

**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 **June 30, 2021**

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: **001-39114**

**Galera Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**2 W. Liberty Blvd #100**

**Malvern, Pennsylvania**

(Address of principal executive offices)

**46-1454898**

(I.R.S. Employer  
Identification No.)

**19355**

(Zip Code)

**(610) 725-1500**

(Registrant's telephone number, including area code)

N/A

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

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

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

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

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

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

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

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

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

As of August 6, 2021, the registrant had 26,365,632 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 clinical utility of our product candidates, our commercialization, 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 our ability to raise additional capital to fund our operations, the anticipated impact of the COVID-19 pandemic on our business, and the plans and objectives of management for future operations, capital needs, 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 and/or maintain 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, 2020 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.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	June 30, 2021	December 31, 2020
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 38,465	\$ 15,872
Short-term investments	28,062	56,904
Royalty agreement receivable	37,500	—
Prepaid expenses and other current assets	4,837	5,153
<b>Total current assets</b>	<b>108,864</b>	<b>77,929</b>
Property and equipment, net	1,020	1,023
Acquired intangible asset	2,258	2,258
Goodwill	881	881
Right-of-use lease assets	450	530
Other assets	1,796	1,477
<b>Total assets</b>	<b>\$ 115,269</b>	<b>\$ 84,098</b>
<b>Liabilities and stockholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 8,272	\$ 5,146
Accrued expenses	8,287	8,584
Lease liabilities	284	238
<b>Total current liabilities</b>	<b>16,843</b>	<b>13,968</b>
Royalty purchase liability	123,424	63,369
Lease liabilities, net of current portion	172	296
Deferred tax liability	273	273
Other liabilities	74	74
<b>Total liabilities</b>	<b>140,786</b>	<b>77,980</b>
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value: 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$0.001 par value: 200,000,000 shares authorized; 25,919,411 and 24,976,142 shares issued and outstanding at June 30, 2021 and December 31, 2020	26	25
Additional paid-in capital	251,123	241,649
Accumulated other comprehensive income	3	12
Accumulated deficit	(276,669)	(235,568)
<b>Total stockholders' equity (deficit)</b>	<b>(25,517)</b>	<b>6,118</b>
<b>Total liabilities and stockholders' equity (deficit)</b>	<b>\$ 115,269</b>	<b>\$ 84,098</b>

*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 June 30,		Six months ended June 30,	
	2021	2020	2021	2020
<b>Operating expenses:</b>				
Research and development	\$ 15,966	\$ 13,839	\$ 28,389	\$ 28,092
General and administrative	5,122	3,874	10,180	7,439
Loss from operations	(21,088)	(17,713)	(38,569)	(35,531)
<b>Other income (expenses):</b>				
Interest income	6	352	25	820
Interest expense	(1,302)	(1,295)	(2,555)	(2,390)
Foreign currency gain (loss)	(2)	(1)	(2)	27
Net loss	\$ (22,386)	\$ (18,657)	\$ (41,101)	\$ (37,074)
Net loss per share of common stock, basic and diluted	\$ (0.88)	\$ (0.75)	\$ (1.63)	\$ (1.49)
Weighted-average shares of common stock outstanding, basic and diluted	25,401,046	24,832,264	25,195,763	24,823,644

*See accompanying notes to unaudited interim consolidated financial statements.*

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

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Net loss	\$ (22,386)	\$ (18,657)	\$ (41,101)	\$ (37,074)
Unrealized gain (loss) on short-term investments	(7)	(370)	(9)	278
Comprehensive loss	<u>\$ (22,393)</u>	<u>\$ (19,027)</u>	<u>\$ (41,110)</u>	<u>\$ (36,796)</u>

*See accompanying notes to unaudited interim consolidated financial statements.*

**GALERA THERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)**  
**(IN THOUSANDS EXCEPT SHARE AMOUNTS)**  
**(unaudited)**

	Common stock		Additional paid-in capital	Accumulated other comprehensive (loss) income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance at January 1, 2021	24,976,142	\$ 25	\$ 241,649	\$ 12	\$ (235,568)	\$ 6,118
Share-based compensation expense	—	—	1,791	—	—	1,791
Exercise of stock options	217,015	—	235	—	—	235
Unrealized loss on short-term investments	—	—	—	(2)	—	(2)
Net loss	—	—	—	—	(18,715)	(18,715)
Balance at March 31, 2021	25,193,157	25	243,675	10	(254,283)	(10,573)
Share-based compensation expense	—	—	1,611	—	—	1,611
Exercise of stock options	60,975	—	120	—	—	120
Sale of shares under Open Market Sale Agreement with Jefferies LLC, net	665,279	1	5,717	—	—	5,718
Unrealized loss on short-term investments	—	—	—	(7)	—	(7)
Net loss	—	—	—	—	(22,386)	(22,386)
Balance at June 30, 2021	25,919,411	\$ 26	\$ 251,123	\$ 3	\$ (276,669)	\$ (25,517)

	Common stock		Additional paid-in capital	Accumulated other comprehensive (loss) 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

*See accompanying notes to unaudited interim consolidated financial statements.*

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

	Six months ended June 30,	
	2021	2020
<b>Operating activities:</b>		
Net loss	\$ (41,101)	\$ (37,074)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	208	175
Noncash interest expense	2,555	2,390
Share-based compensation expense	3,402	2,663
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	316	1,291
Other assets	(240)	140
Accounts payable	3,126	2,822
Accrued expense and other liabilities	(374)	(210)
Cash used in operating activities	<u>(32,108)</u>	<u>(27,803)</u>
<b>Investing activities:</b>		
Purchases of short-term investments	(7,167)	(42,065)
Proceeds from sales of short-term investments	36,000	47,750
Purchase of property and equipment	(205)	(406)
Cash provided by investing activities	<u>28,628</u>	<u>5,279</u>
<b>Financing activities:</b>		
Proceeds from royalty purchase agreement	20,000	20,000
Proceeds from Open Market Sale Agreement with Jefferies LLC, net	5,718	—
Proceeds from exercise of stock options	355	50
Cash provided by financing activities	<u>26,073</u>	<u>20,050</u>
Net increase (decrease) in cash and cash equivalents	22,593	(2,474)
Cash and cash equivalents at beginning of period	15,872	18,356
Cash and cash equivalents at end of period	<u>\$ 38,465</u>	<u>\$ 15,882</u>
Supplemental schedule of non-cash financing activities:		
Issuance of warrants in conjunction with amendment to the royalty purchase agreement	\$ —	\$ 4,712
Deferred offering costs included in accounts payable and accrued expenses	\$ 98	\$ —
Purchase of property and equipment included in accounts payable and accrued expenses	\$ 5	\$ 36

*See accompanying notes to unaudited interim consolidated financial statements.*



**GALERA THERAPEUTICS, INC.**  
**NOTES TO UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization and description of business**

Galera Therapeutics, Inc. was incorporated as a Delaware corporation on November 19, 2012 (inception) and together with its subsidiaries (the Company, or Galera) is a clinical stage biopharmaceutical company focused on developing and commercializing a pipeline of novel, proprietary therapeutics that have the potential to transform radiotherapy in cancer. The Company's lead product candidate, 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. In June 2021, the Company announced completion of enrollment for the ROMAN trial, with topline data expected in the fourth quarter of 2021. Avasopasem 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 a Phase 2b trial of GC4711 in combination with SBRT in patients with locally advanced pancreatic cancer.

***Liquidity***

The Company has incurred recurring losses and negative cash flows from operations since inception and has an accumulated deficit of \$276.7 million as of June 30, 2021. 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 as of June 30, 2021, together with the payment from Blackstone Life Sciences (formerly known as Clarus Ventures) (see Note 6) in the amount of \$37.5 million, received in July 2021, will enable the Company to fund its operating expenses and capital expenditure requirements for at least the next twelve months from the issuance of these financial statements. In the future, if the Company is not able to continue to raise sufficient capital to fund its operations, the Company may determine to delay or discontinue certain activities, including planned programs, hiring plans, manufacturing activities and commercial preparation efforts. In December 2020, the Company filed a registration statement with the SEC which covers the offering, issuance and sale of up to \$200.0 million of the Company's securities, which includes an Open Market Sale Agreement with Jefferies LLC (the Sales Agreement) covering the offering, issuance and sale of up to a maximum aggregate offering price of \$50.0 million of the Company's common stock, which could be utilized to raise funding for future operating expenses and capital expenditure requirements. During the six months ended June 30, 2021, we sold approximately 0.7 million shares of common stock and received net proceeds of \$5.7 million pursuant to the Sales Agreement. As of June 30, 2021, there remains approximately \$44.0 million available under the Sales Agreement. See Note 8.

**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, 2020 and 2019 included in the Company's annual report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 11, 2021 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).

**GALERA THERAPEUTICS, INC.**  
**NOTES TO UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS**

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 June 30, 2021 and its results of operations for the three and six months ended June 30, 2021 and 2020, and statements of changes in stockholder's equity (deficit) and cash flows for the six months ended June 30, 2021 and 2020. Operating results for the three and six months ended June 30, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021, 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, 2020, included in the Company's annual report on Form 10-K and filed with the SEC on March 11, 2021.

***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 share-based compensation assumptions, royalty purchase liability assumptions and accrued research and development expenses.

***Research and development expenses***

Research and development costs are expensed as incurred and consist primarily of funds paid to third parties for the provision of services for product candidate development, clinical and preclinical development and related supply and manufacturing costs, and regulatory compliance costs. The Company accrues and expenses preclinical studies and clinical trial activities performed by third parties based upon estimates of the proportion of work completed over the term of the individual trial and patient enrollment rates in accordance with agreements with clinical research organizations and clinical trial sites. The Company determines the estimates by reviewing contracts, vendor agreements and purchase orders, and through discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services. However, actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending upon a number of factors, including the Company's clinical development plan.

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

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 six months ended June 30, 2021, the Company recorded a reduction to research and development expense of \$0.3 million for expenses for which it has been reimbursed, or 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 stock options and common stock warrants, 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.

**GALERA THERAPEUTICS, INC.**  
**NOTES TO UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS**

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:

	<u>June 30,</u>	
	<u>2021</u>	<u>2020</u>
Stock options	5,009,997	4,596,357
Common stock warrants	550,661	550,661
	<u>5,560,658</u>	<u>5,147,018</u>

**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, or EUSOM trial, due to concerns with patient enrollment. The first patient was dosed in this trial in June 2020, and target enrollment was decreased to approximately 35 patients due to the delay. This trial was expected to contribute to the safety database for avasopasem in patients with HNC receiving radiotherapy. 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 to ensure the Company was positioned to maintain the overall planned size of the safety database in a timely manner. The Company has since completed enrollment in the ROMAN and EUSOM trials and topline data readout from each of these trials is expected in the fourth quarter of 2021.

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 trial aimed to enroll up to 50 hospitalized adult patients critically ill with COVID-19 at several sites across the U.S. On June 16, 2021, the Company ceased enrolling subjects in this trial. Enrollment in the trial was limited at the three centers that participated. Due to the overall decline in COVID-related hospitalizations in the U.S. at the time, the Company determined that it was not feasible to complete the trial.

**Recent accounting pronouncements**

In December 2019, FASB issued ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, which simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in Topic 740 related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill and allocating consolidated income taxes to separate financial statements of entities not subject to income tax. This ASU is effective for fiscal years beginning after December 15, 2020, including interim periods therein. Upon adoption, the Company must apply certain aspects of this standard retrospectively for all periods presented while other aspects are applied on a modified retrospective basis through a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption. The Company adopted this ASU on January 1, 2021. There is no impact to 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.

**GALERA THERAPEUTICS, INC.**  
**NOTES TO UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS**

- 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):

	June 30, 2021		
	(Level 1)	(Level 2)	(Level 3)
<b>Assets</b>			
Money market funds and U.S. Treasury obligations (included in cash equivalents)	\$ 32,194	\$ —	\$ —
Short-term investments			
U.S. government agency securities	\$ —	\$ 415	\$ —
U.S. Treasury obligations	27,647	—	—
Total short-term investments	<u>\$ 27,647</u>	<u>\$ 415</u>	<u>\$ —</u>
	December 31, 2020		
	(Level 1)	(Level 2)	(Level 3)
<b>Assets</b>			
Money market funds and U.S. Treasury obligations (included in cash equivalents)	\$ 14,943	\$ —	\$ —
Short-term investments			
U.S. government agency securities	\$ —	\$ 5,062	\$ —
U.S. Treasury obligations	51,842	—	—
Total short-term investments	<u>\$ 51,842</u>	<u>\$ 5,062</u>	<u>\$ —</u>

There were no changes in valuation techniques during the six months ended June 30, 2021. Certain of 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):

	June 30, 2021	December 31, 2020
Laboratory equipment	\$ 1,327	\$ 1,135
Computer hardware and software	273	260
Leasehold improvements	264	264
Furniture and fixtures	173	173
Property and equipment, gross	2,037	1,832
Less: Accumulated depreciation	(1,017)	(809)
Property and equipment, net	<u>\$ 1,020</u>	<u>\$ 1,023</u>

Depreciation expense was \$0.2 million and \$0.2 million for the six months ended June 30, 2021 and 2020, respectively.

**5. Accrued expenses**

Accrued expenses consist of (amounts in thousands):

	June 30, 2021	December 31, 2020
Compensation and related benefits	\$ 1,308	\$ 2,632
Research and development expenses	6,638	5,525
Professional fees and other expenses	341	427
	<u>\$ 8,287</u>	<u>\$ 8,584</u>

**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, the second tranche of the Royalty Purchase Price in April 2019, and the third tranche of the Royalty Purchase Price in February 2020, in each case in connection with the achievement of the first three milestones, respectively.

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. In June 2021, the Company received the new tranche (\$20.0 million) of the Amendment in connection with the enrollment of the first patient in a Phase 2b trial of GC4711 in combination with SBRT in patients with locally advanced pancreatic cancer, which the Company refers to as the GRECO-2 trial. Also in June, the Company completed enrollment in the ROMAN trial, thereby achieving the milestone associated with the fourth tranche (\$37.5 million) of the Amendment, which was received in July 2021.

The Company accounts for the Royalty Agreement as a debt instrument. The \$80.0 million in proceeds received as of June 30, 2021, along with the \$37.5 million proceeds receivable as of June 30, 2021, have been recorded as a liability on the accompanying consolidated balance sheets. Interest expense is imputed based on the estimated royalty repayment period described below, which takes into consideration the probability and timing of obtaining FDA approval and the potential future revenue from commercializing its product candidates, and which results in a corresponding increase in the liability balance. With the delayed initiation of the EUSOM trial and corresponding increase to the target enrollment of the ROMAN trial in the second quarter of 2020 due to the COVID-19 pandemic, the assumptions underlying the Company's calculation of interest expense on its royalty purchase liability changed. The Company recognized \$2.6 million and \$2.4 million in noncash interest expense during the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021, the effective interest rate was 8.0%.

Pursuant to the Royalty Agreement and the Amendment, 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.

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The Royalty Agreement and the Amendment 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 Creve Coeur, Missouri which, as of June 30, 2021, have remaining lease terms of approximately 1.7 and 0.6 years, respectively. 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:

	June 30, 2021	December 31, 2020
<b>Operating Leases</b>		
Right-of-use lease assets	\$ 450	\$ 530
Lease liabilities, current	284	238
Lease liabilities, net of current portion	172	296
Total operating lease liabilities	\$ 456	\$ 534

The components of lease expense were as follows:

	Three months ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
<b>Operating lease costs</b>				
Operating lease rental expense	\$ 75	\$ 75	\$ 149	\$ 149
Interest on lease liabilities	6	9	13	19
Total operating lease expense	\$ 81	\$ 84	\$ 162	\$ 168

Supplemental cash flow information related to leases was as follows:

	Six Months Ended June 30,	
	2021	2020
<b>Cash paid for amounts included in the measurement of lease liabilities</b>		
Operating cash flows from operating leases	\$ 162	\$ 226
<b>Right-of-use assets obtained in exchange for lease obligation</b>		
Operating leases	70	—

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Future minimum rental payments under the Company’s non-cancelable operating lease liabilities as of June 30, 2021 (amounts in thousands):

Remainder of 2021	\$ 164
2022	266
2023	44
Total	474
Less: imputed interest	(18)
	<u>\$ 456</u>

**8. Equity**

***Equity offerings***

In December 2020, the Company entered into the Sales Agreement with Jefferies LLC (Jefferies) as sales agent, pursuant to which it may, from time to time, issue and sell common stock with an aggregate value of up to \$50.0 million in “at-the-market” offerings under the Company’s Registration Statement on Form S-3 (File No. 333-251061) filed with the SEC on December 1, 2020. Sales of common stock, if any, pursuant to the Sales Agreement, may be made in sales deemed to be an “at the market offering” as defined in Rule 415(a) of the Securities Act, including sales made directly through the Nasdaq Global Market or on any other existing trading market for the Company’s common stock. The Company is required to pay Jefferies a commission equal to three percent of the gross sales proceeds and has provided Jefferies with customary indemnification rights. During the six months ended June 30, 2021, 665,279 shares were sold under the Sales Agreement at a weighted average price per share of \$8.95. Net proceeds to the Company after deducting fees, commissions and other expenses related to the offering were approximately \$5.7 million. As of June 30, 2021, there was approximately \$44.0 million of available capacity under the Sales Agreement.

***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 was 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 and added an additional 999,045 shares to the total shares available for issuance under the 2019 Plan effective January 1, 2021. 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 was 243,621 shares of common stock. In addition, the number of shares of common stock available for issuance under the ESPP 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) 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 and added an additional 249,761 shares to the total shares available for issuance under the ESPP effective January 1, 2021.

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In November 2012, the Company adopted the Equity Incentive Plan (the Prior Plan). The total number of shares subject to outstanding awards under the Prior Plan as of June 30, 2021 was 2,506,357. No shares remain available for issuance under the Prior Plan and 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 six months ended June 30, 2021 and 2020 (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Research and development	\$ 567	\$ 668	\$ 1,351	\$ 1,262
General and administrative	1,044	785	2,051	1,401
	<u>\$ 1,611</u>	<u>\$ 1,453</u>	<u>\$ 3,402</u>	<u>\$ 2,663</u>

The following table summarizes the activity related to stock option grants for the six months ended June 30, 2021:

	Shares	Weighted average exercise price per share	Weighted- average remaining contractual life (years)
Outstanding at January 1, 2021	4,463,078	\$ 7.40	
Granted	1,185,006	11.36	
Exercised	(277,990)	1.28	
Forfeited	(360,097)	12.28	
Outstanding at June 30, 2021	<u>5,009,997</u>	<u>\$ 8.32</u>	<u>7.0</u>
Vested and exercisable at June 30, 2021	<u>2,770,176</u>	<u>\$ 5.85</u>	<u>5.4</u>
Vested and expected to vest at June 30, 2021	<u>5,009,997</u>	<u>\$ 8.32</u>	<u>7.0</u>

As of June 30, 2021, the unrecognized compensation cost was \$18.7 million and will be recognized over an estimated weighted-average amortization period of 2.9 years. The aggregate intrinsic value of options outstanding and options exercisable as of June 30, 2021 was \$14.4 million and \$13.2 million, respectively. Options granted during the six months ended June 30, 2021 and 2020 had weighted-average grant-date fair values of \$8.50 and \$10.45 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 six months ended June 30, 2021 and 2020 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.



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- 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.
- 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:

	Six months ended June 30,	
	2021	2020
Expected term (in years)	6.2	6.2
Expected stock price volatility	91.0%	89.2%
Risk-free interest rate	0.67%	1.26%
Expected dividend yield	0%	0%

**9. Related party transactions**

IntellectMap provides information technology advisory services to the Company. The chief executive officer of IntellectMap is the brother of the Company's chief executive officer. Fees incurred by the Company with respect to IntellectMap during the six months ended June 30, 2021 and 2020 were \$0.1 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 11, 2021, or the 2020 Form 10-K, 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. In June 2021, we announced that we had completed enrollment in the ROMAN trial, and expect to report topline data from this trial in the fourth quarter 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, 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. Enrollment in this trial is complete and we expect to report topline data from this trial in the fourth quarter 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 April 2021, we announced updated 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. The updated results include a minimum follow up of six months on all 42 patients and were consistent with the positive results reported with a minimum follow up of three months. As of this data analysis, median overall survival in the treatment arm was nearly twice as long as observed in the placebo arm, 20.1 months compared to 10.9 months, respectively. Of patients in the treatment arm, 29% of patients achieved a 30% or greater response (partial response) compared to 11% of patients in the placebo arm. Positive results were also observed in local tumor control, time to metastases and progression-free survival. Avasopasem was well tolerated as of this data analysis, with similar rates of adverse events in the treatment and placebo arms. We plan to provide final data from this trial with at least one year of follow-up on all patients in the third quarter of 2021.

We leveraged our observations from the pilot LAPC trial of avasopasem 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 GRECO-1 trial is supported in part by a 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 assess the anti-cancer efficacy and safety of GC4711 in combination with SBRT. We expect to report initial data from this trial in the first half of 2022. We initiated a Phase 2b trial of GC4711 in combination with SBRT in patients with LAPC in May 2021, which we refer to as the GRECO-2 trial. In the future, we intend to assess the anti-cancer efficacy and safety of GC4711 in combination with SBRT and a checkpoint inhibitor.

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 aimed to enroll up to 50 hospitalized adult patients critically ill with COVID-19 at several sites across the U.S. On June 16, 2021, we ceased enrolling subjects in this trial. Enrollment in the trial was limited at the three centers that participated. Due to the overall decline in COVID-related hospitalizations in the United States at the time, we determined that it was not feasible to complete the 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).

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 \$74.2 million and \$51.9 million for the years ended December 31, 2020 and 2019, respectively, and \$22.4 million and \$41.1 million for the three and six months ended June 30, 2021, respectively. As of June 30, 2021, we had \$66.5 million in cash, cash equivalents and short-term investments and an accumulated deficit of \$276.7 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we operate as a public company, advance our product candidates through all stages of development and clinical trials, build our commercial infrastructure and, ultimately, seek regulatory approval of 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 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 as of June 30, 2021, together with the \$37.5 million milestone payment received in July 2021 from Blackstone, will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months from the issuance of our interim consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. 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, including the effectiveness of vaccines and vaccine distribution efforts, the impact of new variants of COVID-19 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 I, Item 1A of the 2020 Form 10-K.

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 EUSOM trial due to concerns with clinical trial enrollment in Europe during the COVID-19 pandemic. The first patient was dosed in this trial in June 2020, and target enrollment was decreased to approximately 35 patients due to the delay. This trial was expected to contribute to the safety database for avasopasem in patients with HNC receiving radiotherapy. 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 to ensure we were positioned to maintain the planned size of the safety database in a timely manner. We have since completed enrollment in the ROMAN and EUSOM trials and topline data readout from each of these trials is expected in the fourth quarter of 2021.

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.

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.

We have also implemented measures designed to protect the health and safety of our workforce. Essential activities at our facilities are continuing and we are taking precautionary measures to protect our employees working in our facilities in such capacities.

### **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 the 2020 Form 10-K and the notes to the unaudited interim consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. During the six months ended June 30, 2021 there were no material changes to our critical accounting policies from those discussed in the 2020 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 personnel-related and share-based compensation expense, early-stage research expenses and other costs that are deployed across multiple projects under development.

The following table summarizes our research and development expenses by program for the three and six months ended June 30, 2021 and 2020 (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Avasopasem manganese (GC4419)	\$ 9,860	\$ 8,572	\$ 17,190	\$ 17,909
GC4711	1,569	1,479	2,489	2,969
Other research and development expense	2,242	1,244	3,799	2,282
Personnel related and share-based compensation expense	2,295	2,544	4,911	4,932
	<u>\$ 15,966</u>	<u>\$ 13,839</u>	<u>\$ 28,389</u>	<u>\$ 28,092</u>

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, 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, including the significant costs associated with our ongoing and planned clinical trials, which likely will vary significantly as a result of many factors, including:

- delays in regulators or institutional review boards authorizing us or our investigators to commence our clinical trials, or in our ability to negotiate agreements with clinical trial sites or CROs;
- our ability to secure adequate supply of our product candidates for our trials;
- the number of clinical sites included in the trials;
- the ability and the length of time required to enroll suitable patients;
- the number of patients that ultimately participate in the trials;
- the number of doses patients receive;
- any side effects associated with our product candidates;
- the duration of patient follow-up;
- the results of our clinical trials;
- significant and changing government regulations; and
- the impact of unforeseen events, such as the COVID-19 pandemic, on the initiation and completion of our preclinical studies, clinical trials and manufacturing scale-up.

Our research and development 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 result in a significant change in the costs of 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.

### ***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 expand our operations and organizational capabilities. 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. As we prepare to commercialize our product candidates, we expect to incur significantly increased expenses associated with building our commercial infrastructure.

### ***Interest Income***

Interest income consists of amounts earned on our cash and cash equivalents 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 and government agency obligations.

### ***Interest Expense***

Interest expense consists of non-cash interest on proceeds received under the Royalty Agreement with Blackstone 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, 2020, we had federal and state tax net operating loss carryforwards of \$135.6 million and \$157.5 million, respectively, which each begin to expire in 2032 unless previously utilized. Approximately \$73.0 million of these federal net operating loss carryforwards are available to be carried forward indefinitely. We also had foreign net operating loss carryforwards of \$1.6 million which do not expire. As of December 31, 2020, we also had federal, state and foreign research and development tax credit carryforwards of \$7.5 million. The federal research and development tax credit carryforwards will begin to expire in 2032 unless previously utilized. The foreign research and development tax credit carryforwards do not have an expiration date.

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, given the current uncertainty over our ability to utilize such amounts.

## Results of Operations

### Comparison of the Three and Six Months Ended June 30, 2021 and 2020

The following table sets forth our results of operations for the three and six months ended June 30, 2021 and 2020 (in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2021 (unaudited)	2020 (unaudited)	Change	2021 (unaudited)	2020 (unaudited)	Change
Operating expenses:						
Research and development	\$ 15,966	\$ 13,839	\$ 2,127	\$ 28,389	\$ 28,092	\$ 297
General and administrative	5,122	3,874	1,248	10,180	7,439	2,741
Loss from operations	(21,088)	(17,713)	(3,375)	(38,569)	(35,531)	(3,038)
Other income (expense):						
Interest income	6	352	(346)	25	820	(795)
Interest expense	(1,302)	(1,295)	(7)	(2,555)	(2,390)	(165)
Foreign currency gain (loss)	(2)	(1)	(1)	(2)	27	(29)
Net loss	<u>\$ (22,386)</u>	<u>\$ (18,657)</u>	<u>\$ (3,729)</u>	<u>\$ (41,101)</u>	<u>\$ (37,074)</u>	<u>\$ (4,027)</u>

#### Research and Development Expense

Research and development expense increased by \$2.1 million from \$13.8 million for the three months ended June 30, 2020 to \$16.0 million for the three months ended June 30, 2021. Avasopasem development costs increased by \$1.3 million, due principally to increased expenses in our ROMAN trial and for CMC activities, partially offset by reduced preclinical expenses following the conclusion of toxicology studies. Other research and development expenses increased by \$1.0 million including costs for independent contractors, regulatory costs and recruiting expenses.

Research and development expense increased by \$0.3 million from \$28.1 million for the six months ended June 30, 2020 to \$28.4 million for the six months ended June 30, 2021. Other research and development expenses increased by \$1.5 million, including costs for independent contractors, regulatory and recruiting expenses, and the costs for development of additional product candidates. Avasopasem development costs decreased by \$0.7 million, due to reduced preclinical expenses following the conclusion of toxicology studies, partially offset by increased expenses for CMC activities and clinical trials. GC4711 development costs decreased by \$0.5 million due to decreased CMC and preclinical expenses, partially offset by expenses for our GRECO-1 and GRECO-2 trials.

#### General and Administrative Expense

General and administrative expense increased by \$1.2 million from \$3.9 million for the three months ended June 30, 2020 to \$5.1 million for the three months ended June 30, 2021. The increase was primarily due to increased employee headcount, increased share-based compensation expense due to grants of stock options to new and existing employees, an increase in expenses related to pre-commercial activities for avasopasem, and increased insurance expense.

General and administrative expense increased by \$2.7 million from \$7.4 million for the six months ended June 30, 2020 to \$10.2 million for the six months ended June 30, 2021. The increase was primarily due to increased employee headcount, increased share-based compensation expense due to grants of stock options to new and existing employees, an increase in expenses related to pre-commercial activities for avasopasem, and increased insurance expense.

#### Interest Income

Interest income decreased from \$0.4 million for the three months ended June 30, 2020 to \$6,000 for the three months ended June 30, 2021 and decreased from \$0.8 million for the six months ended June 30, 2020 to \$25,000 for the six months ended June 30, 2021, respectively. Lower average invested cash balances during the three and six months ended June 30, 2021 were compounded by lower average interest rates.

## Interest Expense

We recognized \$1.3 million in non-cash interest expense during each of the three months ended June 30, 2021 and 2020, and \$2.6 million and \$2.4 million in non-cash interest expense during the six months ended June 30, 2021 and 2020, respectively, in connection with the Royalty Agreement with Blackstone Life Sciences.

## Liquidity and Capital Resources

We do not currently have any approved products and have never generated any revenue from product sales. Through June 30, 2021, we have funded our operations primarily through the sale and issuance of equity and \$80.0 million of proceeds received under the Royalty Agreement with Blackstone Life Sciences, receiving aggregate gross proceeds of \$299.1 million. In November 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.

In December 2020, we entered into an Open Market Sales Agreement, or the Sales Agreement, with Jefferies LLC, or Jefferies, as sales agent, pursuant to which we may, from time to time, issue and sell common stock with an aggregate value of up to \$50.0 million in “at-the-market” offerings under our Registration Statement on Form S-3 (File No. 333-251061) filed with the SEC on December 1, 2020. Sales of common stock, if any, pursuant to the Sales Agreement, may be made in sales deemed to be an “at the market offering” as defined in Rule 415(a) of the Securities Act, including sales made directly through the Nasdaq Global Market or on any other existing trading market for our common stock. During the six months ended June 30, 2021, 665,279 shares were sold under this Sales Agreement at a weighted average price per share of \$8.95. Net proceeds after deducting fees, commissions and other expenses related to the offering were approximately \$5.7 million. As of June 30, 2021, there was \$44.0 million of common stock remaining available for sale under the Sales Agreement.

As of June 30, 2021, we had \$66.5 million in cash, cash equivalents and short-term investments and an accumulated deficit of \$276.7 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):

	Six months ended	
	June 30,	
	2021	2020
Net cash used in operating activities	\$ (32,108)	\$ (27,803)
Net cash provided by investing activities	28,628	5,279
Net cash provided by financing activities	26,073	20,050
Net increase (decrease) in cash and cash equivalents	\$ 22,593	\$ (2,474)

## Operating Activities

During the six months ended June 30, 2021, we used \$32.1 million of net cash in operating activities. Cash used in operating activities reflected our net loss of \$41.1 million, partially offset by non-cash charges of \$6.2 million related to share-based compensation, 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.

During the six months ended June 30, 2020, we used \$27.8 million of net cash in operating activities. Cash used in operating activities reflected our net loss of \$37.1 million, partially offset by non-cash charges of \$5.2 million related to share-based compensation, interest expense on our Royalty Agreement with Blackstone Life Sciences and depreciation expense, and \$4.0 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.



### *Investing Activities*

During the six months ended June 30, 2021, investing activities provided \$28.6 million in net cash proceeds, primarily attributable to \$28.8 million in net sales of our short-term investments, partially offset by \$0.2 million for the purchase of property and equipment.

During the six months ended June 30, 2020, investing activities provided \$5.3 million in net cash proceeds, primarily attributable to \$5.7 million in net sales of our short-term investments, partially offset by \$0.4 million for the purchase of property and equipment.

### *Financing Activities*

During the six months ended June 30, 2021, financing activities provided \$26.1 million, primarily attributable to \$20.0 million in proceeds received in connection with the Royalty Agreement with Blackstone Life Sciences, as disclosed below, \$5.7 million in proceeds from the sale of our common stock under the Sales Agreement with Jefferies, and \$0.4 million in proceeds from the exercise of stock options.

During the six months ended June 30, 2020, financing activities provided \$20.1 million, primarily attributable to the proceeds received in connection with the Royalty Agreement with Blackstone Life Sciences, as disclosed below.

### *Funding Requirements*

Our operating expenses increased substantially in 2020 and we expect our expenses to continue 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 continue to incur significant costs associated with operating as a public company. Accordingly, we would 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 ROMAN trial;
- prepare and potentially file for regulatory approval of avasopasem for the reduction of SOM in patients with HNC;
- advance our ongoing Phase 2a AESOP trial of avasopasem for the reduction in the incidence of radiotherapy-induced esophagitis, Phase 1/2 GRECO-1 trial for GC4711 to increase the anti-cancer efficacy of SBRT, in patients with NSCLC, and Phase 2b GRECO-2 trial for GC4711 to increase the anti-cancer efficacy of SBRT, in patients with pancreatic cancer;
- 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;
- scale-up our sales, marketing and distribution infrastructure and 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 or as a result of commercializing our product candidates.

We expect our existing cash, cash equivalents and short-term investments as of June 30, 2021, together with the payment from Blackstone in the amount of \$37.5 million received in July 2021, will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months from the issuance of our interim consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

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 scaling-up or contracting for sales and marketing capabilities as we prepare for the potential commercialization of 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" in Part I, Item 1A of the December 31, 2020 Form 10-K.

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, our shareholders' 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 received the first tranche of the Royalty Purchase Price in November 2018, the second tranche of the Royalty Purchase Price in April 2019, and the third tranche of the Royalty Purchase Price in February 2020, in each case in connection with the achievement of the first three milestones, respectively, 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. We received the new \$20.0 million tranche of the Amendment in June 2021, in connection with the enrollment of the first patient in the GRECO-2 trial. Also in June 2021, we completed enrollment in the ROMAN trial, thereby achieving the milestone associated with the fourth tranche, and received the associated \$37.5 million in July 2021.

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 six months ended June 30, 2021 or 2020.

### **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 June 30, 2021.

### *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 June 30, 2021 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**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, 2020, filed with the SEC on March 11, 2021. 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.*

**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.

As of June 30, 2021, we had used \$41.2 million of the net proceeds from our IPO. Remaining net proceeds of approximately \$16.8 million have been invested in money market funds and U.S. Treasury and government agency 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.

<u>Exhibit Number</u>	<u>Description</u>	<u>Form</u>	<u>File No.</u>	<u>Exhibit</u>	<u>Filing Date</u>	<u>Filed/ Furnished Herewith</u>
3.1	Restated Certificate of Incorporation of Galera Therapeutics, Inc.	<a href="#">8-K</a>	<a href="#">001-39114</a>	<a href="#">3.1</a>	11/12/2019	
3.2	Amended and Restated Bylaws of Galera Therapeutics, Inc.	<a href="#">8-K</a>	<a href="#">001-39114</a>	<a href="#">3.1</a>	9/25/2020	
31.1	<a href="#">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.</a>					*
31.2	<a href="#">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.</a>					*
32.1	<a href="#">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.</a>					**
32.2	<a href="#">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.</a>					**
101.INS	Inline XBRL Instance Document - the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document					
101.SCH	Inline XBRL Taxonomy Extension Schema Document					
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					

\* Filed herewith.

\*\* Furnished herewith.











**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 June 30, 2021 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: August 10, 2021

By: \_\_\_\_\_ /s/ Christopher Degnan  
Christopher Degnan  
Chief Financial Officer  
(principal executive officer)