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As confidentially submitted to the Securities and Exchange Commission on August 9, 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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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 have applied 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 13 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 170 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 13 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, which to date is not approved for any indication, 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, and we plan to further evaluate its use in 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 median 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 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 Holdings, RA Capital, Rock Springs Capital, Sofinnova Ventures and Tekla Capital.

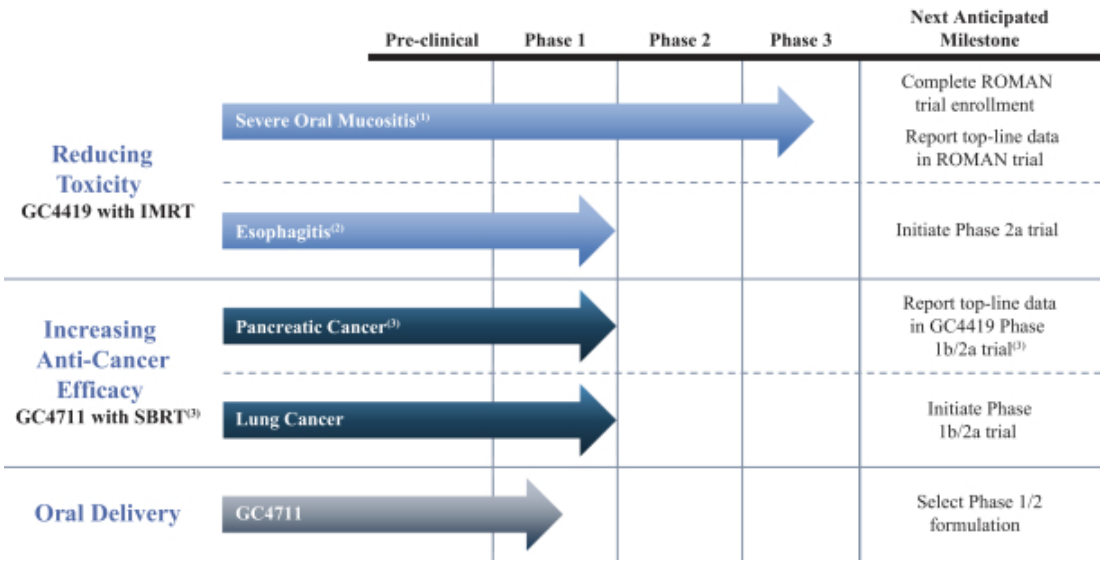
Background on Superoxide Dismutases and Our Dismutase Mimetics

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 have designed, and are developing, our dismutase mimetics to have each of the following essential features—***speed, selectivity, stability, safety and synthesis***.

Our Product Candidates

The following table summarizes our product candidates:



(1) We also plan to conduct a Phase 2a multi-center trial in Europe assessing the safety of 90 mg GC4419 in approximately 40 to 70 patients with HNC undergoing standard-of-care radiotherapy. We plan to initiate this trial in .

(2) Phase 2a trial in patients with lung cancer building on GC4419 safety and tolerability findings in patients with HNC SOM studies.

(3) Observations from our Phase 1b/2a pilot trial of GC4419 in combination with SBRT in patients with LAPC whose tumor cannot be resected will be used 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, which to date is not approved for any indication, 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 a 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 plan to complete 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 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 plan to complete the evaluation of 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 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 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, including as a result of the existence of any clinical holds, 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. However, we are choosing to "opt out" of such extended transition period and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Our decision to opt out of the extended transition period for

complying with new or revised accounting standards is irrevocable. However, we intend to take advantage of the other exemptions discussed above.

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 advance the clinical development of GC4419 and GC4711 and the remainder for new and ongoing research and development activities and working capital and other 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 13 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 June 30, 2019, and excludes:

- shares of our common stock issuable upon the exercise of options outstanding as of June 30, 2019, 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;
- shares of common stock reserved for future issuance pursuant to our 2019 Incentive Award Plan, or the 2019 Plan, which will become effective on the day prior to the first public trading date of our common stock; and
- shares of common stock reserved for future issuance pursuant to our 2019 Employee Stock Purchase Plan, or the 2019 ESPP, which will become effective on the day prior to the first public trading date of our common stock.

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 are derived from our audited consolidated financial statements included elsewhere in this prospectus. The consolidated statements of operations data for the six months ended June 30, 2018 and 2019 and the consolidated balance sheet data as of June 30, 2019 have been derived from our unaudited interim consolidated financial statements to be included elsewhere in this prospectus. In our opinion, the unaudited interim consolidated financial statements have been prepared on a basis consistent with our audited consolidated financial statements and contains all adjustments, consisting only of normal and recurring adjustments, necessary for a fair presentation of such interim financial statements. Our historical results are not necessarily indicative of the results that may be expected in the future and our operating results for the six months ended June 30, 2019 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2019 or any other interim periods or any future year or period. 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,		Six Months Ended June 30,	
	2017	2018	2018	2019
	(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 June 30, 2019		
	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	$	$	$
Working capital(4)			
Total assets			
Royalty purchase liability			
Redeemable convertible preferred stock			
Total stockholders' (deficit) equity			

(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:

- conduct our research and pre-clinical and clinical development of our product candidates, including 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 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 conduct 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 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. For example, on April 29, 2019, we notified the FDA and, shortly thereafter, other regulatory authorities that we had voluntarily suspended dosing of GC4419 in all active clinical studies, including the Phase 3 ROMAN trial, due to testing results of two drug lots showing the appearance of trace amounts of visible fine particles. We elected to suspend use of the affected batches until further characterizing the particles and identifying the root cause. Following our notification to the FDA of the voluntary suspension, our INDs for GC4419 were placed on clinical hold. We have subsequently investigated the issue, identified the particles as manganese carbonate, and confirmed our belief of the absence of patient safety or efficacy concerns. There can be no assurance that this manufacturing issue will not reoccur and one or more of our programs will not be placed on clinical hold.

In addition, our 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. 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.

For example, in an effort to optimize scale-up efficiencies for GC4419, we implemented certain changes to the manufacturing process related to the order of addition of ingredients. However, this manufacturing change inadvertently led to the appearance of trace amounts of visible fine particles in the drug product, which we identified as a manganese carbonate. On April 29, 2019, after becoming aware of the issue, we notified the FDA that we had voluntarily suspended dosing of GC4419 in all active clinical studies, including our Phase 3 ROMAN trial, due to these stability findings. Following notification to the FDA, our INDs for GC4419 were placed on clinical hold. There can be no assurance that this manufacturing issue will not reoccur and one or more of our programs will not be placed on clinical hold.

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.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. On March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the referendum could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business.

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 Phase 3 registrational trial for GC4419 for the reduction in the incidence of SOM in patients with locally advanced HNC receiving radiotherapy and our 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 have applied 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 BofA Securities, Inc. 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.

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.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum to the fullest extent permitted by law, 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 for breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware, our amended and restated certificate of incorporation or our amended and restated bylaws, (4) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws, or (5) any action asserting a claim governed by the internal affairs doctrine. Under our amended and restated certificate of incorporation, this exclusive forum provision will not apply to claims which are vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery of the State of Delaware, or for which the Court of Chancery of the State of Delaware does not have subject matter jurisdiction. For instance, the provision would not apply to actions arising under federal securities laws, including suits brought to enforce any liability or duty created by the Exchange Act or the rules and regulations thereunder. This exclusive forum provision may limit a stockholder's

ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. For example, stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the State of Delaware. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. 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 provisions 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, as follows:

- approximately $ million to advance the clinical development of GC4419 for the reduction of SOM in patients with HNC receiving radiotherapy, including to complete our ROMAN trial, seek regulatory approval and fund pre-commercialization activities and the commercial launch, if approved, of GC4419;
- approximately $ million to advance the clinical development of GC4419 for the reduction of the incidence of radiotherapy-induced esophagitis;
- approximately $ million to advance the clinical development of GC4711 to increase the anti-cancer efficacy of SBRT; and
- the remainder to fund new and ongoing research and development activities, including to develop additional dismutase mimetics and an oral formulation of GC4711, and for working capital and other 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 June 30, 2019 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 June 30, 2019		
	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	$	$	$
Royalty purchase liability	$	$	$
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			
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; 117,000,000 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			
Additional paid-in capital			
Accumulated other comprehensive income			
Accumulated deficit			
Total stockholders’ (deficit) equity			
Total capitalization	$	$	$

(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 June 30, 2019, and excludes:

- shares of common stock issuable upon the exercise of options outstanding as of June 30, 2019, at a weighted-average exercise price of $ per share;
- shares of common stock reserved for future issuance pursuant to our Existing Equity Incentive Plan;
- shares of common stock reserved for future issuance pursuant to our 2019 Plan, which will become effective on the day prior to the first public trading date of our common stock; and
- shares of common stock reserved for future issuance pursuant to the 2019 ESPP, which will become effective on the day prior to the first public trading date of our common stock.

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 June 30, 2019 was $ million, or $ 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 June 30, 2019.

Our pro forma net tangible book value as of June 30, 2019 was $ million, or $ 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 June 30, 2019, 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 June 30, 2019 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 June 30, 2019	$	
Increase per share attributable to the pro forma transactions described above		
Pro forma net tangible book value per share as of June 30, 2019		
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 June 30, 2019, 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 June 30, 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, and excludes:

- shares of common stock issuable upon the exercise of options outstanding as of June 30, 2019, at a weighted-average exercise price of $ per share;
- shares of common stock reserved for future issuance pursuant to our Existing Equity Incentive Plan;

- shares of common stock reserved for future issuance pursuant to our 2019 Plan, which will become effective on the day prior to the first public trading date of our common stock; and

- shares of common stock reserved for future issuance pursuant to the 2019 ESPP, which will become effective on the day prior to the first public trading date of our common stock.

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. We derived the selected consolidated statements of operations data for the six months ended June 30, 2018 and 2019 and the selected consolidated balance sheet data as of June 30, 2019 from our unaudited consolidated interim financial statements to be included elsewhere in this prospectus. In our opinion, the unaudited interim consolidated financial statements have been prepared on a basis consistent with our audited consolidated financial statements and contains all adjustments, consisting only of normal and recurring adjustments, necessary for a fair presentation of such interim financial statements. Our historical results are not necessarily indicative of the results to be expected in the future and our operating results for the six months ended June 30, 2019 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2019 or any other interim periods or any future year or period.

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,		Six Months Ended June 30,	
	2017	2018	2018	2019
	(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	As of December 31, 2018	As of June 30, 2019
		(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, which to date is not approved for any indication, has the potential to be 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 further evaluate its use in 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 $187.8 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;
- fees paid to consultants who assist with research and development activities;
- expenses related to 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 $187.8 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 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 and received the second tranche of the Royalty Purchase Price in April 2019 in connection with the achievement of the second milestone under the Royalty Agreement in March 2019.

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 each of November 2018 and April 2019 and are eligible to receive up to an additional $40.0 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 June 30, 2019 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.

In determining the estimated fair value of common stock, our board of directors considered the subjective factors discussed above in conjunction with the most recent valuations of our common stock that were prepared by an independent third-party. The independent valuation prepared as of December 31, 2016 was utilized by our board of directors when determining the estimated fair value of common stock for the awards granted on January 18, 2017 and March 30, 2017. An independent valuation was also prepared as of December 31, 2017 and utilized for the awards granted on February 28, 2018 and June 21, 2018. The estimated fair value of common stock for the awards granted on January 10, 2019 was determined utilizing the independent valuation prepared as of September 1, 2018. These third-party valuations resulted in a valuation of our common stock of $0.53, $0.86 and $1.40 per share as of December 31, 2016, December 31, 2017 and September 1, 2018, respectively.

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. However, we are choosing to opt out of such extended transition period and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable. However, we may take advantage of the other exemptions discussed below.

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, which to date is not approved for any indication, 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, and we plan to further evaluate its use in 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 median 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 in the first six months from the start of radiotherapy 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. Our market research suggests the potential for significant, rapid uptake of GC4419 for SOM, if approved. In a survey we conducted of 150 U.S. radiation oncologists, respondents stated that they would recommend GC4419 to 69% of their patients with HNC receiving radiotherapy in combination with chemotherapy or targeted therapy. Furthermore, 96% of these physicians stated that they would try GC4419 within the first twelve months of it becoming available and 77% of physicians stated that they would adopt GC4419 within the first 12 months of it becoming available. 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 and between 20% to 30% will develop Grade 4 OM. 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 a 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 plan to complete 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 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.

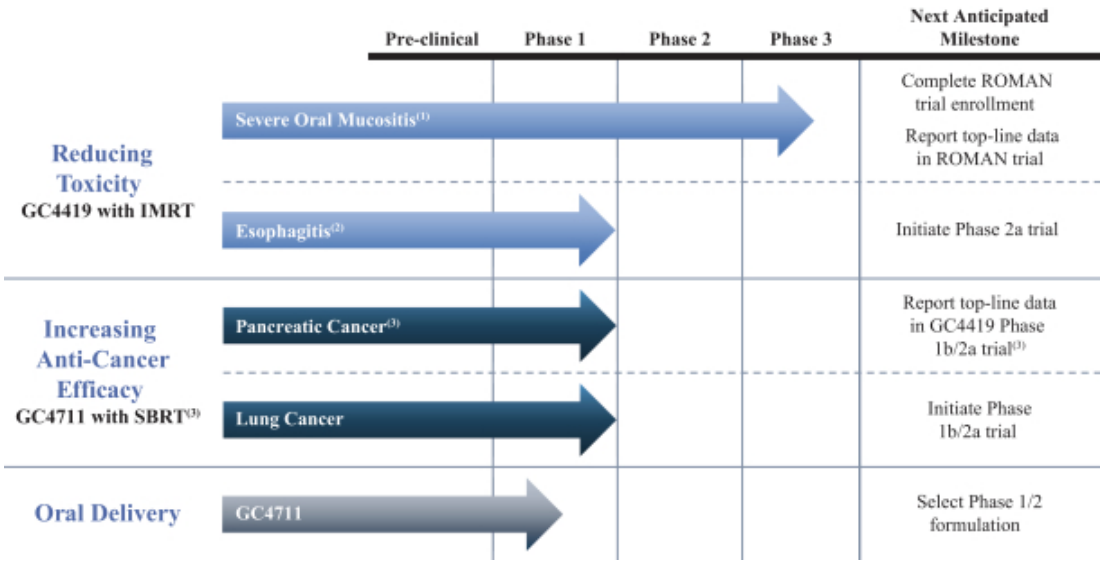
We retain worldwide rights to our product candidate portfolio. Our product candidate portfolio is protected by issued patents with claims directed to composition of matter and method of use, which, when including patent term extensions, are projected to expire between 2027 and 2038 in the United States.

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 Holdings, RA Capital, Rock Springs Capital, Sofinnova Ventures and Tekla Capital.

Our Pipeline

The following table summarizes our product candidates:



(1) We also plan to conduct a Phase 2a multi-center trial in Europe assessing the safety of 90 mg GC4419 in approximately 40 to 70 patients with HNC undergoing standard-of-care radiotherapy. We plan to initiate this trial in .

(2) Phase 2a trial in patients with lung cancer building on GC4419 safety and tolerability findings in patients with HNC SOM studies.

(3) Observations from our Phase 1b/2a pilot trial of GC4419 in combination with SBRT in patients with LAPC whose tumor cannot be resected will be used 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 plan to complete the evaluation of 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 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.

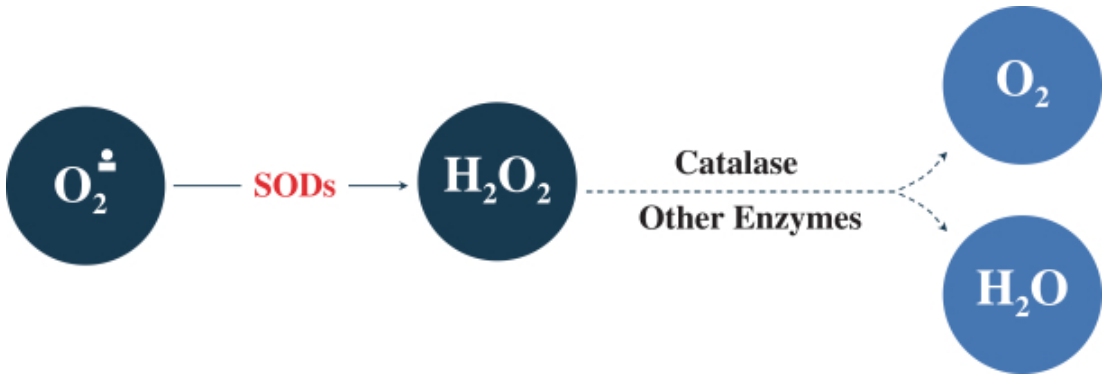
- **Advance the development of GC4711 in combination with SBRT to increase the anti-cancer efficacy of radiotherapy.** Based on extensive pre-clinical research results, we believe that GC4711 has the potential to increase the anti-cancer efficacy and safety profile of SBRT. We successfully completed 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 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;

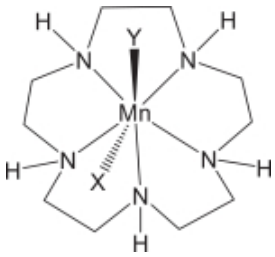
- short half-lives in circulation; and
- inactivation or inhibition by various reactive oxygen species, including hydrogen peroxide.

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



We have designed, and are developing, our dismutase mimetics to have each of the following essential features:

- **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 Patients with Cancer

Over 50% of patients with cancer will be treated with radiotherapy at some time in their treatment cycle. While radiotherapy has variable success depending on the cancer being treated, the toxicity or side effects associated with its use can limit its effectiveness. Radiotherapy causes acute and late toxicities that affect various organs and functions.

One of the most common radiotherapy-induced toxicities results in a condition referred to as mucositis which 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 in the first six months from the start of radiotherapy 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 and between 20% to 30% will develop Grade 4 OM.

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, stated that topical agents are effective in preventing or reducing the incidence of SOM and in treating or reducing the duration of SOM in patients with HNC. The respondents also stated that effectiveness in preventing or reducing the incidence of SOM was the most important product attribute. 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, which to date is not approved for any indication, 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
 	
Currently on clinical hold
	• 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 2a trial for SOM in patients with locally advanced HNC receiving radiotherapy Planned	• Multi-center in Europe • 90 mg GC4419 given before each of typically 35 radiotherapy fractions • Approximately 40 to 70 patients	• Primary objective: assess safety of GC4419 in combination with IMRT and cisplatin • Key secondary objective: evaluate efficacy of GC4419 in reducing the incidence of SOM	• Trial expected to commence in .

Trial and Status	Trial Design	Trial Objectives	Trial Milestones

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 median 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

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.

ROMAN Trial (Phase 3)

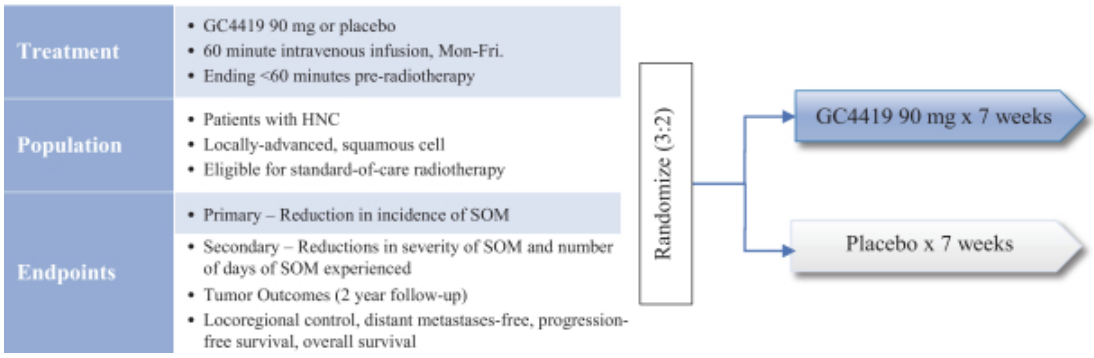
In February 2018, GC4419 was granted Breakthrough Therapy Designation by the FDA for the reduction of the duration, incidence and severity of SOM induced by radiotherapy with or without systemic therapy. As part of our correspondence with the FDA, we received the following guidance:

- 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.

On April 29, 2019, we notified the FDA that we had voluntarily suspended dosing of GC4419 in all active clinical trials due to certain manufacturing issues that we have identified and our INDs for GC4419 were subsequently placed on clinical hold.

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.

Planned European Phase 2a Trial in Patients with HNC

We plan to initiate a Phase 2a multi-center trial of GC4419 in Europe evaluating GC4419 in combination with IMRT and concurrent cisplatin in patients with locally advanced HNC. We expect to enroll approximately 40 to 70 patients in this trial.

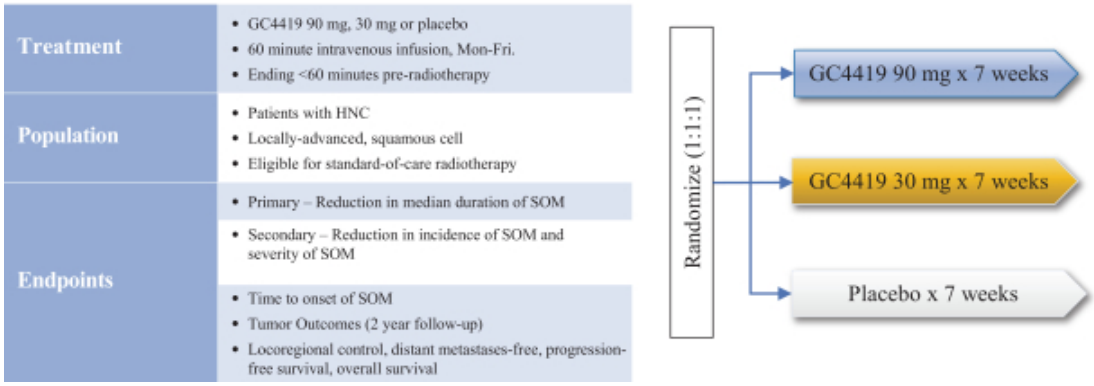
The primary objective of this trial will be to assess the safety of GC4419 in combination with IMRT and concurrent cisplatin. Secondary objectives are expected to include, among others, the reduction in the incidence of SOM through the radiotherapy period.

We expect to initiate this trial in .

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 median 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 median duration of SOM in the 90 mg and 30 mg treatment arms. Median 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).

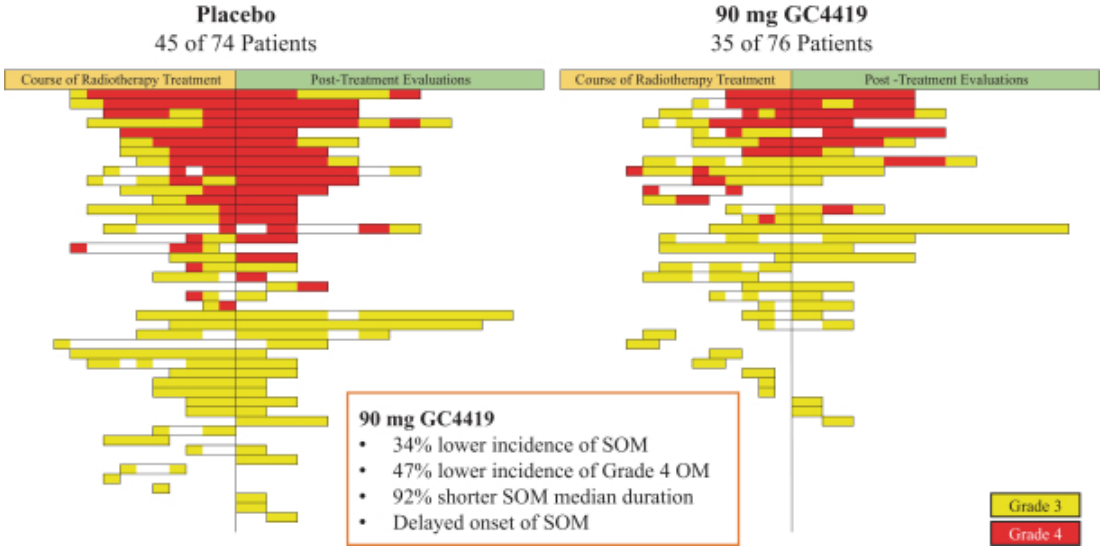
Secondary endpoints included reduction in the incidence and severity of SOM in each of the 90 mg and 30 mg treatment arms. For these purposes, we define the severity of SOM as the incidence of Grade 4 OM. The incidence of SOM in the 90 mg treatment arm was reduced by 36% through 60 Gy and 34% through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

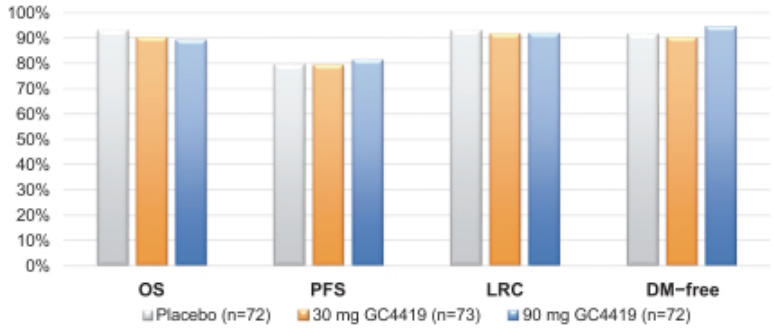
follow-up. Each bar represents a single patient and illustrates the length of time between that patient's first evaluated instance of SOM and his or her last evaluated instance of SOM, along with the severity of his or her SOM during that interval.



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 median duration, incidence and severity.

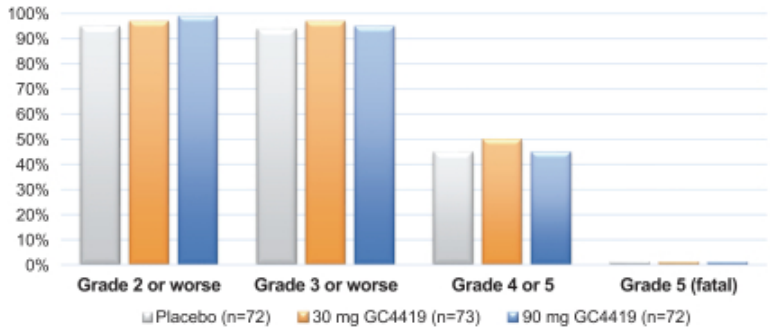
We are following patients from this trial for tumor outcomes out to two years following radiotherapy. In a one-year interim assessment of tumor outcomes, we observed similar outcomes among the three arms in OS, PFS, LRC and DM-free rates.

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. 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	• 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 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 approximately 5%. 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.

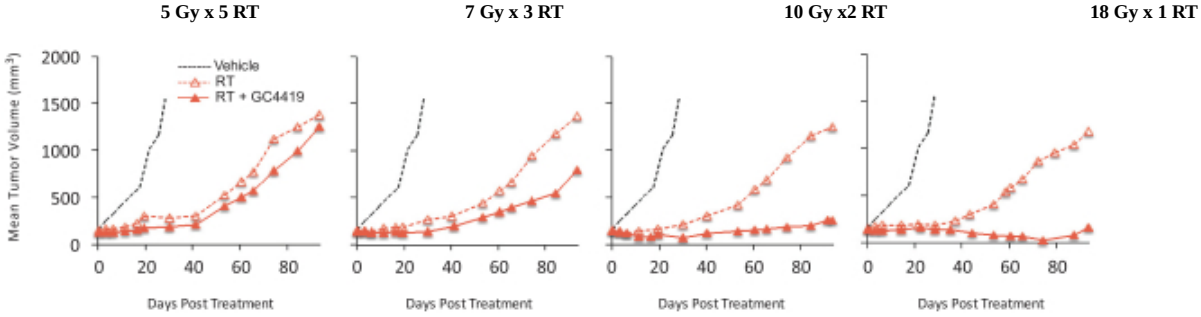
In this trial, GC4711 was observed to be well tolerated, with the most frequently reported adverse events being mild to moderate headache and infusion site pain. There were no Grade 3, 4, or 5 adverse events, and no adverse events led to withdrawal from the study.

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 .

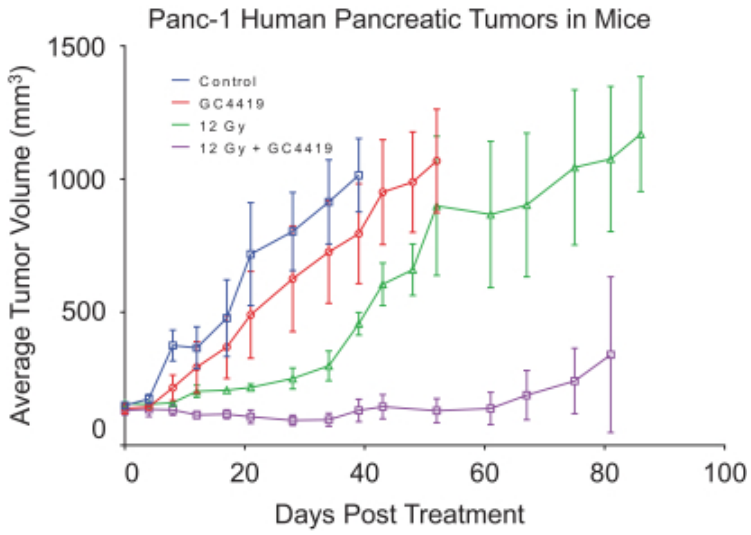
Pre-Clinical Results

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.

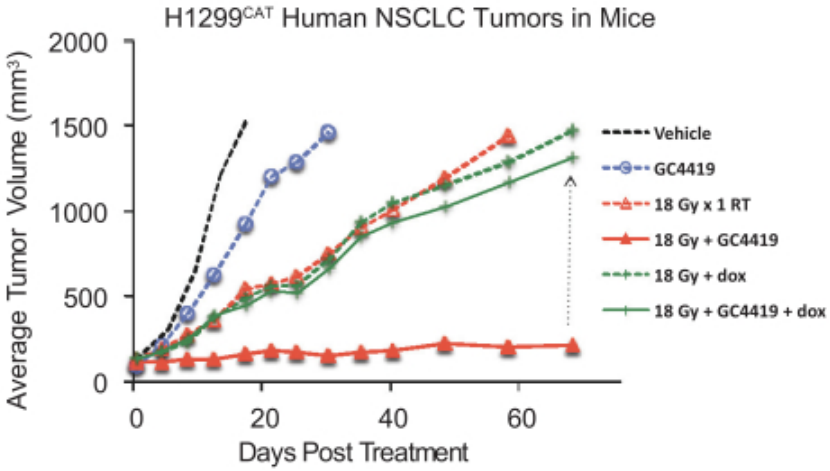
H1299 Human NSCLC Tumors in Mice



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 NSCLC, LAPC and other cancers. SBRT application for large or centrally located NSCLC 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 Commenced in February 2018 Currently on clinical hold 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 .

Trial and Status	Trial Design	Trial Objectives	Trial Milestones

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.

On April 29, 2019, we notified the FDA that we had voluntarily suspended dosing of GC4419 in all active clinical trials due to certain manufacturing issues that we have identified and our INDs for GC4419 were subsequently placed on clinical hold.

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 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 June 30, 2019, our owned and currently pending and/or in-force patent portfolio consisted of approximately 15 issued U.S. patents, six pending U.S. patent applications, 69 issued foreign patents including seven issued European patents that have been validated in many European countries, and 63 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 June 30, 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 and received the second tranche of the Royalty Purchase Price in April 2019 in connection with the achievement of the second milestone under the Royalty Agreement in March 2019.

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.

FDA Expedited 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 June 30, 2019, we had 26 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
Arthur Fratamico, R.Ph	53	Chief Business Officer
Jon T. Holmlund, M.D.	62	Chief Medical Officer
Dennis P. Riley, Ph.D.	72	Chief Scientific Officer
Joel Sussman	70	Chief Accounting Officer
Non-Employee Directors		
Michael Powell, Ph.D.	64	Chairman of the Board
Lawrence Alleva	69	Director
Emmett Cunningham, M.D., Ph.D., MPH	58	Director
Thomas Dyrberg, M.D., D.M.Sc.	64	Director
Jason Fuller, Ph.D.	42	Director
Kevin Lokay	62	Director
Campbell Murray, M.D.(1)	43	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.

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.

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.

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.

Joel Sussman has served as our Chief Accounting Officer since April 2019, and served as our Chief Financial Officer and Treasurer from December 2012 to April 2019. Mr. Sussman is currently a financial management consultant serving as the principal financial officer for Five Eleven Pharma and Oncopia Therapeutics and has served as a financial management consultant for several private life sciences companies. Mr. Sussman serves on the board of directors of Galera Therapeutics Australia, a wholly-owned subsidiary of the Company. Mr. Sussman received a B.A. in English literature from Yale University and an M.B.A. from the Wharton School of the University of Pennsylvania. Mr. Sussman is a licensed certified public accountant.

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.

Lawrence Alleva has served as a member of our board of directors since June 2019 and also serves as Chair of our Audit Committee. He is a former partner with PricewaterhouseCoopers LLP (PwC), where he worked for 39 years from 1971 until his retirement in June 2010, including 28 years' service as a partner. Mr. Alleva worked with numerous pharmaceutical and biotechnology companies as clients and, additionally, served PwC in a variety of office, regional and national practice leadership roles, most recently as the U.S. Ethics and Compliance Leader for the firm's Assurance Practice from 2006 until 2010. Mr. Alleva currently serves on the board of directors of Bright Horizons Family Solutions, Inc., Mersana Therapeutics, Inc. and Adaptimmune Therapeutics PLC and chairs the audit committee for those companies. He previously served on the board of

directors of TESARO, Inc. through the time of its sale to GSK in January 2019, Mirna Therapeutics, Inc. which was merged into another company in 2017 and of GlobalLogic, Inc. through the sale of the company in 2013, and he chaired the audit committee for those companies. Mr. Alleva is a Certified Public Accountant (inactive). He received a B.S. degree in Accounting from Ithaca College and attended Columbia University's Executive M.B.A. non-degree program.

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. 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.

Kevin Lokay has served as a member of our board of directors since March 2019. Mr. Lokay is Head of the U.S. Lung Cancer Franchise at AstraZeneca plc, a position he has held since August 2018. Mr. Lokay served as an advisor to AbbVie Inc. from August 2017 until December 2017. Mr. Lokay was previously Vice President and Business Unit Head, Oncology at Boehringer Ingelheim, a position he held from December 2009 until December 2016. Prior to joining Boehringer Ingelheim, he was President and Chief Executive Officer of Cytogen Corporation from 2007 until 2008 and served in various positions at GlaxoSmithKline from 1997 until 2007 and at Merck & Co. from 1981 until 1997. Mr. Lokay received a B.A. in Economics from Lafayette College and a M.S. from Purdue University. We believe that Mr. Lokay is qualified to serve on our board of directors due to his extensive experience in the biopharmaceutical industry.

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. 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 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 or amended 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 named executive officers 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 named executive officers 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 18,148,833 shares of our common stock for issuance under the Existing Equity Incentive Plan as of June 30, 2019.

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) % of the shares outstanding on the final day of the immediately preceding calendar year and (B) a smaller number of shares as 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 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).

- *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.

2019 Employee Stock Purchase 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 Employee Stock Purchase Plan, or the 2019 ESPP. The material terms of the 2019 ESPP are summarized below.

Shares Available for Awards; Administration

A total of shares of our common stock will initially be reserved for issuance under the 2019 ESPP. In addition, the number of shares available for issuance under the 2019 ESPP will be annually increased on January 1 of each calendar year, beginning in 2020 and ending in and including 2029, by an amount equal to the lesser of (A) % of the shares outstanding on the final day of the immediately preceding calendar year, and (B) a smaller number of shares as determined by our board of directors, provided that no more than shares of our common stock may be issued under the 2019 ESPP. The foregoing numbers are subject to adjustment in certain events, as described below. Our board of directors or a committee of our board of directors will have authority to interpret the terms of the 2019 ESPP and determine eligibility of participants. We expect that the compensation committee will be the initial administrator of the 2019 ESPP.

Eligibility

Unless otherwise determined by the plan administrator and permitted under Section 423 of the Code, all of our employees are eligible to participate in the 2019 ESPP, other than employees that, immediately after the grant, would own (directly or through attribution) stock possessing 5% or more of the total combined voting power or value of all classes of our stock.

Grant of Rights

The 2019 ESPP is intended to qualify under Section 423 of the Code. Stock will be offered under the 2019 ESPP during offering periods. The length of the offering periods will be determined by the plan administrator and may be up to twenty-seven months long. Employee payroll deductions will be used to purchase shares on each purchase date during an offering period. The purchase dates for each offering period will be the final trading day in the offering period. Offering periods under the 2019 ESPP will commence when determined by the plan administrator. The plan administrator may, in its discretion, modify the terms of future offering periods.

The 2019 ESPP permits participants to purchase common stock through payroll deductions up to a percentage determined by the plan administrator of a participant's gross base compensation for services to us, including overtime payments and excluding sales commissions, incentive compensation, bonuses, expense reimbursements, fringe benefits and other special payments. The plan administrator will establish a maximum number of shares that may be purchased by a participant during any offering period, which, in the absence of a contrary designation, will be shares. In addition, no employee will be permitted to accrue the right to purchase stock under the 2019 ESPP at a rate in excess of $25,000 worth of shares during any calendar year in which such a purchase right is outstanding (based on the fair market value per share of our common stock as of the first day of the offering period).

On the first trading day of each offering period, each participant will automatically be granted an option to purchase shares of our common stock. The option will expire at the end of the applicable offering period, and will be exercised at that time to the extent of the payroll deductions accumulated during the offering period. The purchase price of the shares, in the absence of a contrary designation, will be 85% of the lower of the fair

market value of our common stock on the first trading day of the offering period or on the purchase date. Participants may voluntarily end their participation in the 2019 ESPP at any time at least one week prior to the end of the applicable offering period, and will be paid their accrued payroll deductions that have not yet been used to purchase shares of common stock. Participation ends automatically upon a participant's termination of employment.

A participant may not transfer rights granted under the 2019 ESPP other than by will or the laws of descent and distribution.

Certain Transactions

In the event of certain non-reciprocal transactions or events affecting our common stock, known as "equity restructurings," the plan administrator will make equitable adjustments to the 2019 ESPP and outstanding rights. In the event of certain unusual or non-recurring events or transactions, including a change in control, the plan administrator may provide for (1) either the replacement of outstanding rights with other rights or property or termination of outstanding rights in exchange for cash, (2) the assumption or substitution of outstanding rights by the successor or survivor corporation or parent or subsidiary thereof, if any, (3) the adjustment in the number and type of shares of stock subject to outstanding rights, (4) the use of participants' accumulated payroll deductions to purchase stock on a new purchase date prior to the next scheduled purchase date and termination of any rights under ongoing offering periods, or (5) the termination of all outstanding rights.

Plan Amendment

The plan administrator may amend, suspend or terminate the 2019 ESPP at any time. However, stockholder approval will be obtained for any amendment that increases the aggregate number or changes the type of shares that may be sold pursuant to rights under the 2019 ESPP, changes the corporations or classes of corporations whose employees are eligible to participate in the 2019 ESPP or changes the 2019 ESPP in any manner that would cause the 2019 ESPP to no longer be an employee stock purchase plan within the meaning of Section 423(b) of the Code.

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 and received the second tranche of the Royalty Purchase Price in April 2019 in connection with the achievement of the second milestone under the Royalty Agreement in March 2019. 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 and the six months ended June 30, 2019 were $0.2 million and , respectively.

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 June 30, 2019, 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 June 30, 2019, 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 June 30, 2019, 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 June 30, 2019 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)	3,258,626	3.3	
Robert A. Beardsley, Ph.D.(7)	1,872,832	1.9	
Arthur Fratamico, R.Ph(8)	628,129	*	
Jon T. Holmlund, M.D.(9)	730,553	*	
Michael Powell, Ph.D.(10)	11,800,568	12.1	
Lawrence Alleva	—	—	
Emmett Cunningham, M.D.(11)	—	—	
Thomas Dyrberg, M.D.(12)	—	—	
Jason Fuller, Ph.D.(13)	—	—	
Kevin Lokay(14)	10,416	*	
Campbell Murray, M.D.(2)	16,651,609	17.0	
All executive officers and directors as a group (13 individuals)(15)	36,413,168	37.2	

* 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. Novo Holdings A/S, through its board of directors (the "Novo Board"), has the sole power to vote and dispose of the shares. Francis Michael Cyprian Cuss,

Jean-Luc Butel, Viviane Monges, Jeppe Christiansen, Steen Riisgaard, and Lars Rebien Sørensen 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) Consists of (i) 2,334,966 shares of our redeemable convertible preferred stock held of record by Clarus IV-A, L.P., (ii) 1,552,035 shares of our redeemable convertible preferred stock held of record by Clarus IV-B, L.P., (iii) 2,807,372 shares of our redeemable convertible preferred stock held of record by Clarus IV-C, L.P., and (iv) 561,385 shares of our redeemable convertible preferred stock held of record by Clarus IV-D, L.P., or collectively, the Clarus Funds, which shares will convert into an aggregate of shares of our common stock upon the closing of this offering. Clarus IV, GP, L.P., or Clarus GP, is the general partner of each of the Clarus Funds. Blackstone Clarus GP L.P. is the general partner of Clarus GP. Blackstone Clarus GP L.L.C. is the general partner of Blackstone Clarus GP L.P. The sole member of Blackstone Clarus GP L.L.C. is Blackstone Holdings II L.P. The general partner of Blackstone Holdings II L.P. is Blackstone Holdings I/II GP Inc. The controlling shareholder of Blackstone Holdings I/II GP Inc. is The Blackstone Group L.P. The general partner of The Blackstone Group L.P. is Blackstone Group Management L.L.C. Blackstone Group Management L.L.C. is wholly-owned by Blackstone's senior managing directors and controlled by its founder, Stephen A. Schwarzman. Each of such entities and Mr. Schwarzman may be deemed to beneficially own the shares beneficially owned by the Clarus Funds directly or indirectly controlled by it or him, but each (other than the Clarus Funds to the extent of their direct holdings) disclaims beneficial ownership of such shares. The address for each of the Clarus Funds and Clarus GP is c/o Clarus Ventures, 101 Main Street, Suite 1210, Cambridge, Massachusetts 02142. The address for each of the other Blackstone entities and Mr. Schwarzman is c/o The Blackstone Group L.P., 345 Park Avenue, New York, New York 10154.

(6) Includes (i) 76,000 shares of common stock and (ii) 3,182,626 shares of common stock underlying stock options exercisable within 60 days of June 30, 2019.

(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) 1,528,011 shares of common stock underlying stock options exercisable within 60 days of June 30, 2019.

(8) Consists of 628,129 shares of common stock underlying stock options exercisable within 60 days of June 30, 2019.

(9) Consists of 730,553 shares of common stock underlying stock options exercisable within 60 days of June 30, 2019.

(10) 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.

(11) Dr. Cunningham is a Senior Managing Director of an entity affiliated with the Clarus Funds. Dr. Cunningham is not deemed to have any beneficial ownership in the shares held by the Clarus Funds listed in footnote (5) above.

(12) Dr. Dyrberg is a managing partner of Novo Holdings A/S. Dr. Dyrberg is not deemed to have any beneficial ownership or reportable pecuniary interest in the shares held by Novo Holdings A/S listed in footnote (3) above.

(13) Dr. Fuller is a Principal at New Enterprise Associates. Dr. Fuller has no voting or dispositive power with regard to any of the shares held by NEA 14 or Ven 2012 listed in footnote (1) above and disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein.

(14) Consists of 10,416 shares of common stock underlying stock options exercisable within 60 days of June 30, 2019.

(15) Includes 7,151,903 shares of common stock underlying stock options exercisable within 60 days of June 30, 2019.

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 June 30, 2019, 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 June 30, 2019, 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 June 30, 2019, options to purchase 15,824,927 shares of our common stock were outstanding under our Existing Equity Incentive Plan, of which 8,931,695 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. Under our amended and restated certificate of incorporation, this exclusive forum provision will not apply to claims which are vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery of the State of Delaware, or for which the Court of Chancery of the State of Delaware does not have subject matter jurisdiction. For instance, the provision would not apply to actions arising under federal securities laws, including suits brought to enforce any liability or duty created by the Exchange Act or the rules and regulations thereunder. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. 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. 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 have applied 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 have applied 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 June 30, 2019 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 BofA Securities, Inc. 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 BofA Securities, Inc. 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

BofA Securities, Inc., 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
BofA Securities, Inc.	
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 BofA Securities, Inc. 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. BofA Securities, Inc. 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 have applied 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 (each a "Member State"), no shares have been offered or will be offered pursuant to this offering to the public in that Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in that Member State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Member State at any time under the following exemptions under the Prospectus Regulation:

(a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require the Company or any representative to publish a prospectus pursuant to Article 3 of the Prospectus Regulation, or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Member State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with the Company and the representatives that it is a qualified investor within the meaning of the Prospectus Regulation. In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in a Relevant Member State to qualified investors, in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

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

For the purposes of this provision, the expression an "offer to the public" in relation to any shares in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129 (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 Regulation) (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, the shares were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (the "SFA")) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

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

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

(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 or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

(a) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(b) where no consideration is or will be given for the transfer;

(c) where the transfer is by operation of law; or

(d) as specified in Section 276(7) of the SFA.

Notice to Prospective Investors in Canada

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

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 accounts for forfeitures for stock option awards as they occur. 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.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 13,573,118 shares of our common stock, having exercise prices ranging from $0.47 to $1.83 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
10.15#*	Galera Therapeutics, Inc. 2019 Employee Stock Purchase Plan
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.

** Previously filed.

# Indicates management contract or compensatory plan.

† Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

(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
Joel Sussman	Chief Accounting Officer (principal financial and accounting officer)	, 2019
Michael Powell, Ph.D.	Chairman of the Board of Directors	, 2019
Lawrence Alleva	Director	, 2019
Emmett Cunningham, M.D., Ph.D., MPH	Director	, 2019
Thomas Dyrberg, M.D., D.M.Sc.	Director	, 2019
Jason Fuller, Ph.D.	Director	, 2019
Kevin Lokay	Director	, 2019
Campbell Murray, M.D.	Director	, 2019