at the time when the same shall be deposited in the United States mail. Notice to directors may also be given by telegram or telephone.

8.2 Waiver. Whenever any notice is required to be given under the provisions of the statutes or of the Certificate of Incorporation or of these Bylaws, a waiver thereof in writing,

signed by the person or persons entitled to said notice, whether before or after the time stated therein, shall be deemed equivalent thereto.

ARTICLE 9
General Provisions

9.1 Dividends. Dividends upon the capital stock of the Corporation, subject to any restrictions contained in the General Corporation Laws of Delaware or the provisions of the Certificate of Incorporation, if any, may be declared by the Board at any regular or special meeting. Dividends may be paid in cash, in property or in shares of the capital stock, subject to the provisions of the Certificate of Incorporation.

9.2 Dividend Reserve. Before payment of any dividend, there may be set aside out of any funds of the Corporation available for dividends, such sum or sums as the directors from time to time, in their absolute discretion, think proper as a reserve or reserves to meet contingencies, or for equalizing dividends, or for repairing or maintaining any property of the Corporation, or for such other purpose as the directors shall think conducive to the interest of the Corporation, and the directors may modify or abolish any such reserve in the manner in which it was created.

9.3 Annual Statement. The Board shall present at each annual meeting, and at any special meeting of the stockholders when called for by vote of the stockholders, a full and clear statement of the business and condition of the Corporation.

9.4 Checks. All checks or demands for money and notes of the Corporation shall be signed by such officer or officers or such other person or persons as the Board may from time to time designate.

9.5 Corporate Seal. The Board may provide a suitable seal, containing the name of the Corporation, which seal shall be in charge of the Secretary. If and when so directed by the Board or a committee thereof, duplicates of the seal may be kept and used by the Treasurer or by an Assistant Secretary or Assistant Treasurer.

9.6 Execution of Corporate Contracts and Instruments. The Board, except as otherwise provided in these Bylaws, may authorize any officer or officers, or agent or agents, to enter into any contract or execute any instrument in the name of and on behalf of the Corporation; such authority may be general or confined to specific instances. Unless so authorized or ratified by the Board or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the Corporation by any contract or engagement, or to pledge its credit or to render it liable for any purpose or for any amount.

ARTICLE 10
Amendments

In addition to the right of the stockholders of the Corporation to make, alter, amend, change, add to or repeal the Bylaws of the Corporation, the Board of Directors shall have the power (without the assent or vote of the stockholders) to make, alter, amend, change, add to or repeal the Bylaws of the Corporation.

BYLAWS AMENDMENT

Section 3.7 of the Bylaws is hereby replaced with the following:

3.7 Special Meetings. Special meetings of the Board of Directors may be called by the Chairman of the Board, the President or a Vice President, and shall be called by the President or Secretary at the written request of any one director. Except as otherwise required by statute, notice of each special meeting shall be given to each director, if by mail, when addressed to him or her at his or her residence or usual place of business, unless he or she shall have filed with the Secretary a written request that notices intended for him or her be mailed to some other address, in which case it shall be mailed to the address designated in such request, on at least two (2) days' notice prior to the time of the meeting, or shall be sent to him or her at such place by e-mail or other electronic means, or delivered to him or her personally, not later than twenty-four (24) hours before the time the meeting is to be held. Such notice shall state the rime and place of such meeting, but need not state the purposes thereof, unless otherwise required by statute, the Certificate of Incorporation of the Corporation or these Bylaws.

FIRST AMENDMENT TO BYLAWS

OF

Galera Therapeutics, Inc.,
a Delaware corporation

The undersigned, Robert A. Beardsley, being the Secretary of GALERA THERAPEUTICS, INC., a Delaware corporation (the "Corporation"), hereby certifies as follows:

Pursuant to resolutions adopted in an Action by Unanimous Written Consent of the Board of Directors of the Corporation on November 11, 2016, and an Action by Written Consent of the Stockholders of the Corporation on November 15, 2016, the Company's Bylaws were amended as follows, effective as of such date:

1. The first sentence of Article 3, Section 3.1 was amended and restated in its entirety to read as follows:

> "**3.1** The authorized number of directors shall be between five (5) and nine (9), and shall initially be eight (8), such number to be changed from time to time by resolution of the Board and in accordance with any stockholder approval requirements contained in the Certificate of Incorporation."

2. Except as set forth in this amendment, the Bylaws shall be unaffected hereby and shall remain in full force and effect.

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IN WITNESS WHEREOF, this First Amendment to Bylaws is certified by the undersigned this 15th day of November, 2016.

Galera Therapeutics, Inc.,
a Delaware corporation

By: /s/ Robert A. Beardsley
Robert A. Beardsley, Secretary

GALERA THERAPEUTICS, INC.

SECOND AMENDED AND RESTATED

INVESTORS' RIGHTS AGREEMENT

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SECOND AMENDED AND RESTATED INVESTORS' RIGHTS AGREEMENT

THIS SECOND AMENDED AND RESTATED INVESTORS' RIGHTS AGREEMENT (this "**Agreement**") is made as of the 30th day of August, 2018, by and among Galera Therapeutics, Inc., a Delaware corporation (the "**Company**") and each of the investors listed on Schedule A hereto, each of which is referred to in this Agreement as an "**Investor**."

RECITALS

WHEREAS, the Company and certain of the Investors (the "**Exisiting Stockholders**") entered into an Amended and Restated Investors' Rights Agreement, dated October 1, 2015, as amended by that First Amendment to the Amended and Restated Investors' Rights Agreement, dated January 21, 2016, as amended by that Second Amendment to the Amended and Restated Investors' Rights Agreement, dated November 15, 2016 (as amended, the "**Prior Agreement**");

WHEREAS, the Company and certain of the Investors (the "**Purchasers**") are parties to the Series C Preferred Stock Purchase Agreement of even date herewith (as may be amended from time to time, the "**Purchase Agreement**");

WHEREAS, Section 6.6 of the Prior Agreement provides that the Prior Agreement may be amended by the written consent of the Company, (a) the holders of a majority of the Registrable Securities then outstanding, and (b) at least three of New Enterprise Associates 14, L.P., Novartis BioVentures Ltd., Novo Holdings A/S, and Sofinnova Venture Partners IX, L.P. so long as each of such holders owns at least 2,500,000 shares of Registrable Securities (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization) ((a) and (b) the "**Prior Requisite Holders**");

WHEREAS, the Existing Stockholders executing this Agreement constitute the Prior Requisite Holders on the date hereof; and

WHEREAS, in order to induce the Company to enter into the Purchase Agreement and to induce the Purchasers to invest funds in the Company pursuant to the Purchase Agreement, the Investors and the Company desire to amend and restate the Prior Agreement and hereby agree that this Agreement shall govern the rights of the Investors to cause the Company to register shares of Common Stock issuable to the Investors, to receive certain information from the Company, and to participate in future equity offerings by the Company, and shall govern certain other matters as set forth in this Agreement.

NOW, THEREFORE, the parties hereby agree as follows:

1. Definitions.For purposes of this Agreement:

1.1. "**Affiliate**" and correlative terms mean, with respect to any specified Person, any other Person who, directly or indirectly, controls, is controlled by, or is under common control with such Person, including without limitation any general partner, managing member, investment adviser, officer,director or trustee of such Person or any venture capital fund or registered investment company now or hereafter existing that is controlled by one or more general partners or managing members of, or shares the same management company or investment adviser with, such Person.

1.2. **"Clarus Funds**" means, collectively, Clarus IV-A, L.P., Clarus IV-B, L.P., Clarus IV-C, L.P., Clarus IV-D, L.P. together with each of its successors and assigns Affiliated with Clarus IV GP, LLC.

1.3. "**Common Stock**" means shares of the Company's common stock, par value $0.001 per share.

1.4. "**Competitor**" means a competitor of the Company, as reasonably determined by the Board of Directors, including a majority of the Preferred Directors; provided, however, that (i) Novartis Bioventures Ltd. and its Affiliates that are engaged in the business of the Novartis Venture Fund (collectively, the "**NBV Investors**") shall not be deemed to be Competitors for purposes of this definition solely because of any activities undertaken by Novartis AG or any of its Affiliates who are not otherwise NBV Investors; and (ii) Novo Holdings A/S shall not be deemed a Competitor for purposes of this definition solely because of any activities undertaken by Novo Nordisk A/S or any of its Affiliates.

1.5. "**Damages**" means any loss, damage, claim or liability (joint or several) to which a party hereto may become subject under the Securities Act, the Exchange Act, or other federal or state law, insofar as such loss, damage, claim or liability (or any action in respect thereof) arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in any registration statement of the Company, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto; (ii) an omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading; or (iii) any violation or alleged violation by the indemnifying party (or any of its agents or Affiliates) of the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act, or any state securities law.

1.6. "**Derivative Securities**" means any securities or rights convertible into, or exercisable or exchangeable for (in each case, directly or indirectly), Common Stock, including options and warrants.

1.7. "**Exchange Act**" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

1.8. "**Excluded Registration**" means (i) a registration relating to the sale of securities to employees of the Company or a subsidiary pursuant to a stock option, stock purchase, or similar plan; (ii) a registration relating to an SEC Rule 145 transaction; (iii) a registration on any form that does not include substantially the same information as would be required to be included in a registration statement covering the sale of the Registrable Securities; or (iv) a registration in which the only Common Stock being registered is Common Stock issuable upon conversion of debt securities that are also being registered.

1.9. "**FOIA Party**" means a Person that, in the reasonable determination of the Board of Directors, may be subject to, and thereby required to disclose non-public information furnished by or relating to the Company under, the Freedom of Information Act, 5 U.S.C. 552 ("**FOIA**"), any state public records access law, any state or other jurisdiction's laws similar in intent or effect to FOIA, or any other similar statutory or regulatory requirement.

1.10. "**Form S-1**" means such form under the Securities Act as in effect on the date hereof or any successor registration form under the Securities Act subsequently adopted by the SEC.

1.11. "**Form S-3**" means such form under the Securities Act as in effect on the date hereof or any registration form under the Securities Act subsequently adopted by the SEC that permits incorporation of substantial information by reference to other documents filed by the Company with the SEC.

1.12. "**GAAP**" means generally accepted accounting principles in the United States.

1.13. "**Holder**" means any holder of Registrable Securities who is a party to this Agreement.

1.14. "**Immediate Family Member**" means a child, stepchild, grandchild, parent, stepparent, grandparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including adoptive relationships, of a natural person referred to herein.

1.15. "**Initiating Holders**" means, collectively, Holders who properly initiate a registration request under this Agreement.

1.16. "**IPO**" means the Company's first underwritten public offering of its Common Stock under the Securities Act.

1.17. "**Key Employee**" means any employee of the Company at the level of vice president or above, and any other employee who develops, invents, programs or designs any Company Intellectual Property.

1.18. "**Major Investor**" means any Investor that, individually or together with such Investor's Affiliates, holds at least 2,000,000 shares of Registrable Securities (as adjusted for any stock split, stock dividend, combination, or other recapitalization or reclassification effected after the date hereof). Notwithstanding the foregoing, Blackwell Partners LLC—Series A shall also be considered a "Major Investor".

1.19. "**New Securities**" means, collectively, equity securities of the Company, whether or not currently authorized, as well as rights, options, or warrants to purchase such equity securities, or securities of any type whatsoever that are, or may become, convertible or exchangeable into or exercisable for such equity securities. For the avoidance of doubt, any royalty interest in the Company's products in any form shall not be equity securities under this Agreement.

1.20. "**Person**" means any individual, corporation, partnership, trust, limited liability company, association or other entity.

1.21. "**Preferred Director**" means any director of the Company that the holders of the Preferred Stock are entitled to elect pursuant to the Company's Certificate of Incorporation.

1.22. "**Preferred Stock**" means the Series A Preferred Stock, the Series B Preferred Stock, the Series B-1 Preferred Stock, Series B-2 Preferred Stock and Series C Preferred Stock.

1.23. "**Registrable Securities**" means (i) the Common Stock issuable or issued upon conversion of the Preferred Stock; (ii) any Common Stock, or any Common Stock issued or issuable (directly or indirectly) upon conversion and/or exercise of any other securities of the Company, acquired by the Investors after the date hereof; and (iii) any Common Stock issued as (or issuable upon the conversion or exercise of any warrant, right, or other security that is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, the shares referenced in clauses (i), (ii) and (iii) above; excluding in all cases, however, any Registrable Securities sold by a Person in a transaction in which the applicable rights under this Agreement are not assigned pursuant to Subsection 6.1, and excluding for purposes of Section 2 any shares for which registration rights have terminated pursuant to Subsection 2.13 of this Agreement.

1.24. "**Registrable Securities then outstanding**" means the number of shares determined by adding the number of shares of outstanding Common Stock that are Registrable Securities and the number of shares of Common Stock issuable (directly or indirectly) pursuant to then exercisable and/or convertible securities that are Registrable Securities.

1.25. "**Restricted Securities**" means the securities of the Company required to bear the legend set forth in Subsection 2.12(b) hereof.

1.26. "**SEC**" means the Securities and Exchange Commission.

1.27. "**SEC Rule 144**" means Rule 144 promulgated by the SEC under the Securities Act.

1.28. "**SEC Rule 145**" means Rule 145 promulgated by the SEC under the Securities Act.

1.29. "**Securities Act**" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

1.30. "**Selling Expenses**" means all underwriting discounts, selling commissions, and stock transfer taxes applicable to the sale of Registrable Securities, and fees and disbursements of counsel for any Holder, except for the fees and disbursements of the Selling Holder Counsel borne and paid by the Company as provided in Subsection 2.6.

1.31. "**Series A Preferred Stock**" means shares of the Company's Series A Preferred Stock, par value $0.001 per share.

1.32. "**Series B Preferred Stock**" means shares of the Company's Series B Preferred Stock, par value $0.001 per share.

1.33. "**Series B-1 Preferred Stock**" means shares of the Company's Series B-1 Preferred Stock, par value $0.001 per share.

1.34. **"Series B-2 Preferred Stock**" means shares of the Company's Series B-2 Preferred Stock, par value $0.001 per share.

1.35. "**Series C Preferred Stock**" means shares of the Company's Series C Preferred Stock, par value $0.001 per share.

1.36. "**Requisite Holders**" means (a) the holders of a majority of the Registrable Securities then outstanding, and (b) at least three of the Clarus Funds, New Enterprise Associates 14, L.P., Novartis BioVentures Ltd., Novo Holdings A/S, and Sofinnova Venture Partners IX, L.P. so long as each of such holders owns at least 2,500,000 shares of Registrable Securities (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization) (such holders, the "**Major Holders**"); provided that if one or more of the Clarus Funds, New Enterprise Associates 14, L.P., Novartis Bioventures Ltd., Novo Holdings A/S, or Sofinnova Venture Partners IX, L.P. shall cease to be a Major Holder, then a majority of the remaining Major Holders shall be required pursuant to clause (b) of the definition of "Requisite Holders".

2. Registration Rights.The Company covenants and agrees as follows:

2.1. Demand Registration.

(a) Form S-1 Demand. If at any time after the earlier of (i) five (5) years after the date of this Agreement or (ii) one hundred eighty (180) days after the effective date of the registration statement for the IPO, the Company receives a request from Holders of at least thirty percent (30%) of the Registrable Securities then outstanding that the Company file a Form S-1 registration statement with respect to outstanding Registrable Securities of such Holders having an anticipated aggregate offering price, net of Selling Expenses, of at least $10.0 million, then the Company shall (i) within ten (10) days after the date such request is given, give notice thereof (the "**Demand Notice**") to all Holders other than the Initiating Holders; and (ii) as soon as practicable, and in any event within sixty (60) days after the date such request is given by the Initiating Holders, file a Form S-1 registration statement under the Securities Act covering all Registrable Securities that the Initiating Holders requested to be registered and any additional Registrable Securities requested to be included in such registration by any other Holders, as specified by notice given by each such Holder to the Company within twenty (20) days of the date the Demand Notice is given, and in each case, subject to the limitations of Subsection 2.1(c) and Subsection 2.3.

(b) Form S-3 Demand. If at any time when it is eligible to use a Form S-3 registration statement, the Company receives a request from Holders of at least twenty percent (20%) of the Registrable Securities then outstanding that the Company file a Form S-3 registration statement with respect to outstanding Registrable Securities of such Holders having an anticipated aggregate offering price, net of Selling Expenses, of at least $1.0 million, then the Company shall (i) within ten (10) days after the date such request is given, give a Demand Notice to all Holders other than the Initiating Holders; and (ii) as soon as practicable, and in any event within forty-five (45) days after the date such request is given by the Initiating Holders, file a Form S-3 registration statement under the Securities Act covering all Registrable Securities requested to be included in such registration by any other Holders, as specified by notice given by each such Holder to the Company within twenty (20) days of the date the Demand Notice is given, and in each case, subject to the limitations of Subsection 2.1(c) and Subsection 2.3.

(c) Notwithstanding the foregoing obligations, if the Company furnishes to Holders requesting a registration pursuant to this Subsection 2.1 a certificate signed by the Company's chief executive officer stating that in the good faith judgment of the Company's Board of Directors it would be materially detrimental to the Company and its stockholders for such registration statement to either become effective or remain effective for as long as such registration statement otherwise would be required to remain effective, because such action would (i) materially interfere with a significant acquisition, corporate reorganization, or other similar transaction involving the Company; (ii) require premature disclosure of material information that the Company has a bona fide business purpose for preserving as confidential; or (iii) render the Company unable to comply with requirements under the Securities Act or Exchange Act, then the Company shall have the right to defer taking action with respect to such filing, and any time periods with respect to filing or effectiveness thereof shall be tolled correspondingly, for a period of not more than sixty (60) days after the request of the Initiating Holders is given; provided, however, that the Company may not invoke this right more than twice in any twelve (12) month period; and provided further that the Company shall not register any securities for its own account or that of any other stockholder during such sixty (60) day period other than an Excluded Registration.

(d) The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to Subsection 2.1(a), (i) during the period that is sixty (60) days before the Company's good faith estimate of the date of filing of, and ending on a date that is one hundred eighty (180) days after the effective date of, a Company-initiated registration, provided, that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; (ii) after the Company has effected two registrations pursuant to Subsection 2.1(a); or (iii) if the Initiating Holders propose to dispose of shares of Registrable Securities that may be immediately registered on Form S-3 pursuant to a request made pursuant to Subsection 2.1(b). The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to Subsection 2.1(b), (i) during the period that is thirty (30) days before the Company's good faith estimate of the date of filing of, and ending on a date that is ninety (90) days after the effective date of, a Company-initiated registration, provided, that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; or (ii) if the Company has effected two registrations pursuant to Subsection 2.1(b) within the twelve (12) month period immediately preceding the date of such request. A registration shall not be counted as "effected" for purposes of this Subsection 2.1(d) until such time as the applicable registration statement has been declared effective by the SEC, unless the Initiating Holders constituting a majority of Registrable

Securities then held by such Initiating Holders withdraw their request for such registration, elect not to pay the registration expenses therefor, and forfeit their right to one demand registration statement pursuant to Subsection 2.6, in which case such withdrawn registration statement shall be counted as "effected" for purposes of this Subsection 2.1(d).

2.2. Company Registration. If the Company proposes to register (including, for this purpose, a registration effected by the Company for stockholders other than the Holders) any of its Common Stock under the Securities Act in connection with the public offering of such securities solely for cash (other than in an Excluded Registration), the Company shall, at such time, promptly give each Holder notice of such registration. Upon the request of each Holder given within twenty (20) days after such notice is given by the Company, the Company shall, subject to the provisions of Subsection 2.3, cause to be registered all of the Registrable Securities that each such Holder has requested to be included in such registration. The Company shall have the right to terminate or withdraw any registration initiated by it under this Subsection 2.2 before the effective date of such registration, whether or not any Holder has elected to include Registrable Securities in such registration. The expenses (other than Selling Expenses) of such withdrawn registration shall be borne by the Company in accordance with Subsection 2.6.

2.3. Underwriting Requirements.

(a) If, pursuant to Subsection 2.1, the Initiating Holders intend to distribute the Registrable Securities covered by their request by means of an underwriting, they shall so advise the Company as a part of their request made pursuant to Subsection 2.1, and the Company shall include such information in the Demand Notice. The underwriter(s) will be selected by the Company and shall be reasonably acceptable to a majority in interest of the Initiating Holders. In such event, the right of any Holder to include such Holder's Registrable Securities in such registration shall be conditioned upon such Holder's participation in such underwriting and the inclusion of such Holder's Registrable Securities in the underwriting to the extent provided herein. All Holders proposing to distribute their securities through such underwriting shall (together with the Company as provided in Subsection 2.4(e)) enter into an underwriting agreement in customary form with the underwriter(s) selected for such underwriting; provided, however, the liability of any such Holder shall be several and not joint, and limited to an amount equal to the net proceeds from the offering received by such Holder. Notwithstanding any other provision of this Subsection 2.3, if the managing underwriter(s) advise(s) the Initiating Holders in writing that marketing factors require a limitation on the number of shares to be underwritten, then the Initiating Holders shall so advise all Holders of Registrable Securities that otherwise would be underwritten pursuant hereto, and the number of Registrable Securities that may be included in the underwriting shall be allocated among such Holders of Registrable Securities, including the Initiating Holders, in proportion (as nearly as practicable) to the number of Registrable Securities owned by each Holder or in such other proportion as shall mutually be agreed to by all such selling Holders; provided, however, that the number of Registrable Securities held by the Holders to be included in such underwriting shall not be reduced unless all other securities are first entirely excluded from the underwriting. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to any Holder to the nearest 100 shares.

(b) In connection with any offering involving an underwriting of shares of the Company's capital stock pursuant to Subsection 2.2, the Company shall not be required to include any of the Holders' Registrable Securities in such underwriting unless the Holders accept the terms of the underwriting as agreed upon between the Company and its underwriters, and then only in such quantity as the underwriters in their sole discretion determine will not jeopardize the success of the offering by the Company. If the total number of securities, including Registrable Securities, requested by stockholders to be included in such offering exceeds the number of securities to be sold (other than by the Company) that the underwriters in their reasonable discretion determine is compatible with the success of the offering, then the Company shall be required to include in the offering only that number of such securities, including Registrable Securities, which the underwriters and the Company in their sole discretion determine will not jeopardize the success of the offering. If the underwriters determine that less than all of the Registrable Securities requested to be registered can be included in such offering, then the Registrable Securities that are included in such offering shall be allocated among the selling Holders in proportion (as nearly as practicable to) the number of Registrable Securities owned by each selling Holder or in such other proportions as shall mutually be agreed to by all such selling Holders. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to any Holder to the nearest 100 shares. Notwithstanding the foregoing, in no event shall (i) the number of Registrable Securities included in the offering be reduced unless all other securities (other than securities to be sold by the Company) are first entirely excluded from the offering, or (ii) the number of Registrable Securities included in the offering be reduced below thirty percent (30%) of the total number of securities included in such offering, unless such offering is the IPO, in which case the selling Holders may be excluded further if the underwriters make the determination described above and no other stockholder's securities are included in such offering. For purposes of the provision in this Subsection 2.3(b) concerning apportionment, for any selling Holder that is a partnership, limited liability company, or corporation, the partners, members, retired partners, retired members, stockholders, and Affiliates of such Holder, or the estates and Immediate Family Members of any such partners, retired partners, members, and retired members and any trusts for the benefit of any of the foregoing Persons, shall be deemed to be a single "selling Holder," and any pro rata reduction with respect to such "selling Holder" shall be based upon the aggregate number of Registrable Securities owned by all Persons included in such "selling Holder," as defined in this sentence.

2.4. Obligations of the Company. Whenever required under this Section 2 to effect the registration of any Registrable Securities, the Company shall, as expeditiously as reasonably possible:

(a) prepare and file with the SEC a registration statement with respect to such Registrable Securities and use its commercially reasonable efforts to cause such registration statement to become effective and, upon the request of the Holders of a majority of the Registrable Securities registered thereunder, keep such registration statement effective for a period of up to one hundred twenty (120) days or, if earlier, until the distribution contemplated in the registration statement has been completed; provided, however, that (i) such one hundred twenty (120) day period shall be extended for a period of time equal to the period the Holder refrains, at the request of an underwriter of Common Stock (or other securities) of the Company, from selling any securities included in such registration, and (ii) in the case of any registration of

Registrable Securities on Form S-3 that are intended to be offered on a continuous or delayed basis, subject to compliance with applicable SEC rules, such one hundred twenty (120) day period shall be extended for up to an additional sixty (60) days, if necessary, to keep the registration statement effective until all such Registrable Securities are sold;

(b) prepare and file with the SEC such amendments and supplements to such registration statement, and the prospectus used in connection with such registration statement, as may be necessary to comply with the Securities Act in order to enable the disposition of all securities covered by such registration statement;

(c) furnish to the selling Holders such numbers of copies of a prospectus, including a preliminary prospectus, as required by the Securities Act, and such other documents as the Holders may reasonably request in order to facilitate their disposition of their Registrable Securities;

(d) use its commercially reasonable efforts to register and qualify the securities covered by such registration statement under such other securities or blue-sky laws of such jurisdictions as shall be reasonably requested by the selling Holders; provided that the Company shall not be required to qualify to do business or to file a general consent to service of process in any such states or jurisdictions, unless the Company is already subject to service in such jurisdiction and except as may be required by the Securities Act;

(e) in the event of any underwritten public offering, enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the underwriter(s) of such offering;

(f) use its commercially reasonable efforts to cause all such Registrable Securities covered by such registration statement to be listed on a national securities exchange or trading system and each securities exchange and trading system (if any) on which similar securities issued by the Company are then listed;

(g) provide a transfer agent and registrar for all Registrable Securities registered pursuant to this Agreement and provide a CUSIP number for all such Registrable Securities, in each case not later than the effective date of such registration;

(h) promptly make available for inspection by the selling Holders, any underwriter(s) participating in any disposition pursuant to such registration statement, and any attorney or accountant or other agent retained by any such underwriter or selected by the selling Holders, all financial and other records, pertinent corporate documents, and properties of the Company, and cause the Company's officers, directors, employees, and independent accountants to supply all information reasonably requested by any such seller, underwriter, attorney, accountant, or agent, in each case, as necessary or advisable to verify the accuracy of the information in such registration statement and to conduct appropriate due diligence in connection therewith;

(i) notify each selling Holder, promptly after the Company receives notice thereof, of the time when such registration statement has been declared effective or a supplement to any prospectus forming a part of such registration statement has been filed; and

(j) after such registration statement becomes effective, notify each selling Holder of any request by the SEC that the Company amend or supplement such registration statement or prospectus.

In addition, the Company shall ensure that, at all times after any registration statement covering a public offering of securities of the Company under the Securities Act shall have become effective, its insider trading policy shall provide that the Company's directors may implement a trading program under Rule 10b5-1 of the Exchange Act.

2.5. Furnish Information. It shall be a condition precedent to the obligations of the Company to take any action pursuant to this Section 2 with respect to the Registrable Securities of any selling Holder that such Holder shall furnish to the Company such information regarding itself, the Registrable Securities held by it, and the intended method of disposition of such securities as is reasonably required to effect the registration of such Holder's Registrable Securities.

2.6. Expenses of Registration. All expenses (other than Selling Expenses) incurred in connection with registrations, filings, or qualifications pursuant to Section 2, including all registration, filing, and qualification fees; printers' and accounting fees; fees and disbursements of counsel for the Company; and the reasonable fees and disbursements of one counsel for the selling Holders ("**Selling Holder Counsel**"), shall be borne and paid by the Company; provided, however, that the Company shall not be required to pay for any expenses of any registration proceeding begun pursuant to Subsection 2.1 if the registration request is subsequently withdrawn at the request of the Holders of a majority of the Registrable Securities to be registered (in which case all selling Holders shall bear such expenses pro rata based upon the number of Registrable Securities that were to be included in the withdrawn registration), unless the holders of a majority of the Registrable Securities agree to forfeit their right to one registration pursuant to Subsection 2.1(a) or Subsection 2.1(b), as the case may be; provided further that if, at the time of such withdrawal, the Holders shall have learned of a material adverse change in the condition, business, or prospects of the Company from that known to the Holders at the time of their request and have withdrawn the request with reasonable promptness after learning of such information then the Holders shall not be required to pay any of such expenses and shall not forfeit their right to one registration pursuant to Subsection 2.1(a) or Subsection 2.1(b). All Selling Expenses relating to Registrable Securities registered pursuant to this Section 2 shall be borne and paid by the Holders pro rata on the basis of the number of Registrable Securities registered on their behalf.

2.7. Delay of Registration. No Holder shall have any right to obtain or seek an injunction restraining or otherwise delaying any registration pursuant to this Agreement as the result of any controversy that might arise with respect to the interpretation or implementation of this Section 2.

2.8. Indemnification. If any Registrable Securities are included in a registration statement under this Section 2:

(a) To the extent permitted by law, the Company will indemnify and hold harmless each selling Holder, and the partners, members, officers, directors, trustees and stockholders of each such Holder; legal counsel and accountants for each such Holder; any underwriter (as defined in the Securities Act) for each such Holder; and each Person, if any, who controls such Holder or underwriter within the meaning of the Securities Act or the Exchange Act, against any Damages, and the Company will pay to each such Holder, underwriter, controlling Person, or other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; provided, however, that the indemnity agreement contained in this Subsection 2.8(a) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Company, which consent shall not be unreasonably withheld, nor shall the Company be liable for any Damages to the extent that they arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of any such Holder, underwriter, controlling Person, or other aforementioned Person expressly for use in connection with such registration.

(b) To the extent permitted by law, each selling Holder, severally and not jointly, will indemnify and hold harmless the Company, and each of its directors, each of its officers who has signed the registration statement, each Person (if any), who controls the Company within the meaning of the Securities Act, legal counsel and accountants for the Company, any underwriter (as defined in the Securities Act), any other Holder selling securities in such registration statement, and any controlling Person of any such underwriter or other Holder, against any Damages, in each case only to the extent that such Damages arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of such selling Holder expressly for use in connection with such registration; and each such selling Holder will pay to the Company and each other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; provided, however, that the indemnity agreement contained in this Subsection 2.8(b) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Holder, which consent shall not be unreasonably withheld; and provided further that in no event shall the aggregate amounts payable by any Holder by way of indemnity or contribution under Subsections 2.8(b) and 2.8(d) exceed the proceeds from the offering received by such Holder (net of any Selling Expenses paid by such Holder), except in the case of fraud or willful misconduct by such Holder.

(c) Promptly after receipt by an indemnified party under this Subsection 2.8 of notice of the commencement of any action (including any governmental action) for which a party may be entitled to indemnification hereunder, such indemnified party will, if a claim in respect thereof is to be made against any indemnifying party under this Subsection 2.8, give the indemnifying party notice of the commencement thereof. The indemnifying party shall have the right to participate in such action and, to the extent the indemnifying party so desires, participate jointly with any other indemnifying party to which

notice has been given, and to assume the defense thereof with counsel mutually satisfactory to the parties; provided, however, that an indemnified party (together with all other indemnified parties that may be represented without conflict by one counsel) shall have the right to retain one separate counsel, with the fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such action. The failure to give notice to the indemnifying party within a reasonable time of the commencement of any such action shall relieve such indemnifying party of any liability to the indemnified party under this Subsection 2.8, to the extent that such failure materially prejudices the indemnifying party's ability to defend such action. The failure to give notice to the indemnifying party will not relieve it of any liability that it may have to any indemnified party otherwise than under this Subsection 2.8.

(d) To provide for just and equitable contribution to joint liability under the Securities Act in any case in which either (i) any party otherwise entitled to indemnification hereunder makes a claim for indemnification pursuant to this Subsection 2.8 but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case, notwithstanding the fact that this Subsection 2.8 provides for indemnification in such case, or (ii) contribution under the Securities Act may be required on the part of any party hereto for which indemnification is provided under this Subsection 2.8, then, and in each such case, such parties will contribute to the aggregate losses, claims, damages, liabilities, or expenses to which they may be subject (after contribution from others) in such proportion as is appropriate to reflect the relative fault of each of the indemnifying party and the indemnified party in connection with the statements, omissions, or other actions that resulted in such loss, claim, damage, liability, or expense, as well as to reflect any other relevant equitable considerations. The relative fault of the indemnifying party and of the indemnified party shall be determined by reference to, among other things, whether the untrue or allegedly untrue statement of a material fact, or the omission or alleged omission of a material fact, relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information, and opportunity to correct or prevent such statement or omission; provided, however, that, in any such case, (x) no Holder will be required to contribute any amount in excess of the public offering price of all such Registrable Securities offered and sold by such Holder pursuant to such registration statement, and (y) no Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation; and provided further that in no event shall a Holder's liability pursuant to this Subsection 2.8(d), when combined with the amounts paid or payable by such Holder pursuant to Subsection 2.8(b), exceed the proceeds from the offering received by such Holder (net of any Selling Expenses paid by such Holder), except in the case of willful misconduct or fraud by such Holder.

(e) Notwithstanding the foregoing, to the extent that the provisions on indemnification and contribution contained in the underwriting agreement entered into in connection with the underwritten public offering are in conflict with the foregoing provisions, the provisions in the underwriting agreement shall control.

(f) Unless otherwise superseded by an underwriting agreement entered into in connection with the underwritten public offering, the obligations of the Company and Holders under this Subsection 2.8 shall survive the completion of any offering of Registrable Securities in a registration under this Section 2, and otherwise shall survive the termination of this Agreement.

2.9. Reports Under Exchange Act. With a view to making available to the Holders the benefits of SEC Rule 144 and any other rule or regulation of the SEC that may at any time permit a Holder to sell securities of the Company to the public without registration or pursuant to a registration on Form S-3, the Company shall:

(a) make and keep available adequate current public information, as those terms are understood and defined in SEC Rule 144, at all times after the effective date of the registration statement filed by the Company for the IPO;

(b) use commercially reasonable efforts to file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act (at any time after the Company has become subject to such reporting requirements); and

(c) furnish to any Holder, so long as the Holder owns any Registrable Securities, forthwith upon request (i) to the extent accurate, a written statement by the Company that it has complied with the reporting requirements of SEC Rule 144 (at any time after ninety (90) days after the effective date of the registration statement filed by the Company for the IPO), the Securities Act, and the Exchange Act (at any time after the Company has become subject to such reporting requirements), or that it qualifies as a registrant whose securities may be resold pursuant to Form S-3 (at any time after the Company so qualifies); (ii) a copy of the most recent annual or quarterly report of the Company and such other reports and documents so filed by the Company; and (iii) such other information as may be reasonably requested in availing any Holder of any rule or regulation of the SEC that permits the selling of any such securities without registration (at any time after the Company has become subject to the reporting requirements under the Exchange Act) or pursuant to Form S-3 (at any time after the Company so qualifies to use such form).

2.10. Limitations on Subsequent Registration Rights. From and after the date of this Agreement, the Company shall not, without the prior written consent of the Requisite Holders, enter into any agreement with any holder or prospective holder of any securities of the Company that would (i) allow such holder or prospective holder to include such securities in any registration unless, under the terms of such agreement, such holder or prospective holder may include such securities in any such registration only to the extent that the inclusion of such securities will not reduce the number of the Registrable Securities of the Holders that are included or (ii) allow such holder or prospective holder to initiate a demand for registration of any securities held by such holder or prospective holder.

2.11. "Market Stand-off" Agreement. (a) Without the prior written consent of the managing underwriter, during the period commencing on the date of the final prospectus relating to the registration by the Company of shares of its Common Stock or any other equity securities under the Securities Act on a registration statement on Form S-1 or Form S-3 and ending on the date specified by the Company and the managing underwriter, each Holder hereby agrees that it will not, for a period not to exceed one hundred eighty (180) days in the case of the IPO; and each Affiliated Holder hereby agrees that it will not, for a period not to exceed ninety (90) days in the case of any registration other than the IPO; or, in each case such other period as may be requested by the Company or an underwriter to accommodate regulatory restrictions on (1) the publication or other distribution of research reports and (2) analyst recommendations and opinions, including, but not limited to, the restrictions contained in FINRA Rule 2711(f)(4) or NYSE Rule 472(f)(4), or any successor provisions or amendments thereto), (i) lend; offer; pledge; sell; contract to sell; sell any option or contract to purchase; purchase any option or contract to sell; grant any option, right, or warrant to purchase; or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Common Stock held immediately before the effective date of the registration statement for such offering or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of such securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of Common Stock or other securities, in cash, or otherwise. For purposes of this Subsection 2.11, an "**Affiliated Holder**" is a Holder that holds 10% or more of the Company's outstanding Common Stock or that has an Affiliate as a member of the Company's Board of Directors at the time such registration statement is filed. For the avoidance of doubt, the foregoing 90 day lockup period referenced in this Subsection 2.11 shall apply only to Affiliated Holders and not to any other Holders.

(b) The foregoing provisions of this Subsection 2.11 shall not apply to (i) the sale of any shares to an underwriter pursuant to an underwriting agreement, (ii) any shares purchased in the IPO or in the open market following the IPO or (iii) the transfer of any shares to an Affiliate of a Holder or to any trust for the direct or indirect benefit of the Holder or the immediate family of the Holder, provided that the Affiliate or the trustee of the trust, as applicable, agrees to be bound in writing by the restrictions set forth herein, and provided further that any such transfer shall not involve a disposition for value, and shall be applicable to the Holders only if all officers and directors are subject to the same restrictions and the Company uses commercially reasonable efforts to obtain a similar agreement from all stockholders individually owning more than one percent (1%) of the Company's outstanding Common Stock (after giving effect to conversion into Common Stock of all outstanding Preferred Stock). The underwriters in connection with such registration are intended third party beneficiaries of this Subsection 2.11 and shall have the right, power, and authority to enforce the provisions hereof as though they were a party hereto. Each Holder further agrees to execute such agreements as may be reasonably requested by the underwriters in connection with such registration that are consistent with this Subsection 2.11 or that are necessary to give further effect thereto. Any discretionary waiver or termination of the restrictions of any or all of such agreements by the Company or the underwriters shall apply pro rata to all Holders subject to such agreements, based on the number of shares subject to such agreements.

2.12. Restrictions on Transfer.

(a) The Preferred Stock and the Registrable Securities shall not be sold, pledged, or otherwise transferred, and the Company shall not recognize and shall issue stop-transfer instructions to its transfer agent with respect to any such sale, pledge, or transfer, except upon the conditions specified in this Agreement, which conditions are intended to ensure compliance with the provisions of the Securities Act. A transferring Holder will cause any proposed purchaser, pledgee, or transferee of the Preferred Stock and the Registrable Securities held by such Holder to agree to take and hold such securities subject to the provisions and upon the conditions specified in this Agreement.

(b) Each certificate or instrument representing (i) the Preferred Stock, (ii) the Registrable Securities, and (iii) any other securities issued in respect of the securities referenced in clauses (i) and (ii), upon any stock split, stock dividend, recapitalization, merger, consolidation, or similar event, shall (unless otherwise permitted by the provisions of Subsection2.12(c)) be stamped or otherwise imprinted with a legend substantially in the following form:

> THE SECURITIES REPRESENTED HEREBY HAVE BEEN ACQUIRED FOR INVESTMENT AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933. SUCH SHARES MAY NOT BE SOLD, PLEDGED, OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR A VALID EXEMPTION FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS OF SAID ACT.
>
> THE SHARES REPRESENTED HEREBY MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH THE TERMS OF AN AGREEMENT BETWEEN THE COMPANY AND THE STOCKHOLDER, A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF THE COMPANY.

The Holders consent to the Company making a notation in its records and giving instructions to any transfer agent of the Restricted Securities in order to implement the restrictions on transfer set forth in this Subsection 2.12.

(c) The holder of each certificate representing Restricted Securities, by acceptance thereof, agrees to comply in all respects with the provisions of this Section 2. Before any proposed sale, pledge, or transfer of any Restricted Securities, unless there is in effect a registration statement under the Securities Act covering the proposed transaction, the Holder thereof shall give notice to the Company of such Holder's intention to effect such sale, pledge, or transfer. Each such notice shall describe the manner and circumstances of the proposed sale, pledge, or transfer in sufficient detail and, if reasonably requested by the Company, shall be accompanied at such Holder's expense by either (i) a written opinion of legal counsel who shall, and whose legal opinion shall, be reasonably satisfactory to the Company, addressed to the Company, to the effect that the proposed transaction may be effected without registration under the Securities Act; (ii) a "no action" letter from the SEC to the effect that the proposed sale, pledge, or transfer of such Restricted Securities without registration will not result in a recommendation by the staff of the SEC that action be taken with respect thereto; or (iii) any other evidence reasonably satisfactory to counsel to the Company to the effect that the proposed sale, pledge, or transfer of the Restricted Securities may be effected without registration under the Securities Act, whereupon the Holder of such Restricted Securities shall be entitled to sell,

pledge, or transfer such Restricted Securities in accordance with the terms of the notice given by the Holder to the Company. The Company will not require such a legal opinion or "no action" letter (x) in any transaction in compliance with SEC Rule 144 or (y) in any transaction in which such Holder distributes Restricted Securities to an Affiliate of such Holder for no consideration; provided that each transferee agrees in writing to be subject to the terms of this Subsection 2.12. Each certificate or instrument evidencing the Restricted Securities transferred as above provided shall bear, except if such transfer is made pursuant to SEC Rule 144, the appropriate restrictive legend set forth in Subsection 2.12(b), except that such certificate shall not bear such restrictive legend if, in the opinion of counsel for such Holder and the Company, such legend is not required in order to establish compliance with any provisions of the Securities Act.

2.13. Termination of Registration Rights. The right of any Holder to request registration or inclusion of Registrable Securities in any registration pursuant to Subsection 2.1 or Subsection 2.2 shall terminate upon the earliest to occur of:

(a) the closing of a Deemed Liquidation Event, as such term is defined in the Company's Certificate of Incorporation;

(b) such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such Holder's shares without limitation during a three-month period without registration; and

(c) the fifth (5th) anniversary of the IPO.

3. Information Rights.

3.1. Delivery of Financial Statements and Other Information. The Company shall deliver to each Major Investor (provided that such Major Investor is not a Competitor):

(a) as soon as practicable, but in any event within one hundred eighty (180) days after the end of each fiscal year of the Company beginning with the fiscal year ending December 31, 2018, (1) financial statements of the Company for such fiscal year containing (i) a balance sheet as of the end of such year, (ii) statements of income and of cash flows for such year, and a comparison between the actual amounts as of and for such fiscal year and the comparable amounts for the prior year and (iii) a statement of stockholders' equity as of the end of such year, all such financial statements audited and certified by independent public accountants of recognized standing selected by the Company's Board of Directors, and (2) a comparison of the actual results to those included in the Budget (as defined in Subsection 3.1(e)) for such year;

(b) as soon as practicable, but in any event within forty-five (45) days after the end of each of the first three (3) quarters of each fiscal year of the Company, unaudited statements of income and of cash flows for such fiscal quarter, and an unaudited balance sheet, all prepared in accordance with GAAP (except that such financial statements may (i) be subject to normal year-end audit adjustments and (ii) not contain all notes thereto that may be required in accordance with GAAP);

(c) as soon as practicable, but in any event within forty-five (45) days after the end of each quarter of each fiscal year of the Company, a statement showing the number of shares of each class and series of capital stock and securities convertible into or exercisable for shares of capital stock outstanding at the end of the period, the Common Stock issuable upon conversion or exercise of any outstanding securities convertible or exercisable for Common Stock and the exchange ratio or exercise price applicable thereto, and the number of shares of issued stock options and stock options not yet issued but reserved for issuance, if any, all in sufficient detail as to permit the Major Investors to calculate their respective percentage equity ownership in the Company, and certified by the chief financial officer or chief executive officer of the Company as being true, complete, and correct;

(d) as soon as practicable, but in any event within thirty (30) days of the end of each month, an unaudited income statement and statement of cash flows for such month, and an unaudited balance sheet and statement of stockholders' equity as of the end of such month, all prepared in accordance with GAAP (except that such financial statements may (i) be subject to normal year-end audit adjustments and (ii) not contain all notes thereto that may be required in accordance with GAAP);

(e) as soon as practicable, but in any event thirty (30) days before the end of each fiscal year, a budget and business plan for the next fiscal year (collectively, the "**Budget**"), approved by the Board of Directors, including a majority of the Preferred Directors, and prepared on a monthly basis, including balance sheets, income statements, and statements of cash flow for such months and, promptly after prepared, any other budgets or revised budgets prepared by the Company; and

(f) such other information relating to the financial condition, business, prospects, or corporate affairs of the Company as any Major Investor may from time to time reasonably request; provided, however, that the Company shall not be obligated under this Subsection 3.1 to provide information (i) that the Company reasonably determines in good faith to be a trade secret or confidential information (unless such confidential information is covered by an enforceable confidentiality agreement, in form acceptable to the Company) or (ii) the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel.

If, for any period, the Company has any subsidiary whose accounts are consolidated with those of the Company, then in respect of such period the financial statements delivered pursuant to the foregoing sections shall be the consolidated and consolidating financial statements of the Company and all such consolidated subsidiaries.

Notwithstanding anything else in this Subsection 3.1 to the contrary, the Company may cease providing the information set forth in this Subsection 3.1 during the period starting with the date thirty (30) days before the Company's good-faith estimate of the date of filing of a registration statement if it reasonably concludes it must do so to comply with the SEC rules applicable to such registration statement and related offering; provided that the Company's covenants under this Subsection 3.1 shall be reinstated at such time as the Company is no longer actively employing its commercially reasonable efforts to cause such registration statement to become effective.

3.2. Inspection. The Company shall permit each Major Investor (provided that such Major Investor is not a Competitor), at such Major Investor's expense, to visit and inspect the Company's properties; examine its books of account and records; and discuss the Company's affairs, finances, and accounts with its officers, during normal business hours of the Company as may be reasonably requested by the Major Investor; provided, however, that the Company shall not be obligated pursuant to this Subsection 3.2 to provide access to any information that it reasonably and in good faith considers to be a trade secret or confidential information (unless such confidential information is covered by an enforceable confidentiality agreement, in form acceptable to the Company) or the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel.

3.3. Termination of Information Rights. The covenants set forth in Subsection 3.1 and Subsection 3.2 shall terminate and be of no further force or effect (i) immediately before the consummation of the IPO, (ii) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act, or (iii) upon a Deemed Liquidation Event, as such term is defined in the Company's Certificate of Incorporation, whichever event occurs first.

3.4. Confidentiality. Each Investor agrees that such Investor will keep confidential and will not disclose, divulge, or use for any purpose (other than to monitor its investment in the Company) any confidential information obtained from the Company pursuant to the terms of this Agreement (including notice of the Company's intention to file a registration statement), unless such confidential information (a) is known or becomes known to the public in general (other than as a result of a breach of this Subsection 3.4 by such Investor), (b) is or has been independently developed or conceived by the Investor without use of the Company's confidential information, or (c) is or has been made known or disclosed to the Investor by a third party without a breach of any obligation of confidentiality such third party may have to the Company; provided, however, that an Investor may disclose confidential information (i) to its attorneys, accountants, consultants, and other professionals to the extent necessary to obtain their services in connection with monitoring its investment in the Company and to the extent necessary in connection with such Investor's tax filings, financial reporting (including with the SEC) and accounting matters; (ii) to any prospective purchaser of any Registrable Securities from such Investor, if such prospective purchaser agrees in writing with the Company to be bound by the provisions of this Subsection 3.4; (iii) to any Affiliate, partner, member, stockholder, or wholly owned subsidiary of such Investor in the ordinary course of business, provided that such Investor informs such Person that such information is confidential and directs such Person to maintain the confidentiality of such information; or (iv) as may otherwise be required by law, provided that the Investor promptly notifies the Company of such disclosure and takes reasonable steps to minimize the extent of any such required disclosure.

4. Rights to Future Stock Issuances.

4.1. Right of First Offer. Subject to the terms and conditions of this Subsection 4.1 and applicable securities laws, if the Company proposes to offer or sell any New Securities, the Company shall first offer such New Securities to each Investor. An Investor shall be entitled to apportion the right of first offer hereby granted to it in such proportions as it deems appropriate, among (i) itself and (ii) its Affiliates; provided that, each such Affiliate: (x) is not a

Competitor or a FOIA Party, unless such party's purchase of New Securities is otherwise consented to by the Board of Directors, (y) agrees to enter into this Agreement and each of the Voting Agreement and Right of First Refusal and Co-Sale Agreement of even date herewith among the Company, the Investors and the other parties named therein, as an "Investor" under each such agreement (provided that, any Competitor or FOIA Party shall not be entitled to any rights as a Major Investor under Subsections 3.1 and 3.2 hereof), and (z) agrees to purchase, together with the applicable Investor and any of its other Affiliates to whom this right is apportioned, an aggregate of at least such number of New Securities as are allocable hereunder to the Investor holding the fewest number of Preferred Stock and any other Derivative Securities.

(a) The Company shall give notice (the "**Offer Notice**") to each Investor, stating (i) its bona fide intention to offer such New Securities, (ii) the number of such New Securities to be offered, and (iii) the price and terms, if any, upon which it proposes to offer such New Securities.

(b) By notification to the Company within twenty (20) days after the Offer Notice is given, each Investor may elect to purchase or otherwise acquire, at the price and on the terms specified in the Offer Notice, up to that portion of such New Securities which equals the proportion that the Preferred Stock issued and held by such Investor bears to the total Preferred Stock issued and outstanding. At the expiration of such twenty (20) day period, the Company shall promptly notify each Investor that elects to purchase or acquire all the shares available to it (each, a "**Fully Exercising Investor**") of any other Investor's failure to do likewise. During the ten (10) day period commencing after the Company has given such notice, each Fully Exercising Investor may, by giving notice to the Company, elect to purchase or acquire, in addition to the number of shares specified above, up to that portion of the New Securities for which Investors were entitled to subscribe but that were not subscribed for by the Investors which is equal to the proportion that the Preferred Stock issued and held by such Fully Exercising Investor bears to the Preferred Stock issued and held by all Fully Exercising Investors who wish to purchase such unsubscribed shares.The closing of any sale pursuant to this Subsection 4.1(b) shall occur within the later of one hundred and twenty (120) days of the date that the Offer Notice is given and the date of initial sale of New Securities pursuant to Subsection 4.1(c).

(c) If all New Securities referred to in the Offer Notice are not elected to be purchased or acquired as provided in Subsection 4.1(b), the Company may, during the ninety (90) day period following the expiration of the periods provided in Subsection 4.1(b), offer and sell the remaining unsubscribed portion of such New Securities to any Person or Persons at a price not less than, and upon terms no more favorable to the offeree than, those specified in the Offer Notice. If the Company does not enter into an agreement for the sale of the New Securities within such period, or if such agreement is not consummated within thirty (30) days of the execution thereof, the right provided hereunder shall be deemed to be revived and such New Securities shall not be offered unless first reoffered to the Investors in accordance with this Subsection 4.1.

(d) The right of first offer in this Subsection 4.1 shall not be applicable to (i) Exempted Securities (as defined in the Company's Certificate of Incorporation); and (ii) shares of Common Stock issued in the IPO.

4.2. Termination. The covenants set forth in Subsection 4.1 shall terminate and be of no further force or effect (i) immediately before the consummation of the IPO, (ii) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act, or (iii) upon a Deemed Liquidation Event, as such term is defined in the Company's Certificate of Incorporation, whichever event occurs first.

5. Additional Covenants

5.1. Insurance. The Company shall use its commercially reasonable efforts to maintain Directors and Officers liability insurance in an amount and on terms and conditions satisfactory to the Board of Directors, including a majority of the Preferred Directors, until such time as the Board of Directors, including a majority of the Preferred Directors, determines that such insurance should be discontinued. Such policy shall not be cancelable by the Company without prior approval by the Board of Directors, including a majority of the Preferred Directors.

5.2. Employee Agreements. The Company will cause (i) each person now or hereafter employed by it or by any subsidiary (or engaged by the Company or any subsidiary as a consultant/independent contractor) with access to confidential information and/or trade secrets to enter into a nondisclosure and proprietary rights assignment agreement and (ii) each Key Employee to enter into a one (1) year noncompetition and nonsolicitation agreement, substantially in the form approved by the Board of Directors; *provided*, that the nondisclosure and proprietary rights assignment agreements and noncompetition and nonsolicitation agreements entered into prior to or concurrently with the date hereof are deemed to be in the form approved by the Board of Directors. In addition, the Company shall not amend, modify, terminate, waive, or otherwise alter, in whole or in part, any of the above-referenced agreements in a manner that materially affects the applicable service provider's nondisclosure, proprietary rights assignment, noncompetition or nonsolicitation obligations or any restricted stock or stock repurchase agreement between the Company and any employee, without the consent of a majority of the Preferred Directors.

5.3. Employee Stock. Unless otherwise approved by the Board of Directors, including a majority of the Preferred Directors, all future employees of the Company who purchase, receive options to purchase, or receive awards of shares of the Company's capital stock after the date hereof shall be required to execute restricted stock or option agreements, as applicable, providing for vesting of shares over a four (4) year period, with the first twenty five percent (25%) of such shares vesting following twelve (12) months of continued employment or service, and the remaining shares vesting in equal monthly installments over the following thirty-six (36) months; *provided*, that such vesting would be accelerated in the event of a termination of employment without cause or resignation for good reason within twelve months following a change of control.

5.4. Matters Requiring Investor Director Approval. So long as the holders of Preferred Stock are entitled to elect a Preferred Director, the Company hereby covenants and agrees with each of the Investors that it shall not, without approval of the Board of Directors, which approval must include the affirmative vote of a majority of the Preferred Directors:

(a) make, or permit any subsidiary to make, any loan or advance to, or own any stock or other securities of, any subsidiary or other corporation, partnership, or other entity unless it is wholly owned by the Company;

(b) make, or permit any subsidiary to make, any loan or advance to any Person, including, without limitation, any employee or director of the Company or any subsidiary, except advances and similar expenditures in the ordinary course of business or under the terms of an employee stock or option plan approved by the Board of Directors;

(c) guarantee, directly or indirectly, or permit any subsidiary to guarantee, directly or indirectly, any indebtedness except for trade accounts of the Company or any subsidiary arising in the ordinary course of business, in an aggregate amount not to exceed $50,000;

(d) make, or permit any subsidiary to make, any investment inconsistent with any investment policy approved by the Board of Directors;

(e) incur, or permit any subsidiary to incur, any indebtedness in excess of $100,000 in the aggregate among the Company and all of its subsidiaries that is not already included in a budget approved by the Board of Directors, other than trade credit incurred in the ordinary course of business;

(f) otherwise enter into or be a party to, or permit any subsidiary to enter into or be a party to, any transaction with any director, officer, or employee of the Company or any subsidiary or any “associate” (as defined in Rule 12b-2 promulgated under the Exchange Act) of any such Person;

(g) hire, terminate, or change the compensation of the executive officers of the Company or any subsidiary, including approving any option grants or stock awards to such executive officers;

(h) change the principal business of the Company, enter new lines of business, or exit the current line of business, or permit any subsidiary to do any of the foregoing;

(i) acquire, sell, assign, license, pledge, or encumber material technology or intellectual property, or permit any subsidiary to do any of the foregoing, other than licenses granted in the ordinary course of business;

(j) enter into, or permit any subsidiary to enter into, any corporate strategic relationship involving the payment, contribution, or assignment by the Company or any subsidiary or to the Company or any subsidiary of money or assets greater than $100,000;

(k) create or authorize the creation of any stock option or other equity incentive plan or arrangement, increase the number of shares available for issuance under any such plan or arrangement or otherwise amend, waive or terminate any of the terms and provisions of such plan or arrangement, or permit any subsidiary to do any of the foregoing with respect to any equity interests in such subsidiary; or

(l) enter into any material acquisition, transfer, license or other disposition of intellectual property rights or other assets outside the ordinary course of business or cause any subsidiary of the Company to do any of the foregoing.

5.5. Board Matters. Unless otherwise determined by the vote of a majority of the directors then in office, the Board of Directors shall meet at least quarterly in accordance with an agreed-upon schedule. All meetings may take place by teleconference or videoconference. The Company shall reimburse the nonemployee directors for all reasonable out-of-pocket travel expenses incurred in connection with attending meetings of the Board of Directors (including any committee thereof). The Company shall cause to be established, as soon as practicable after such request, and will maintain, audit and compensation committees, each of which shall consist solely of non-management directors and include at least three Preferred Directors. Each Preferred Director shall be entitled in such director's discretion to be a member of (or an observer of) any committee of the Board of Directors.

5.6. Successor Indemnification. If the Company or any of its successors or assignees consolidates with or merges into any other Person and is not the continuing or surviving corporation or entity of such consolidation or merger, then to the extent necessary, proper provision shall be made so that the successors and assignees of the Company assume the obligations of the Company with respect to indemnification of members of the Board of Directors as in effect immediately before such transaction, whether such obligations are contained in the Company's Bylaws, its Certificate of Incorporation, or elsewhere, as the case may be.

5.7. Termination of Covenants. The covenants set forth in this Section 5, except for Subsection 5.6, shall terminate and be of no further force or effect (i) immediately before the consummation of the IPO, (ii) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act, or (iii) upon a Deemed Liquidation Event, as such term is defined in the Company's Certificate of Incorporation, whichever event occurs first.

5.8. Right to Conduct Activities. The Company hereby agrees and acknowledges that Novo Holdings A/S, Novartis BioVentures Ltd., New Enterprise Associates 14, L.P., NEA Ventures 2012 Limited Partnership, Correlation Ventures, L.P., Sofinnova Venture Partners IX, L.P., the Clarus Funds, the Tekla Funds (as defined in Section 6.16), Rock Springs Capital Master Fund LP, RA Capital Healthcare Fund, L.P., Blackwell Partners LLC —Series A, Pivotal Alpha Limited, Adage Capital Partners, LP and HBM Healthcare Investments (Cayman) Ltd. (together with their affiliates, the "**Venture Fund Purchasers**") are professional investment funds, and as such invest in numerous portfolio companies, some of which may be deemed competitive with the Company's business (as currently conducted or as currently propose to be conducted). The Company hereby agrees that, to the extent permitted under applicable law, the Venture Fund Purchasers shall not be liable to the Company for any claim arising out of, or based upon, (i) the investment by the Venture Fund Purchasers in any entity competitive with the Company, or (ii) actions taken by any partner, officer or other representative of, or advisor to, the Venture Fund Purchasers to assist any such competitive company, whether or not such action was taken as a member of the board of directors of such competitive company or otherwise, and whether or not such action has a

detrimental effect on the Company; provided, however, that the foregoing shall not relieve (x) any of the Investors from liability associated with the unauthorized disclosure of the Company's confidential information obtained pursuant to this Agreement or through participation on the Board of Directors, or (y) any director or officer of the Company from any liability associated with his or her fiduciary duties to the Company.

5.9. Board Observation Rights.

(a) For so long as Enso Ventures 2 Limited ("**Enso**") holds at least 1,000,000 shares of Series B-1 Preferred Stock (as adjusted to stock splits, stock dividends or any subdivision of shares), it shall have the right to designate one individual to attend each regularly scheduled, special and other meeting (including telephonic meetings) of the Board of Directors (including each committee of the Board of Directors) of the Company as a non-voting observer (the "**Observer**"). Without the consent of a majority of the Board of Directors, the Observer shall not be permitted to participate in any meeting beyond his or her capacity as a silent observer. The Observer shall not be entitled to the board observation rights described in this Section 5.9(a) unless and until the Observer signs a confidentiality agreement in a form reasonably acceptable to the Company and Enso, pursuant to which the Observer agrees to hold in confidence and trust all information provided or obtained at or in connection with any such meeting that he or she has a right to observe. The Company may withhold any information and exclude any such Observer from any meeting or portion thereof if access to such information or attendance at such meeting could, in the determination of Company's counsel, adversely affect the attorney-client privilege between the Company and its counsel, or could result in disclosure of trade secrets or relates to a point of a conflict of interest, or if such individual is employed by or affiliated with any competitor of the Company.

(b) For so long as Tekla Funds holds at least 1,000,000 shares of Series C Preferred Stock (as adjusted to stock splits, stock dividends or any subdivision of shares), it shall have the right to designate one individual to attend each regularly scheduled, special and other meeting (including telephonic meetings) of the Board of Directors (including each committee of the Board of Directors) of the Company as a non-voting observer (the "**Tekla Observer**"). Without the consent of a majority of the Board of Directors, the Tekla Observer shall not be permitted to participate in any meeting beyond his or her capacity as a silent observer. The Tekla Observer shall not be entitled to the board observation rights described in this Section 5.9(b) unless and until the Observer signs a confidentiality agreement in a form reasonably acceptable to the Company and Tekla Funds, pursuant to which the Tekla Observer agrees to hold in confidence and trust all information provided or obtained at or in connection with any such meeting that he or she has a right to observe. The Company may withhold any information and exclude any such Tekla Observer from any meeting or portion thereof if access to such information or attendance at such meeting could, in the determination of Company's counsel, adversely affect the attorney-client privilege between the Company and its counsel, or could result in disclosure of trade secrets or relates to a point of a conflict of interest, or if such individual is employed by or affiliated with any competitor of the Company.

5.10. Anti-Corruption. The Company covenants to comply with the FCPA or any other anti-bribery or anti-corruption law applicable to the Company or its subsidiaries (such as Part 12 of the United States Anti-Terrorism, Crime and Security Act of 2001; the United States Money Laundering Control Act of 1986; the United States International Money Laundering Abatement and Anti-Terrorist Financing Act of 2001; and the United States Foreign Corrupt Practices Act, as amended.

6. Miscellaneous

6.1. Successors and Assigns. The rights under this Agreement may be assigned (but only with all related obligations) by a Holder to a transferee of Registrable Securities that (i) is an Affiliate of a Holder; (ii) is a Holder's Immediate Family Member or any custodian or trustee of any trust, partnership or limited liability company for the benefit of, or the ownership interests of which are owned wholly by, such Holder or any such Immediate Family Members; or (iii) after such transfer, holds at least 500,000 shares of Registrable Securities (subject to appropriate adjustment for stock splits, stock dividends, combinations, and other recapitalizations); provided, however, that (x) the Company is, within a reasonable time after such transfer, furnished with written notice of the name and address of such transferee and the Registrable Securities with respect to which such rights are being transferred; and (y) such transferee agrees in a written instrument delivered to the Company to be bound by and subject to the terms and conditions of this Agreement, including the provisions of Subsection 2.11. For the purposes of determining the number of shares of Registrable Securities held by a transferee, the holdings of a transferee (1) that is an Affiliate or stockholder of a Holder; (2) who is a Holder's Immediate Family Member; or (3) that is a trust for the benefit of an individual Holder or such Holder's Immediate Family Member shall be aggregated together and with those of the transferring Holder; provided further that all transferees who would not qualify individually for assignment of rights shall have a single attorney-in-fact for the purpose of exercising any rights, receiving notices, or taking any action under this Agreement. The terms and conditions of this Agreement inure to the benefit of and are binding upon the respective successors and permitted assignees of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assignees any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided herein.

6.2. Governing Law. This Agreement shall be governed by the internal law of the State of Delaware.

6.3. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

6.4. Titles and Subtitles. The titles and subtitles used in this Agreement are for convenience only and are not to be considered in construing or interpreting this Agreement.

6.5. Notices. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given upon the earlier of actual receipt or: (i) personal delivery to the party to be notified; (ii) when sent, if sent by electronic mail or facsimile during the recipient's normal business hours, and if not sent during

normal business hours, then on the recipient's next business day; (iii) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (iv) one (1) business day after the business day of deposit with a nationally recognized overnight courier, freight prepaid, specifying next-day delivery, with written verification of receipt. All communications shall be sent to the respective parties at their addresses as set forth on Schedule A hereto, or to the principal office of the Company and to the attention of the Chief Executive Officer, in the case of the Company, or to such email address, facsimile number, or address as subsequently modified by written notice given in accordance with this Subsection 6.5. If notice is given to the Company, a copy shall also be sent to C. Brendan Johnson, Esq., Bryan Cave Leighton Paisner LLP, 211 North Broadway, Suite 3600, St. Louis, MO 63102.

6.6. Amendments and Waivers. Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance, and either retroactively or prospectively) only with the written consent of the Company and the Requisite Holders; provided that if an amendment or a waiver adversely affects one series of Preferred Stock, then such waiver or amendment will be effective only with the written consent of the Company and the holders of a majority of the class of Preferred Stock so affected; provided that the Company may in its sole discretion waive compliance with Subsection 2.12(c) (and the Company's failure to object promptly in writing after notification of a proposed assignment allegedly in violation of Subsection 2.12(c) shall be deemed to be a waiver); provided further that any provision hereof may be waived by any waiving party on such party's own behalf, without the consent of any other party. Notwithstanding the foregoing, (a) Sections 5.9(a) and (b) of this Agreement may not be amended or terminated and the observance of thereof may not be waived with respect to the Observer without the written consent of Enso and with respect to the Tekla Observer without the written consent of the Tekla Funds (defined below), and (b) this Agreement may not be amended or terminated and the observance of any term hereof may not be waived with respect to any Investor without the written consent of such Investor, unless such amendment, termination, or waiver applies to all Investors in the same fashion (it being agreed that a waiver of the provisions of Section 4 with respect to a particular transaction shall be deemed to apply to all Investors in the same fashion if such waiver does so by its terms, notwithstanding the fact that certain Investors may nonetheless, by agreement with the Company, purchase securities in such transaction). The Company shall give prompt notice of any amendment or termination hereof or waiver hereunder to any party hereto that did not consent in writing to such amendment, termination, or waiver. Any amendment, termination, or waiver effected in accordance with this Subsection 6.6 shall be binding on all parties hereto, regardless of whether any such party has consented thereto. No waivers of or exceptions to any term, condition, or provision of this Agreement, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, condition, or provision.

6.7. Severability. In case any one or more of the provisions contained in this Agreement is for any reason held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision of this Agreement, and such invalid, illegal, or unenforceable provision shall be reformed and construed so that it will be valid, legal, and enforceable to the maximum extent permitted by law.

6.8. Aggregation of Stock. All shares of Registrable Securities held or acquired by Affiliates shall be aggregated together for the purpose of determining the availability of any rights under this Agreement and such Affiliated persons may apportion such rights as among themselves in any manner they deem appropriate.

6.9. Entire Agreement. This Agreement (including any Schedules and Exhibits hereto), the Certificate and the other Transaction Agreements (as defined in the Purchase Agreement) constitute the full and entire understanding and agreement between the parties with respect to the subject matter hereof, and any other written or oral agreement relating to the subject matter hereof existing between the parties is expressly canceled.

6.10. Dispute Resolution. The parties (a) hereby irrevocably and unconditionally submit to the jurisdiction of the state courts of New Castle County, Delaware and to the jurisdiction of the United States District Court for the District of Delaware for the purpose of any suit, action or other proceeding arising out of or based upon this Agreement, (b) agree not to commence any suit, action or other proceeding arising out of or based upon this Agreement except in the state courts of New Castle County, Delaware or the United States District Court for the District of Delaware, and (c) hereby waive, and agree not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court. If any action at law or in equity is necessary to enforce or interpret the terms of this Agreement, the prevailing party shall be entitled to reasonable attorney's fees, costs, and disbursements in addition to any other relief to which such party may be entitled.

6.11. WAIVER OF JURY TRIAL. EACH PARTY HEREBY WAIVES ITS RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, THE OTHER TRANSACTION AGREEMENTS, THE SECURITIES OR THE SUBJECT MATTER HEREOF OR THEREOF. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL-ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS TRANSACTION, INCLUDING, WITHOUT LIMITATION, CONTRACT CLAIMS, TORT CLAIMS (INCLUDING NEGLIGENCE), BREACH OF DUTY CLAIMS, AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS. THIS SECTION HAS BEEN FULLY DISCUSSED BY EACH OF THE PARTIES HERETO AND THESE PROVISIONS WILL NOT BE SUBJECT TO ANY EXCEPTIONS. EACH PARTY HERETO HEREBY FURTHER WARRANTS AND REPRESENTS THAT SUCH PARTY HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL, AND THAT SUCH PARTY KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL.

6.12. Dispute Resolution Fees. If any action at law or in equity is necessary to enforce or interpret the terms of this Agreement, the prevailing party shall be entitled to reasonable attorney's fees, costs, and disbursements in addition to any other relief to which such party may be entitled.

6.13. Delays or Omissions. No delay or omission to exercise any right, power, or remedy accruing to any party under this Agreement, upon any breach or default of any other party under this Agreement, shall impair any such right, power, or remedy of such nonbreaching or nondefaulting party, nor shall it be construed to be a waiver of or acquiescence to any such breach or default, or to any similar breach or default thereafter occurring, nor shall any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. All remedies, whether under this Agreement or by law or otherwise afforded to any party, shall be cumulative and not alternative.

6.14. Acknowledgment. The Company acknowledges that the Investors are in the business of venture capital investing and therefore review the business plans and related proprietary information of many enterprises, including enterprises which may have products or services which compete directly or indirectly with those of the Company. Nothing in this Agreement shall preclude or in any way restrict the Investors from investing or participating in any particular enterprise whether or not such enterprise has products or services which compete with those of the Company.

6.15. Prior Agreement. The Prior Agreement is hereby amended and restated in its entirety in the manner set forth in this Agreement and such Prior Agreement is hereby terminated.

6.16. Tekla Funds. A copy of the Declaration of Trust, as amended and restated, for each of Tekla Healthcare Investors, Tekla Life Sciences Investors, Tekla Healthcare Opportunities Fund and Tekla World Healthcare Fund (collectively, the "**Tekla Funds**") is on file with the Secretary of State of The Commonwealth of Massachusetts, and notice is hereby given that this Agreement is executed on behalf of the Tekla Funds by an officer or trustee of the Tekla Funds in his or her capacity as an officer or trustee of the Tekla Funds, and not individually and that the obligations of or arising out of this Agreement are not binding upon any of the trustees, officers or shareholders individually but are binding only upon the assets and property of each of the respective Tekla Funds.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

COMPANY:

Galera Therapeutics, Inc.

By: /s/ Mel Sorensen
Name: Mel Sorensen
Title: President and Chief Executive Officer

Address:
2 West Liberty Boulevard, Suite 110
Malvern, PA 19355

INVESTOR:

Clarus IV-A, L.P.
By: Clarus IV GP, L.P.,
its General Partner
By: Clarus IV GP, LLC,
its General Partner

/s/ Emmett T. Cunningham
Name: Emmett T. Cunningham, MD
Title: Managing Director

Clarus IV-B, L.P.
By: Clarus IV GP, L.P.,
its General Partner
By: Clarus IV GP, LLC,
its General Partner

/s/ Emmett T. Cunningham
Name: Emmett T. Cunningham, MD
Title: Managing Director

Clarus IV-C, L.P.
By: Clarus IV GP, L.P.,
its General Partner
By: Clarus IV GP, LLC,
its General Partner

/s/ Emmett T. Cunningham
Name: Emmett T. Cunningham, MD
Title: Managing Director

Clarus IV-D, L.P.
By: Clarus IV GP, L.P.,
its General Partner
By: Clarus IV GP, LLC,
its General Partner

/s/ Emmett T. Cunningham
Name: Emmett T. Cunningham, MD
Title: Managing Director

TEKLA HEALTHCARE INVESTORS*

By: /s/ Daniel R. Omstead
Name: Daniel R. Omstead, Ph.D.
Title: President

* The name Tekla Healthcare Investors is the designation of the Trustees for the time being under an Amended & Restated Declaration of Trust dated April 21, 1987, as amended, and all persons dealing with Tekla Healthcare Investors must look solely to the trust property for the enforcement of any claim against Tekla Healthcare Investors, as neither the Trustees, officers nor shareholders assume any personal liability for the obligations entered into on behalf of Tekla Healthcare Investors.

TEKLA LIFE SCIENCES INVESTORS*

By: /s/ Daniel R. Omstead
Name: Daniel R. Omstead, Ph.D.
Title: President

* The name Tekla Life Sciences Investors is the designation of the Trustees for the time being under a Declaration of Trust dated February 20, 1992, as amended, and all persons dealing with Tekla Life Sciences Investors must look solely to the trust property for the enforcement of any claim against Tekla Life Sciences Investors, as neither the Trustees, officers nor shareholders assume any personal liability for the obligations entered into on behalf of Tekla Life Sciences Investors.

TEKLA HEALTHCARE OPPORTUNITIES FUND*

By: /s/ Daniel R. Omstead
Name: Daniel R. Omstead, Ph.D.
Title: President

* The name Tekla Healthcare Opportunities Fund is the designation of the Trustees for the time being under an Amended & Restated Declaration of Trust dated June 11, 2014, and all persons dealing with Tekla Healthcare Opportunities Fund must look solely to the trust property for the enforcement of any claim against Tekla Healthcare Opportunities Fund, as neither the Trustees, officers nor shareholders assume any personal liability for the obligations entered into on behalf of Tekla Healthcare Opportunities Fund.

TEKLA WORLD HEALTHCARE FUND*

By: /s/ Daniel R. Omstead
Name: Daniel R. Omstead, Ph.D.
Title: President

* The name Tekla World Healthcare Fund is the designation of the Trustees for the time being under an Amended & Restated Declaration of Trust dated May 18, 2015, and all persons dealing with Tekla World Healthcare Fund must look solely to the trust property for the enforcement of any claim against Tekla World Healthcare Fund, as neither the Trustees, officers nor shareholders assume any personal liability for the obligations entered into on behalf of Tekla World Healthcare Fund.

INVESTOR:

SOFINNOVA VENTURE PARTNERS IX, L.P.
By: Sofinnova Management IX, L.L.C.
Its General Partner

By: /s/ Mike Powell
Mike Powell, Managing Member

INVESTOR:

NOVO HOLDINGS A/S

By: /s/ Thomas Dyrberg
Name: Thomas Dyrberg, under specific power of attorney
Title: Managing Partner

INVESTOR:

Novartis BioVentures Ltd.

By: /s/ Stephan Sandmeier
Name: Stephan Sandmeier
Title: Authorized Signatory

By: /s/ Florian Muellershausen
Name: Florian Muellershausen
Title: Authorized Signatory

INVESTOR:

New Enterprise Associates 14, L.P.
By: NEA Partners 14, L.P., its general partner
By: NEA 14 GP, LTD, its general partner

By: /s/ Louis S. Citron
Name: Louis S. Citron
Title: Chief Legal Officer

INVESTOR:

NEA Ventures 2012 Limited Partnership
By: , its general partner

By: /s/ Louis S. Citron
Name: Louis S. Citron
Title: Vice President

INVESTOR:

Correlation Ventures, L.P.
as nominee for
Correlation Ventures, L.P.
Correlation Ventures Executives Fund, L.P.

By: Correlation Ventures GP, LLC

By: /s/ David E. Coats
Name: David E. Coats
Title: Managing Member

INVESTOR:

RA CAPITAL HEALTHCARE FUND, L.P.

By: RA Capital Management, LLC
Its: General Partner

By: /s/ James Schneider
Name: James Schneider
Title: Authorized Signatory

Address: RA Capital Management, LLC
20 Park Plaza
Suite 1200
Boston, MA 02116
Attn: General Counsel

INVESTOR:

BLACKWELL PARTNERS LLC – SERIES A

By: /s/ Abayomi A. Adigun
Name: Abayomi A. Adigun
Title: Investment Manager, DUMAC, Inc.
Authorized Signatory

By: /s/ Jannine M. Lall
Name: Jannine M. Lall
Title: Controller, DUMAC, Inc.
Authorized Signatory

Address: Blackwell Partners LLC – Series A
280 S. Mangum Street
Suite 210
Durham, NC 27701
Attn: XXX

INVESTOR:

BioGenerator

By: /s/ Eric Gulve
Name: Eric Gulve
Title: President

INVESTOR:

Galera Angels LLC

By: /s/ Robert Calcaterra
Name: Robert Calcaterra
Title: Managing Member

INVESTOR:

/s/ Robert A. Beardsley
Robert A. Beardsley

INVESTOR:

/s/ Dennis Riley
Dennis Riley

SIGNATURE PAGE TO SECOND AMENDED AND RESTATED INVESTORS' RIGHTS AGREEMENT

INVESTOR:

/s/ Jeffery Keene

Jeffery Keene

INVESTOR:

The Catherine L. Matthes Trust

By: /s/ Catherine L. Matthes
Name: Catherine L. Matthes

INVESTOR:

Adage Capital Partners, LP

By: Adage Capital Partners, GP, LLC, its General Partner
By: Adage Capital Advisors, LLC its Managing Member

By: /s/ Dan Lehan
Name: Dan Lehan
Its: Chief Operating Officer

INVESTOR: **HBM HEALTHCARE INVESTMENTS (CAYMAN) LTD.**

By: /s/ Jean-Marc LeSieur
Name: Jean-Marc LeSieur
Title: Managing Director

ADDRESS: Attention: XXX
Governors Square, Suite #4-212-2
23 Lime Tree Bay Avenue
West Bay
Grand Cayman, Cayman Islands

INVESTOR:

Rock Springs Capital Master Fund LP
By: Rock Springs General Partner LLC, its general partner

By: /s/ Graham McPhail
Name: Graham McPhail
Its: Managing Member

INVESTOR:

Pivotal Alpha Limited

By: /s/ Sun Xintong /s/ Tang Chun Wai Nelson
Name: Sun Xintong Tang Chun Wai Nelson
Its: Directors

Address: c/o 23/F Nan Fung Tower
88 Connaught Road C
Central, Hong Kong
Attn: Terence Lam

SIGNATURE PAGE TO SECOND AMENDED AND RESTATED INVESTORS' RIGHTS AGREEMENT

SCHEDULE A

Investors

Clarus IV-A, L.P.
Clarus IV-B, L.P.
Clarus IV-C, L.P.
Clarus IV-D, L.P.
101 Main Street, Suite 1210
Cambridge, MA 02142
Attn: XXX
Email: XXX@clarusfunds.com

With a copy to:
Latham & Watkins LLP
140 Scott Drive
Menlo Park, CA 94025
Attn: XXX
Email: XXX@lw.com

Tekla Healthcare Investors
Tekla Life Sciences Investors
Tekla Healthcare Opportunities Fund
Tekla World Healthcare Fund
c/o Tekla Capital Management LLC
100 Federal Street, 19th Floor
Boston, MA 02110

Attention: XXX
Telephone: (XXX) XXX-XXXX
Facsimile: (XXX) XXX-XXXX
Email: XXX@teklacap.com

With a copy (which shall not constitute notice) to:
Reitler Kailas & Rosenblatt LLC
4 Independence Way, Suite 120
Princeton, NJ 08540

Attention: XXX
Facsimile: (XXX) XXX-XXXX
Email: XXX@reitlerlaw.com

Enso Ventures 2 Limited
c/o Albecq Trust Company Limited
Suite 6, Provident House
Havilland Street, St. Peter Port
Guernsey, GY1 2QE

Sofinnova Venture Partners IX, L.P.
3000 Sand Hill Road, Bldg. 4, Suite 250
Menlo Park, CA 94025

Novo Holdings A/S
Tuborg Havnevej 19
DK-2900 Hellerup
Denmark
Attn: XXX
Email: XXX@novo.dk

with a copy (which shall not constitute notice) to:

Novo Ventures (US), Inc.
501 2nd Street, Suite 300
San Francisco, CA 94107
Attention: XXX
Email:XXX@novo.dk

Novartis BioVentures Ltd.
Novartis Campus, Forum 1-1.32
Attn: Stephan Sandmeier
CH-4056 Basel, Switzerland
Email: XXX@novartis.com

With a copy to:
Novartis Venture Fund
Attn: XXX
100 Technology Square, Suite 3150
Cambridge, MA 02139
Email: XXX@nvfund.com

New Enterprise Associates 14, L.P.
1954 Greenspring Drive, Suite 600
Timonium, MD 21093
Attn: XXX
Email: XXX@nea.com

NEA Ventures 2012 Limited Partnership
1954 Greenspring Drive, Suite 600
Timonium, MD 21093
Attn: XXX
Email: XXX@nea.com

Correlation Ventures, L.P.
9255 Towne Centre Drive, Suite 350
San Diego, CA 92121
(XXX) XXX-XXXX Main
(XXX) XXX-XXXX Fax

BioGenerator
20 South Sarah Street
St. Louis, MO 63108

Galera Angels LLC
148 Bon Chateau Drive
St. Louis, MO 63141

Northfork Grindstone Creek LLC
c/o Marberry Eagle, CPAs, p.c.
414 E. Broadway, Suite 300
Columbia, MO 65201

Robert A. Beardsley, PhD
XXX
XXX

Regina A. Buckler
XXX
XXX

Jeffery Keene, PhD
XXX
XXX

The Catherine L. Matthes Trust
XXX
XXX

Homer Pearce
XXX
XXX

Dennis Riley, PhD
XXX
XXX

The Weiss Family Revocable Living Trust, Randy Herman Weiss and Rose Gene Weiss, Trustees, Date of Trust: March 26, 2002, amended April 5, 2010
XXX
XXX

RA Capital Healthcare Fund, L.P.
RA Capital Management, LLC
20 Park Plaza
Suite 1200
Boston, MA 02116
Attn: General Counsel

Blackwell Partners LLC – Series A
280 S. Mangum Street
Suite 210
Durham, NC 27701
Attn: XXX

Rock Springs Capital Master Fund LP
Rock Springs Capital
650 South Exeter Street Suite 1070

Baltimore, Maryland. 21202
Attention: General Counsel
With copies by email as follows:
XXX@rockspringscapital.com; XXX@rockspringscapital.com

Adage Capital Partners, LP
200 Clarendon St, 52nd Floor
Boston, MA 02116

HBM Healthcare Investments (Cayman) Ltd.
Attention: XXX
Governors Square, Suite #4-212-2
23 Lime Tree Bay Avenue
West Bay
Grand Cayman, Cayman Islands

Pivotal Alpha Limited
c/o 23/F Nan Fung Tower
88 Connaught Road C
Central, Hong Kong
Attn: XXX

GALERA THERAPEUTICS, INC.
EQUITY INCENTIVE PLAN

1. Purposes of the Plan. The purpose of the Plan is to provide the Company with a means to assist in recruiting, retaining and rewarding certain employees, directors and consultants and to motivate such individuals to exert their best efforts on behalf of the Company by providing incentives through the granting of Awards. By granting Awards to such individuals, the Company expects that the interests of the recipients will be better aligned with those of the Company. The Plan permits the grant of Incentive Stock Options, Nonstatutory Stock Options, Stock Appreciation Rights and Restricted Stock.

2. Definitions. As used herein, the following definitions will apply:

(a) "Administrator" means the Committee with the responsibility of administering the Plan, as set forth in Section 4 of the Plan.

(b) "Affiliate" shall mean any entity that directly or indirectly through one or more intermediaries is controlled by, or is under common control, with the Company.

(c) "Award" means, individually or collectively, a grant under the Plan of an Option, Stock Appreciation Right or Restricted Stock.

(d) "Award Agreement" means the written or electronic agreement setting forth the terms and provisions applicable to each Award granted under the Plan. The Award Agreement is subject to the terms and conditions of the Plan.

(e) "Board" means the Board of Directors of the Company.

(f) "Change in Control" means the occurrence of any of the following events:

(i) any one person, or more than one person acting as a group ("Person"), acquires ownership of the stock of the Company that, together with the stock held by such Person, constitutes more than 50% of the total voting power of the stock of the Company. However, if any one person, or more than one person acting as a group, is considered to own more than 50 percent of the total fair market value or total voting power of the stock of a corporation, the acquisition of additional stock by the same person or persons is not considered to cause a Change in Control of the Company;

(ii) any one person, or more than one person acting as a group acquires (or has acquired during the 12-month period ending on the date of the most recent acquisition by such person or persons) ownership of stock of the Company possessing 30 percent or more of the total voting power of the stock of such corporation;

(iii) a majority of members of the Board is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of the appointment or election;

(iv) any one person, or more than one person acting as a group acquires (or has acquired during the 12-month period ending on the date of the most recent acquisition by such person or persons) assets from the Company that have a total gross fair market value equal to or more than 40 percent of the total gross fair market value of all of the assets of the Company immediately before such acquisition or acquisitions. For this purpose, gross fair market value means the value of the assets of the Company, or the value of the assets being disposed of, determined without regard to any liabilities associated with such assets.

(g) "Code" means the Internal Revenue Code of 1986, as amended. Any reference to a section of the Code herein will be a reference to any successor or amended section of the Code.

(h) "Committee" means a committee appointed by the Board to administer the Plan.

(i) "Common Stock" means the common stock of the Company.

(j) "Company" means Galera Therapeutics Inc., a Delaware corporation, or any successor thereto.

(k) "Consultant" means any individual, including an advisor, engaged by the Company or any Subsidiary to render services to such entity. For the avoidance of doubt, the term "Consultant" shall not include any entity or non-natural person.

(l) "Director" means a member of the Board.

(m) "Disability" means an individual's inability to engage in any substantial gainful activity by reasons of a medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of at least 12 months.

(n) "Employee" means any person, including an officer or Director, employed by the Company or any Subsidiary. Neither service as a Director nor payment of a director's fee by the Company will be sufficient to constitute "employment" by the Company.

(o) "Fair Market Value" means, with respect to Shares, the fair market value per Share as determined by application of one of the following valuation methods:

(i) if the Common Stock is not readily tradable on an established securities market, the valuation of the Common Stock shall be determined by an independent appraisal that meets the requirements of Code Section 401(a)(28)(C) and the regulations promulgated thereunder, as of a date that is no more than 12 months earlier than the date for which the valuation is being used;

(ii) if the Common Stock is readily tradable on an established securities market, the fair market value per Share shall be the closing price on the exchange on the date of determination (or, if there are no sales on such date, on the first preceding day on which there were reported sales), as reported in The Wall Street Journal or as reported in such other manner as the Board deems reliable and consistent with the requirements of Code Section 409A.

(p) "Incentive Stock Option" means an Option that by its terms qualifies and is otherwise intended to qualify as an incentive stock option within the meaning of Code Section 422 and the regulations promulgated thereunder.

(q) "Nonstatutory Stock Option" means an Option that by its terms does not qualify or is not intended to qualify as an Incentive Stock Option.

(r) "Option" means a stock option granted pursuant to the Plan.

(s) "Participant" means the holder of an outstanding Award.

(t) "Period of Restriction" means the period during which the transfer of Shares of Restricted Stock are subject to restrictions and therefore, the Shares are subject to a substantial risk of forfeiture. Such restrictions may be based on the passage of time, the achievement of target levels of performance, or the occurrence of other events as determined by the Administrator.

(u) "Plan" means this Galera Therapeutics, Inc. Equity Incentive Plan.

(v) "Restricted Stock" means Shares issued pursuant to an Award of Restricted Stock under Section 8 of the Plan.

(w) "Service Provider" means an Employee, Director or Consultant.

(x) "Share" means a share of the Common Stock, as adjusted in accordance with Section 15 of the Plan.

(y) "Stock Appreciation Right" means an Award, granted alone or in connection with an Option, that pursuant to Section 7 is designated as a Stock Appreciation Right.

(z) "Subsidiary" means a "subsidiary corporation" of the Company, whether now or hereafter existing, as defined in Code Section 424(f).

3. Stock Subject to the Plan.

(a) Stock Subject to the Plan. Subject to the provisions of Section 15 of the Plan, the maximum aggregate number of Shares that may be subject to Awards and issued under the Plan is 2,879,913 Shares. The Shares may be authorized but unissued or reacquired Common Stock. The Company may, in its discretion, use shares held in the treasury in lieu of authorized but unissued shares. Awards settled in cash shall not reduce the number of Shares available for purposes of the Plan. If any Award shall expire or terminate for any reason, the shares subject to the Award shall again be available for the purposes of the Plan. Any Shares which are used by a Participant as full or partial payment to the Company to satisfy the purchase price related to an Award, and any Shares subject to an Award which are not delivered to a Participant because such Shares are used to satisfy an applicable tax withholding obligation, shall not be available for the purposes of the Plan, and shall not be included in the number of Shares reserved hereunder.

4. Administration of the Plan.

(a) The Plan shall be administered by the Committee; however, in the event the Committee shall cease to exist or cannot function for any reason, the Board may take any action under the Plan that would otherwise be the responsibility of the Committee.

(b) The Committee is authorized, subject to the provisions of the Plan, to establish such rules and regulations as it may deem appropriate for the proper administration of the Plan. All actions of the Committee shall be taken by majority vote of its members. Without limiting the generality of the foregoing, the Committee shall have full discretionary power, subject to any limitations of the Plan, to: (i) select the Service Providers to whom Awards may from time to time be granted hereunder; (ii) determine the type or types of Awards, not inconsistent with the provisions of the Plan, to be granted to each Participant hereunder; (iii) determine the number of Shares to be covered by each Award granted hereunder; (iv) determine the terms and conditions, of any Award granted hereunder; (v) determine whether, to what extent and under what circumstances any Award shall be canceled or suspended; (vi) interpret and administer the Plan and any instrument or agreement entered into under or in connection with the Plan, including any Award Agreement; (vi) correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Award in the manner and to the extent that the Committee shall deem desirable to carry it into effect; (vii) establish such rules and regulations and appoint such agents as it shall deem appropriate for the proper administration of the Plan; (viii) to modify or amend each Award (subject to Section 21(c) of the Plan); and (ix) make any other determination and take any other action that the Committee deems necessary or desirable for administration of the Plan.

(c) Decisions of the Committee shall be final, conclusive and binding on all persons or entities, including the Company, any Participant and any Subsidiary. Notwithstanding the foregoing, any action or determination by the Committee specifically affecting or relating to an Award to a member of the Committee shall require the prior approval of the Board (excluding persons who are also members of the Committee).

(d) The Committee may delegate to one or more of its members or to one or more officers of the Company such administrative duties or powers as it may deem advisable, and the Committee or any individuals to whom it has delegated duties or powers as aforesaid may employ one or more individuals to render advice with respect to any responsibility the Committee or such individuals may have under this Plan.

(e) The Administrator's decisions, determinations and interpretations will be final and binding on all Participants and any other holders of Awards.

5. Eligibility. Subject to the express provisions of the Plan, the Administrator shall have plenary authority, in its discretion, to determine the Service Providers to whom, and the time or times at which, Awards shall be granted, the number of Shares to be subject to each Award and the term of any Award. In making such determinations, the Committee may take into account the nature of services rendered by the respective Service Providers, their present and potential contributions to the Company's success and such other factors as the Administrator, in its discretion, shall deem relevant. Awards may be granted under the Plan only to such Employees, Consultants and Independent Directors of the Company or any of its Subsidiaries, as the Committee shall select from time to time. The Administrator's designation of Service Provider to receive Awards or grants under one portion of the Plan shall not require the Administrator to include such Service Provider under other portions of the Plan.

6. Stock Options.

(a) Grant of Options. Subject to the terms and provisions of the Plan, the Administrator, at any time and from time to time, may grant Options in such amounts as the Administrator, in its sole discretion, will determine. Incentive Stock Options may be granted to any individual classified as an Employee. A Non-Qualified Stock Option may be granted to any Employee, Director or Consultant of the Company or a Subsidiary.

(b) Option Agreement. Each Award of an Option will be evidenced by an Award Agreement that will specify the exercise price, the term of the Option, the number of Shares subject to the Option, the exercise restrictions, if any, applicable to the Option, and such other terms and conditions as the Administrator, in its sole discretion, will determine.

(c) Limitations. Each Option will be designated in the Award Agreement as either an Incentive Stock Option or a Nonstatutory Stock Option. Notwithstanding such designation, however, to the extent that the aggregate Fair Market Value of the Shares with respect to which Incentive Stock Options are exercisable for the first time by the Participant during any calendar year (under all plans of the Company and any Affiliate or Subsidiary) exceeds one hundred thousand dollars ($100,000), such Options will be treated as Nonstatutory Stock Options. For purposes of this Section 6(c), Incentive Stock Options will be taken into account in the order in which they were granted, the Fair Market Value of the Shares will be determined as of the time the Option with respect to such Shares is granted, and calculation will be performed in accordance with Code Section 422 and Treasury Regulations promulgated thereunder.

(d) Term of Option. The term of each Option will be stated in the Award Agreement; provided, however, that the term will be no more than ten (10) years from the date of grant thereof. In the case of an Incentive Stock Option granted to a Participant who, at the time the Incentive Stock Option is granted, owns stock representing more than ten percent (10%) of the total combined voting power of all classes of stock of the Company or any Affiliate or Subsidiary, the term of the Incentive Stock Option will be five (5) years from the date of grant or such shorter term as may be provided in the Award Agreement.

(e) Option Exercise Price and Consideration.

(i) Exercise Price. The per Share exercise price for the Shares to be issued pursuant to the exercise of an Option will be determined by the Administrator, but will be no less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant. In addition, in the case of an Incentive Stock Option granted to an Employee who owns stock representing more than ten percent (10%) of the voting power of all classes of stock of the Company or any Affiliate or Subsidiary, the per Share exercise price will be no less than one hundred ten percent (110%) of the Fair Market Value per Share on the date of grant. Notwithstanding the foregoing provisions of this Section 6(e)(i), Options may be granted with a per Share exercise price of less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant pursuant to a transaction described in, and in a manner consistent with, Code Section 424(a).

(f) Exercise of Option.

(i) Procedure for Exercise; Rights as a Stockholder. Any Option granted hereunder will be exercisable according to the terms of the Plan and at such times and under such conditions as determined by the Administrator and set forth in the Award Agreement. An Option may not be exercised for a fraction of a Share. An Option will be deemed exercised when the Company receives: (i) notice of exercise (in such form as the Administrator may specify from time to time) from the person entitled to exercise the Option, and (ii) full payment for the Shares with respect to which the Option is exercised (together with applicable tax withholding). Shares issued upon exercise of an Option will be issued in the name of the Participant or, if requested by the Participant, in the name of the Participant and his or her spouse. Exercising an Option in any manner will decrease the number of Shares thereafter available, both for purposes of the Plan and for sale under the Option, by the number of Shares as to which the Option is exercised.

(ii) Payment of Exercise Price. The exercise price under an Option is to be paid in full upon the exercise of the Option, either (i) in cash, (ii) in the discretion of the Administrator, by the tender to the Company (either actual or by attestation) of Shares already owned by the Participant and registered in his or her name, having a Fair Market Value equal to the cash purchase price under the Option being exercised, (iii) in the discretion of the Administrator, by any combination of the payment methods specified in clauses (i) and (ii) hereof; provided that, no Shares may be tendered in exercise of an Incentive Stock Option if such shares were acquired by the Participant through the exercise of an Incentive Stock Option unless (1) such shares have been held by the Participant for at least one year, and (2) at least two years have elapsed since such prior Incentive Stock Option was granted. At the discretion of the Administrator, in the case of a Non-Qualified Stock Option, the exercise price may be paid by means of a net exercise in which the person entitled to exercise the Non-Qualified Stock Option shall receive the number of Shares equal to the aggregate number of Shares being purchased less the number of Shares having a Fair Market Value equal to the aggregate purchase price of the Shares being purchased.

(iii) Shareholder Rights. Until the Shares are issued (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), no right to vote or receive dividends or any other rights as a stockholder will exist with respect to the Shares subject to an Option, notwithstanding the exercise of the Option. The Company will issue (or cause to be issued) such Shares promptly after the Option is exercised. No adjustment will be made for a dividend or other right for which the record date is prior to the date the Shares are issued, except as provided in Section 14 of the Plan.

(g) Termination of Relationship as a Service Provider.

(i) General Termination. If a Participant ceases to be a Service Provider, other than upon the Participant's termination as the result of the Participant's death or Disability, the Participant may exercise his or her Option within such period of time as is specified in the Award Agreement (but in no event later than the expiration of the term of such Option as set forth in the Award Agreement) to the extent that the Option is vested on the date of termination. In the absence of a specified period of time in the Award Agreement, the Option shall remain exercisable for three (3) months following the Participant's termination. Unless otherwise provided by the Administrator, if on the date of termination the Participant is not vested as to his or her entire Option, the Shares covered by the unvested portion of the Option will revert to the Plan. If after termination the Participant does not exercise his or her Option within the time specified by the Administrator, the Option will terminate, and the Shares covered by such Option will revert to the Plan.

(ii) Disability of Participant. If a Participant ceases to be a Service Provider as a result of the Participant's Disability, the Participant may exercise his or her Option within such period of time as is specified in the Award Agreement (but in no event later than the expiration of the term of such Option as set forth in the Award Agreement) to the extent the Option is vested on the date of termination. In the absence of a specified time in the Award Agreement, the Option shall remain exercisable for twelve (12) months following the Participant's termination. Unless otherwise provided by the Administrator, if on the date of termination the Participant is not vested as to his or her entire Option, the Shares covered by the unvested portion of the Option will revert to the Plan. If after termination the Participant does not exercise his or her Option within the time specified herein, the Option will terminate, and the Shares covered by such Option will revert to the Plan.

(iii) Death of Participant. If a Participant dies while a Service Provider, the Option may be exercised within such period of time as is specified in the Award Agreement (but in no event later than the expiration of the term of such Option as set forth in the Award Agreement) to the extent that the Option is vested on the date of death, by the Participant's designated beneficiary, provided such beneficiary has been designated prior to the Participant's death in a form acceptable to the Administrator. If no such beneficiary has been designated by the Participant, then such Option may be exercised by the personal representative of the Participant's estate or by the person(s) to whom the Option is transferred pursuant to the Participant's will or in accordance with the laws of descent and distribution. In the absence of a specified time in the Award Agreement, the Option shall remain exercisable for twelve (12) months following Participant's termination. Unless otherwise provided by the Administrator, if at the time of death Participant is not vested as to his or her entire Option, the Shares covered by the unvested portion of the Option will immediately revert to the Plan. If the Option is not so exercised within the time specified herein, the Option will terminate, and the Shares covered by such Option will revert to the Plan.

7. Stock Appreciation Rights.

(a) Grant of Stock Appreciation Rights. Subject to the terms and conditions of the Plan, a Stock Appreciation Right may be granted to a Service Provider at any time and from time to time as will be determined by the Administrator, in its sole discretion.

(b) Number of Shares. The Administrator will have complete discretion to determine the number of Shares subject to any Award of Stock Appreciation Rights.

(c) Exercise Price and Other Terms. The per Share exercise price for the Shares that will determine the amount of the payment to be received upon exercise of a Stock Appreciation Right as set forth in Section 7(f) will be determined by the Administrator and will be no less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant. In the event a Stock Appreciation Right is granted in tandem with an Option, the exercise of the Stock Appreciation Right shall automatically result in the cancellation of the Option. Otherwise, the Administrator, subject to the provisions of the Plan, will have complete discretion to determine the terms and conditions of Stock Appreciation Rights granted under the Plan.

(d) Stock Appreciation Right Agreement. Each Stock Appreciation Right grant will be evidenced by an Award Agreement that will specify the exercise price, the term of the Stock Appreciation Right, the conditions of exercise, and such other terms and conditions as the Administrator, in its sole discretion, will determine.

(e) Expiration of Stock Appreciation Rights. A Stock Appreciation Right granted under the Plan will expire upon the date determined by the Administrator, in its sole discretion, and set forth in the Award Agreement. Notwithstanding the foregoing, the rules of Section 6(d) relating to the maximum term also will apply to Stock Appreciation Rights.

(f) Payment of Stock Appreciation Right Amount. Upon exercise of a Stock Appreciation Right, a Participant will be entitled to receive a payment from the Company in an amount determined by multiplying:

(i) The difference between the Fair Market Value of a Share on the date of exercise over the exercise price; times

(ii) The number of Shares with respect to which the Stock Appreciation Right is exercised.

At the discretion of the Administrator, the payment upon Stock Appreciation Right exercise may be in cash, in Shares of equivalent value, or in some combination thereof.

8. Restricted Stock.

(a) Grant of Restricted Stock. Subject to the terms and provisions of the Plan, the Administrator, at any time and from time to time, may grant Shares of Restricted Stock to Service Providers in such manner, and subject to such terms and conditions relating to vesting, forfeitability and restrictions on delivery and transfer (whether based on periods of service or otherwise) or otherwise as the Administrator shall establish. The terms of any Restricted Stock Award granted under this Plan shall be set forth in an Award Agreement which shall contain provisions determined by the Administrator and not inconsistent with this Plan. The provisions of Restricted Stock Awards need not be the same for each Participant receiving such Awards.

(b) Issuance and Delivery of Restricted Shares. As soon as practicable after the date of grant of a Restricted Stock Award by the Administrator, the Company shall cause to be transferred on the books of the Company, Shares registered in the name of the Participant, evidencing the Restricted Shares covered by the Restricted Stock Award, but subject to forfeiture to the Company. The Share certificates representing such Restricted Shares shall, unless otherwise determined by the Administrator, be maintained in the custody of or on behalf of the Company until all applicable vesting conditions have been satisfied. In addition to any legends placed on certificates reflecting the restrictions, each certificate representing Shares acquired pursuant to a Restricted Shares Award under this Plan may bear a legend such as the following or as otherwise determined by the Administrator in its sole discretion:

THE SALE, TRANSFER OR DISPOSITION OF THIS CERTIFICATE AND THE SHARES REPRESENTED, WHETHER VOLUNTARY, INVOLUNTARY, OR BY OPERATION OF LAW, IS RESTRICTED PURSUANT TO THE TERMS OF THE GALERA THERAPEUTICS, INC. EQUITY INCENTIVE PLAN AND A RESTRICTED STOCK AWARD AGREEMENT, BETWEEN GALERA THERAPEUTICS, INC. AND THE SHAREHOLDER. COPIES OF SUCH PLAN AND AWARD AGREEMENT ARE ON FILE AT THE PRINCIPAL OFFICE OF GALERA THERAPEUTICS, INC. AND WILL BE FURNISHED WITHOUT CHARGE UPON THE WRITTEN REQUEST OF THE HOLDER TO THE COMPANY.

Such certificates shall be delivered to the Participant as soon as administratively practicable after the Period of Restriction has lapsed.

(c) Transferability. Shares of Restricted Stock may not be sold, transferred, pledged, assigned, or otherwise alienated or hypothecated until the end of the applicable Period of Restriction.

(d) Removal of Restrictions. Shares of Restricted Stock covered by each Restricted Stock grant made under the Plan will be released from the custody of the Company as soon as practicable after the last day of the Period of Restriction or at such other time as the Administrator may determine. The Administrator, in its discretion, may accelerate the time at which any restrictions will lapse or be removed.

(e) Voting Rights. During the Period of Restriction, Participants holding Shares of Restricted Stock granted hereunder may exercise full voting rights with respect to those Shares, unless the Administrator determines otherwise.

(f) Dividends and Other Distributions. The Administrator may establish terms and conditions under which a Participant granted a Restricted Stock Award shall be entitled to receive a credit equivalent to any dividend payable with respect to the number of Shares which, as of the record date for such dividend, have been awarded to the Participant but remain subject to limitations and restrictions under such Restricted Stock Award. Any such dividend equivalents shall be paid to the Participant only at such time, if any, that the limitations and restrictions applicable to such shares lapse, but in no event later than 2½ months after the end of the year in which such limitations and restrictions lapse. Any arrangement for the payment of dividend equivalents shall terminate if, in accordance with the limitations and restrictions under the Restricted Stock Award, the Shares being held pursuant to the terms of such Restricted Stock Award are forfeited.

(g) Return of Restricted Stock to Company. On the date set forth in the Award Agreement, the Restricted Stock for which restrictions have not lapsed shall revert to the Company and again will become available for grant under the Plan.

9. Repurchase Right.

(a) Commencement of Repurchase Right. Unless otherwise provided in the Award Agreement, if the Participant ceases to be a Service Provider for any reason, then the Company shall have the right to repurchase any and all of the unvested Shares acquired or received pursuant to an Award to a Participant under the Plan, at a price to be determined as set forth below. Such right on the part of the Company shall commence upon the last day of such Participant's status as an Service Provider (the "Termination Date") and shall expire on the 180th calendar day after the Termination Date.

(b) Repurchase Price. The aggregate repurchase price for any such unvested Shares shall be an amount equal to the original purchase price per Share paid by the Participant times the number of Shares to be repurchased.

(c) Exercise of Repurchase Right. The right of repurchase shall be exercisable by written notice delivered to the Participant or beneficiary setting forth the date on which the repurchase is to be effected, which date shall not be more than thirty (30) days after the date of the notice. Prior to the close of business on the date specified for the repurchase, the Participant or beneficiary shall deliver to the Company instrument(s) of transfer, in form and substance reasonably acceptable to the Company, sufficient to transfer, free and clear of any encumbrance or restrictions, the unvested Shares to be repurchased. The Company shall, concurrently with receipt of such instrument(s) of transfer, pay to the Participant the repurchase price determined as set forth herein. If the Company makes available, at the time and place and in the amount and form provided in this Section 9, the consideration for such unvested Shares to be repurchased, then from and after such time, the Participant or beneficiary shall no longer have any rights as a holder of such Shares (other than the right to receive payment of such consideration in accordance with this Section 9).

(d) Form of Payment. Payment for the purchased Shares will be made by the Company in a cash lump sum payment.

10. Right of First Refusal. In the event that a Participant desires at any time to sell or otherwise transfer all or any part of his or her Shares (other than Shares of Restricted Stock which by their terms are not transferrable), the Participant first shall give written notice to the Company of the Participant's intention to make such transfer. Such notice shall state the number of Shares that the Participant proposes to sell (the "Offered Shares"), the price and the terms at which the proposed sale is to be made and the name and address of the proposed transferee. At any time within 30 days after the receipt of such notice by the Company and except for transfers made for bona fide estate planning purposes, the Company or its assigns may elect to purchase all or any portion of the Offered Shares at the price and on the terms offered by the proposed transferee and specified in the notice. The Company or its assigns shall exercise this right by mailing or delivering written notice to the Participant within the foregoing 30-day period. If the Company or its assigns elect to exercise its purchase rights under this Section 10, the closing for such purchase shall, in any event, take place within 45 days after the receipt by the Company of the initial notice from the Participant. In the event that the Company or its assigns do not elect to exercise such purchase right, or in the event that the Company or its assigns do not pay the full purchase price within such 45-day period, the Participant may, within 60 days thereafter, sell the Offered Shares to the proposed transferee and at the same price and on the same terms as specified in the Participant's notice. Any Shares not sold to the proposed transferee shall remain subject to the Plan. If the Participant is a party to any stockholders agreements or other agreements with the Company and/or certain other of the Company's stockholders relating to the Shares, (i) the transferring Participant shall comply with the requirements of such stockholders agreements or other agreements relating to any proposed transfer of the Offered Shares, and (ii) any proposed transferee that purchases Offered Shares shall enter into such stockholders agreements or other agreements with the Company and/or certain of the Company's stockholders relating to the Offered Shares on the same terms and in the same capacity as the transferring Participant.

11. Lockup. If requested by the Company, a Participant shall not sell or otherwise transfer or dispose of any Shares (including, without limitation, pursuant to Rule 144 under the Securities Act of 1933, as amended) held by him or her for such period following the effective date of a public offering by the Company of Shares as the Company shall specify reasonably and in good faith. If requested by the underwriter engaged by the Company, each Participant shall execute a separate letter confirming his or her agreement to comply with this Section 11.

12. Other Agreements. To the extent a Participant is subject to an agreement with the Company containing (i) a right of first refusal with respect to the transfer of such Participant's Shares or (ii) an obligation to refrain from selling, transferring or disposing of Shares in connection with a public offering, then Section 9, Section 10 and Section 11, respectively, shall not apply to such Participant.

13. Compliance With Code Section 409A. Awards will be designed and operated in such a manner that they are either exempt from the application of, or comply with, the requirements of Code Section 409A, except as otherwise determined in the sole discretion of the Administrator. The Plan and each Award Agreement under the Plan is intended to meet the requirements of Code Section 409A and will be construed and interpreted in accordance with such intent, except as otherwise determined in the sole discretion of the Administrator. To the extent that an Award or payment or the settlement thereof, is subject to Code Section 409A the Award will be granted, paid or settled in a manner that will meet the requirements of Code Section 409A, such that the grant, payment or settlement will not be subject to the additional tax or interest applicable under Code Section 409A.

14. Limited Transferability of Awards. Unless determined otherwise by the Administrator and set forth in an Award Agreement, Awards may not be sold, pledged, assigned, hypothecated, or otherwise transferred in any manner other than by will or by the laws of descent and distribution, and may be exercised, during the lifetime of the Participant, only by the Participant.

15. Adjustments; Dissolution or Liquidation; Merger or Change in Control.

(a) Adjustments. In the event that any dividend or other distribution (whether in the form of cash, Shares, other securities, or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of Shares or other securities of the Company, or other change in the corporate structure of the Company affecting the Shares occurs, the Administrator, in order to prevent diminution or enlargement of the benefits or potential benefits intended to be made available under the Plan, will adjust the number and class of Shares that may be delivered under the Plan and/or the number, class, and price of Shares covered by each outstanding Award.

(b) Dissolution or Liquidation. In the event of the proposed dissolution or liquidation of the Company, the Administrator will notify each Participant as soon as practicable prior to the effective date of such proposed transaction. To the extent it has not been previously exercised, an Award will terminate immediately prior to the consummation of such proposed action.

(c) Change in Control. The terms of any Award may provide in the Award Agreement evidencing the Award that, upon a Change in Control of the Company, (a) Options and Stock Appreciation Rights outstanding as of the date of the Change in Control immediately vest and become fully exercisable, (b) Restricted Stock becomes free of all restrictions and limitations and becomes fully vested, (c) the restrictions and other conditions applicable to any other Awards shall lapse, and such other Awards shall become free of all restrictions, limitations or conditions and become fully vested and transferable to the full extent of the original grant, and (d) such other additional benefits as the Committee deems appropriate shall apply, subject in each case to any terms and conditions contained in the Award Agreement evidencing such Award.

(d) Assumption/Substitution Upon Change in Control. Notwithstanding the foregoing, the terms of any Award Agreement may also provide that, if in the event of a Change in Control the successor company assumes an Award or issues a substitute award to substantially preserve the terms of any Awards previously granted under the Plan and not previously exercised or settled, then each outstanding Award assumed or substituted for under this Section 15(d) shall not be accelerated as described above. Notwithstanding the foregoing, no Award shall be assumed or substituted pursuant to this Section 15(d) if such action would cause an Award not otherwise "deferred compensation" within the meaning of Code Section 409A to become or create "deferred compensation" within the meaning of Code Section 409A or otherwise trigger adverse tax consequences under Code Section 409A.

(e) Committee Discretion Upon Change in Control. Notwithstanding any other provision of the Plan or Award Agreement to the contrary, the Committee may, in its sole and absolute discretion, determine that, upon the occurrence of a Change in Control of the Company, any vested or unvested Award outstanding as of the effective date of such Change in Control will be cancelled in consideration for a cash payment or alternative award (whether from the Company or another entity that is a party to the Change in Control) or a combination thereof made to the holder of such cancelled Award substantially equivalent in value to the fair market value of the consideration to be paid per share of Stock in the Change in Control, reduced by the exercise or purchase price per share, if any, under such Award. The determination of fair market value shall be made by the Committee in its sole and absolute discretion.

16. Tax Withholding. All payments or distributions made pursuant to the Plan to a Participant shall be net of any applicable federal, state and local withholding taxes arising as a result of the grant of any Award, exercise of an Option or any other event occurring pursuant to this Plan. The Company shall have the right to withhold from such Participant such withholding taxes as may be required by law, or to otherwise require the Participant to pay such withholding taxes. If the Participant shall fail to make such tax payments as are required, the Company or its Subsidiaries shall, to the extent permitted by law, have the right to deduct any such taxes from any payment of any kind otherwise due to such Participant or to take such other action as may be necessary to satisfy such withholding obligations. In satisfaction of the requirement to pay withholding taxes, the Participant may make a written election, which may be accepted or rejected in the discretion of the Committee, to have withheld a portion of the Shares then issuable to the or Participant pursuant to the Plan, having an aggregate Fair Market Value equal to the withholding taxes.

17. No Effect on Employment or Service. Neither the Plan nor any Award will confer upon a Participant any right with respect to continuing the Participant's relationship as a Service Provider with the Company, nor will they interfere in any way with the Participant's right or the Company's right to terminate such relationship at any time, with or without cause, to the extent permitted by Applicable Laws.

18. Effectiveness of the Plan. This Plan shall become effective upon adoption by the Board subject, however, to its further approval by the stockholders of the Company given within twelve (12) months of the date the Plan is adopted by the Board. Such stockholder approval will be obtained in the manner and to the degree required under applicable laws.

19. Term of Plan. The Plan shall terminate ten (10) years after the date on which this Plan is approved and adopted by the Board and no Award shall be granted hereunder after the expiration of such ten (10) year period. Awards outstanding at the termination of the Plan shall continue in accordance with their terms and shall not be affected by such termination.

20. Time of Granting of an Award. An Award grant under the Plan shall be deemed to be made on the date on which the Committee, by formal action of its members duly recorded in the records thereof, makes an Award to a Participant (but in no event prior to the adoption of the Plan by the Board); provided that such Award is evidenced by a written Award Agreement duly executed on behalf of the Company and on behalf of the Participant within a reasonable time after the date of the Committee action.

21. Amendment and Termination of the Plan.

(a) Amendment and Termination. The Board may at any time amend, alter, suspend or terminate the Plan.

(b) Stockholder Approval. The Company will obtain stockholder approval of any Plan amendment to the extent necessary and desirable to comply with applicable laws.

(c) Effect of Amendment or Termination. No amendment, alteration, suspension or termination of the Plan will impair the rights of any Participant, unless mutually agreed otherwise between the Participant and the Administrator, which agreement must be in writing and signed by the Participant and the Company. Termination of the Plan will not affect the Administrator's ability to exercise the powers granted to it hereunder with respect to Awards granted under the Plan prior to the date of such termination.

22. Conditions Upon Issuance of Shares.

(a) Legal Compliance. Shares will not be issued pursuant to the exercise of an Award unless the exercise of such Award and the issuance and delivery of such Shares will comply with Applicable Laws and will be further subject to the approval of counsel for the Company with respect to such compliance.

(b) Investment Representations. As a condition to the exercise of an Award, the Company may require the person exercising such Award to represent and warrant at the time of any such exercise that the Shares are being purchased only for investment and without any present intention to sell or distribute such Shares if, in the opinion of counsel for the Company, such a representation is required.

23. Inability to Obtain Authority. The inability of the Company to obtain authority from any regulatory body having jurisdiction, which authority is deemed by the Company's counsel to be necessary to the lawful issuance and sale of any Shares hereunder, will relieve the Company of any liability in respect of the failure to issue or sell such Shares as to which such requisite authority will not have been obtained.

24. Choice of Law. The Plan shall be governed by and construed in accordance with the laws of the State of Delaware without regard to conflicts of law.

IN WITNESS WHEREOF, the Company has adopted this Plan on this 26th day of November, 2012.

GALERA THERAPEUTICS, INC

/s/ Mel Sorensen

By: Mel Sorensen
Title: President and Chief Executive Officer

FIRST AMENDMENT TO THE
GALERA THERAPEUTICS, INC. EQUITY INCENTIVE PLAN

WHEREAS, Galera Therapeutics, Inc. ("Company") previously adopted the Galera Therapeutics, Inc. Equity Incentive Plan ("Plan"); and

WHEREAS, the Company desires to amend the Plan to increase the number of Shares of Common Stock available for issuance thereunder by 224,932 shares;

WHEREAS, the stockholders of the Company have approved the proposed amendment of the Plan to increase the number of Shares of Common Stock available for issuance thereunder by 224,932 shares; and

WHEREAS, the Company maintains the right to amend the Plan pursuant to Section 21 therein;

NOW THEREFORE, Section 3 of the Plan is deleted in its entirety and replaced with the following, effective July 28, 2014:

3. Stock Subject to the Plan.

(a) Stock Subject to the Plan. Subject to the provisions of Section 15 of the Plan, the maximum aggregate number of Shares that may be subject to Awards and issued under the Plan is 3,104,845 Shares. The Shares may be authorized but unissued or reacquired Common Stock. The Company may, in its discretion, use shares held in the treasury in lieu of authorized but unissued shares. Awards settled in cash shall not reduce the number of Shares available for purposes of the Plan. If any Award shall expire or terminate for any reason, the shares subject to the Award shall again be available for the purposes of the Plan. Any Shares which are used by a Participant as full or partial payment to the Company to satisfy the purchase price related to an Award, and any Shares subject to an Award which are not delivered to a Participant because such Shares are used to satisfy an applicable tax withholding obligation, shall not be available for the purposes of the Plan, and shall not be included in the number of Shares reserved hereunder.

IN WITNESS WHEREOF, this Amendment is hereby executed by a duty authorized officer of the Company this 28th day of July, 2014.

GALERA THERAPEUTICS, INC.

By: /s/ Mel Sorensen

Title: President and CEO

SECOND AMENDMENT TO THE
GALERA THERAPEUTICS, INC. EQUITY INCENTIVE PLAN

October 1, 2015

WHEREAS, Galera Therapeutics, Inc. ("Company") previously adopted the Galera Therapeutics, Inc. Equity Incentive Plan (as amended, the "Plan"); and

WHEREAS, the Company desires to amend the Plan to increase the number of Shares of Common Stock available for issuance thereunder by 5,095,068 shares;

WHEREAS, the stockholders of the Company have approved the proposed amendment of the Plan to increase the number of Shares of Common Stock available for issuance thereunder by 5,095,068 shares; and

WHEREAS, the Company maintains the right to amend the Plan pursuant to Section 21 therein;

NOW THEREFORE, Section 3 of the Plan is deleted in its entirety and replaced with the following, effective October 1, 2015:

3. Stock Subject to the Plan.

(a) Stock Subject to the Plan. Subject to the provisions of Section 15 of the Plan, the maximum aggregate number of Shares that may be subject to Awards and issued under the Plan is 8,199,913 Shares. The Shares may be authorized but unissued or reacquired Common Stock. The Company may, in its discretion, use shares held in the treasury in lieu of authorized but unissued shares. Awards settled in cash shall not reduce the number of Shares available for purposes of the Plan. If any Award shall expire or terminate for any reason, the shares subject to the Award shall again be available for the purposes of the Plan. Any Shares which are used by a Participant as full or partial payment to the Company to satisfy the purchase price related to an Award, and any Shares subject to an Award which are not delivered to a Participant because such Shares are used to satisfy an applicable tax withholding obligation, shall not be available for the purposes of the Plan, and shall not be included in the number of Shares reserved hereunder.

[*Signature Page Follows*]

IN WITNESS WHEREOF, this Amendment is hereby executed by a duly authorized officer of the Company as of the first date written above.

GALERA THERAPEUTICS, INC.

By: /s/ Mel Sorensen
Name: Mel Sorensen
Title: President and Chief Executive Officer

[Signature Page to Amendment to Equity Incentive Plan]

THIRD AMENDMENT TO THE
GALERA THERAPEUTICS, INC. EQUITY INCENTIVE PLAN

January 18, 2017

WHEREAS, Galera Therapeutics, Inc. ("Company") previously adopted the Galera Therapeutics, Inc. Equity Incentive Plan (as amended, the "Plan"); and

WHEREAS, the Company desires to amend the Plan to increase the number of Shares of Common Stock available for issuance thereunder by 2,500,000 shares;

WHEREAS, the stockholders of the Company have approved the proposed amendment of the Plan to increase the number of Shares of Common Stock available for issuance thereunder by 2,500,000 shares; and

WHEREAS, the Company maintains the right to amend the Plan pursuant to Section 21 therein;

NOW THEREFORE, subject to the authorization by stockholders of the Company in accordance with the requirements of the Delaware General Corporation Law, the Third Amended and Restated Certificate of Incorporation and the Bylaws, as amended, Section 3(a) of the Plan is deleted in its entirety and replaced with the following, effective January 18, 2017:

"(a) Stock Subject to the Plan. Subject to the provisions of Section 15 of the Plan, the maximum aggregate number of Shares that may be subject to Awards and issued under the Plan is 10,699,913 Shares. The Shares may be authorized but unissued or reacquired Common Stock. The Company may, in its discretion, use shares held in the treasury in lieu of authorized but unissued shares. Awards settled in cash shall not reduce the number of Shares available for purposes of the Plan. If any Award shall expire or terminate for any reason, the shares subject to the Award shall again be available for the purposes of the Plan. Any Shares which are used by a Participant as full or partial payment to the Company to satisfy the purchase price related to an Award, and any Shares subject to an Award which are not delivered to a Participant because such Shares are used to satisfy an applicable tax withholding obligation, shall not be available for the purposes of the Plan, and shall not be included in the number of Shares reserved hereunder."

Except as specifically amended hereby, the Plan shall continue in full force and effect in accordance with its terms.

[*Signature Page Follows*]

IN WITNESS WHEREOF, this Amendment is hereby executed by a duly authorized officer of the Company as of the first date written above.

GALERA THERAPEUTICS, INC.

By: /s/ J. Mel Sorensen
Name: J. Mel Sorensen
Title: President and Chief Executive Officer

FOURTH AMENDMENT TO THE
GALERA THERAPEUTICS, INC. EQUITY INCENTIVE PLAN

August 30, 2018

WHEREAS, Galera Therapeutics, Inc. ("Company") previously adopted the Galera Therapeutics, Inc. Equity Incentive Plan (as amended, the "Plan"); and

WHEREAS, the Company desires to amend the Plan to increase the number of Shares of Common Stock available for issuance thereunder by 5,048,920 shares;

WHEREAS, the stockholders of the Company have approved the proposed amendment of the Plan to increase the number of Shares of Common Stock available for issuance thereunder by 5,048,920 shares; and

WHEREAS, the Company maintains the right to amend the Plan pursuant to Section 21 therein;

NOW THEREFORE, subject to the authorization by stockholders of the Company in accordance with the requirements of the Delaware General Corporation Law, the Fourth Amended and Restated Certificate of Incorporation and the Bylaws, as amended, Section 3(a) of the Plan is deleted in its entirety and replaced with the following, effective August 30, 2018:

"(a) Stock Subject to the Plan. Subject to the provisions of Section 15 of the Plan, the maximum aggregate number of Shares that may be subject to Awards and issued under the Plan is 15,748,833 Shares. The Shares may be authorized but unissued or reacquired Common Stock. The Company may, in its discretion, use shares held in the treasury in lieu of authorized but unissued shares. Awards settled in cash shall not reduce the number of Shares available for purposes of the Plan. If any Award shall expire or terminate for any reason, the shares subject to the Award shall again be available for the purposes of the Plan. Any Shares which are used by a Participant as full or partial payment to the Company to satisfy the purchase price related to an Award, and any Shares subject to an Award which are not delivered to a Participant because such Shares are used to satisfy an applicable tax withholding obligation, shall not be available for the purposes of the Plan, and shall not be included in the number of Shares reserved hereunder."

Except as specifically amended hereby, the Plan shall continue in full force and effect in accordance with its terms.

[*Signature Page Follows*]

IN WITNESS WHEREOF, this Amendment is hereby executed by a duly authorized officer of the Company as of the first date written above.

GALERA THERAPEUTICS, INC.

By: /s/ J. Mel Sorensen
Name: J. Mel Sorensen
Title: President and Chief Executive Officer

Exhibit 21.1

Subsidiaries of Galera Therapeutics, Inc.

Legal Name of Subsidiary	Jurisdiction of Organization
Galera Labs, LLC	Missouri, United States
Galera Therapeutics Australia Pty Ltd	Australia