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, 2023

or

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

For the transition period from _____ to _____

Commission File Number: 001-39114

Galera Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**46-1454898**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
45 Liberty Blvd, Suite 230 Malvern, Pennsylvania	**19355**
(Address of principal executive offices)	**(Zip Code)**

(610) 725-1500

(Registrant's telephone number, including area code)

N/A

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

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

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

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

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

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

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

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

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

As of August 10, 2023, the registrant had 43,928,666 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 the expected financial and operational impacts of our recent reduction in force; our intention to request and hold a Type A meeting with the FDA; our plans to evaluate strategic alternatives; our plans to develop and commercialize our product candidates, the timing of and our plans regarding 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, expected coverage and reimbursement for avasopasem and our other product candidates, the sufficiency of our cash, cash equivalents and short-term investments and our ability to raise additional capital to fund our operations, our plans to mitigate the risk that we are unable to continue as a going concern, the anticipated impact of the COVID-19 pandemic and general economic conditions 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; substantial doubt regarding our ability to continue as a going concern; needing substantial funding and the ability to raise capital; our dependence on avasopasem manganese (GC4419) and our other product candidates; 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; 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; our recent reduction in force undertaken to significantly reduce our ongoing operating expenses may not result in our intended outcomes and may yield unintended consequences and additional costs; we may not be able to enter into any desired strategic alternative or partnership on a timely basis, on acceptable terms, or at all; if we are unable to secure additional funding or enter into any desired strategic alternative or partnership, we may need to cease operations; the impact of the COVID-19 pandemic and general economic conditions on our business and operations, including clinical trials; 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, 2022 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, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 24,302	$ 4,266
Short-term investments	14,453	27,331
Restricted cash	50	50
Refundable PDUFA fee	—	3,242
Prepaid expenses and other current assets	3,198	3,646
Total current assets	42,003	38,535
Property and equipment, net	210	438
Acquired intangible asset	2,258	2,258
Goodwill	881	881
Right-of-use lease assets	1,286	43
Other assets	1,638	1,881
Total assets	$ 48,276	$ 44,036
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 5,516	$ 3,581
Accrued expenses	7,978	9,754
Lease liabilities	128	44
Total current liabilities	13,622	13,379
Royalty purchase liability	148,257	139,635
Lease liabilities, net of current portion	1,193	—
Deferred tax liability	203	203
Total liabilities	163,275	153,217
Stockholders' deficit:		
Preferred stock, $0.001 par value: 10,000,000 shares authorized; no shares issued and outstanding.	—	—
Common stock, $0.001 par value: 200,000,000 shares authorized; 43,826,833 and 28,510,066 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	44	28
Additional paid-in capital	301,698	269,137
Accumulated other comprehensive gain (loss)	5	(22)
Accumulated deficit	(416,746)	(378,324)
Total stockholders' deficit	(114,999)	(109,181)
Total liabilities and stockholders' deficit	$ 48,276	$ 44,036

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,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 7,561	$ 6,636	$ 14,833	$ 14,743
General and administrative	9,246	5,293	15,855	10,340
Loss from operations	(16,807)	(11,929)	(30,688)	(25,083)
Other income (expenses):				
Interest income	494	71	889	85
Interest expense	(4,399)	(2,699)	(8,622)	(5,002)
Foreign currency loss	—	(1)	(1)	(1)
Net loss	(20,712)	(14,558)	(38,422)	(30,001)
Net loss per share of common stock, basic and diluted	$ (0.48)	$ (0.54)	$ (0.98)	$ (1.12)
Weighted-average shares of common stock outstanding, basic and diluted	42,916,962	26,821,303	39,077,876	26,785,540

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,	
	2023	2022	2023	2022
Net loss	$ (20,712)	$ (14,558)	$ (38,422)	$ (30,001)
Unrealized gain (loss) on short-term investments	(11)	(49)	27	(96)
Comprehensive loss	$ (20,723)	$ (14,607)	$ (38,395)	$ (30,097)

See accompanying notes to unaudited interim consolidated financial statements.

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

	Common stock		Additional paid-in	Accumulated other comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	capital	gain (loss)	Deficit	Deficit
Balance at January 1, 2023	28,510,066	$ 28	$ 269,137	$ (22)	$ (378,324)	$ (109,181)
Share-based compensation expense	—	—	1,458	—	—	1,458
Exercise of stock options	76,767	1	183	—	—	184
Sale of common stock and common stock warrants in registered direct offering, net of issuance costs of $2,403	14,320,000	14	27,584	—	—	27,598
Unrealized gain on short-term investments	—	—	—	38	—	38
Net loss	—	—	—	—	(17,710)	(17,710)
Balance at March 31, 2023	42,906,833	43	298,362	16	(396,034)	(97,613)
Share-based compensation expense	—	—	1,525	—	—	1,525
Exercise of common stock warrants	920,000	1	1,811	—	—	1,812
Unrealized loss on short-term investments	—	—	—	(11)	—	(11)
Net loss	—	—	—	—	(20,712)	(20,712)
Balance at June 30, 2023	43,826,833	$ 44	$ 301,698	$ 5	$ (416,746)	$ (114,999)

	Common stock		Additional paid-in	Accumulated other comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	capital	loss	Deficit	Deficit
Balance at January 1, 2022	26,458,767	$ 26	$ 258,086	$ (14)	$ (316,102)	$ (58,004)
Share-based compensation expense	—	—	1,848	—	—	1,848
Exercise of stock options	46,358	—	58	—	—	58
Sale of shares under Open Market Sale Agreement, net	314,296	1	1,116	—	—	1,117
Unrealized loss on short-term investments	—	—	—	(47)	—	(47)
Net loss	—	—	—	—	(15,443)	(15,443)
Balance at March 31, 2022	26,819,421	27	261,108	(61)	(331,545)	(70,471)
Share-based compensation expense	—	—	1,830	—	—	1,830
Exercise of stock options	2,168	—	2	—	—	2
Unrealized loss on short-term investments	—	—	—	(49)	—	(49)
Net loss	—	—	—	—	(14,558)	(14,558)
Balance at June 30, 2022	26,821,589	$ 27	$ 262,940	$ (110)	$ (346,103)	$ (83,246)

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,	
	2023	**2022**
Operating activities:		
Net loss	$ (38,422)	$ (30,001)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	32	61
Noncash interest expense	8,622	5,002
Share-based compensation expense	2,983	3,678
Gain on disposal of property and equipment	(72)	—
Changes in operating assets and liabilities:		
Refundable PDUFA fee	3,242	—
Prepaid expenses and other current assets	768	2,994
Other assets	309	(12)
Accounts payable	1,935	(1,456)
Accrued expenses	(1,777)	(407)
Other liabilities	(32)	(130)
Cash used in operating activities	(22,412)	(20,271)
Investing activities:		
Purchases of short-term investments	(18,596)	(34,529)
Proceeds from sales of short-term investments	31,500	51,160
Purchase of property and equipment	(50)	(20)
Cash provided by investing activities	12,854	16,611
Financing activities:		
Proceeds from the sale of common stock and common stock warrants, net of issuance costs	27,598	1,117
Proceeds from the exercise of common stock warrants	1,812	—
Proceeds from exercise of stock options	184	60
Cash provided by financing activities	29,594	1,177
Net increase (decrease) in cash, cash equivalents and restricted cash	20,036	(2,483)
Cash, cash equivalents and restricted cash at beginning of period	4,316	19,859
Cash, cash equivalents and restricted cash at end of period	$ 24,352	$ 17,376
Supplemental schedule of non-cash investing and financing activities:		
Right-of-use asset obtained in exchange for lease obligation	$ 1,310	$ —
Sale of property and equipment in exchange for prepaid future services	$ 319	$ —

See accompanying notes to unaudited interim consolidated financial statements.

1. Organization and description of business

Galera Therapeutics, Inc. was incorporated as a Delaware corporation on November 19, 2012 (inception) and together with its subsidiaries (the Company, or Galera) is a clinical stage biopharmaceutical company focused on developing and commercializing a pipeline of novel, proprietary therapeutics that have the potential to transform radiotherapy in cancer. Galera's technology consists of selective small molecule dismutase mimetics that are in late-stage development in patients with cancer. Avasopasem manganese (avasopasem, or GC4419) is in development for radiotherapy-induced toxicities, including severe oral mucositis (SOM) in patients with locally advanced head and neck cancer (HNC) and esophagitis in patients with lung cancer. The Company is also exploring the potential for avasopasem to reduce cisplatin-induced kidney damage. The U.S. Food and Drug Administration (FDA) has granted Fast Track and Breakthrough Therapy designations to avasopasem for the reduction of SOM induced by radiotherapy. Galera's second dismutase mimetic product candidate, rucosopasem manganese (rucosopasem, or GC4711), is in clinical-stage development to augment the anti-cancer efficacy of stereotactic body radiation therapy (SBRT) in patients with non-small cell lung cancer (NSCLC) and locally advanced pancreatic cancer (LAPC). The FDA has granted orphan drug designation to rucosopasem for the treatment of pancreatic cancer.

In December 2021, the Company announced topline efficacy results from a Phase 3 trial (referred to as the ROMAN trial) evaluating avasopasem for the reduction of radiotherapy-induced SOM in patients with locally advanced HNC. The results demonstrated efficacy across multiple SOM endpoints with a statistically significant reduction on the primary endpoint of reduction in the incidence of SOM and a statistically significant reduction on the secondary endpoint of number of days of SOM, with a median of 18 days in the placebo arm versus 8 days in the avasopasem arm. The Company had previously announced topline results from the ROMAN trial in October 2021 that incorrectly stated the reduction on the primary endpoint was not statistically significant. Upon further analysis, an error by the contract research organization was identified in the statistical program. Correction of this error yielded the correct, statistically significant p-values for the primary and a key secondary endpoint. Exploratory analyses, such as time to SOM onset and SOM incidence at various landmarks of radiotherapy delivered, further demonstrated the potential clinical utility of avasopasem in reducing the burden of SOM. Avasopasem appeared to be generally well tolerated compared to placebo.

The ROMAN trial is the Company's second randomized, placebo-controlled trial conducted in patients with HNC to achieve statistical significance and demonstrate clinical benefit in reducing SOM. In December 2022, the Company submitted an NDA to the FDA for avasopasem for radiotherapy-induced SOM in patients with HNC undergoing standard-of-care treatment. The NDA is supported by the data from the two randomized, double-blinded, placebo-controlled trials (ROMAN and Phase 2b GT-201), as well as data from other clinical trials of avasopasem in the proposed indication. In February 2023, the FDA accepted the NDA and granted priority review with a Prescription Drug User Fee Act (PDUFA) target date of August 9, 2023. The FDA indicated in its acceptance of filing letter that it is not planning to hold an advisory committee meeting on the application.

On August 9, 2023, the Company announced that it had received a Complete Response Letter (CRL) from the FDA regarding the Company's NDA for avasopasem for radiotherapy-induced SOM in patients with HNC undergoing standard-of-care treatment. In the CRL, the FDA communicated that the results from the Phase 3 ROMAN trial together with the supporting data from the Phase 2b GT-201 trial are not sufficiently persuasive to establish substantial evidence of avasopasem's effectiveness and safety for reducing SOM in patients with HNC. FDA stated that results from an additional clinical trial will be required for resubmission. The Company intends to request a Type A meeting with the FDA to understand the FDA's rationale for its decision and discuss next steps to support an NDA resubmission seeking approval of avasopasem.

In addition to developing avasopasem for the reduction of normal tissue toxicity from radiotherapy, the Company is developing its second dismutase mimetic product candidate, rucosopasem, to increase the anti-cancer efficacy of higher daily doses of radiotherapy, or SBRT. In September 2021, in support of rucosopasem, the Company announced final results from its Phase 1/2 pilot trial of avasopasem in combination with SBRT in patients with unresectable or borderline resectable LAPC. In this proof-of-concept trial, survival and tumor outcome benefits were observed. The Company used its observations from this pilot trial to inform the design of rucosopasem clinical trials in combination with SBRT. The Company has successfully completed Phase 1 trials of intravenous rucosopasem in healthy volunteers and is currently evaluating rucosopasem in combination with SBRT in a Phase 1/2 safety and anti-cancer efficacy trial in NSCLC and a Phase 2b trial of rucosopasem in combination with SBRT in patients with LAPC.

In connection with the CRL announcement, on August 9, 2023, the Company further announced that it will focus resources on exploring a potential approval path for avasopasem in radiotherapy-induced SOM, progressing its ongoing clinical trials for rucosopasem, and concurrently evaluating strategic alternatives, including partnering, for the continued development of avasopasem and rucosopasem. As a result, the Company is winding down its commercial readiness efforts for avasopasem and reducing headcount across several departments. This reduction in force, which was approved by the Company's Board of Directors,

reduces the Company's current workforce by 22 employees, or approximately 70%, as of August 9, 2023 (the Workforce Reduction). The decision was based on cost-reduction initiatives intended to reduce operating expenses. The Company currently estimates that it will incur charges of approximately $2.0 to $2.5 million in connection with the Workforce Reduction, primarily consisting of severance payments, employee benefits and related costs. The Company expects that the majority of these charges will be incurred in the third quarter of 2023. The Workforce Reduction and other cost savings actions being implemented are expected to extend the Company's cash runway into the second quarter of 2024.

Liquidity

The Company has incurred recurring losses and negative cash flows from operations since inception and has an accumulated deficit of $416.7 million as of June 30, 2023. 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 follows the provisions of Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 205-40, *Presentation of Financial Statements—Going Concern*, which requires management to assess the Company's ability to continue as a going concern for one year after the date the financial statements are issued. The Company expects its existing cash, cash equivalents and short-term investments as of June 30, 2023 will enable the Company to fund its operating expenses and capital expenditure requirements into the second quarter of 2024, but not for more than one year after the date of the filing of this Quarterly Report on Form 10-Q, and therefore management has concluded that substantial doubt exists about the Company's ability to continue as a going concern. Management's plans to mitigate this risk include raising additional capital through equity or debt financings, or through strategic transactions. Management's plans may also include the deferral of certain operating expenses unless and until additional capital is received. However, there can be no assurance that the Company will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to the Company, or that the Company will be successful in deferring certain operating expenses. If the Company is unable to raise sufficient additional capital or defer sufficient operating expenses, the Company may be compelled to reduce the scope of its operations and planned capital expenditures. In the future, if the Company is not able to continue to raise sufficient capital to fund its operations, the Company may decide to delay or discontinue certain activities, including planned research and development activities, hiring plans, manufacturing activities and commercial preparation efforts. If we continue to have insufficient funds, particularly if we are unable to undertake any strategic alternative, we may be required to cease our operations altogether. The interim consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the continuity of operations, the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

In December 2020, the Company filed a registration statement with the Securities and Exchange Commission (SEC) which covers the offering, issuance and sale of up to $200.0 million in Company 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. No securities were issued pursuant to the Sales Agreement during the six months ended June 30, 2023. As of June 30, 2023, there remained $37.8 million available under the Sales Agreement.

On February 17, 2023, the Company completed a registered direct offering, which resulted in the issuance and sale of 14,320,000 shares of its common stock and warrants to purchase up to 14,320,000 shares of common stock at a combined offering price of $2.095 per share and accompanying warrant, generating gross proceeds of $30.0 million. The warrants have an exercise price of $1.97 per share of common stock, are exercisable immediately following their issuance and will expire five years from the date of issuance. The Company received net proceeds of $27.6 million from this offering, after deducting placement agent fees and offering expenses.

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, 2022 and 2021 included in the Company's annual report on Form 10-K filed with the SEC on March 8, 2023 have not materially changed, except as set forth below.

Basis of presentation and consolidation

The accompanying unaudited interim consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles (U.S. GAAP) for interim financial information. Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) of the Financial Accounting Standards Board (FASB).

In the opinion of management, the accompanying interim consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's financial position as of June 30, 2023 and its results of operations for the three and six months ended June 30, 2023 and 2022, and statements of changes in stockholder's equity (deficit) and cash flows for the six months ended June 30, 2023 and 2022. Operating results for the three and six months ended June 30, 2023 are not necessarily indicative of the results that may be expected for the year ending December 31, 2023, 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, 2022, included in the Company's annual report on Form 10-K and filed with the SEC on March 8, 2023.

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.

Cash and cash equivalents

The Company considers all highly liquid investments that have maturities of three months or less when acquired to be cash equivalents. Cash and cash equivalents as of June 30, 2023 and December 31, 2022 consisted of bank deposits, U.S. Treasury obligations, U.S. government agency securities, and a money market mutual fund invested in U.S. Treasury obligations. We maintain a portion of our cash and cash equivalents in accounts with major financial institutions, and our deposits at these institutions exceed insured limits.

Restricted cash

Restricted cash represents collateral provided under a commercial credit card agreement entered into with TD Bank, N.A. during July 2022. Restricted cash was $50,000 as of June 30, 2023. The Company has recorded this deposit and accumulated interest thereon as restricted cash on its consolidated balance sheet.

Refundable PDUFA fee

In December 2022, the Company paid a $3.2 million PDUFA fee to the FDA in conjunction with the filing of its NDA for avasopasem. The Company requested and was granted a small business waiver of this PDUFA fee from the FDA. The Company received the refund of the PDUFA fee from the FDA in May 2023.

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.

Net loss per share

The Company uses the two-class method to compute net income per common share during periods the Company realizes net income and has securities that entitle the holder to participate in dividends and earnings of the Company. The two-class method is not applicable during periods with a net loss, as the participating securities are not obligated to fund losses. Basic loss per share of common stock is computed by dividing net loss 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.

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:

	June 30,	
	2023	2022
Stock options	7,773,866	5,814,022
Common stock warrants	13,950,661	550,661
	21,724,527	6,364,683

Recent Accounting Pronouncements

In August 2020, FASB issued ASU 2020-06, *"Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity,"* which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, and it also simplifies the diluted earnings per share calculation in certain areas. This guidance is effective for fiscal years beginning after December 15, 2023, including interim periods therein. Early adoption is permitted. The Company adopted this ASU on January 1, 2023. There was 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.
- 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, 2023		
	(Level 1)	(Level 2)	(Level 3)
Assets			
Cash equivalents			
Money market funds and U.S. Treasury obligations	$ 16,075	$ —	$ —
U.S. government agency securities	—	6,152	—
Total cash equivalents	$ 16,075	$ 6,152	$ —
Short-term investments			
U.S. government agency securities	$ —	$ 14,453	$ —
Total short-term investments	$ —	$ 14,453	$ —

	December 31, 2022		
	(Level 1)	(Level 2)	(Level 3)
Assets			
Money market funds and U.S. Treasury obligations (included in cash equivalents)	$ 3,467	$ —	$ —
Short-term investments			
U.S. government agency securities	$ —	$ 8,172	$ —
U.S. Treasury obligations	19,159	—	—
Total short-term investments	$ 19,159	$ 8,172	$ —

There were no changes in valuation techniques during the six months ended June 30, 2023. The Company's short-term investment instruments classified using Level 1 inputs within the fair value hierarchy are classified as such 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, 2023	December 31, 2022
Laboratory equipment	$ 571	$ 1,398
Computer hardware and software	305	292
Leasehold improvements	36	270
Furniture and fixtures	179	179
Property and equipment, gross	1,091	2,139
Less: Accumulated depreciation and amortization	(881)	(1,701)
Property and equipment, net	$ 210	$ 438

Depreciation and amortization expense was $32,000 and $0.1 million for the six months ended June 30, 2023 and 2022, respectively.

5. Accrued expenses

Accrued expenses consist of (amounts in thousands):

	June 30, 2023	December 31, 2022
Compensation and related benefits	$ 1,792	$ 2,655
Research and development expenses	5,560	6,764
Professional fees and other expenses	626	335
	$ 7,978	$ 9,754

6. Royalty purchase liability

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

The Company accounts for the Royalty Agreement as a debt instrument. The $117.5 million in proceeds received as of June 30, 2023 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. The Company updated the assumptions underlying the calculation of interest expense on the royalty purchase liability based on the FDA acceptance of the Company's NDA in February 2023 with Priority Review designation. The Company recognized $8.6 million and $5.0 million in noncash interest expense during the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, the effective interest rate was 12.3%.

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 rucosopasem (collectively, the Products) and (ii) all amounts received by the Company or its affiliates, licensees and sublicensees with respect to Product-related damages (collectively, the Product Payments) during the Royalty Period. The Royalty Period means, on a Product-by-Product and country-by-country basis, the period of time commencing on the commercial launch of such Product in such country and ending on the latest to occur of (i) the 12th anniversary of such commercial launch, (ii) the expiration of all valid claims of the Company’s patents covering such Product in such country, and (iii) the expiration of regulatory data protection or market exclusivity or similar regulatory protection afforded by the health authorities in such country, to the extent such protection or exclusivity effectively prevents generic versions of such Product from entering the market in such country.

The 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. If no Products

are commercialized, the Company would not have an obligation to make Product Payments to Blackstone, which is the sole mechanism for repaying the liability.

Upon execution of the Amendment, the Company issued common stock warrants to the Blackstone Purchaser, each of which became exercisable upon the receipt by the Company of the applicable specified milestone payment. The issued warrants expire six years after the initial exercise dates, as follows:

	Shares	Exercise Price	Initial Exercise Date	Expiration Date
New Milestone Warrant	293,686	$ 13.62	6/7/2021	6/6/2027
Fourth Milestone Warrant	256,975	$ 13.62	7/19/2021	7/18/2027

The warrants are equity-classified and were valued at $4.7 million using the Black-Scholes option pricing model. The warrants were recorded as a discount to the royalty purchase liability. The Company amortizes 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 a non-cancelable operating lease for office space in Malvern, Pennsylvania which, as of June 30, 2023, has a remaining lease term of approximately 7.3 years. The discount rate used to account for the Company's operating leases under FASB ASU No. 2018-11, Leases (Topic 842), is the Company's estimated incremental borrowing rate of 5.4%.

Supplemental balance sheet information related to leases was as follows:

	June 30, 2023	December 31, 2022
Operating Leases		
Right-of-use lease assets	$ 1,286	$ 43
Lease liabilities, current	128	44
Lease liabilities, net of current portion	1,193	0
Total operating lease liabilities	$ 1,321	$ 44

Lease cost, as presented below, includes costs associated with leases for which right-of-use (ROU) assets have been recognized as well as short-term leases. The components of lease expense were as follows:

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Operating lease costs				
Operating lease rental expense	$ 36	$ 65	$ 84	$ 136
Total operating lease expense	$ 36	$ 65	$ 84	$ 136

Supplemental cash flow information related to leases was as follows:

	Six months ended June 30,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows for operating leases	$ 44	$ 135
Right-of-use assets obtained in exchange for lease obligation		
Operating leases	1,310	—

Future minimum rental payments under the Company's non-cancelable operating lease liabilities as of June 30, 2023 (amounts in thousands):

Remainder of 2023	106
2024	195
2025	217
2026	220
2027 and after	856
Total	1,594
Less: imputed interest	(273)
	$ 1,321

8. Equity

Equity offerings

In February 2023, the Company completed a registered direct offering, which resulted in the issuance and sale of 14,320,000 shares of its common stock and warrants to purchase up to 14,320,000 shares of common stock at a combined offering price of $2.095 per share and accompanying warrant, and received net proceeds of $27.6 million after deducting placement agent fees and offering expenses. The warrants are equity-classified, have an exercise price of $1.97 per share of common stock, are exercisable immediately following their issuance, and will expire five years from the date of issuance. During the three months ended June 30, 2023, warrants were exercised in exchange for 920,000 shares of common stock resulting in proceeds of $1.8 million.

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" (ATM) 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. No securities were issued pursuant to the Sales Agreement during the six months ended June 30, 2023. As of June 30, 2023, there was $37.8 million of available capacity under the Sales Agreement.

Share-based compensation

Equity Incentive Plan

In November 2012, the Company adopted the Galera Therapeutics, Inc. Equity Incentive Plan (the Prior Plan). The Prior Plan provided for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, and stock appreciation rights. In connection with the adoption of the 2019 Plan (as defined below), the Company ceased issuing awards under the Prior Plan. As a result, no shares remain available for issuance under the Prior Plan; however, the Prior Plan continues to govern awards that are outstanding under it. The total number of shares subject to outstanding awards under the Prior Plan as of June 30, 2023 was 1,714,906.

2019 Incentive Award Plan

In connection with the Company's Initial Public Offering, or 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.

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. As of June 30, 2023, there were 492,171 shares available for future issuance under the 2019 Plan, including 1,140,402 shares added pursuant to this provision effective January 1, 2023. 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. As of June 30, 2023, there were 1,291,184 shares available for issuance under the ESPP, including 285,100 shares added pursuant to this provision effective January 1, 2023.

2023 Employment Inducement Award Plan

On April 28, 2023, the Board of Directors adopted the Galera Therapeutics, Inc. 2023 Employment Inducement Award Plan (Inducement Plan), which became effective on such date without stockholder approval pursuant to Rule 5635(c)(4) of The Nasdaq Stock Market LLC listing rules ("Rule 5635(c)(4)"). The Inducement Plan provides for the grant of nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units, and other stock-based awards. In accordance with Rule 5635(c)(4), awards under the Inducement Plan may only be granted to persons who (a) were not previously an employee or director of the Company, or (b) are commencing employment with the Company following a bona fide period of non-employment, in either case as an inducement material to the individual's entering into employment with the Company. A total of 1,500,000 shares of common stock was reserved for issuance under the Inducement Plan. Any shares subject to awards previously granted under the Inducement Plan that expire, terminate or are otherwise surrendered, canceled, or forfeited, in a manner that results in the Company (i) acquiring the shares covered by the award at a price not greater than the price (as adjusted to reflect any equity restructuring) paid by the participant for such shares or (ii) not issuing any shares covered by the award, the unused shares covered by such awards will again be available for award grants under the Inducement Plan. As of June 30, 2023, there were 1,185,000 shares available for issuance under the Inducement Plan.

Share-based Compensation

Share-based compensation expense was as follows for the three and six months ended June 30, 2023 and 2022 (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Research and development	$ 448	$ 646	$ 900	$ 1,307
General and administrative	1,077	1,184	2,083	2,371
	$ 1,525	$ 1,830	$ 2,983	$ 3,678

The following table summarizes the activity related to stock option grants for the six months ended June 30, 2023:

	Shares	Weighted average exercise price per share	Weighted-average remaining contractual life (years)
Outstanding at January 1, 2023	5,783,185	$ 6.86	6.8
Granted	2,378,700	2.11	
Exercised	(76,767)	2.39	
Forfeited	(311,252)	6.47	
Outstanding at June 30, 2023	7,773,866	$ 5.47	7.6
Vested and exercisable at June 30, 2023	3,999,316	$ 7.17	6.1
Vested and expected to vest at June 30, 2023	7,773,866	$ 5.47	7.6

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.

As of June 30, 2023, the unrecognized compensation cost was $10.3 million and will be recognized over an estimated weighted-average amortization period of 2.3 years. The aggregate intrinsic value of options outstanding and of options exercisable as of June 30, 2023 were $4.5 million and $1.4 million, respectively. Options granted during the six months ended June 30, 2023 and 2022 had weighted-average grant-date fair values of $1.66 and $1.67 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, 2023 and 2022 was determined using the methods and assumptions discussed below.

- The expected term of employee stock options with service-based vesting is determined using the "simplified" method, as prescribed in SEC's Staff Accounting Bulletin (SAB) No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to the Company's lack of sufficient historical data. The expected term of nonemployee options is equal to the contractual term.

- The expected stock price volatility is based on historical volatilities of comparable public entities within the Company's industry which were commensurate with the expected term assumption as described in SAB No. 107.

- The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the expected term.

- The expected dividend yield is 0% because the Company has not historically paid, and does not expect for the foreseeable future to pay, a dividend on its common stock.

- The Company's board of directors has determined the 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 six months ended June 30, 2023 and 2022 using the Black-Scholes option-pricing model using the following weighted-average assumptions:

	Six months ended June 30,	
	2023	2022
Expected term (in years)	6.2	6.2
Expected stock price volatility	95.3%	91.4%
Risk-free interest rate	4.05%	1.86%
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 both of the six months ended June 30, 2023 and 2022 were $0.1 million.

10. Subsequent events

On August 9, 2023, the Company announced that it had received a CRL from the FDA regarding the Company's NDA for avasopasem for radiotherapy-induced SOM in patients with HNC undergoing standard-of-care treatment. In the CRL, the FDA communicated that the results from the Phase 3 ROMAN trial together with the supporting data from the Phase 2b GT-201 trial are not sufficiently persuasive to establish substantial evidence of avasopasem's effectiveness and safety for reducing SOM in patients with HNC. FDA stated that results from an additional clinical trial will be required for resubmission. The Company intends to request a Type A meeting with the FDA to understand the FDA's rationale for its decision and discuss next steps to support an NDA resubmission seeking approval of avasopasem. The CRL is expected to have an impact on the amounts the Company records for interest expense on the royalty purchase liability under the Royalty Agreement, and may impact the carrying value of the royalty purchase liability, and such impacts may be material. In addition, we may perform impairment testing on the carrying value of the acquired intangible asset and goodwill on our balance sheet during the third quarter of 2023.

On August 9, 2023, the Company also announced a plan to reduce expenses and extend its cash runway. In connection with this plan, the Board of Directors of the Company approved the Workforce Reduction. The decision was based on cost-reduction initiatives intended to reduce operating expenses. The Company currently estimates that it will incur charges of approximately $2.0 to $2.5 million in connection with the Workforce Reduction, primarily consisting of severance payments, employee benefits and related costs. The Company expects that the majority of these charges will be incurred in the third quarter of 2023. The Workforce Reduction and other cost savings actions being implemented are expected to extend the Company's cash runway into the second quarter of 2024. The estimates of the charges and expenditures that the Company expects to incur in connection with the Workforce Reduction, and the timing thereof, are subject to several assumptions and the actual amounts incurred may differ materially from these estimates. In addition, the Company may incur other charges or cash expenditures not currently contemplated due to unanticipated events that may occur, including in connection with the implementation of the Workforce Reduction.

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 for the fiscal year ended December 31, 2022, filed with the SEC on March 8, 2023, or the 2022 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. Avasopasem manganese (avasopasem, or GC4419) is a highly selective small molecule dismutase mimetic in development for the reduction of severe oral mucositis, or SOM, in patients with head and neck cancer, or HNC, and for the reduction of esophagitis in patients with lung cancer. We are also exploring the potential for avasopasem to reduce cisplatin-induced kidney damage. SOM is a common, debilitating complication of radiotherapy in patients with HNC. The U.S. Food and Drug Administration, or FDA, has granted Fast Track and Breakthrough Therapy designations to avasopasem for the reduction of SOM induced by radiotherapy. Our second dismutase mimetic product candidate, rucosopasem manganese (rucosopasem, or GC4711), is in clinical-stage development to augment the anti-cancer efficacy of stereotactic body radiation therapy, or SBRT, in patients with non-small cell lung cancer, or NSCLC, and locally advanced pancreatic cancer, or LAPC. The FDA has granted orphan drug designation to rucosopasem for the treatment of pancreatic cancer.

Radiotherapy-induced SOM can lead to devastating complications for patients. A majority will suffer severe pain which is often managed with the use of opioids. Patients with SOM are at risk of dehydration and malnutrition as a result of the inability to eat or drink, and often require nutrition through an intravenous line or surgical placement of a feeding tube. Each year in the United States approximately 67,000 patients are diagnosed with HNC, according to the American Cancer Society. In the five largest European markets, approximately 68,000 patients are diagnosed annually with HNC, and an additional 23,000 in Japan. We estimate that approximately 65% of patients diagnosed with HNC will be treated with radiotherapy. All patients with HNC treated with radiotherapy are at risk for developing SOM, which suggests a target patient population of approximately 43,500 patients in the United States alone for our lead indication. We believe that SOM in patients with HNC represents a total market opportunity of more than $1.5 billion in the United States based on branded supportive care price analogs. There are currently no FDA-approved drugs for SOM in these patients and we believe avasopasem, which to date is not approved for any indication, has the potential to become the standard of care for the reduction of SOM in patients with HNC receiving radiotherapy.

In December 2022, we submitted a New Drug Application, or NDA, to the FDA for avasopasem for the reduction of radiotherapy-induced SOM in patients with HNC undergoing standard-of-care treatment. The NDA was supported by the data from two randomized, double-blinded, placebo-controlled trials (Phase 3 ROMAN and Phase 2b GT-201), as well as data from other clinical trials of avasopasem in the proposed indication. In February 2023, the FDA accepted the NDA for filing and granted priority review with a Prescription Drug User Fee Act, or PDUFA, target date of August 9, 2023. On August 9, 2023, we announced receipt of a Complete Response Letter, or CRL, from the FDA regarding our NDA for avasopasem for radiotherapy-induced SOM in patients with HNC undergoing standard-of-care treatment. In the CRL, the FDA communicated that the results from the Phase 3 ROMAN trial together with the supporting data from the Phase 2b GT-201 trial are not sufficiently persuasive to establish substantial evidence of avasopasem's effectiveness and safety for reducing SOM in patients with HNC. FDA stated that results from an additional clinical trial will be required for resubmission. We intend to request a Type A meeting with the FDA to understand the FDA's rationale for its decision and discuss next steps to support an NDA resubmission seeking approval of avasopasem.

In connection with the CRL announcement, on August 9, 2023, we further announced that we will focus resources on exploring a potential approval path for avasopasem in radiotherapy-induced SOM, progressing our ongoing clinical trials for rucosopasem, and concurrently evaluating potential strategic alternatives, including partnering, for the continued development of avasopasem and rucosopasem. As a result, we are winding down our commercial readiness efforts for avasopasem and reducing headcount across several departments. This reduction in force, which was approved by our Board of Directors, reduces our current workforce by 22 employees, or approximately 70%, as of August 9, 2023, or the Workforce Reduction. The decision was based on cost-reduction initiatives intended to reduce operating expenses.

In December 2021, we announced topline efficacy results from a Phase 3 trial of avasopasem for the reduction of radiotherapy-induced SOM in patients with locally advanced HNC, which we refer to as the Reduction in Oral Mucositis with Avasopasem Manganese, or ROMAN, trial. The results demonstrated efficacy across multiple SOM endpoints with a statistically significant reduction on the primary endpoint of reduction in the incidence of SOM and a statistically significant reduction on the secondary endpoint of number of days of SOM, with a median of 18 days in the placebo arm versus 8 days in the avasopasem arm. We had previously announced topline results from the ROMAN trial in October 2021 that incorrectly stated the reduction on the primary endpoint was not statistically significant. Upon further analysis, an error by the contract research organization was identified in the statistical program. Correction of this error yielded the correct, statistically significant p-values for the primary and a key secondary endpoint. Exploratory analyses, such as time to SOM onset and SOM incidence at various landmarks of radiotherapy delivered, further demonstrated the potential clinical utility of avasopasem in reducing the burden of SOM. Avasopasem appeared to be generally well tolerated compared to placebo.

In October 2022, we announced the presentation of the one-year tumor and renal function outcomes data from the ROMAN trial as well as topline results from a recently completed meta-analysis of the ROMAN and GT-201 (Phase 2b) SOM trial results at the 2022 American Society for Radiation Oncology, or ASTRO, Annual Meeting. After one-year follow-up, patients with HNC treated with avasopasem in combination with the standard-of-care regimen (intensity-modulated radiation therapy, or IMRT, plus cisplatin) demonstrated comparable tumor outcomes and overall survival to patients in the placebo arm, showing that avasopasem protected HNC patients from SOM without affecting the treatment benefit of standard-of-care chemoradiotherapy. In addition, after one year of follow-up, patients treated with avasopasem in combination with IMRT plus cisplatin had a 10% incidence of chronic kidney disease, or CKD, compared to 20% of patients in the placebo arm, which was a pre-defined exploratory endpoint evaluating renal function. CKD (eGFR <60) is a known toxicity risk with cisplatin, which can have significant long-term consequences. The prospective exploration of this potential benefit of avasopasem was driven by published preclinical data and a post hoc assessment of patients from the GT-201 trial presented at the 2020 American Society of Clinical Oncology, or ASCO, Annual Meeting. We believe these CKD data suggest another potential benefit of avasopasem for these patients beyond reducing SOM. In addition to the ROMAN long-term endpoints, a meta-analysis of the Company's two randomized placebo-controlled trials (ROMAN and GT-201; n=551) was included in the ASTRO presentation; these results reinforced that across both trials avasopasem therapy resulted in clinically meaningful improvements in radiotherapy-induced SOM, including reductions in the incidence, number of days, severity, and delay in the onset of SOM compared to placebo.

In December 2021, we also announced topline results from a Phase 2a multi-center trial in Europe assessing the safety and efficacy of avasopasem in patients with HNC undergoing standard-of-care radiotherapy, which we refer to as the EUSOM trial. Avasopasem appeared to be generally well tolerated, and the incidence of SOM and median number of days of SOM observed in the EUSOM trial were in line with the ROMAN trial results. We plan to meet with the European Medicines Agency, or EMA, in 2023 to discuss the potential registration pathway in Europe for avasopasem for radiotherapy-induced SOM.

In May 2022, we announced topline results from an open-label, single-arm Phase 2a trial evaluating avasopasem for its ability to reduce the incidence of radiotherapy-induced esophagitis in patients with lung cancer, which we refer to as the AESOP trial. This multi-center trial enrolled 39 patients (62 screened) of which 35 completed treatment with 60 gray of radiotherapy plus chemotherapy over six weeks. Of these 35 patients, 29 received at least five weeks of 90 mg of avasopasem on the days they underwent radiotherapy. These 29 patients were evaluated as the pre-specified per protocol population. The results demonstrated that avasopasem substantially reduced the incidence of severe esophagitis in patients with lung cancer receiving chemoradiotherapy compared to expectations based on review of historical data in the literature. Avasopasem was generally well tolerated. The adverse events experienced are comparable to those expected with chemoradiotherapy. There are currently no FDA-approved drugs and no established guidelines for the treatment of radiotherapy-induced esophagitis.

In addition to developing avasopasem for the reduction of normal tissue toxicity from radiotherapy, we are developing rucosopasem to increase the anti-cancer efficacy of higher daily doses of radiotherapy, or SBRT. SBRT typically involves a patient receiving one to five large doses of radiotherapy, in contrast to the 30 to 35 small daily doses typical of intensity modulated radiation therapy, or IMRT. Clinically, SBRT is increasingly used in patients with certain tumors, such as LAPC and NSCLC, that are less responsive to the small daily doses typical of IMRT. Even with the use of SBRT, there is need for improvement in treatment outcomes for certain tumors. In September 2021, in support of rucosopasem, we announced final results from our pilot Phase 1/2 safety and anti-cancer efficacy trial of avasopasem in combination with SBRT in patients with unresectable or borderline resectable LAPC. In this proof-of-concept trial, improvements were observed with avasopasem plus SBRT in overall survival, progression-free survival, local tumor control and time to distant metastases relative to patients treated with placebo plus SBRT.

We used our observations from the pilot LAPC trial to inform the design of our rucosopasem clinical trials in combination with SBRT. We have successfully completed Phase 1 trials of intravenous rucosopasem in healthy volunteers and initiated a Phase 1/2 trial in patients with NSCLC in October 2020, which we refer to as the GRECO-1 trial, and in May 2021, initiated a Phase 2b trial in patients with LAPC, which we refer to as the GRECO-2 trial.

The GRECO-1 trial is supported in part by a Small Business Innovation Research grant from the National Cancer Institute, or NCI, of the National Institutes of Health, or NIH, 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 rucosopasem in combination with SBRT. In June 2022, we reported interim results from the open-label Phase 1 stage of the trial with six months follow-up on all seven patients. Rucosopasem in combination with SBRT appeared to be well tolerated through the cutoff date of June 14, 2022. The most frequent adverse events were fatigue, cough, and nausea, which are common in patients with lung cancer receiving radiotherapy. Through six months, in-field partial responses were observed in three patients and stable disease was observed in three others based on RECIST criteria. These results included target tumor reductions in five patients of 61%, 58%, 33%, 29% and 27% and one patient with an 8% increase. Preservation of pulmonary lung function was also observed compared to our expectations based on review of historical literature evaluating pulmonary function in a similar patient population with SBRT alone. We expect to complete enrollment in the randomized, placebo-controlled Phase 2 stage of this trial in the second half of 2023, and topline data readout is expected in the second half of 2024.

The GRECO-2 trial is a 220-patient trial designed to assess rucosopasem in combination with SBRT in patients with LAPC, based on our observations from the pilot LAPC trial with avasopasem. The primary endpoint of this trial is overall survival. We expect to complete enrollment in the GRECO-2 trial in the first half of 2024, and topline data readout is expected by the end of 2024. The FDA has granted orphan drug designation to rucosopasem for the treatment of pancreatic cancer.

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). On February 17, 2023, we completed a registered direct offering, which resulted in the issuance and sale of 14,320,000 shares of our common stock and warrants to purchase up to 14,320,000 shares of common stock at a combined offering price of $2.095 per share and accompanying warrant, generating gross proceeds of $30.0 million. The warrants have an exercise price of $1.97 per share of common stock, are exercisable immediately following their issuance and will expire five years from the date of issuance. We received net proceeds of $27.6 million from this offering, after deducting placement agent fees and offering expenses.

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, including through potential strategic partnerships. Our net loss was $62.2 million and $80.5 million for the years ended December 31, 2022 and 2021, respectively, and $20.7 million and $38.4 million for the three and six months ended June 30, 2023, respectively. As of June 30, 2023, we had $38.8 million in cash, cash equivalents and short-term investments and an accumulated deficit of $416.7 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, potentially rebuild 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, including through a potential strategic transaction, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more product candidates, delay our pursuit of potential in-licenses or acquisitions, or cease our operations altogether.

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 cease our operations.

We expect our existing cash, cash equivalents and short-term investments as of June 30, 2023, taking into account the implementation of the Workforce Reduction, will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2024, but not for more than one year after the date of the filing of this Quarterly Report on Form 10-Q, and as a result there is substantial doubt about our ability to continue as a going concern through the year from the date of the filing of this

Quarterly Report on Form 10-Q. Our anticipated operating expenses involve significant risks and uncertainties and are dependent on our current assessment of the extent and costs of activities required to advance our product candidates. In the future, we anticipate that we will need to raise substantial additional financing to fund our operations through equity or debt financings, or through strategic transactions. To meet these requirements, we may seek to sell equity or convertible securities in public or private transactions that may result in significant dilution to our stockholders. We may offer and sell shares of our common stock under an existing registration statement or any registration statement we may file in the future. If we raise additional funds through the issuance of convertible securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. We may also defer certain operating expenses unless and until additional capital is received. However, there can be no assurance that we will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to us, or that we will be successful in deferring certain operating expenses. If we are unable to raise sufficient additional capital or defer sufficient operating expenses, we may be compelled to reduce the scope of our operations and planned capital expenditures and may decide to delay or discontinue certain activities, including planned research and development activities, hiring plans, manufacturing activities and commercial preparation efforts. If we continue to have insufficient funds, particularly if we are unable to undertake any strategic alternative, we may be required to cease our operations altogether.

Critical Accounting Policies and Estimates

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 described below. 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 2022 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, 2023 there were no material changes to our critical accounting policies from those discussed in the 2022 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, 2023 and 2022 (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Avasopasem manganese	$ 1,517	$ 1,880	$ 3,383	$ 4,276
Rucosopasem manganese	3,328	2,010	6,253	4,534
Other research and development expense	780	739	1,352	1,293
Personnel related and share-based compensation expense	1,936	2,007	3,845	4,640
	$ 7,561	$ 6,636	$ 14,833	$ 14,743

Research and development activities are central to our business model. Product candidates in later stages of clinical development 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. Our research and development expenses may increase, depending on the progress of our clinical development programs.

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. As discussed above, we received a CRL from the FDA regarding our NDA for avasopasem for radiotherapy-induced SOM in patients with HNC undergoing standard-of-care treatment, in which the FDA stated that results from the Phase 3 ROMAN trial together with the supporting data from the Phase 2b GT-201 trial are not sufficiently persuasive to establish substantial evidence of avasopasem's effectiveness and safety for reducing SOM in patients with HNC, and that results from an additional clinical trial will be required for resubmission. We intend to meet with the FDA to discuss next steps. If the FDA confirms we are required to conduct an additional clinical trial to support resubmission of our NDA, our research and development expenditures would increase materially.

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, legal, information technology, commercial, 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 decrease in the near future due to our recent Workforce Reduction. We may incur significant costs, however, related to our exploration of strategic alternatives, such as partnering, for the continued development of avasopasem and rucosopasem, including legal, accounting and advisory expenses and other related charges.

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 Loss

Foreign currency loss consists 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, 2022, we had federal and state tax net operating loss carryforwards of $162.3 million and $184.4 million, respectively, which each begin to expire in 2032 unless previously utilized. We also had foreign net operating loss carryforwards of $1.7 million which do not expire. As of December 31, 2022, we also had federal, state and foreign research and development tax credit carryforwards of $7.3 million. The federal and state research and development tax credit carryforwards will begin to expire in 2032 and 2036, respectively, 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, 2023 and 2022

The following table sets forth our results of operations for the three and six months ended June 30, 2023 and 2022 (in thousands):

	Three Months Ended June 30,			Six months ended June 30,		
	2023	2022	Change	2023	2022	Change
Operating expenses:						
Research and development	$ 7,561	$ 6,636	$ 925	$ 14,833	$ 14,743	$ 90
General and administrative	9,246	5,293	3,953	15,855	10,340	5,515
Loss from operations	(16,807)	(11,929)	(4,878)	(30,688)	(25,083)	(5,605)
Other income (expense):						
Interest income	494	71	423	889	85	804
Interest expense	(4,399)	(2,699)	(1,700)	(8,622)	(5,002)	(3,620)
Foreign currency loss	—	(1)	1	(1)	(1)	—
Net loss	$ (20,712)	$ (14,558)	$ (6,154)	$ (38,422)	$ (30,001)	$ (8,421)

Research and Development Expense

Research and development expense increased by $1.0 million from $6.6 million for the three months ended June 30, 2022 to $7.6 million for the three months ended June 30, 2023. Rucosopasem development costs increased by $1.3 million due to increased expenses in the GRECO trials reflecting increased enrollment. Partially offsetting this increase, avasopasem development costs decreased by $0.4 million, due to decreased manufacturing expenses.

Research and development expense increased by $0.1 million from $14.7 million for the six months ended June 30, 2022 to $14.8 million for the six months ended June 30, 2023. Rucosopasem development costs increased by $1.7 million, due to increased expenses for the GRECO trials. Partially offsetting this increase, avasopasem development costs decreased by $0.9 million, due to decreased expenses for clinical trials, primarily due to the completion of the EUSOM and AESOP trials, and personnel related expenses decreased by $0.8 million, reflecting lower headcount and stock compensation expense.

General and Administrative Expense

General and administrative expense increased by $3.9 million from $5.3 million for the three months ended June 30, 2022 to $9.2 million for the three months ended June 30, 2023, principally due to avasopasem commercial preparations and medical affairs activities.

General and administrative expense increased by $5.6 million from $10.3 million for the six months ended June 30, 2022 to $15.9 million for the six months ended June 30, 2023, due to avasopasem commercial preparations and medical affairs activities, as well as increased legal expenses.

Interest Income

Interest income increased from $71,000 for the three months ended June 30, 2022 to $0.5 million for the three months ended June 30, 2023 and increased from $85,000 for the six months ended June 30, 2022 to $0.9 million for the six months ended June 30, 2023, due to increased interest rates on invested cash and securities.

Interest Expense

We recognized $4.4 million and $2.7 million in non-cash interest expense during the three months ended June 30, 2023 and 2022, respectively, and $8.6 million and $5.0 million in non-cash interest expense during the six months ended June 30, 2023 and 2022, respectively, in connection with the Royalty Agreement with Blackstone Life Sciences. The increases are attributable to an increase in the imputed interest rate. In February 2023, the FDA accepted and granted Priority Review designation to our NDA for avasopasem for the reduction of SOM in patients with HNC. As a result, we updated the assumptions underlying the calculation of imputed interest expense on the royalty purchase liability.

Liquidity and Capital Resources

We do not currently have any approved products and have never generated any revenue from product sales. Through June 30, 2023, we have funded our operations primarily through the sale and issuance of equity and $117.5 million of proceeds received under the Royalty Agreement with Blackstone Life Sciences, receiving aggregate gross proceeds of $374.7 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 February 2023, we completed a registered direct offering, which resulted in the issuance and sale of 14,320,000 shares of our common stock and warrants to purchase up to 14,320,000 shares of common stock at a combined offering price of $2.095 per share and accompanying warrant, and received net proceeds of $27.6 million, after deducting placement agent fees and offering expenses. The warrants are equity-classified, have an exercise price of $1.97 per share of common stock, are exercisable immediately following their issuance and will expire five years from the date of issuance. During the three months ended June 30, 2023, warrants were exercised in exchange for 920,000 shares of common stock resulting in proceeds of $1.8 million.

In December 2020, we entered into an Open Market Sale 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,” or ATM, 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. No securities were issued pursuant to the Sales Agreement during the six months ended June 30, 2023. As of June 30, 2023, there was $37.8 million of common stock remaining available for sale under the Sales Agreement.

As of June 30, 2023, we had $38.8 million in cash, cash equivalents and short-term investments and an accumulated deficit of $416.7 million. We maintain a portion of our cash and cash equivalents in accounts with major financial institutions, and our deposits at these institutions exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position. 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,	
	2023	**2022**
Net cash used in operating activities	$ (22,412)	$ (20,271)
Net cash provided by investing activities	12,854	16,611
Net cash provided by financing activities	29,594	1,177
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 20,036	$ (2,483)

Operating Activities

During the six months ended June 30, 2023, we used $22.4 million of net cash in operating activities. Cash used in operating activities reflected our net loss of $38.4 million, partially offset by non-cash charges of $11.6 million primarily related to share-based compensation, interest expense on our Royalty Agreement with Blackstone Life Sciences and depreciation expense, $3.2 million from the refund of the PDUFA fee, and $1.2 million from other changes in operating assets and liabilities. The primary use of cash was to fund our operations related to the development of our product candidates.

During the six months ended June 30, 2022, we used $20.3 million of net cash in operating activities. Cash used in operating activities reflected our net loss of $30.0 million, partially offset by non-cash charges of $8.7 million related to share-based compensation, interest expense on our Royalty Agreement with Blackstone Life Sciences and depreciation expense, and $1.0 million

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, 2023, investing activities provided $12.9 million in cash proceeds, primarily from the net sales of our short-term investments.

During the six months ended June 30, 2022, investing activities provided $16.6 million in cash proceeds from the net sales of our short-term investments.

Financing Activities

During the six months ended June 30, 2023, financing activities provided $29.6 million from the sale of our common stock and common stock warrants in our registered direct offering in February 2023, and from the exercise of common stock warrants and stock options during the period.

During the six months ended June 30, 2022, financing activities provided $1.2 million from the sale of our common stock under the Sales Agreement with Jefferies and the exercise of stock options.

Funding Requirements

Our operating expenses increased during the six months ended June 30, 2023 as compared to the six months ended June 30, 2022. We currently expect our expenses to decrease for the remainder of 2023 as we implement the Workforce Reduction, wind down our commercial readiness efforts for avasopasem and explore strategic alternatives for the development of our product candidates, but research and development expenses may increase in the future in connection with certain of our ongoing activities, particularly as we explore next steps for avasopasem following our receipt of the CRL from FDA and progress the ongoing clinical trials for rucosopasem. In addition, while we are currently winding down our commercial readiness efforts as a result of the CRL, if in the future we were to obtain marketing approval for any of our product candidates, we would expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, we will continue to incur significant costs associated with operating as a public company and we currently estimate that we will incur charges of approximately $2.0 to $2.5 million in connection with the Workforce Reduction, primarily consisting of severance payments, employee benefits and related costs, the majority of which are expected to be incurred in the third quarter of 2023. 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, or cease our operations altogether.

We expect our existing cash, cash equivalents and short-term investments as of June 30, 2023, taking into account the implementation of the Workforce Reduction, will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2024, but not for more than one year after the date of the filing of this Quarterly Report on Form 10-Q, and as a result there is substantial doubt about our ability to continue as a going concern through the year from the date of the filing of this Quarterly Report on Form 10-Q. Our anticipated operating expenses involve significant risks and uncertainties and are dependent on our current assessment of the extent and costs of activities required to advance our product candidates. In the future, we anticipate that we will need to raise substantial additional financing to fund our operations through equity or debt financings, or through strategic transactions. To meet these requirements, we may seek to sell equity or convertible securities in public or private transactions that may result in significant dilution to our stockholders. We may offer and sell shares of our common stock under an existing registration statement or any registration statement we may file in the future. If we raise additional funds through the issuance of convertible securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. We may also defer certain operating expenses unless and until additional capital is received. However, there can be no assurance that we will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to us, or that we will be successful in deferring certain operating expenses. If we are unable to raise sufficient additional capital or defer sufficient operating expenses, we may be compelled to reduce the scope of our operations and planned capital expenditures and may decide to delay or discontinue certain activities, including planned research and development activities, hiring plans, manufacturing activities and commercial preparation efforts. If we continue to have insufficient funds, particularly if we are unable to undertake any strategic alternative, we may be required to cease our operations altogether.

In addition, our resource requirements could materially change depending on the outcome of our intended discussions with the FDA and exploration of strategic alternatives, including partnering, for the development of our product candidates. Because of this, and due to 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 general economic conditions and 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, if approved. 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 disruptions and extreme volatility in the global economy, including rising inflation and interest rates, declines in economic growth, the conflict between Russia and Ukraine, the COVID-19 pandemic and uncertainty about economic stability. 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 2022 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, rucosopasem and any pharmaceutical product comprising or containing avasopasem or rucosopasem, 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. If no Products are commercialized, we would not have an obligation to make Product Payments to Blackstone, which is the sole mechanism for repaying the liability.

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 became exercisable upon the receipt by us of the applicable specified milestone payment. The issued warrants expire six years after the initial exercise date of each respective warrant.

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 control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (2) not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier to occur of (a) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more, (b) the last day of the fiscal year following the fifth anniversary of the date of the completion of our IPO (December 31, 2024), (c) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years, or (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter.

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, 2023.

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, 2023 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may be involved in claims and proceedings arising in the course of our business. The outcome of any such claim or proceeding, regardless of the merits, is inherently uncertain.

On May 30, 2023, we filed a lawsuit in the Court of Common Pleas in Chester County, Pennsylvania against Alira Health Clinical, LLC and IQVIA Biotech, LLC (the CROs) alleging breach of contract and negligence specifically related to an error by the CROs in 2021 in the statistical program for the Phase 3 ROMAN trial of avasopasem for the reduction of severe oral mucositis induced by radiotherapy in patients with locally advanced head and neck cancer (the Phase 3 ROMAN trial) and seeking damages. In December 2021, the Company announced that the error in the statistical program for the Phase 3 ROMAN trial had been detected and that correction of this error yielded the correct, statistically significant p-values for the primary endpoint and a key secondary endpoint of the Phase 3 ROMAN trial.

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, 2022, filed with the SEC on March 8, 2023. Except as disclosed below, there have been no material changes to the risk factors described in that report. The occurrence of any of the events or developments described in our Risk Factors could adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Financial Position and Capital Needs

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

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. We currently expect our expenses to decrease as we implement the reduction in our workforce by 70% approved in August 2023, or the Workforce Reduction, wind down our commercial readiness efforts for avasopasem and explore strategic alternatives for the development of our product candidates, but research and development expenses may increase in the future in connection with certain of our ongoing activities, particularly as we explore next steps for avasopasem following our receipt of the CRL from FDA and progress the ongoing clinical trials for rucosopasem. In addition, while we are currently winding down our commercial readiness efforts, if in the future we were to obtain marketing approval for any of our product candidates, we would expect to incur significant commercialization expenses related to manufacturing, product sales, marketing and distribution. Furthermore, we will continue to incur significant costs associated with operating as a public company and we currently estimate that we will incur charges of approximately $2.0 to $2.5 million in connection with the Workforce Reduction. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed on attractive terms, if at all, we will be forced to delay, reduce or eliminate certain of our clinical development plans, research and development programs or future commercialization efforts, or cease our operations altogether.

The development process for our product candidates is highly uncertain, and we cannot estimate with certainty the actual amounts necessary to successfully complete the development, regulatory approval process and commercialization of our product candidates. Based on our current operating plan and assumptions, including the implementation of the Workforce Reduction, we believe that our existing cash, cash equivalents and short-term investments as of June 30, 2023 will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2024. Our resource requirements could materially change depending on the outcome of our ongoing strategic alternative review process. As a result, we are unable to estimate the exact amount of our working capital requirements.

We maintain a portion of our cash and cash equivalents in accounts with major financial institutions, and our deposits at these institutions exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

Our operating plans may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than expected, through public or private equity, debt financings or other sources. Our future capital requirements will depend on and could increase significantly as a result of many factors, including:

- the results, time and cost necessary for completing our ongoing clinical trials;
- the number, size and type of any additional clinical trials, including any additional clinical trial required by the FDA to support the resubmission of our NDA for avasopasem for radiotherapy-induced SOM in patients with HNC undergoing standard-of-care treatment;
- the costs, timing and outcomes of seeking and potentially obtaining approvals from the U.S. Food and Drug Administration, or FDA, or comparable foreign regulatory authorities, such as the European Commission, or the competent authorities of the member states of the European Union, or EU, including the potential for the FDA or comparable regulatory authorities to require that we conduct more studies and trials than those that we currently expect to conduct and the costs of post-marketing studies or risk evaluation and mitigation strategies, or REMS, or similar risk management measures that could be required by regulatory authorities;
- the costs and timing of transferring manufacturing technology to third-party manufacturers, producing product candidates to support clinical trials and preparing to manufacture our product candidates;
- our ability to successfully commercialize any of our product candidates, including the cost and timing of potentially rebuilding and expanding our sales organization and marketing capabilities;
- the amount of sales revenues from our product candidates, if approved, including the sales price and the availability of coverage and adequate third-party reimbursement;
- competitive and potentially competitive products and technologies and patients' receptivity to our product candidates and the technology underlying them in light of competitive products and technologies;
- the cash requirements of any future acquisitions, developments or discovery of additional product candidates, including any licensing or collaboration agreements;
- the time and cost necessary to respond to technological and market developments;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- any product liability or other lawsuits related to our product candidates or any products;
- the costs associated with being a public company;
- our need and ability to hire additional personnel; and
- the receptivity of the capital markets to financings by biotechnology companies generally and companies with product candidates and technologies such as ours specifically.

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

Risks Related to the Discovery and Development of Our Product Candidates

We are heavily dependent on the success of our lead product candidate, avasopasem, and if avasopasem does not receive regulatory approval, our business may be harmed.

We currently have no products that are approved for commercial sale.

On August 9, 2023, we announced that we had received a Complete Response Letter, or CRL, from the FDA regarding our NDA for avasopasem for radiotherapy-induced SOM in patients with HNC undergoing standard-of-care treatment. In the CRL, the FDA communicated that the results from the Phase 3 ROMAN trial together with the supporting data from the Phase 2b GT-201 trial are not sufficiently persuasive to establish substantial evidence of avasopasem's effectiveness and safety for reducing SOM in patients with HNC. FDA stated that results from an additional clinical trial will be required for resubmission. We intend to request a Type A meeting with the FDA to understand the FDA's rationale for its decision and discuss next steps to support an NDA resubmission seeking approval of avasopasem.

We cannot be certain that we will have the resources required to pursue additional development activities for avasopasem or that avasopasem will receive regulatory approval, or be successfully commercialized even if we receive regulatory approval. We have not completed the development of any product candidates and we may never be able to develop marketable products. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of products are, and will remain, subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market avasopasem in the United States until we receive approval of a New Drug Application, or NDA, or in any foreign country until we receive the requisite approvals from the appropriate authorities in such countries for marketing authorization. As discussed above, we intend to request a Type A meeting with the FDA to discuss next steps to support an NDA resubmission seeking approval of avasopasem, but there can be no assurance we will be able to secure the funding required to make such a resubmission.

Obtaining approval of an NDA or similar regulatory approval is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or other foreign regulatory authorities may delay, limit or deny approval of any of our current or future product candidates for many reasons, including the following risks, certain of which have already materialized in connection with our receipt of the CRL from FDA:

- we may not be able to demonstrate that avasopasem is effective as a treatment for any of our targeted indications to the satisfaction of the FDA or other relevant regulatory authorities;
- the relevant regulatory authorities may require additional pre-approval studies or clinical trials, which would increase our costs and prolong our development timelines;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or other relevant regulatory authorities for marketing approval;
- the FDA or other relevant regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the contract research organizations, or CROs, that we retain to conduct clinical trials may take actions outside of our control, or otherwise commit errors or breaches of protocols, that materially adversely impact our clinical trials and ability to obtain market approvals;
- the FDA or other relevant regulatory authorities may not find the data from preclinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of avasopasem outweigh their safety risks;
- the FDA or other relevant regulatory authorities may not be convinced that avasopasem has an acceptable safety profile;
- the FDA or other relevant regulatory authorities may disagree with our interpretation of data or significance of results from the preclinical studies and clinical trials of avasopasem, or may require that we conduct additional studies;
- the FDA or other relevant regulatory authorities may not accept data generated from our clinical trial sites;
- if our NDA or other foreign application is reviewed by an advisory committee, the FDA or other relevant regulatory authority, as the case may be, may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA or other relevant regulatory authority, as the case may be, require, as a condition of approval, additional nonclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA or other relevant regulatory authorities may require additional post-marketing studies, which would be costly;
- the FDA or other relevant regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; and
- the FDA or other relevant regulatory authorities may change their approval policies or adopt new regulations.

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

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

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

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

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

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

For example, in the CRL we received from the FDA in August 2023 related to our NDA for avasopasem for the reduction of SOM in patients with HNC, the FDA communicated that the results from the Phase 3 ROMAN trial together with the supporting data from the Phase 2b GT-201 trial are not sufficiently persuasive to establish substantial evidence of avasopasem's effectiveness and safety for reducing SOM in patients with HNC. FDA stated that results from an additional clinical trial will be required for resubmission. We intend to request a Type A meeting with the FDA to understand the FDA's rationale for its decision and discuss next steps to support an NDA resubmission seeking approval of avasopasem, but there can be no assurance we will be able to secure the funding required to make such a resubmission.

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

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

Risks Related to Our Dependence on Third Parties

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

Our product development programs and the potential commercialization of our product candidates will require substantial additional capital. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. For example, in connection with the CRL announcement, in August 2023 we announced that we will focus resources on exploring a potential approval path for avasopasem in radiotherapy-induced SOM, progressing our ongoing clinical trials for rucosopasem, and concurrently evaluating strategic alternatives, including partnering, for the continued development of avasopasem and rucosopasem.

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

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

Risks Related to Competition, Retaining Key Employees and Managing Growth

Our recent reduction in force undertaken to significantly reduce our ongoing operating expenses may not result in our intended outcomes and may yield unintended consequences and additional costs.

In August 2023, we implemented a reduction in force affecting 22 employees, or 70% of our workforce, or the Workforce Reduction. The decision was based on cost-reduction initiatives intended to reduce operating expenses. We currently estimate that we will incur charges of approximately $2.0 to $2.5 million in connection with the Workforce Reduction, primarily consisting of severance payments, employee benefits and related costs. The Workforce Reduction and other cost savings actions being implemented are expected to extend our cash runway into the second quarter of 2024. In connection with the Workforce Reduction, we are winding down our commercial readiness efforts for avasopasem and reducing headcount across several departments. We are concurrently evaluating strategic alternatives, including partnering, for the continued development of avasopasem and rucosopasem.

The Workforce Reduction may result in unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended number of employees, decreased morale among our remaining employees, and the risk that we may not achieve the anticipated benefits of the Workforce Reduction. In addition, while positions have been eliminated certain functions necessary to our operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. We may also be unsuccessful in negotiating any desired strategic alternative or partnership relating to such functions on a timely basis, on acceptable terms, or at all. The Workforce Reduction could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives. If we are unable to realize the anticipated benefits from the Workforce Reduction, or if we experience significant adverse consequences from the reduction in force, our business, financial condition, and results of operations may be materially adversely affected.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

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

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
3.1	Restated Certificate of Incorporation of Galera Therapeutics, Inc.	8-K	001-39114	3.1	11/12/2019	
3.2	Amended and Restated Bylaws of Galera Therapeutics, Inc.	8-K	001-39114	3.1	9/25/2020	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					*
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					**
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					**
101.INS	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.

SIGNATURES

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

Galera Therapeutics, Inc.

Date: August 14, 2023

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

Date: August 14, 2023

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

Exhibit 31.1

CERTIFICATION

I, J. Mel Sorensen, certify that:

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

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: August 14, 2023

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

Exhibit 31.2

CERTIFICATION

I, Christopher Degnan, certify that:

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

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: August 14, 2023

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Galera Therapeutics, Inc. (the "Company") for the period ended June 30, 2023 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 14, 2023

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

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Galera Therapeutics, Inc. (the "Company") for the period ended June 30, 2023 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 14, 2023

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