

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2019

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 001-39114

Galera Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2 W Liberty Blvd #100
Malvern, Pennsylvania
(Address of principal executive offices)

46-1454898
(I.R.S. Employer
Identification No.)

19355
(Zip Code)

(610) 725-1500

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	GRTX	The Nasdaq Global Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of December 9, 2019, the registrant had 24,807,789 shares of common stock, \$0.001 par value per share, outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. All statements other than statements of historical facts contained in this Quarterly Report 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. All statements other than statements of historical fact contained in this Quarterly Report, including without limitation statements regarding our plans to develop and commercialize our product candidates, the timing of our ongoing or planned clinical trials, the timing of and our ability to obtain and maintain regulatory approvals, 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 our product candidates, the sufficiency of our cash, cash equivalents and short-term investments, and the plans and objectives of management for future operations and capital expenditures are forward-looking statements.

The forward-looking statements in this Quarterly Report 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 Quarterly Report and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the sections in this Quarterly Report entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Quarterly Report.

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. We intend the forward-looking statements contained in this Quarterly Report to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

GALERA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS EXCEPT SHARE AND PER-SHARE AMOUNTS)
(unaudited)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 15,719	\$ 14,811
Short-term investments	52,226	66,706
Tax incentive receivable	—	870
Prepaid expenses and other current assets	4,197	1,465
Total current assets	72,142	83,852
Property and equipment, net	970	568
Acquired intangible asset	2,258	2,258
Goodwill	881	881
Deferred offering costs	2,103	—
Right-of-use lease asset	876	—
Other assets	528	497
Total assets	\$ 79,758	\$ 88,056
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 5,218	\$ 3,867
Accrued expenses	3,574	2,577
Lease liability	291	—
Total current liabilities	9,083	6,444
Royalty purchase liability	42,313	20,220
Deferred rent	—	12
Lease liability, net of current portion	604	—
Deferred tax liability	298	298
Total liabilities	52,298	26,974
Redeemable convertible preferred stock, \$0.001 par value: 96,385,795 shares authorized, issued and outstanding at September 30, 2019 and December 31, 2018, respectively (liquidation value of \$174,746 at September 30, 2019)	172,080	165,902
Stockholders' deficit:		
Preferred stock, \$0.001 par value: 10,000,000 shares authorized; no shares issued and outstanding.	—	—
Common stock, \$0.001 par value: 200,000,000 shares authorized; 300,597 shares issued and outstanding at September 30, 2019 and December 31, 2018	—	—
Accumulated other comprehensive income	55	3
Accumulated deficit	(144,675)	(104,823)
Total stockholders' deficit	(144,620)	(104,820)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	\$ 79,758	\$ 88,056

See accompanying notes to unaudited interim consolidated financial statements.

GALERA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS EXCEPT SHARE AND PER SHARE AMOUNTS)
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	\$ 11,040	\$ 4,162	\$ 29,057	\$ 11,551
General and administrative	1,816	1,245	5,466	3,846
Loss from operations	(12,856)	(5,407)	(34,523)	(15,397)
Other income (expenses):				
Interest income	426	117	1,397	170
Interest expense	(918)	—	(2,094)	—
Foreign currency loss	(3)	(11)	(38)	(27)
Loss before income tax benefit	(13,351)	(5,301)	(35,258)	(15,254)
Income tax benefit	—	52	—	141
Net loss	(13,351)	(5,249)	(35,258)	(15,113)
Accretion of redeemable convertible preferred stock to redemption value	(2,108)	(1,468)	(6,178)	(3,879)
Net loss attributable to common stockholders	\$ (15,459)	\$ (6,717)	\$ (41,436)	\$ (18,992)
Net loss per share of common stock, basic and diluted	\$ (51.43)	\$ (22.35)	\$ (137.85)	\$ (63.18)
Weighted-average shares of common stock outstanding, basic and diluted	300,597	300,597	300,597	300,597

See accompanying notes to unaudited interim consolidated financial statements.

GALERA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(IN THOUSANDS)
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Net loss	\$ (13,351)	\$ (5,249)	\$ (35,258)	\$ (15,113)
Unrealized gain on short-term investments	(26)	—	52	3
Comprehensive loss	<u>\$ (13,377)</u>	<u>\$ (5,249)</u>	<u>\$ (35,206)</u>	<u>\$ (15,110)</u>

See accompanying notes to unaudited interim consolidated financial statements.

GALERA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)
(unaudited)

	Nine months ended September 30,	
	2019	2018
Operating activities:		
Net loss	\$ (35,258)	\$ (15,113)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	188	86
Noncash interest expense	2,094	—
Share-based compensation expense	1,584	654
Reserve for tax incentive receivable	241	—
Deferred tax liability	—	(141)
Deferred rent	7	(1)
Changes in operating assets and liabilities:		
Tax incentive receivable	629	(149)
Prepaid expenses and other current assets	(2,732)	(168)
Other assets	(31)	(255)
Accounts payable	1,131	(308)
Accrued expense	762	(153)
Cash used in operating activities	<u>(31,385)</u>	<u>(15,548)</u>
Investing activities:		
Purchases of short-term investments	(63,468)	(16,406)
Proceeds from sales of short-term investments	78,000	9,000
Purchase of property and equipment	(567)	(48)
Cash provided by (used in) investing activities	<u>13,965</u>	<u>(7,454)</u>
Financing activities:		
Proceeds from royalty purchase agreement	20,000	—
Proceeds from the sale of Series C redeemable convertible preferred stock, net of issuance costs	—	69,850
Payment of deferred offering costs	(1,672)	—
Cash provided by financing activities	<u>18,328</u>	<u>69,850</u>
Net increase in cash and cash equivalents	908	46,848
Cash and cash equivalents at beginning of period	14,811	6,169
Cash and cash equivalents at end of period	<u>\$ 15,719</u>	<u>\$ 53,017</u>
Supplemental schedule of non-cash financing activities:		
Accretion of redeemable convertible preferred stock to redemption value	\$ 6,178	\$ 3,879
Deferred offering costs included in accounts payable and accrued expenses	\$ 431	\$ —
Purchase of property and equipment included in accounts payable and accrued expenses	\$ 24	\$ 268
Initial recognition of operating lease right-of-use asset and operating lease liability	\$ 1,084	\$ —

See accompanying notes to unaudited interim consolidated financial statements.

GALERA THERAPEUTICS, INC.
NOTES TO UNAUDITED INTERIM 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 (SOM). In February 2018, the U.S. Food and Drug Administration (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 (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 locally advanced pancreatic cancer (LAPC) to prepare a GC4711 SBRT combination Phase 1b/2a trial in non-small cell lung cancer (NSCLC).

Reverse Stock Split

The Company effected a one-for-5.056564 reverse stock split of its common stock on October 25, 2019. The reverse stock split combined each approximately five shares of the Company's issued and outstanding common stock into one share of common stock and correspondingly adjusted the conversion price of its redeemable convertible preferred stock. No fractional shares were issued in connection with the reverse stock split. Any fractional share resulting from the reverse stock split was rounded down to the nearest whole share, and in lieu of any fractional shares, the Company will pay in cash to the holders of such fractional shares an amount equal to the fair value, as determined by the board of directors, of such fractional shares. All common stock, per share and related information presented in the unaudited interim consolidated financial statements and accompanying notes have been retroactively adjusted to reflect the reverse stock split.

Liquidity

The Company has incurred recurring losses and negative cash flows from operations since inception and has an accumulated deficit of \$144.7 million as of September 30, 2019. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its product candidates currently in development.

On November 12, 2019, the Company completed an initial public offering (IPO) of its common stock, which resulted in the issuance and sale of 5,000,000 shares of its common stock at a public offering price of \$12.00 per share, generating net proceeds of \$53.1 million after deducting underwriting discounts and other offering costs. On December 9, 2019, in connection with the partial exercise of the over-allotment option granted to the underwriters of the Company's IPO, 445,690 additional shares of common stock were sold at the IPO price of \$12.00 per share, generating net proceeds of approximately \$5.0 million after deducting underwriting discounts and other offering costs. Upon the closing of the IPO, all outstanding shares of the Company's Series A, Series B and Series C redeemable convertible preferred stock were automatically converted into 19,061,502 shares of the Company's common stock. In addition, upon the closing of the IPO, the Company's amended and restated certificate of incorporation authorized the Company to issue up to 200,000,000 shares of common stock, \$0.001 par value per share, and 10,000,000 shares of preferred stock, \$0.001 par value per share, all of which shares of preferred stock will be undesignated.

2. Basis of presentation and significant accounting policies

The summary of significant accounting policies disclosed in the Company's annual consolidated financial statements for the years ended December 31, 2018 and 2017 included in the Company's final prospectus dated November 6, 2019 and filed with the Securities and Exchange Commission (SEC) on November 8, 2019 pursuant to Rule 424(b)(4) have not materially changed, except as set forth below.

Basis of presentation and consolidation

The accompanying unaudited interim consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles (U.S. GAAP) for interim financial information. Any reference in these notes to applicable

guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) of the Financial Accounting Standards Board (FASB).

In the opinion of management, the accompanying interim consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's financial position as of September 30, 2019 and its results of operations for the three and nine months ended September 30, 2019 and 2018, and statement of changes in redeemable convertible preferred stock and stockholder's deficit and cash flows for the nine months ended September 30, 2019 and 2018. Operating results for the three and nine months ended September 30, 2019, respectively, are not necessarily indicative of the results that may be expected for the year ending December 31, 2019, or for any future period. The interim consolidated financial statements, presented herein, do not contain the required disclosures under U.S. GAAP for annual financial statements. Therefore, these interim consolidated financial statements should be read in conjunction with the annual audited consolidated financial statements and related notes as of and for the year ended December 31, 2018, included in the Company's final prospectus for its IPO dated as of November 6, 2019 and filed with the SEC on November 8, 2019 pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended.

Use of estimates

The preparation of unaudited interim 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 unaudited interim 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 unaudited interim 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.

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.

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' deficit, until realized. Short-term investments at September 30, 2019 and December 31, 2018 consisted of U.S. Treasury obligations with fair values of \$52.2 million and \$66.7 million, respectively, and unrealized gains of \$52,000 and \$3,000 during the nine months ended September 30, 2019 and 2018, respectively.

Tax incentive receivable

The Company's wholly owned subsidiary, Galera Therapeutics Australia Pty Ltd (Galera Australia), is eligible to participate in an Australian research and development tax incentive program under which the Company may 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 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.

Since November 2018, the Company has received \$40.0 million in proceeds from its royalty purchase agreement (Note 6). Proceeds from the royalty purchase agreement are recognized as revenue for income tax reporting purposes in the United States. While the Company believes proceeds from its royalty purchase agreement do not represent recurring revenue streams, the Company has recorded a reserve against the tax incentive receivable in its entirety, recognizing that the Australian tax authorities might take a different position. As of September 30, 2019, the Company had a tax incentive receivable and corresponding reserve of \$0.6 million. The Company has requested a private ruling from the Australian Taxation Office regarding its eligibility to participate in the research

and development program. Should such eligibility be confirmed, the related tax credit would result in a reduction to the Company's future research and development expenses.

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 September 30, 2019, the Company believes that no revision of the remaining useful lives or write-down of long-lived assets is required.

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 nine months ended September 30, 2019 and 2018, the Company determined that there was no impairment to goodwill or IPR&D.

Leases

At lease commencement, the Company records a lease liability based on the present value of lease payments over the expected lease term including any options to extend the lease that the Company is reasonably certain to exercise. The Company calculates the present value of lease payments using an incremental borrowing rate as the Company's leases do not provide an implicit interest rate. The Company's incremental borrowing rate for a lease is the rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms. At the lease commencement date, the Company records a corresponding right-of-use lease asset based on the lease liability, adjusted for any lease incentives received and any initial direct costs paid to the lessor prior to the lease commencement date. The Company may enter into leases with an initial term of 12 months or less (Short-Term Leases). For Short-Term Leases, the Company records the rent expense on a straight-line basis and does not record the leases on the interim unaudited balance sheet. The Company had no Short-Term Leases as of September 30, 2019 or December 31, 2018.

After lease commencement, the Company measures its leases as follows: (i) the lease liability based on the present value of the remaining lease payments using the discount rate determined at lease commencement, and (ii) the right-of-use lease asset based on the remeasured lease liability, adjusted for any unamortized lease incentives received, any unamortized initial direct costs and the cumulative difference between rent expense and amounts paid under the lease agreement. Any lease incentives received and any initial direct costs are amortized on a straight-line basis over the expected lease term. Rent expense is recorded on a straight-line basis over the expected lease term.

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 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 of 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 by 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:

	September 30,	
	2019	2018
Stock options	3,099,089	2,071,616
Redeemable convertible preferred stock	19,061,502	19,061,502
	<u>22,160,591</u>	<u>21,133,118</u>

Amounts in the above table reflect the common stock equivalents for the redeemable convertible preferred stock.

Recent accounting pronouncements

In February 2016, the FASB issued 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 Company adopted ASU 2016-02 on January 1, 2019 (Note 7) using the modified retrospective transition approach and elected to apply the package of practical expedients.

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 Company adopted this ASU on January 1, 2019 and it did not have a material impact on the Company's consolidated financial statements.

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. This 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.

The following table presents the Company's assets and liabilities that are measured at fair value on a recurring basis (amounts in thousands):

	September 30, 2019		
	(Level 1)	(Level 2)	(Level 3)
Assets			
Money market funds and U.S. Treasury obligations (included in cash equivalents)	\$ 13,844	\$ —	\$ —
Short-term investments	\$ 52,226	\$ —	\$ —
Assets			
	December 31, 2018		
	(Level 1)	(Level 2)	(Level 3)
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 three or nine months ended September 30, 2019. 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):

	September 30, 2019	December 31, 2018
Laboratory equipment	\$ 741	\$ 507
Computer hardware and software	217	109
Leasehold improvements	243	—
Furniture and fixtures	132	159
Property and equipment, gross	1,333	775
Less: Accumulated depreciation	(363)	(207)
Property and equipment, net	\$ 970	\$ 568

Depreciation expense was \$0.2 million and \$0.1 million for the nine months ended September 30, 2019 and 2018, respectively.

5. Accrued expenses

Accrued expenses consist of (amounts in thousands):

	September 30, 2019	December 31, 2018
Compensation and related benefits	\$ 806	\$ 776
Research and development expenses	2,318	1,665
Professional fees	450	136
	\$ 3,574	\$ 2,577

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. In April 2019, the Company received \$20.0 million in connection with the achievement of the second milestone under the Royalty Agreement.

The Company accounts for the Royalty Agreement as a debt instrument. The \$40.0 million proceeds from the first and second tranche under the Royalty Agreement have been recorded as a liability on the Company's consolidated balance sheets. 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 \$2.1 million in noncash interest expense during the nine months ended September 30, 2019. As of September 30, 2019, 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 \$40.0 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. Leases

The Company has non-cancelable operating leases for office and laboratory space in Malvern, Pennsylvania and St. Louis, Missouri which, as of September 30, 2019, have remaining lease terms of approximately 3.4 and 1.3 years, respectively. The Company adopted ASC 842 on January 1, 2019 resulting in the recognition of a current operating lease liability of \$0.3 million and a noncurrent operating lease liability of \$0.8 million with a corresponding \$1.1 million right-of-use (ROU) asset, which is based on the present value of the minimum rental payments of the lease. The discount rate used to account for the Company's operating lease under ASC 842 is the Company's estimated incremental borrowing rate of 5.3%.

Rent expense related to the Company's operating leases was approximately \$0.3 million during each of the nine months ended September 30, 2019 and 2018. Future minimum rental payments under the Company's non-cancelable operating leases were as follows as of September 30, 2019 (amounts in thousands):

Remainder of 2019	\$	84
2020		332
2021		264
2022		262
2023		45
Total		987
Less: imputed interest		(75)
	\$	<u>912</u>

Future minimum lease payments under non-cancelable operating leases as of December 31, 2018 were as follows (amounts in thousands):

2019	\$ 440
2020	460
2021	392
2022	391
2023	65
	<u>\$ 1,748</u>

8. Redeemable convertible preferred stock

As of September 30, 2019, the authorized, issued and outstanding shares of redeemable convertible preferred stock and their principal terms were as disclosed below (in thousands except share amounts). All of the preferred shares were converted in common stock at the time of the IPO.

	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Liquidation Value
Series A	22,280,087	22,280,087	\$ 29,652	\$ 30,298
Series B	29,682,000	29,682,000	45,264	46,001
Series B-1	3,636,363	3,636,363	5,988	6,107
Series B-2	9,090,909	9,090,909	17,274	17,586
Series C	31,696,436	31,696,436	73,902	74,754
	<u>96,385,795</u>	<u>96,385,795</u>	<u>\$ 172,080</u>	<u>\$ 174,746</u>

9. Share-based compensation

In November 2012, the Company adopted the Equity Incentive Plan (the Prior Plan). The total number of shares authorized under the Prior Plan as of September 30, 2019 was 3,589,163. Of this amount, 490,074 shares were available for future grants as of September 30, 2019. Eligible participants include employees, directors and consultants. The Prior 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 three and nine months ended September 30, 2019 and 2018 (amounts in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Research and development	\$ 274	\$ 111	\$ 787	\$ 328
General and administrative	246	109	797	326
	<u>\$ 520</u>	<u>\$ 220</u>	<u>\$ 1,584</u>	<u>\$ 654</u>

The following table summarizes the activity related to stock option grants for the nine months ended September 30, 2019:

	Shares	Weighted average exercise price per share	Weighted- average remaining contractual life (years)
Outstanding at January 1, 2019	2,071,616	\$ 2.17	
Granted	1,146,367	7.45	
Forfeited	(118,894)	5.36	
Outstanding at September 30, 2019	3,099,089	\$ 4.00	7.1
Vested and exercisable at September 30, 2019	1,906,827	\$ 2.42	6.0
Vested and expected to vest at September 30, 2019	3,099,089	\$ 4.00	7.1

As of September 30, 2019, the unrecognized compensation cost was \$5.6 million and will be recognized over an estimated weighted-average amortization period of 3.1 years. The aggregate intrinsic value of options outstanding and options exercisable as of September 30, 2019 was \$17.4 million and \$13.7 million, respectively. Options granted during the nine months ended September 30, 2019 and 2018 had weighted-average grant-date fair values of \$5.61 and \$3.48 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 nine months ended September 30, 2019 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 was not publicly traded prior to the IPO, its board of directors has 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:

	Nine months ended September 30,	
	2019	2018
Expected term (in years)	6.2	7.8
Expected stock price volatility	90.0%	88.0%
Risk-free interest rate	2.51%	2.79%
Expected dividend yield	0%	0%
Fair value of common stock	\$ 7.45	\$ 4.38

10. Related party transactions

IntellectMap provides advisory services to the Company. The chief executive officer of IntellectMap is the brother of the Company's chief executive officer. Fees incurred by us with respect to IntellectMap during the nine months ended September 30, 2019 and 2018 were \$0.2 million and \$0.2 million, respectively.

11. Subsequent events

On November 12, 2019, the Company completed the IPO, which resulted in the issuance and sale of 5,000,000 shares of its common stock at a public offering price of \$12.00 per share, generating net proceeds of \$53.1 million after deducting underwriting discounts and other offering costs. On December 9, 2019, in connection with the partial exercise of the over-allotment option granted to the underwriters of the Company's IPO, 445,690 additional shares of common stock were sold at the IPO price of \$12.00 per share, generating net proceeds of approximately \$5.0 million after deducting underwriting discounts and other offering costs. Upon the closing of the IPO, all outstanding shares of the Company's Series A, Series B and Series C convertible preferred stock were automatically converted into 19,061,502 shares of the Company's common stock. In addition, upon the closing of the IPO, the Company's amended and restated certificate of incorporation authorized the Company to issue up to 200,000,000 shares of common stock, \$0.001 par value per share, and 10,000,000 shares of preferred stock, \$0.001 par value per share, all of which shares of preferred stock will be undesignated.

In November 2019, the Company's board of directors adopted and the Company's stockholders approved the Galera Therapeutics, Inc. 2019 Incentive Award Plan (the 2019 Plan), which became effective upon the effectiveness of the registration statement on Form S-1 for the IPO. Upon effectiveness of the 2019 Plan, the Company ceased granting new awards under the Prior Plan.

The 2019 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, restricted stock units, stock appreciation rights and other stock-based awards. The number of shares of common stock initially available for issuance under the 2019 Plan is 1,948,970 shares of common stock plus the number of shares subject to awards outstanding under the Prior Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company on or after the effective date of the 2019 Plan. In addition, the number of shares of common stock available for issuance under the 2019 Plan is subject to an annual increase on the first day of each calendar year beginning on January 1, 2020 and ending on and including January 1, 2029 equal to the lesser of (i) 4% of the Company's outstanding shares of common stock on the final day of the immediately preceding calendar year, and (ii) such smaller number of shares of common stock as determined by the Company's board of directors, provided that not more than 14,130,029 shares of common stock may be issued under the 2019 Plan upon the exercise of incentive stock options.

In November 2019, the Company's board of directors adopted and the Company's stockholders approved the Galera Therapeutics, Inc. 2019 Employee Stock Purchase Plan (the ESPP). The ESPP allows employees to buy Company stock through after-tax payroll deductions at a discount from market value. The number of shares of common stock initially available for issuance under the ESPP is 243,621 shares of common stock plus an annual increase on the first day of each calendar year beginning on January 1, 2020 and ending on and including January 1, 2029 equal to the lesser of (i) 1% of the Company's outstanding shares of common stock on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of common stock as determined by the Company's board of directors, provided that not more than 3,288,886 shares of common stock may be issued under the ESPP.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many important factors including those set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in, or implied, by these forward-looking statements.

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. 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. In October 2018, we began evaluating GC4419 in a Phase 3 registrational trial and we expect to report top-line data from this trial in the first half of 2021. 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 equity and proceeds received under the Royalty Agreement with Clarus, receiving aggregate gross proceeds of \$187.8 million through September 30, 2019. On November 12, 2019, we completed our initial public offering, or IPO, which resulted in the issuance and sale of 5,000,000 shares of common stock at the IPO price of \$12.00 per share, generating net proceeds of \$53.1 million after deducting underwriting discounts and other offering costs. On December 9, 2019, in connection with the partial exercise of the over-allotment option granted to the underwriters of our IPO, 445,690 additional shares of common stock were sold at the IPO price of \$12.00 per share, generating net proceeds of approximately \$5.0 million after deducting underwriting discounts and other offering costs. 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 \$23.7 million and \$23.5 million for the years ended December 31, 2018 and 2017, respectively, and \$35.3 million and \$15.1 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had \$67.9 million in cash, cash equivalents and short-term investments and an accumulated deficit of \$144.7 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we operate as a public company, 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.

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 our IPO and assumed payments from Clarus to us in the amount of \$40.0 million upon the achievement of the two remaining specified clinical milestones in our *Phase 3 Reduction in Oral Mucositis with Avasopasem Manganese Trial* (ROMAN trial), will enable us to fund our operating expenses and capital expenditure requirements into 2022.

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.

Our critical accounting policies are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies" in our final prospectus for our IPO dated November 6, 2019 and filed with the SEC on November 8, 2019 pursuant to Rule 424(b)(4) under the Securities Act and the notes to the unaudited interim consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. During the three months ended September 30, 2019 there were no material changes to our critical accounting policies from those discussed in our final prospectus filed on November 8, 2019.

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 contract research organizations, or CROs, as well as investigative sites and consultants that conduct our pre-clinical studies and clinical trials;
- expenses incurred under agreements with contract manufacturing organizations, or 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 three and nine months ended September 30, 2019 and 2018:

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
GC4419	\$ 7,271	\$ 1,956	\$ 18,471	\$ 5,767
GC4711	1,566	792	4,367	1,756
Other research and development expense	436	308	1,425	668
Personnel related and share-based compensation expense	1,767	1,106	4,794	3,360
	<u>\$ 11,040</u>	<u>\$ 4,162</u>	<u>\$ 29,057</u>	<u>\$ 11,551</u>

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 to enable us to operate as a public company. These increases will likely include increased costs related to the hiring of additional personnel, fees to outside consultants, lawyers and accountants and 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

Comparison of the Three and Nine Months Ended September 30, 2019 and 2018

The following table sets forth our results of operations for the three and nine months ended September 30, 2019 and 2018.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(unaudited)		(unaudited)	
Operating expenses:				
Research and development	\$ 11,040	\$ 4,162	\$ 29,057	\$ 11,551
General and administrative	1,816	1,245	5,466	3,846
Loss from operations	(12,856)	(5,407)	(34,523)	(15,397)
Other income (expense):				
Interest income	426	117	1,397	170
Interest expense	(918)	—	(2,094)	—
Foreign exchange loss	(3)	(11)	(38)	(27)
Net loss before income tax benefit	(13,351)	(5,301)	(35,258)	(15,254)
Income tax benefit	—	52	—	141
Net loss	\$ (13,351)	\$ (5,249)	\$ (35,258)	\$ (15,113)

Research and Development Expense

Research and development expense increased by \$6.9 million from \$4.2 million for the three months ended September 30, 2018 to \$11.0 million for the three months ended September 30, 2019. The increase was primarily attributable to increases of \$5.3 million and \$0.8 million for GC4419 and GC4711 development costs, respectively, as we initiated our ROMAN trial in October 2018, began additional toxicology studies of GC4419 and began a new clinical trial and additional toxicology studies of GC4711. Personnel related and share-based compensation expense increased by \$0.7 million primarily due to increases in employee headcount.

Research and development expense increased by \$17.5 million from \$11.6 million for the nine months ended September 30, 2018 to \$29.1 million for the nine months ended September 30, 2019. The increase was primarily attributable to increases of \$12.7 million and \$2.6 million for GC4419 and GC4711 development costs, respectively, as we initiated our ROMAN trial in October 2018, incurred startup costs for additional trials of GC4419, began additional toxicology studies of GC4419 and began a new clinical trial and additional toxicology studies of GC4711. We also had an increase in other research and development expenses of \$0.8 million due primarily to increased regulatory and facility costs and a \$0.2 million reserve against our tax incentive receivable. Personnel related and share-based compensation expense increased by \$1.4 million primarily due to increases in employee headcount.

General and Administrative Expense

General and administrative expense increased by \$0.6 million from \$1.2 million for the three months ended September 30, 2018 to \$1.8 million for the three months ended September 30, 2019. General and administrative expense increased by \$1.6 million from \$3.8 million for the nine months ended September 30, 2018 to \$5.5 million for the nine months ended September 30, 2019. In both periods, the increase was primarily due to an increase in employee-related costs as we increased our employee headcount to support our growth.

Interest Income

Interest income increased by \$0.3 million from \$0.1 million for the three months ended September 30, 2018 to \$0.4 million for the three months ended September 30, 2019. Interest income increased by \$1.2 million from \$0.2 million for the nine months ended September 30, 2018 to \$1.4 million for the nine months ended September 30, 2019. In both periods, the increase was primarily due to higher average invested cash balances.

Interest Expense

We recognized \$0.9 million and \$2.1 million in non-cash interest expense during the three and nine months ended September 30, 2019, respectively, in connection with the Royalty Agreement with Clarus.

Income Tax Benefit

We recorded an income tax benefit of less than \$0.1 million and \$0.1 million during the three and nine months ended September 30, 2018, respectively, 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 equity and proceeds received under the Royalty Agreement with Clarus, receiving aggregate gross proceeds of \$187.8 million through September 30, 2019. As of September 30, 2019, we had \$67.9 million in cash, cash equivalents and short-term investments and an accumulated deficit of \$144.7 million. On November 12, 2019, we completed our IPO, which resulted in the issuance and sale of 5,000,000 shares of common stock at a public offering price of \$12.00 per share, generating net proceeds of \$53.1 million after deducting underwriting discounts and other offering costs. On December 9, 2019, in connection with the partial exercise of the over-allotment option granted to the underwriters of our IPO, 445,690 additional shares of common stock were sold at the IPO price of \$12.00 per share, generating net proceeds of approximately \$5.0 million after deducting underwriting discounts and other offering costs. 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:

	Nine months ended September 30,	
	2019	2018
	(in thousands)	
Net cash used in operating activities	\$ (31,385)	\$ (15,548)
Net cash provided by (used in) investing activities	13,965	(7,454)
Net cash provided by financing activities	18,328	69,850
Net increase in cash and cash equivalents	<u>\$ 908</u>	<u>\$ 46,848</u>

Operating Activities

During the nine months ended September 30, 2019, we used \$31.4 million of net cash in operating activities. Cash used in operating activities reflected our net loss of \$35.3 million offset by non-cash charges of \$3.9 million principally related to share-based compensation, interest expense on our Royalty Agreement with Clarus and depreciation expense. The primary use of cash was to fund our operations related to the development of our product candidates.

During the nine months ended September 30, 2018, we used \$15.5 million of net cash in operating activities. Cash used in operating activities reflected our net loss of \$15.1 million and a \$1.2 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 \$0.7 million principally related to share-based compensation expense and depreciation expense.

Investing Activities

During the nine months ended September 30, 2019, investing activities provided \$14.0 million in net cash proceeds, primarily attributable to the \$14.5 million in net cash proceeds received from the purchases and sales of our short-term investments. These activities were offset by \$0.6 million for the purchase of property and equipment.

During the nine months ended September 30, 2018, we used \$7.5 million in net cash proceeds, primarily attributable to \$7.4 million in net purchases of short-term investments and \$0.1 million for the purchase of property and equipment.

Financing Activities

During the nine months ended September 30, 2019, financing activities provided \$18.3 million, attributable to the \$20.0 million in proceeds received in connection with the Royalty Agreement with Clarus. We also paid \$1.7 million in deferred

offering costs in connection with our IPO. During the nine months ended September 30, 2018, financing activities provided \$69.9 million, attributable to the \$69.9 million in net proceeds from the sale of our Series C redeemable convertible preferred stock.

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, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We anticipate that our expenses will increase substantially as we:

- complete clinical development of GC4419 for the reduction of SOM in patients with locally advanced HNC, including our ongoing Phase 3 clinical trial;
- prepare and file for regulatory approval of GC4419 for the reduction of SOM in patients with HNC;
- initiate and advance our planned Phase 2a clinical trial of GC4419 for the reduction in the incidence of radiotherapy-induced esophagitis;
- initiate and advance our planned Phase 1b/2a clinical trial for GC4711 to increase the anti-cancer efficacy of stereotactic body radiation therapy, or SBRT, in patients with non-small cell lung cancer, or 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, insurance 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 our IPO and assumed payments from Clarus to us in the amount of \$40.0 million upon the achievement of the two remaining specified clinical milestones in our ROMAN trial, will enable us to fund our operating expenses and capital expenditure requirements into 2022.

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 our existing stockholders' rights. 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, 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., or, collectively, Clarus. Pursuant to the Royalty Agreement, Clarus agreed to pay us, in the aggregate, up to \$80.0 million, or the Royalty Purchase Price, in four tranches of \$20.0 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 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.

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.

Recent Accounting Pronouncements

See Note 2 to our interim consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for a description of recent accounting pronouncements applicable to our consolidated financial statements.

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 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 have chosen 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.

Subject to certain conditions, as an emerging growth company we may rely on certain exemptions and reduced reporting requirements, including, without limitation, (1) not being required to provide 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) 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, 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 our IPO, (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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of September 30, 2019, we had cash, cash equivalents and short-term investments of \$67.9 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-for-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.

Item 4. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2019.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the quarter ended September 30, 2019 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not subject to any material legal proceedings.

Item 1A. 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 Quarterly Report on Form 10-Q, 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, 2018 and 2017 were \$23.7 million and \$23.5 million, respectively, and \$35.2 million for the nine months ended September 30, 2019. As of September 30, 2019, we had an accumulated deficit of \$144.6 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we:

- continue our research and pre-clinical and clinical development of our product candidates, including our ongoing Phase 3 registrational trial for our lead product candidate, GC4419, a potent and highly selective small molecule dismutase mimetic we are initially developing for the reduction of severe oral mucositis, or SOM, in patients with locally advanced head and neck cancer, or HNC, receiving radiotherapy and our ongoing Phase 1b/2a pilot trial of GC4419 in patients with locally advanced pancreatic cancer, or LAPC, receiving stereotactic body radiation therapy, or SBRT, and commence our planned 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, our second dismutase mimetic product candidate, in patients with non-small cell lung cancer, or 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 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;
- 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. We expect to 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.

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

Identifying potential product candidates and conducting pre-clinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. We expect our expenses to increase in connection with our ongoing activities as we continue enrolling patients in and complete our Phase 3 registrational trial of GC4419 for the reduction in the incidence of severe oral mucositis, or 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, 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 and assumptions, we believe that the net proceeds from our IPO, the assumed payments from Clarus to us in the amount of \$40 million upon the achievement of the two remaining specified clinical milestones in our *Phase 3 Reduction in Oral Mucositis with Avasopasem Manganese Trial*, or ROMAN trial, and our current cash, cash equivalents and short-term investments will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into 2022. Our operating plans may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than expected, through public or private equity, debt financings or other sources. Our future capital requirements will depend on and could increase significantly as a result of many factors, including:

- the results, time and cost necessary for completing our Phase 3 registrational trial for GC4419 for the reduction in the incidence of SOM in patients with locally advanced HNC receiving radiotherapy and our ongoing Phase 1b/2a pilot trial of GC4419 in patients with LAPC receiving SBRT, and commencing our planned Phase 2a trial of GC4419 for the reduction in the incidence of esophagitis in patients with lung cancer receiving radiotherapy and our planned Phase 1b/2a trial of GC4711 in patients with NSCLC receiving radiotherapy;
- the number, size and type of any additional clinical trials;
- the costs, timing and outcomes of seeking and potentially obtaining approvals from the U.S. Food and Drug Administration, or 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, 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 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, as a result of the appearance of trace amounts of visible fine particles identified through stability testing of our GC4419 drug product candidate, our two INDs for GC4419 were temporarily placed on clinical hold in May and July 2019, respectively, following our April 2019 decision to voluntarily suspend dosing of GC4419 in all active clinical trials. We have since identified the particles as manganese carbonate, determined that the particles do not present safety or efficacy concerns for patients who may already have been dosed and have designed the manufacturing process to reduce formation of the particles. The FDA lifted the clinical holds in August 2019. Subsequently, in our ongoing stability testing of GC4419, we have observed the appearance of visible manganese carbonate particles in drug product batches stored at room temperature (25°C) at the one-month time point, also known as accelerated stability testing. In our active clinical trials, we have notified the FDA that we are adding a filtration step to the preparation procedure for both GC4419 and placebo before administration to trial subjects to remove any particles that might form in the future, and we have notified the FDA of the reasons for this change. There can be no assurance that we will be able to eliminate the formation of particles such as manganese carbonate, that a similar or different manufacturing issue will not occur, or that one or more of our programs will not be placed on clinical hold in the future.

As a result of the clinical hold on our ROMAN trial, the data from the approximately 30 patients in the trial that did not complete dosing with GC4419 during the time the trial was on clinical hold will not be considered for purposes of our efficacy analysis in the trial. However, the data from these patients will be considered for purposes of evaluating the safety of GC4419 in our ROMAN trial. Following the lifting of the clinical hold, we increased the size of our ROMAN trial from 335 patients to approximately 365 patients.

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, such as the interim data on our pilot Phase 1b/2a trial of GC4419 in combination with SBRT in patients with LAPC, 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 the treatment phase of 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. Following notification to the FDA in April 2019 that we had voluntarily suspended dosing of GC4419 in all active clinical trials until we were able to resolve the issue, our INDs for GC4419 were temporarily placed on clinical hold. While we have now resolved the issue by modifying the manufacturing process and the FDA lifted the clinical holds in August 2019, there can be no assurance that a similar or different manufacturing issue will not occur and one or more of our programs will not be placed on clinical hold in the future.

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 ongoing Phase 3 registrational trial for GC4419 for the reduction in the incidence of SOM in patients with locally advanced HNC receiving radiotherapy, our ongoing Phase 1b/2a pilot trial of GC4419 in patients with LAPC, and expect to engage a CRO for future clinical trials of GC4419, GC4711 and any other product candidates that we may progress to clinical development. We expect to continue to rely on third parties, such as clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials. If any of our relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. In addition, any third parties conducting our clinical trials will not be our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

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

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

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

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

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

We do not have any manufacturing facilities or personnel. We do not have any long-term contractual arrangements with manufacturers and instead rely on third parties to manufacture our product candidates on a purchase-order or work-order basis. We currently have limited manufacturing arrangements, and we cannot be certain that we will be able to establish redundancy in manufacturers for our product candidates, which could lead to reliance on a limited number of manufacturers for one or more of our product candidates. This reliance increases the risk that we will not have sufficient quantities of our drug candidates or products, if approved, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

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

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

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

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

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

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

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

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected, including compliance with all applicable regulatory requirements;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

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

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

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

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

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate revenue.

Risks Related to Commercialization

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

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

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

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

We do not currently have a sales, marketing or distribution infrastructure. We have never sold, marketed or distributed any therapeutic products. To achieve commercial success for any approved product candidate, we will need to establish a sales and marketing organization. Under the Royalty Agreement with Clarus, we are required to establish a trained sales force sufficiently in advance of any anticipated commercial launch in a country where we seek to commercialize GC4419 or related product candidates. We expect to build a specialized sales and marketing organization of approximately 40 sales representatives to market our product candidates to the approximately 4,000 radiation oncologists in the United States. There are risks involved with establishing our own sales and marketing capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any drug launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting “transfers of value” made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. For example, the Tax Cuts and Jobs Act of 2017, or the Tax Act, was enacted, which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseparable 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 entered into in connection with our IPO.

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.

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 GC4419 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 Health Information Technology for Economic and Clinical Health Act, or the HITECH Act. 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

An active trading market for our common stock may not be sustained.

An active public trading market for our common stock may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

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.

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 a price that you consider reasonable. 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, 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. As of December 9, 2019, we have 24,807,789 shares of common stock outstanding. Of these shares, 19,362,099 shares are currently restricted as a result of securities laws or 180-day lock-up agreements entered into in connection with our IPO (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 our IPO, 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. Moreover, holders of an aggregate of up to 19,061,502 shares of our common stock 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. We have also registered all shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market, subject to volume limitations applicable to affiliates and the lock-up agreements referred to above.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in 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.

Our officers, directors and principal stockholders each holding more than 5% of our common stock, collectively, control approximately 72.2% 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 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 our IPO; (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.

We may choose to take advantage of some, but not all, of the available exemptions. 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. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company 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 have incurred and expect to continue to 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, we have incurred, and particularly after we are no longer an “emerging growth company,” expect to continue to 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 need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made 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 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 Securities Act, 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

On November 6, 2019, the SEC declared effective our registration statement on Form S-1 (File No. 333-234184), as amended, filed in connection with our IPO, or the Registration Statement. Pursuant to the Registration Statement, we registered the offer and sale of 5,750,000 shares of our common stock with a proposed maximum aggregate offering price of approximately \$92.0 million. BofA Securities, Inc., Citigroup Global Markets Inc. and Credit Suisse Securities (USA) LLC acted as representatives of the underwriters for the offering. On November 12, 2019, we issued and sold 5,000,000 shares of our common stock at a price to the public of \$12.00 per share. Upon completion of the IPO on November 12, 2019, we received net proceeds of approximately \$53.1 million, after deducting the underwriting discount of \$4.2 million and offering expenses of \$2.7 million. On December 9, 2019, in connection with the partial exercise of the over-allotment option granted to the underwriters of our IPO, we issued and sold 445,690 additional shares of common stock at a price of \$12.00 per share, generating net proceeds of approximately \$5.0 million after deducting underwriting discounts of \$0.4 million. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

The Registration statement granted the underwriters a 30-day option to purchase up to an additional 750,000 shares of our common stock at the IPO price less the underwriting discounts and commissions, of which 445,690 shares were purchased pursuant to the underwriters' partial exercise of the over-allotment option on December 9, 2019. The offering will terminate after the sale of all securities registered pursuant to the Registration Statement. Net proceeds of approximately \$58.1 million have been invested in money market funds and U.S. Treasury obligations. There has been no material change in the expected use of the net proceeds from our IPO as described in our final prospectus, dated November 6, 2019, filed with the SEC pursuant to Rule 424(b) under the Securities Act relating to the Registration Statement.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibits listed on the Exhibit Index are either filed or furnished with this report or incorporated herein by reference.

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
3.1	Restated Certificate of Incorporation of Galera Therapeutics, Inc.	8-K	001-39114	3.1	11/12/2019	
3.2	Amended and Restated Bylaws of Galera Therapeutics, Inc.	8-K	001-39114	3.2	11/12/2019	
4.1	Form of Certificate of Common Stock	S-1/A	333-234184	4.1	10/28/2019	
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, as amended	S-1/A	333-234184	4.2	10/28/2019	
10.1	Employment Agreement, dated October 25, 2019, by and between Galera Therapeutics, Inc. and J. Mel Sorensen, M.D.	S-1/A	333-234184	10.2	10/28/2019	
10.2	Employment Agreement, dated October 25, 2019, by and between Galera Therapeutics, Inc. and Robert A. Beardsley, Ph.D.	S-1/A	333-234184	10.3	10/28/2019	
10.3	Employment Agreement, dated October 25, 2019 by and between Galera Therapeutics, Inc. and Christopher Degnan	S-1/A	333-234184	10.4	10/28/2019	
10.4	Employment Agreement, dated October 25, 2019, by and between Galera Therapeutics, Inc. and Jon T. Holmlund, M.D.	S-1/A	333-234184	10.5	10/28/2019	
10.5	Employment Agreement, dated October 25, 2019, by and between Galera Therapeutics, Inc. and Arthur J. Fratamico, R.Ph.	S-1/A	333-234184	10.6	10/28/2019	
10.6	Form of Indemnification Agreement between Galera Therapeutics, Inc. and its directors and officers	S-1/A	333-234184	10.7	10/28/2019	
10.7	Galera Therapeutics, Inc. 2019 Incentive Award Plan	S-1/A	333-234184	10.9	10/28/2019	
10.8	Form of Stock Option Award Agreement under the Galera Therapeutics, Inc. 2019 Incentive Award Plan	S-1/A	333-234184	10.10	10/28/2019	
10.9	Form of Restricted Stock Award Agreement under the Galera Therapeutics, Inc. 2019 Incentive Award Plan	S-1/A	333-234184	10.11	10/28/2019	
10.10	Form of Restricted Stock Unit Award Agreement under the Galera Therapeutics, Inc. 2019 Incentive Award Plan	S-1/A	333-234184	10.12	10/28/2019	
10.11	Galera Therapeutics, Inc. Non-Employee Director Compensation Policy	S-1/A	333-234184	10.13	10/28/2019	
10.12	Galera Therapeutics, Inc. 2019 Employee Stock Purchase Plan	S-1/A	333-234184	10.14	10/28/2019	
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					**
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					**
101.INS	XBRL Instance Document					
101.SCH	XBRL Taxonomy Extension Schema Document					
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					

* Filed herewith.

** Furnished herewith.

