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, 2020

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	**46-1454898**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2 W. Liberty Blvd #100 **Malvern, Pennsylvania**	**19355**
(Address of principal executive offices)	**(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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 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 November 5, 2020, the registrant had 24,951,352 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 within the meaning of the safe harbor provisions of 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. 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 anticipated direct and indirect impact of the COVID-19 pandemic on our business and operations, including manufacturing, research and development costs, clinical trials and employees, 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 that could cause actual results to differ materially from those projected in the forward-looking statements, including, but not limited to, the following: our limited operating history; anticipating continued losses for the foreseeable future; needing substantial funding and the ability to raise capital; our dependence on avasopasem manganese (GC4419); uncertainties inherent in the conduct of clinical trials; difficulties or delays enrolling patients in clinical trials; the FDA's acceptance of data from clinical trials outside the United States; undesirable side effects from our product candidates; risks relating to the regulatory approval process; failure to capitalize on more profitable product candidates or indications; ability to receive Breakthrough Therapy Designation or Fast Track Designation for product candidates; failure to obtain regulatory approval of product candidates in the United States or other jurisdictions; ongoing regulatory obligations and continued regulatory review; risks related to commercialization; risks related to competition; ability to retain key employees and manage growth; risks related to intellectual property; inability to maintain collaborations or the failure of these collaborations; our reliance on third parties; the possibility of system failures or security breaches; liability related to the privacy of health information obtained from clinical trials and product liability lawsuits; unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives; environmental, health and safety laws and regulations; the impact of the COVID-19 pandemic on our business and operations, including preclinical studies and clinical trials, and general economic conditions; risks related to ownership of our common stock; significant costs as a result of operating as a public company; and those described under the sections in our Annual Report on Form 10-K for the year ended December 31, 2019 and this Quarterly Report entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations".

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. 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.

Item 1. Financial Statements.

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

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 15,232	$ 18,356
Short-term investments	73,919	93,934
Prepaid expenses and other current assets	3,153	5,280
Total current assets	92,304	117,570
Property and equipment, net	1,073	934
Acquired intangible asset	2,258	2,258
Goodwill	881	881
Right-of-use lease assets	603	815
Other assets	956	918
Total assets	$ 98,075	$ 123,376
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,013	$ 3,945
Accrued expenses	6,240	5,452
Lease liabilities	250	297
Total current liabilities	10,503	9,694
Royalty purchase liability	62,114	43,251
Lease liabilities, net of current portion	356	534
Deferred tax liability	289	289
Other liabilities	118	—
Total liabilities	73,380	53,768
Stockholders' equity:		
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; 24,912,516 and 24,811,567 shares issued and outstanding at September 30, 2020 and December 31, 2019	25	25
Additional paid-in capital	240,049	230,895
Accumulated other comprehensive income	123	38
Accumulated deficit	(215,502)	(161,350)
Total stockholders' equity	24,695	69,608
Total liabilities and stockholders' equity	$ 98,075	$ 123,376

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,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 12,133	$ 11,040	$ 40,225	$ 29,057
General and administrative	3,945	1,816	11,384	5,466
Loss from operations	(16,078)	(12,856)	(51,609)	(34,523)
Other income (expenses):				
Interest income	235	426	1,055	1,397
Interest expense	(1,235)	(918)	(3,625)	(2,094)
Foreign currency gain (loss)	—	(3)	27	(38)
Net loss	(17,078)	(13,351)	(54,152)	(35,258)
Accretion of redeemable convertible preferred stock to redemption value	—	(2,108)	—	(6,178)
Net loss attributable to common stockholders	$ (17,078)	$ (15,459)	$ (54,152)	$ (41,436)
Net loss per share of common stock, basic and diluted	$ (0.69)	$ (51.43)	$ (2.18)	$ (137.85)
Weighted-average shares of common stock outstanding, basic and diluted	24,874,805	300,597	24,840,822	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,	
	2020	2019	2020	2019
Net loss	$ (17,078)	$ (13,351)	$ (54,152)	$ (35,258)
Unrealized gain (loss) on short-term investments	(193)	(26)	85	52
Comprehensive loss	$ (17,271)	$ (13,377)	$ (54,067)	$ (35,206)

See accompanying notes to unaudited interim consolidated financial statements.

GALERA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(IN THOUSANDS EXCEPT SHARE AMOUNTS)
(unaudited)

	Common stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2020	24,811,567	$ 25	$ 230,895	$ 38	$ (161,350)	$ 69,608
Share-based compensation expense	—	—	1,210	—	—	1,210
Exercise of stock options	8,503	—	9	—	—	9
Unrealized gain on short-term investments	—	—	—	648	—	648
Net loss	—	—	—	—	(18,417)	(18,417)
Balance at March 31, 2020	24,820,070	25	232,114	686	(179,767)	53,058
Issuance of common stock warrants	—	—	4,712	—	—	4,712
Share-based compensation expense	—	—	1,453	—	—	1,453
Exercise of stock options	25,728	—	41	—	—	41
Unrealized loss on short-term investments	—	—	—	(370)	—	(370)
Net loss	—	—	—	—	(18,657)	(18,657)
Balance at June 30, 2020	24,845,798	25	238,320	316	(198,424)	40,237
Share-based compensation expense	—	—	1,505	—	—	1,505
Exercise of stock options	66,718	—	224	—	—	224
Unrealized loss on short-term investments	—	—	—	(193)	—	(193)
Net loss	—	—	—	—	(17,078)	(17,078)
Balance at September 30, 2020	24,912,516	$ 25	$ 240,049	$ 123	$ (215,502)	$ 24,695

	Redeemable convertible preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at January 1, 2019	96,385,795	$ 165,902	300,597	$ —	$ —	$ 3	$ (104,823)	$ (104,820)
Share-based compensation expense	—	—	—	—	499	—	—	499
Accretion of redeemable convertible preferred stock to redemption value	—	2,011	—	—	(499)	—	(1,512)	(2,011)
Unrealized gain on short-term investments	—	—	—	—	—	10	—	10
Net loss	—	—	—	—	—	—	(10,349)	(10,349)
Balance at March 31, 2019	96,385,795	167,913	300,597	—	—	13	(116,684)	(116,671)
Share-based compensation expense	—	—	—	—	565	—	—	565
Accretion of redeemable convertible preferred stock to redemption value	—	2,060	—	—	(565)	—	(1,495)	(2,060)
Unrealized gain on short-term investments	—	—	—	—	—	68	—	68
Net loss	—	—	—	—	—	—	(11,558)	(11,558)
Balance at June 30, 2019	96,385,795	169,973	300,597	—	—	81	(129,737)	(129,656)
Share-based compensation expense	—	—	—	—	520	—	—	520
Accretion of redeemable convertible preferred stock to redemption value	—	2,107	—	—	(520)	—	(1,587)	(2,107)
Unrealized gain on short-term investments	—	—	—	—	—	(26)	—	(26)
Net loss	—	—	—	—	—	—	(13,351)	(13,351)
Balance at September 30, 2019	96,385,795	$ 172,080	300,597	$ —	$ —	$ 55	$ (144,675)	$ (144,620)

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,	
	2020	2019
Operating activities:		
Net loss	$ (54,152)	$ (35,258)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	272	188
Noncash interest expense	3,625	2,094
Share-based compensation expense	4,168	1,584
Reserve for tax incentive receivable	—	241
Deferred rent	—	7
Changes in operating assets and liabilities:		
Tax incentive receivable	—	629
Prepaid expenses and other current assets	2,089	(2,732)
Other assets	212	(31)
Accounts payable	68	1,131
Accrued expense and other liabilities	631	762
Cash used in operating activities	(43,087)	(31,385)
Investing activities:		
Purchases of short-term investments	(53,650)	(63,468)
Proceeds from sales of short-term investments	73,750	78,000
Purchase of property and equipment	(411)	(567)
Cash provided by investing activities	19,689	13,965
Financing activities:		
Proceeds from royalty purchase agreement	20,000	20,000
Payment of deferred offering costs	—	(1,672)
Proceeds from exercise of stock options	274	—
Cash provided by financing activities	20,274	18,328
Net increase (decrease) in cash and cash equivalents	(3,124)	908
Cash and cash equivalents at beginning of period	18,356	14,811
Cash and cash equivalents at end of period	$ 15,232	$ 15,719
Supplemental schedule of non-cash financing activities:		
Issuance of warrants in conjunction with amendment to the royalty purchase agreement	$ 4,712	$ —
Accretion of redeemable convertible preferred stock to redemption value	$ —	$ 6,178
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ 431
Purchase of property and equipment included in accounts payable and accrued expenses	$ —	$ 24
Initial recognition of operating lease right-of-use asset and operating lease liability	$ —	$ 1,084

See accompanying 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, avasopasem manganese (GC4419, also referred to as avasopasem), 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 avasopasem for the reduction of SOM induced by radiotherapy with or without systemic therapy. The Company is currently evaluating avasopasem in a Phase 3 registrational trial (referred to as the ROMAN trial) for its ability to reduce the incidence and severity of SOM induced by radiotherapy in patients with locally advanced head and neck cancer (HNC), its lead indication. It is also being studied in a Phase 2a multi-center trial in Europe assessing the safety of avasopasem in patients with head and neck cancer undergoing standard-of-care radiotherapy and in a Phase 2a trial for its ability to reduce the incidence of esophagitis induced by radiotherapy in patients with lung cancer. In addition to developing avasopasem 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 Phase 1 trials of intravenous GC4711 in healthy volunteers. The Company leveraged its observations from the pilot Phase 1/2 safety and anti-cancer efficacy trial of avasopasem in combination with SBRT in patients with locally advanced pancreatic cancer to prepare GC4711 clinical trials in combination with SBRT. The Company is currently evaluating GC4711 in combination with SBRT in a Phase 1/2 safety and anti-cancer efficacy trial in non-small cell lung cancer and plans to initiate a Phase 2b trial of GC4711 in combination with SBRT in patients with pancreatic cancer.

Liquidity

The Company has incurred recurring losses and negative cash flows from operations since inception and has an accumulated deficit of $215.5 million as of September 30, 2020. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its product candidates currently in development. The Company expects its existing cash, cash equivalents and short-term investments, together with the expected payments from Blackstone Life Sciences (formerly known as Clarus Ventures) in the amount of $57.5 million upon the achievement of certain clinical enrollment milestones in the ROMAN trial and the anti-cancer program in combination with SBRT under the Royalty Agreement and the Amendment (each as defined below), will enable the Company to fund its operating expenses and capital expenditure requirements into the second half of 2022. See Note 6.

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 $53.0 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.

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, 2019 and 2018 included in the Company's annual report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 10, 2020 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, 2020 and its results of operations for the three and nine months ended September 30, 2020 and 2019, and statements of changes in redeemable convertible preferred stock and stockholder's equity (deficit) and cash flows for the nine months ended September 30, 2020 and 2019. Operating results for the three and nine months ended September 30, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020, 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, 2019, included in the Company's annual report on Form 10-K and filed with the SEC on March 10, 2020.

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 prior to the IPO, share-based compensation assumptions, royalty purchase liability assumptions and accrued research and development expenses.

The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, including manufacturing, clinical trials, research and development costs and employee-related amounts, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19, as well as the economic impact on local, regional, national and international customers and markets. Management has made estimates regarding the impact of COVID-19 within the Company's financial disclosures and there may be changes to those estimates in future periods. Actual results may differ from these estimates.

Research and Development Activities

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.

In September 2020, the Company was awarded a Small Business Innovation Research grant from the National Cancer Institute of the National Institutes of Health, which will partially fund its Phase 1/2 safety and anti-cancer efficacy trial in NSCLC (the Grant). Costs entitled to reimbursement under the Grant are accounted for as a reduction to research and development expenses. During the three and nine months ended September 30, 2020, the Company recorded a reduction to research and development expense of $0.2 million for expenses to which it is entitled to reimbursement under the Grant.

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,	
	2020	2019
Stock options	4,475,467	3,099,089
Common stock warrants	550,661	—
Redeemable convertible preferred stock	—	19,061,502
	5,026,128	22,160,591

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

COVID-19 Update

The COVID-19 pandemic and related precautions have directly or indirectly impacted the timeline for some of the Company's clinical trials. In April 2020, the Company delayed the initiation of the Phase 2a multi-center trial in Europe assessing the safety of avasopasem in patients with HNC undergoing standard-of-care radiotherapy, due to concerns with patient enrollment. In June 2020, the Company dosed the first patient in the trial. This trial was originally expected to enroll up to 70 patients and contribute to the safety database for avasopasem in patients with HNC receiving radiotherapy. The Company now expects to enroll approximately 35 patients in this trial and continues to monitor the COVID-19 pandemic in Europe regarding the enrollment prospects for this trial. As a result of the delay in initiating the trial in Europe, the target enrollment for the ROMAN trial was increased to approximately 450 patients in order to ensure the Company is positioned to maintain the planned size of the safety database in a timely manner. Completion of enrollment for the ROMAN trial is expected in the first half of 2021 and topline data is expected in the second half of 2021, subject to the continuing impact of the COVID-19 pandemic on the Company's business. With this change in the ROMAN trial, the assumptions underlying the Company's calculation of interest expense on its royalty purchase liability have changed. The Company imputes interest expense on its royalty purchase obligations by estimating risk adjusted future royalty payments over the term of the Royalty Agreement, which takes into consideration the probability and timing of obtaining FDA approval and the potential future revenue from commercializing its product candidates.

In September 2020, the Company initiated a pilot Phase 2 clinical trial of avasopasem to evaluate its ability to improve 28-day mortality in hospitalized patients who are critically ill with COVID-19. The Company expects to report topline data from this trial in the first half of 2021.

Recent accounting pronouncements

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. The Company adopted this ASU on January 1, 2020 and it did not have an impact on the Company's consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles – Goodwill and Other- Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Service Arrangement that is a Service Contract,* which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. This guidance is effective for fiscal years beginning after December 15, 2019, including interim periods therein, The Company adopted this guidance on January 1, 2020 and it did not 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, 2020		
	(Level 1)	(Level 2)	(Level 3)
Assets			
Money market funds and U.S. Treasury obligations (included in cash equivalents)	$ 14,468	$ —	$ —
Short-term investments			
U.S. government agency securities	$ —	$ 5,094	$ —
U.S. Treasury obligations	68,825	—	—
Total short-term investments	$ 68,825	$ 5,094	$ —

	December 31, 2019		
	(Level 1)	(Level 2)	(Level 3)
Assets			
Money market funds and U.S. Treasury obligations (included in cash equivalents)	$ 17,447	$ —	$ —
Short-term investments	$ 93,934	$ —	$ —

There were no changes in valuation techniques during the nine months ended September 30, 2020. 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. The fair value of Level 2 securities is estimated based on observable inputs other than quoted prices in active markets for identical assets and liabilities, quoted prices for identical or similar assets or liabilities in inactive markets, or other inputs that are observable or can be corroborated by observable market data for substantially the full term on the assets or liabilities.

4. Property and equipment

Property and equipment consist of (amounts in thousands):

	September 30, 2020	December 31, 2019
Laboratory equipment	$ 1,119	$ 748
Computer hardware and software	229	218
Leasehold improvements	264	262
Furniture and fixtures	173	147
Property and equipment, gross	1,785	1,375
Less: Accumulated depreciation	(712)	(441)
Property and equipment, net	$ 1,073	$ 934

Depreciation expense was $0.3 million and $0.2 million for the nine months ended September 30, 2020 and 2019, respectively.

5. Accrued expenses

Accrued expenses consist of (amounts in thousands):

	September 30, 2020	December 31, 2019
Compensation and related benefits	$ 1,975	$ 1,160
Research and development expenses	3,958	3,882
Professional fees and other expenses	307	410
	$ 6,240	$ 5,452

6. Royalty purchase liability

In November 2018, the Company entered into an Amended and Restated Purchase and Sale Agreement (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. (collectively, Blackstone or Blackstone Life Sciences). Pursuant to the Royalty Agreement, Blackstone 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. In February 2020, the Company received a $20.0 million payment in connection with the achievement of the third milestone under the Royalty Agreement.

The Company accounts for the Royalty Agreement as a debt instrument. The $60.0 million proceeds from the first three tranches 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 $3.6 million and $2.1 million in noncash interest expense during the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, the effective interest rate was 8.0%.

In May 2020, the Company entered into Amendment No. 1 to the Royalty Agreement (the Amendment) with Clarus IV Galera Royalty AIV, L.P. (the Blackstone Purchaser). The Blackstone Purchaser is affiliated with Blackstone Life Sciences, the successor in interest to Clarus Ventures. The Amendment increased the Royalty Purchase Price by $37.5 million, to $117.5 million by increasing the fourth tranche from $20.0 million to $37.5 million and adding a new $20.0 million tranche upon the achievement of an additional clinical enrollment milestone. The Company accounted for the Amendment as a debt modification and is amortizing fees paid to the Blackstone Purchaser related to the Amendment over the estimated term of the royalty purchase liability utilizing the effective-interest method.

Pursuant to the amended Royalty Agreement, in connection with the payment of each tranche of the Royalty Purchase Price, the Company has agreed to sell, convey, transfer and assign to Blackstone all of its right, title and interest in a high single-digit

percentage of (i) worldwide net sales of avasopasem and GC4711 (collectively, the Products) and (ii) all amounts received by the Company or its affiliates, licensees and sublicensees with respect to Product-related damages (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 the Company's 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 amended Royalty Agreement will remain in effect until the date on which the aggregate amount of the Product Payments paid to Blackstone 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 Blackstone.

Upon execution of the Amendment, the Company issued common stock warrants to the Blackstone Purchaser to purchase an aggregate of 550,661 shares of the Company's common stock with an exercise price of $13.62 per share, each of which will become exercisable upon the receipt by Galera of the applicable specified milestone payment. The issued warrants expire six years after the initial exercise dates. The warrants are equity-classified and were valued at $4.7 million using the Black-Scholes valuation technique. The warrants were recorded as a discount to the royalty purchase liability. The Company will amortize the debt discount to interest expense over the estimated term of the royalty purchase liability utilizing the effective-interest method.

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, 2020, have remaining lease terms of approximately 2.4 and 0.3 years, respectively. The Company adopted FASB ASU No. 2018-11, *Leases (Topic 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 was 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%.

Supplemental balance sheet information related to leases was as follows:

	September 30, 2020	December 31, 2019
Operating Leases		
Right-of-use lease assets	$ 603	$ 815
Lease liabilities, current	250	297
Lease liabilities, net of current portion	356	534
Total operating lease liabilities	$ 606	$ 831

The components of lease expense were as follows:

	Three months ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating lease costs				
Operating lease rental expense	$ 76	$ 71	$ 225	$ 192
Interest on lease liabilities	8	12	27	39
Total operating lease expense	$ 84	$ 83	$ 252	$ 231

Supplemental cash flow information related to leases was as follows:

	Nine Months Ended September 30,	
	2020	2019
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows from operating leases	$ 344	$ 324
Right-of-use assets obtained in exchange for lease obligation		
Operating leases	—	1,084

Future minimum rental payments under the Company's non-cancelable operating leases were as follows as of September 30, 2020 (amounts in thousands):

Remainder of 2020	$ 80
2021	259
2022	260
2023	44
Total	643
Less: imputed interest	(37)
	$ 606

8. Share-based compensation

In connection with the Company's IPO, 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 (as defined herein).

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. Pursuant to this provision, the Company added 992,463 shares to the total shares available for issuance under the 2019 Plan effective January 1, 2020. The maximum number of shares of common stock that may be issued under the 2019 Plan upon the exercise of incentive stock options is 14,130,029.

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. Pursuant to this provision, the Company added 248,115 shares to the total shares available for issuance under the ESPP effective January 1, 2020.

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 December 31, 2019 was 3,038,259, all of which were subject to outstanding awards. No further grants will be made under the Prior Plan; however, the Prior Plan continues to govern awards that are outstanding under it.

The Company's stock option awards vest based on the terms in the governing agreements and generally vest over four years and have a term of 10 years.

Share-based compensation expense was as follows for the three and nine months ended September 30, 2020 and 2019 (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Research and development	$ 662	$ 274	$ 1,923	$ 787
General and administrative	843	246	2,245	797
	$ 1,505	$ 520	$ 4,168	$ 1,584

The following table summarizes the activity related to stock option grants for the nine months ended September 30, 2020:

	Shares	Weighted average exercise price per share	Weighted-average remaining contractual life (years)
Outstanding at January 1, 2020	3,537,946	$ 5.17	
Granted	1,108,573	14.04	
Exercised	(100,949)	2.71	
Forfeited	(70,103)	10.34	
Outstanding at September 30, 2020	4,475,467	$ 7.35	7.2
Vested and exercisable at September 30, 2020	2,431,537	$ 3.92	5.7
Vested and expected to vest at September 30, 2020	4,475,467	$ 7.35	7.2

As of September 30, 2020, the unrecognized compensation cost was $16.2 million and will be recognized over an estimated weighted-average amortization period of 3.0 years. The aggregate intrinsic value of options outstanding and options exercisable as of September 30, 2020 was $14.6 million and $13.4 million, respectively. Options granted during the nine months ended September 30, 2020 and 2019 had weighted-average grant-date fair values of $10.45 and $5.61 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, 2020 and 2019 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.

- Prior to the Company's IPO, its board of directors had 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.* Since the closing of the IPO, the Company's board of directors has determined the price per share value of the Company's common stock based on the closing price as reported by the NASDAQ Global Market on the date of the grant.

The grant date fair value of each option grant was estimated throughout the quarter using the Black-Scholes option-pricing model using the following weighted-average assumptions:

	Nine months ended September 30,	
	2020	2019
Expected term (in years)	6.2	6.2
Expected stock price volatility	89.3%	90.0%
Risk-free interest rate	1.26%	2.51%
Expected dividend yield	0%	0%

9. 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, 2020 and 2019 were $0.2 million and $0.2 million, respectively.

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 our Annual Report on Form 10-K, filed with the SEC on March 10, 2020, and 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, avasopasem manganese (GC4419, also referred to as avasopasem), 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 avasopasem for the reduction of SOM induced by radiotherapy with or without systemic therapy. In October 2018, we began evaluating avasopasem in a Phase 3 registrational trial, which we refer to as the ROMAN trial, and we expect to report topline data from this trial in the second half of 2021. We believe avasopasem, 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. In January 2020, we announced that the first patient was dosed in a Phase 2a trial evaluating the efficacy of avasopasem in reducing the incidence of radiotherapy-induced esophagitis in patients with lung cancer, which we refer to as the AESOP trial. We expect to report topline data from this trial in the first half of 2022. In June 2020, following a delay in the planned initiation of the trial due to the COVID-19 pandemic, the first patient was dosed in a Phase 2a multi-center trial in Europe assessing the safety of avasopasem in patients with HNC undergoing standard-of-care radiotherapy, which we refer to as the EUSOM trial. We expect to report topline data from this trial in the second half of 2021.

In addition to developing avasopasem for the reduction of normal tissue toxicity from radiotherapy, we are also developing our dismutase mimetics to increase the anti-cancer efficacy of higher daily doses of radiotherapy, including stereotactic body radiation therapy, or SBRT. Our second dismutase mimetic product candidate, GC4711, is being developed to increase the anti-cancer efficacy of SBRT and we have successfully completed Phase 1 trials of intravenous GC4711 in healthy volunteers. In October 2020, we announced interim data from our pilot Phase 1/2 safety and anti-cancer efficacy trial of avasopasem in combination with SBRT in patients with locally advanced pancreatic cancer, or LAPC. In the analysis of the intent-to-treat population, multiple endpoints to date show a positive trend in favor of improved anti-cancer efficacy with avasopasem compared to placebo. While many of the patients are early in their follow-up post treatment, addition of the dismutase mimetic to SBRT appears to improve overall survival (OS) versus placebo (HR=0.4, 95% CI: 0.12-1.11; median OS not yet reached for avasopasem vs. 38.7 weeks for placebo; p=0.06). Best overall response within the SBRT field was partial response, according to modified RECIST criteria, or better in 33% of avasopasem patients versus 17% of placebo patients. Five patients in the avasopasem arm and two in the placebo arm were surgically resected. Among the resected avasopasm patients, all five achieved clear margins (R0), compared to only one of the two in the placebo arm. Progression-free survival hazard ratio as of the cut-off date also appears to favor the avasopasem arm (HR=0.6, 95% CI: 0.23-1.56; p=0.29). Toxicity was comparable across both treatment arms, with no significant differences in overall or Grade 3 GI toxicity post-SBRT. The data presented included all patients followed for a minimum of three months and 19 for more than one year, with data through August 24, 2020. We plan to provide an update on this trial with at least one year of follow-up on all patients in the second half of 2021.

We leveraged our observations from the pilot LAPC trial to prepare our GC4711 clinical trials in combination with SBRT. We initiated a Phase 1/2 trial in patients with non-small cell lung cancer, or NSCLC, in October 2020, which we refer to as the GRECO-1 trial. The Phase 1/2 GRECO-1 trial is supported in part by a recently awarded Small Business Innovation Research grant from the National Cancer Institute of the National Institutes of Health for the investigation of our dismutase mimetics in combination with SBRT for the treatment of lung cancer. We intend for this trial to be a two stage trial with the first stage designed to assess the anti-cancer efficacy and safety of GC4711 in combination with SBRT, and the second stage to assess the anti-cancer efficacy and safety of GC4711 in combination with SBRT and a checkpoint inhibitor. We expect to report topline data from the first stage of this trial in the first half of 2022. We also plan to initiate a Phase 2b trial of GC4711 in combination with SBRT in patients with pancreatic cancer in the first half of 2021, which we refer to as the GRECO-2 trial.

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 Amended and Restated Purchase and Sale Agreement, which we refer to as 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, Blackstone or Blackstone Life Sciences (formerly known as Clarus Ventures), receiving aggregate gross proceeds of $273.1 million through September 30, 2020. 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 $53.0 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 $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 $51.9 million and $23.7 million for the years ended December 31, 2019 and 2018, respectively, and $17.1 million and $54.2 million for the three and nine months ended September 30, 2020. As of September 30, 2020, we had $89.2 million in cash, cash equivalents and short-term investments and an accumulated deficit of $215.5 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 is no assurance 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 expected payments from Blackstone Life Sciences in the amount of $57.5 million upon the achievement of certain clinical enrollment milestones in the ROMAN trial and the anti-cancer program in combination with SBRT under the amended Royalty Agreement, will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2022. See “Royalty Agreement with Blackstone Life Sciences (Formerly Known as Clarus Ventures)” below.

Business Update Regarding COVID-19

The current COVID-19 pandemic continues to present a substantial public health and economic challenge around the world and is affecting our employees, communities, clinical trial sites and business operations, as well as the U.S. economy and international financial markets. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact, and the economic impact on local, regional, national and international markets. See “Risk Factors—Other Risks Related to Our Business—The COVID-19 pandemic caused by the novel strain of coronavirus has adversely impacted, and could continue to adversely impact, our business, including our preclinical studies and clinical trials, results of operations and financial condition” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

While we are currently continuing our ongoing clinical trials, the COVID-19 pandemic and related precautions have directly or indirectly impacted the timeline for certain of our clinical trials. We delayed the initiation of the Phase 2a multi-center trial in Europe assessing the safety of avasopasem in patients with HNC undergoing standard-of-care radiotherapy due to concerns with clinical trial enrollment in Europe during the COVID-19 pandemic. In June 2020, the first patient was dosed in this trial. This trial was originally expected to enroll up to 70 patients and contribute to the safety database for avasopasem in patients with HNC receiving radiotherapy. We now expect to enroll approximately 35 patients in this trial and continue to monitor the COVID-19 pandemic in Europe regarding the enrollment prospects for this trial. As a result of the delay in initiating the trial in Europe, the target enrollment for the ROMAN trial was increased to approximately 450 patients in order to ensure we are positioned to maintain the planned size of the safety database in a timely manner. Completion of enrollment for the ROMAN trial is expected in the first half of 2021 and topline data is expected in the second half of 2021, subject to the continuing impact of the COVID-19 pandemic on our business.

Mitigation activities to minimize COVID-19-related operation disruptions are ongoing given the severity and evolving nature of the situation, and we are continuing to monitor the impact of the COVID-19 pandemic on our operations and ongoing clinical development activity, generally.

In September 2020, we initiated a pilot Phase 2 clinical trial of avasopasem to evaluate its ability to improve 28-day mortality in hospitalized patients who are critically ill with COVID-19. The randomized, double-blind, placebo-controlled Phase 2 trial is designed to assess the safety and efficacy of avasopasem in improving 28-day mortality, compared to placebo. The trial will enroll up to 50 hospitalized adult patients critically ill with COVID-19 at several sites across the U.S. We expect to report topline data from this trial in the first half of 2021.

Our third-party contract manufacturing partners continue to operate at or near normal levels. While we currently do not anticipate any material interruptions in our clinical trial supply or manufacturing scale-up activities, it is possible that the COVID-19 pandemic and response efforts may have an impact in the future on our third-party suppliers and contract manufacturing partners' ability to manufacture our clinical trials supply or progress manufacturing scale-up activities.

In response to the spread of COVID-19, beginning in March 2020, we closed our executive offices with our administrative employees continuing their work outside of our offices, restricted on-site staff to only those required on-site to execute their job responsibilities and limited the number of staff in our research and development laboratory.

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 Annual Report on Form 10-K filed with the SEC on March 10, 2020 and the notes to the unaudited interim consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. During the nine months ended September 30, 2020 there were no material changes to our critical accounting policies from those discussed in our Annual Report on Form 10-K.

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 preclinical 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 preclinical 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 preclinical 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 preclinical 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, 2020 and 2019 (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Avasopasem manganese (GC4419)	$ 7,867	$ 7,271	$ 25,776	$ 18,471
GC4711	966	1,566	3,935	4,367
Other research and development expense	898	436	3,180	1,425
Personnel related and share-based compensation expense	2,402	1,767	7,334	4,794
	$ 12,133	$ 11,040	$ 40,225	$ 29,057

Research and development activities are central to our business model. Product candidates in later stages of clinical development, such as avasopasem, 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 avasopasem 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;
- the impact of unforeseen events, such as the COVID-19 pandemic, on our preclinical studies, clinical trials and manufacturing scale-up; 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, information technology, 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 Blackstone Life Sciences and non-cash interest expense associated with the amortization of the debt discount recorded for the Blackstone warrants.

Foreign Currency Gains (Losses)

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

Net Operating Loss and Research and Development Tax Credit Carryforwards

As of December 31, 2019, we had federal and state tax net operating loss carryforwards of $91.5 million and $113.6 million, respectively, which each begin to expire in 2032 unless previously utilized. We also had foreign net operating loss carryforwards of $1.2 million which do not expire. As of December 31, 2019, we also had federal, state and foreign research and development tax credit carryforwards of $5.1 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, 2020 and 2019

The following table sets forth our results of operations for the three and nine months ended September 30, 2020 and 2019 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(unaudited)		(unaudited)	
Operating expenses:				
Research and development	$ 12,133	$ 11,040	$ 40,225	$ 29,057
General and administrative	3,945	1,816	11,384	5,466
Loss from operations	(16,078)	(12,856)	(51,609)	(34,523)
Other income (expense):				
Interest income	235	426	1,055	1,397
Interest expense	(1,235)	(918)	(3,625)	(2,094)
Foreign currency gain (loss)	—	(3)	27	(38)
Net loss	$ (17,078)	$ (13,351)	$ (54,152)	$ (35,258)

Research and Development Expense

Research and development expense increased by $1.1 million from $11.0 million for the three months ended September 30, 2019 to $12.1 million for the three months ended September 30, 2020. Avasopasem development costs increased by $0.6 million, due to increased expenses in our ROMAN trial, costs related to additional clinical trials including the Phase 2a trial for the treatment of esophagitis in patients with lung cancer and the Phase 2a multi-center trial in Europe assessing the safety of avasopasem in patients with HNC. In addition, personnel related and share-based compensation expense increased by $0.6 million primarily due to increases in employee headcount and grants of stock options to new and existing employees. These increases were partially offset by decreased avasopasem preclinical spend and decreased GC4711 development expenses.

Research and development expense increased by $11.2 million from $29.1 million for the nine months ended September 30, 2019 to $40.2 million for the nine months ended September 30, 2020. The increase was primarily attributable to an increase of $7.3 million for avasopasem development costs, due to increased expenses in our ROMAN trial, costs related to additional clinical trials including the Phase 2a trial for the treatment of esophagitis in patients with lung cancer and the Phase 2a multi-center trial in Europe assessing the safety of avasopasem in patients with HNC, and incurrence of costs associated with manufacturing scale-up activities. In addition, personnel related and share-based compensation expense increased by $2.5 million primarily due to increases in employee headcount and grants of stock options to new and existing employees. These increases were partially offset by decreased avasopasem and GC4711 preclinical spend.

General and Administrative Expense

General and administrative expense increased by $2.1 million from $1.8 million for the three months ended September 30, 2019 to $3.9 million for the three months ended September 30, 2020. The increase was primarily due to increased employee headcount and share-based compensation expense, and increased insurance, professional fees and operating costs as a result of becoming a public company.

General and administrative expense increased by $5.9 million from $5.5 million for the nine months ended September 30, 2019 to $11.4 million for the nine months ended September 30, 2020. The increase was primarily due to increased employee headcount and share-based compensation expense, and increased insurance, professional fees and operating costs as a result of becoming a public company.

Interest Income

Interest income decreased from $0.4 million and $1.4 million for the three and nine months ended September 30, 2019, respectively, to $0.2 million and $1.1 million for the three and nine months ended September 30, 2020, respectively. Higher average invested cash balances during the three and nine months ended September 30, 2020 were more than offset by lower average interest rates.

Interest Expense

We recognized $1.2 million and $0.9 million in non-cash interest expense during the three months ended September 30, 2020 and 2019, respectively, and $3.6 million and $2.1 million in non-cash interest expense during the nine months ended September 30, 2020 and 2019, respectively, in connection with the Royalty Agreement with Blackstone Life Sciences.

Liquidity and Capital Resources

Through September 30, 2020, we have funded our operations primarily through the sale and issuance of equity and $60.0 million of proceeds received under the Royalty Agreement with Blackstone Life Sciences, receiving aggregate gross proceeds of $273.1 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 $53.0 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. As of September 30, 2020, we had $89.2 million in cash, cash equivalents and short-term investments and an accumulated deficit of $215.5 million. We have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years.

Cash Flows

The following table shows a summary of our cash flows for the periods indicated (in thousands):

	Nine months ended September 30,	
	2020	2019
Net cash used in operating activities	$ (43,087)	$ (31,385)
Net cash provided by investing activities	19,689	13,965
Net cash provided by financing activities	20,274	18,328
Net increase (decrease) in cash and cash equivalents	$ (3,124)	$ 908

Operating Activities

During the nine months ended September 30, 2020, we used $43.1 million of net cash in operating activities. Cash used in operating activities reflected our net loss of $54.2 million, partially offset by non-cash charges of $8.1 million related to share-based compensation, interest expense on our Royalty Agreement with Blackstone Life Sciences and depreciation expense, and $3.0 million in cash from changes in operating assets and liabilities. 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, 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, partially offset by $3.9 million in non-cash charges, principally related to share-based compensation expense, interest expense on our Royalty Agreement with Blackstone Life Sciences and depreciation expense. The primary use of cash was to fund our operations related to the development of our product candidates.

Investing Activities

During the nine months ended September 30, 2020, investing activities provided $19.7 million in net cash proceeds, primarily attributable to $20.1 million in net sales of our short-term investments, partially offset by $0.4 million for the purchase of property and equipment.

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

Financing Activities

During the nine months ended September 30, 2020, financing activities provided $20.3 million, primarily attributable to the $20.0 million in proceeds received in connection with the Royalty Agreement with Blackstone Life Sciences, as disclosed below.

During the nine months ended September 30, 2019, financing activities provided $18.3 million, primarily attributable to the $20.0 million in proceeds received in connection with the Royalty Agreement with Blackstone Life Sciences. We also paid $1.7 million in offering costs in connection with our November 2019 IPO.

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 avasopasem 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 avasopasem for the reduction of SOM in patients with HNC;
- advance our ongoing Phase 2a clinical trial of avasopasem for the reduction in the incidence of radiotherapy-induced esophagitis;
- advance our ongoing Phase 1/2 clinical trial for GC4711 to increase the anti-cancer efficacy of SBRT, in patients with NSCLC;
- initiate and advance our planned Phase 2b clinical trial for GC4711 to increase the anti-cancer efficacy of SBRT, in patients with pancreatic cancer;
- advance our ongoing pilot Phase 2 clinical trial of avasopasem to improve 28-day mortality in hospitalized patients who are critically ill with COVID-19;
- advance our ongoing preclinical development activities for our existing product candidates;
- seek to discover and develop additional preclinical and clinical product candidates and/or additional indications for our existing 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 expected payments from Blackstone Life Sciences in the amount of $57.5 million upon the achievement of certain clinical enrollment milestones in the ROMAN trial and the anti-cancer program in combination with SBRT under the amended Royalty Agreement, will enable us to fund our operating expenses and capital expenditure requirements into the second half of 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 direct and indirect impact of COVID-19 on our business and operations;
- the scope, progress, results and costs of preclinical 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 preclinical 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. For example, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms. See "Risk Factors—Other Risks Related to Our Business—The COVID-19 pandemic caused by the novel strain of coronavirus has adversely impacted and could continue to adversely impact, our business, including our preclinical studies and clinical trials, results of operations and financial condition" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

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 Blackstone Life Sciences (Formerly Known as Clarus Ventures)

In November 2018, we entered into the Royalty Agreement with Blackstone Life Sciences. Pursuant to the Royalty Agreement, Blackstone 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 avasopasem, GC4711 and any pharmaceutical product comprising or containing avasopasem 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, 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, and received the third tranche of the Royalty Purchase Price in February 2020 in connection with the achievement of the third milestone under the Royalty Agreement.

In May 2020, we entered into Amendment No. 1 to the Royalty Agreement, or the Amendment, with Clarus IV Galera Royalty AIV, L.P., or the Blackstone Purchaser. The Blackstone Purchaser is affiliated with Blackstone Life Sciences, successor in interest to Clarus Ventures. The Amendment increased the Royalty Purchase Price by $37.5 million to $117.5 million by increasing the fourth tranche from $20.0 million to $37.5 million and adding a new $20.0 million tranche upon the achievement of an additional clinical enrollment milestone.

Pursuant to the amended 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 Blackstone all of our right, title and interest in a high single-digit percentage of (i) worldwide net sales of the Products and (ii) all amounts received by us or our affiliates, licensees and sublicensees with respect to Product-related damages (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 amended Royalty Agreement will remain in effect until the date on which the aggregate amount of the Product Payments paid to Blackstone 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 Blackstone.

In May 2020, as partial consideration for the Amendment, we issued two warrants to the Blackstone Purchaser to purchase an aggregate of 550,661 shares of our common stock at an exercise price equal to $13.62 per share, each of which will become exercisable upon the receipt by Galera of the applicable specified milestone payment. The issued warrants expire six years after the initial exercise date of each respective warrant.

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.

Effect of Inflation

Inflation did not have a significant impact on our net loss for the three and nine months ended September 30, 2020 or 2019.

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 earliest to occur of: (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, or December 31, 2024, (b) in which we have total annual gross revenues of $1.07 billion or more, or (c) in which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our outstanding common stock held by non-affiliates exceeds $700 million as of last business day of our most recently completed second fiscal quarter, and (2) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined in Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this Item 3.

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, 2020.

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, 2020 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. In addition to the other information set forth in this quarterly report on Form 10-Q, you should carefully consider the factors described in Part I, Item 1A. "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the Securities and Exchange Commission on March 10, 2020. Except as disclosed below, there have been no material changes to the risk factors described in that report. The occurrence of any of the events or developments described in our Risk Factors 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.

Other Risks Related to Our Business

The COVID-19 pandemic caused by the novel strain of coronavirus has adversely impacted and could continue to adversely impact, our business, including our preclinical studies and clinical trials, results of operations and financial condition.

In December 2019, a novel strain of coronavirus causing the COVID-19 disease was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries, including the United States. In response to the spread of COVID-19, we have closed our executive offices with our administrative employees continuing their work outside of our offices, restricted on-site staff to only those required on-site to execute their job responsibilities and limited the number of staff in any given research and development laboratory. While we are currently continuing our ongoing clinical trials, the COVID-19 pandemic and related precautions have directly or indirectly impacted the timeline for certain of our clinical trials. In April 2020, we delayed the initiation of the Phase 2a multi-center trial in Europe assessing the safety of avasopasem manganese in patients with HNC undergoing standard-of-care radiotherapy, and dosed the first patient in the trial in June 2020. This trial was originally expected to enroll up to 70 patients and contribute to the safety database for avasopasem in patients with HNC receiving radiotherapy. We now expect to enroll approximately 35 patients in this trial and continue to monitor the COVID-19 pandemic in Europe regarding the enrollment prospects for this trial. As a result of the delay in initiating the trial in Europe, the target enrollment for the ROMAN trial was increased to approximately 450 patients in order to ensure we are positioned to maintain the planned size of the safety database in a timely manner. Completion of enrollment for the ROMAN trial is expected in the first half of 2021 and topline data is expected in the second half of 2021, subject to the continued impact of the COVID-19 pandemic on our business. We are continuing to monitor the impact of the COVID-19 pandemic on our operations and ongoing clinical development activity, generally. As a result of the COVID-19 pandemic, we may experience further disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;

- interruption or delays in the operations of the FDA, which may impact approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing or supply shortages, production slowdowns, global shipping delays or stoppages and disruptions in delivery systems;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.
- refusal of the FDA to accept data from clinical trials in affected geographies;
- impacts from prolonged remote work arrangements, such as increased cybersecurity risks and strains on our business continuity plans; and
- delays or difficulties with equity offerings due to disruptions and uncertainties in the securities market.

In addition, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms. The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak further impacts our business, including our preclinical studies and clinical trials, results of operations and financial condition will depend on future developments which are highly uncertain and cannot be predicted with confidence. Such factors include but are not limited to the duration of the outbreak, travel restrictions, quarantines, shelter-in-place orders and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

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

Use of Proceeds

On November 12, 2019, we completed our IPO and issued and sold 5,000,000 shares of our common stock at a price to the public of $12.00 per share for net proceeds of approximately $53.0 million, after deducting the underwriting discounts and offering expenses. 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.

Net proceeds of approximately $58.0 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	3.1	9/25/2020	
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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Galera Therapeutics, Inc.

Date: November 10, 2020

By: /s/ J. Mel Sorensen, M.D.
J. Mel Sorensen, M.D.
Chief Executive Officer and President

Date: November 10, 2020

By: /s/ Christopher Degnan
Christopher Degnan
Chief Financial Officer

Exhibit 31.1

CERTIFICATION

I, J. Mel Sorensen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Galera Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [omitted];

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2020

By: /s/ J. Mel Sorensen, M.D.

J. Mel Sorensen, M.D.
Chief Executive Officer and President
(principal executive officer)

Exhibit 31.2

CERTIFICATION

I, Christopher Degnan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Galera Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [omitted];

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2020

By: /s/ Christopher Degnan
Christopher Degnan
Chief Financial Officer (principal financial and accounting officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Galera Therapeutics, Inc. (the "Company") for the period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 10, 2020

By: /s/ J. Mel Sorensen, M.D.
J. Mel Sorensen, M.D.
Chief Executive Officer and President
(principal executive officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Galera Therapeutics, Inc. (the "Company") for the period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 10, 2020

By: /s/ Christopher Degnan
Christopher Degnan
Chief Financial Officer (principal financial and accounting officer)