

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 March 31, 2024

or

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

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

Commission File Number: 001-39114

**Galera Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of  
incorporation or organization)

45 Liberty Blvd, Suite 230

Malvern, Pennsylvania

(Address of principal executive offices)

46-1454898

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

19355

(Zip Code)

(610) 725-1500

(Registrant's telephone number, including area code)

N/A

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	GRTX	The Nasdaq 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 May 8, 2024, the registrant had 54,392,170 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 impact of our discontinuation of the development of our product candidates; our plans to evaluate strategic alternatives; the sufficiency of our cash and cash equivalents and our ability to raise additional capital to fund our operations; and the plans and objectives of management for future operations, capital needs, and capital expenditures are forward-looking statements.

The forward-looking statements in this Quarterly Report are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of known and unknown risks, uncertainties and assumptions that could cause actual results to differ materially from those projected in the forward-looking statements, including, but not limited to, the following: our limited operating history; anticipating continued losses for the foreseeable future; needing substantial funding and the ability to raise capital; our dependence on avasopasem manganese (GC4419) 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; 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; 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 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; Nasdaq may delist our securities from trading on its exchange, which could limit investors’ ability to make transactions in our securities and subject us to additional trading restrictions; and those described under the sections in our Annual Report on Form 10-K for the year ended December 31, 2023 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)**

	March 31, 2024	December 31, 2023
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 13,466	\$ 18,257
Prepaid expenses and other current assets	1,720	3,372
Total current assets	15,186	21,629
Property and equipment, net	62	71
Acquired intangible asset	2,258	2,258
Goodwill	881	881
Right-of-use lease assets	1,174	1,212
Other assets	90	90
Total assets	<u>\$ 19,651</u>	<u>\$ 26,141</u>
<b>Liabilities and stockholders' deficit</b>		
Current liabilities:		
Accounts payable	\$ 1,046	\$ 1,375
Accrued expenses	831	3,449
Lease liabilities	136	133
Total current liabilities	2,013	4,957
Royalty purchase liability	151,049	151,049
Lease liabilities, net of current portion	1,077	1,117
Deferred tax liability	203	203
Total liabilities	154,342	157,326
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; 54,392,170 shares issued and outstanding at March 31, 2024 and December 31, 2023	54	54
Additional paid-in capital	307,042	306,167
Accumulated deficit	(441,787)	(437,406)
Total stockholders' deficit	(134,691)	(131,185)
Total liabilities and stockholders' deficit	<u>\$ 19,651</u>	<u>\$ 26,141</u>

*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 March 31,	
	2024	2023
Operating expenses:		
Research and development	\$ 1,488	\$ 7,272
General and administrative	3,089	6,609
Loss from operations	(4,577)	(13,881)
Other income (expenses):		
Interest income	196	395
Interest expense	—	(4,223)
Foreign currency loss	—	(1)
Net loss	(4,381)	(17,710)
Net loss per share of common stock, basic and diluted	\$ (0.08)	\$ (0.50)
Weighted-average shares of common stock outstanding, basic and diluted	54,392,170	35,196,134

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

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

	Three months ended March 31,	
	2024	2023
Net loss	\$ (4,381)	\$ (17,710)
Unrealized gain on short-term investments	—	38
Comprehensive loss	\$ (4,381)	\$ (17,672)

*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 capital	Accumulated other comprehensive gain (loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount				
Balance at January 1, 2024	54,392,170	\$ 54	\$ 306,167	\$ —	\$ (437,406)	\$ (131,185)
Share-based compensation expense	—	—	875	—	—	875
Net loss	—	—	—	—	(4,381)	(4,381)
Balance at March 31, 2024	<u>54,392,170</u>	<u>\$ 54</u>	<u>\$ 307,042</u>	<u>\$ —</u>	<u>\$ (441,787)</u>	<u>\$ (134,691)</u>

	Common stock		Additional paid-in capital	Accumulated other comprehensive gain (loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount				
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	<u>42,906,833</u>	<u>\$ 43</u>	<u>\$ 298,362</u>	<u>\$ 16</u>	<u>\$ (396,034)</u>	<u>\$ (97,613)</u>

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

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

	Three months ended March 31,	
	2024	2023
<b>Operating activities:</b>		
Net loss	\$ (4,381)	\$ (17,710)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	9	20
Noncash interest expense	—	4,223
Share-based compensation expense	875	1,458
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,652	446
Other assets	38	10
Accounts payable	(329)	2,356
Accrued expenses	(2,618)	(2,425)
Other liabilities	(37)	(44)
Cash used in operating activities	<u>(4,791)</u>	<u>(11,666)</u>
<b>Investing activities:</b>		
Purchases of short-term investments	—	(12,445)
Proceeds from sales of short-term investments	—	17,750
Cash provided by investing activities	<u>—</u>	<u>5,305</u>
<b>Financing activities:</b>		
Proceeds from the sale of common stock and common stock warrants in registered direct offering, net of issuance costs	—	27,598
Proceeds from exercise of stock options	—	184
Cash provided by financing activities	<u>—</u>	<u>27,782</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	(4,791)	21,421
Cash, cash equivalents and restricted cash at beginning of period	18,257	4,316
Cash, cash equivalents and restricted cash at end of period	<u>\$ 13,466</u>	<u>\$ 25,737</u>

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



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

**1. Organization and description of business**

Galera Therapeutics, Inc. was incorporated as a Delaware corporation on November 19, 2012 (inception) and together with its subsidiaries (the Company, or Galera) is a biopharmaceutical company that was historically focused on developing a pipeline of novel, proprietary therapeutics that have the potential to transform radiotherapy in cancer. The Company's lead product candidate, avasopasem manganese (avasopasem), was being developed for the reduction of severe oral mucositis (SOM) in patients with head and neck cancer (HNC), the reduction of esophagitis in patients with lung cancer, and the reduction of cisplatin-induced kidney damage in patients with cancer. The Company's second product candidate, rucosopasem manganese (rucosopasem), was in 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 U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) have granted orphan drug designation and orphan medicinal product designation, respectively, to rucosopasem for the treatment of pancreatic cancer.

In August 2023, the Company announced that it had received a Complete Response Letter (CRL) from the FDA regarding the Company's New Drug Application (NDA) for avasopasem for radiotherapy-induced SOM in patients with HNC undergoing standard-of-care treatment. In the CRL, the FDA communicated that results from an additional clinical trial will be required for resubmission. During the Type A meeting held in September 2023, and in the subsequently received meeting minutes, the FDA reiterated the need for a second Phase 3 trial to support resubmission of the NDA. It is not feasible to conduct an additional trial with the Company's current resources.

In connection with the CRL, the Company wound down its commercial readiness efforts for avasopasem, reduced headcount across several departments and began to pursue strategic alternatives. The reduction in force, which was approved by the Company's board of directors, reduced the Company's 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.

In October 2023, the Company halted its Phase 2b GRECO-2 trial of rucosopasem in patients with LAPC, following a futility analysis of the trial, which indicated that the trial was unlikely to succeed as designed. At the same time, the Company also halted its Phase 1/2 GRECO-1 trial of rucosopasem in patients with NSCLC.

In October 2023, the Company also announced that it had engaged Stifel, Nicolaus & Company, Inc. (Stifel), as its financial advisor, to assist in reviewing strategic alternatives with the goal of maximizing value for its stockholders. Such alternatives may include a merger, sale, divestiture of assets, licensing, or other strategic transaction. There can be no assurance that this process will result in the Company pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms. Should a strategic alternative be implemented, the Company anticipates using available net proceeds to discharge its liabilities and outstanding obligations, distribute the remainder, if any, to stockholders and wind down its operations. Should the Company be unable to identify and implement a meaningful strategic alternative in a timely manner, the Company's board of directors is likely to consider dissolution and liquidation of the Company.

***Liquidity***

The Company has incurred recurring losses and negative cash flows from operations since inception and has an accumulated deficit of \$441.8 million as of March 31, 2024. The Company expects its existing cash and cash equivalents as of March 31, 2024 will enable the Company to fund its operating expenses and capital expenditure requirements into the third quarter of 2025.

The Company's future capital requirements will depend on the results of its ongoing strategic evaluation. If the Company is unable to undertake any strategic alternative, its board of directors may decide to pursue a dissolution and liquidation of the Company.

**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, 2023 and 2022 included in the Company's annual report on Form 10-K filed with the SEC on March 28, 2024 have not materially changed, except as set forth below.

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

***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 March 31, 2024 and its results of operations for the three months ended March 31, 2024 and 2023, and statements of changes in stockholders' deficit and cash flows for the three months ended March 31, 2024 and 2023. Operating results for the three months ended March 31, 2024 are not necessarily indicative of the results that may be expected for the year ending December 31, 2024, 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, 2023, included in the Company's annual report on Form 10-K and filed with the SEC on March 28, 2024.

***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 March 31, 2024 and December 31, 2023 consisted of bank deposits 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.

***Goodwill and acquired intangible asset***

In November 2012, the Company completed a Series A redeemable convertible preferred stock (Series A) financing with venture capital investors and simultaneously acquired Galera Therapeutics, LLC (LLC), a limited liability company incorporated in Missouri in 2009. LLC was renamed Galera Labs, LLC in January 2013 and operates as a wholly-owned subsidiary of the Company. The Company applied the purchase method of accounting under which the consideration given to the LLC members and noteholders was allocated to the fair value of the net assets assumed from the LLC at the date of the acquisition. The sole intangible asset acquired represented the fair value of in-process research and development (IPR&D) which has been recorded on the accompanying consolidated balance sheets as an indefinite life intangible asset. A deferred tax liability was recorded for the difference between the fair value of the acquired IPR&D and its tax basis of zero which was recognized as goodwill in applying the purchase method of accounting.

Intangible assets related to IPR&D are considered indefinite-lived intangible assets and, along with goodwill, are not amortized, but are assessed for impairment annually or more frequently if impairment indicators exist. For those compounds that reach commercialization, the IPR&D assets will be amortized over their estimated useful lives. If the associated research and development effort related to IPR&D is abandoned, the related assets will be written-off and the Company will record a noncash impairment loss on its consolidated statements of operations. For the three months ended March 31, 2024 and 2023, the Company determined that there was no impairment to goodwill or IPR&D.

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

The Company believes it has sufficient future cash flows to support the value of its goodwill and IPR&D. The Company will continue to evaluate its timelines for commercialization and probability of success of development of its IPR&D assets. Further reductions to probabilities of success, decrease in market share, additional development and commercial launch delays, increases in underlying discount rates, or any decision to undertake any strategic alternative that the Company has initiated, have the potential to result in future goodwill or IPR&D impairments.

***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.

***Restructuring Costs***

As a result of the Workforce Reduction, the Company incurred total restructuring-related charges of \$2.3 million during the year ended December 31, 2023. As of March 31, 2024, \$0.1 million of the total restructuring-related charges remain unpaid and are included in accrued expenses in the accompanying consolidated balance sheet. See Note 11.

***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:

	March 31,	
	2024	2023
Stock options	5,570,963	7,269,032
Common stock warrants	13,850,661	14,870,661
	19,421,624	22,139,693

***Recent Accounting Pronouncements Not Yet Adopted***

In November 2023, FASB issued ASU 2023-07, "Improvements to Reportable Segment Disclosures," which improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The guidance is effective for the Company beginning in the annual reporting period ending December 31, 2024 and interim periods

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

beginning in fiscal year 2025. Early adoption is permitted. The Company is assessing the impact of adopting this guidance on its consolidated financial statements.

In December 2023, FASB issued ASU 2023-09, "Improvements to Income Tax Disclosures," which enhances the transparency and decision usefulness of income tax disclosures. The guidance is effective for the Company's annual reporting period ending December 31, 2025. Early adoption is permitted. The Company is assessing the impact of adopting this guidance on its 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):

	March 31, 2024		
	(Level 1)	(Level 2)	(Level 3)
<b>Assets</b>			
Money market funds and U.S. Treasury obligations (included in cash equivalents)	\$ 13,133	\$ —	\$ —
<b>Assets</b>			
	(Level 1)	(Level 2)	(Level 3)
December 31, 2023			
Money market funds and U.S. Treasury obligations (included in cash equivalents)	\$ 17,964	\$ —	\$ —

There were no changes in valuation techniques during the three months ended March 31, 2024. 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.

**4. Prepaid expenses and other current assets**

Prepaid expenses and other current assets consist of (amounts in thousands):

	March 31, 2024	December 31, 2023
Prepaid clinical expenses	\$ 421	\$ 1,450
Prepaid insurance	919	1,302
Other prepaid expenses and other current assets	380	620
	<u>\$ 1,720</u>	<u>\$ 3,372</u>

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

**5. Property and equipment**

Property and equipment consist of (amounts in thousands):

	March 31, 2024	December 31, 2023
Computer hardware and software	\$ 305	\$ 305
Leasehold improvements	46	46
Furniture and fixtures	179	179
Property and equipment, gross	530	530
Less: Accumulated depreciation and amortization	(468)	(459)
Property and equipment, net	<u>\$ 62</u>	<u>\$ 71</u>

Depreciation and amortization expense was \$9,000 and \$20,000 for the three months ended March 31, 2024 and 2023, respectively.

**6. Accrued expenses**

Accrued expenses consist of (amounts in thousands):

	March 31, 2024	December 31, 2023
Compensation and related benefits	\$ 45	\$ 121
Restructuring costs	144	443
Research and development expenses	549	2,672
Professional fees and other expenses	93	213
	<u>\$ 831</u>	<u>\$ 3,449</u>

**7. 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 March 31, 2024 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 CRL received from the FDA in August 2023 on the Company's NDA for avasopasem for

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radiotherapy-induced SOM. The Company recognized \$4.2 million in noncash interest expense during the three months ended March 31, 2023. The Company suspended recognizing interest expense on the royalty purchase liability after October 2023, as the result of the uncertainty of any future royalties following its decision to discontinue the rucosopasem GRECO trials and that it is not feasible with its current resources for the Company to conduct another Phase 3 trial of avasopasem. Accordingly, no interest was recognized during the three months ended March 31, 2024.

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 at the time of issuance 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.

The Company suspended amortizing the debt discount to interest expense after October 2023, as the result of the uncertainty of any future royalties following its decision to discontinue the rucosopasem GRECO trials and that it is not feasible with its current resources for the Company to conduct another Phase 3 trial of avasopasem.

## 8. Leases

The Company has a non-cancelable operating lease for office space in Malvern, Pennsylvania which, as of March 31, 2024, has a remaining lease term of approximately 6.5 years. The discount rate used to account for the Company's operating leases is the Company's estimated incremental borrowing rate of 5.4%.

Supplemental balance sheet information related to leases was as follows:

	March 31, 2024	December 31, 2023
Operating Leases		
Right-of-use lease assets	\$ 1,174	\$ 1,212
Lease liabilities, current	136	133
Lease liabilities, net of current portion	1,077	1,117
Total operating lease liabilities	\$ 1,213	\$ 1,250

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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 March 31,	
	2024	2023
Operating lease costs		
Operating lease rental expense	\$ 54	\$ 48
Total operating lease expense	\$ 54	\$ 48

Supplemental cash flow information related to leases was as follows:

	Three months ended March 31,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows for operating leases	\$ 53	\$ 44
Right-of-use assets obtained in exchange for lease obligation		
Operating leases	—	—

Future minimum rental payments under the Company's non-cancelable operating lease liabilities as of March 31, 2024 (amounts in thousands):

Remainder of 2024	143
2025	217
2026	220
2027	224
2028 and after	633
Total	1,437
Less: imputed interest	(224)
	\$ 1,213

## 9. 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. In the event the Company's board of directors approves a fundamental transaction (defined as a merger, sale of substantially all assets, tender offer or share exchange), warrant holders may elect to exercise their warrants and receive cash consideration equal to a Black-Scholes option value, as defined in the warrant agreement, in lieu of other consideration received by the common shareholders. Warrants to purchase up to 13,300,000 shares of common stock remain unexercised as of March 31, 2024.

In December 2020, the Company entered into an Open Market Sale Agreement (the Sales Agreement) with Jefferies LLC (Jefferies) as sales agent, pursuant to which it could, 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 pursuant to the Sales Agreement were 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 was required to pay Jefferies a commission equal to three percent of the gross sales proceeds and provided Jefferies with customary indemnification rights. The S-3 expired on December 1, 2023, and therefore no further sales are available under the Sales Agreement.

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***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 March 31, 2024 was 1,573,748.

***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 March 31, 2024, there were 4,879,254 shares available for future issuance under the 2019 Plan, including 2,175,686 shares added pursuant to this provision effective January 1, 2024. 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 March 31, 2024, there were 1,835,105 shares available for issuance under the ESPP, including 543,921 shares added pursuant to this provision effective January 1, 2024.

***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 March 31, 2024, there were 1,500,000 shares available for issuance under the Inducement Plan.



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*Share-based Compensation*

Share-based compensation expense was as follows for the three months ended March 31, 2024 and 2023 (in thousands):

	Three months ended March 31,	
	2024	2023
Research and development	\$ 255	\$ 452
General and administrative	620	1,006
	<u>\$ 875</u>	<u>\$ 1,458</u>

The following table summarizes the activity related to stock option grants for the three months ended March 31, 2024:

	Shares	Weighted average exercise price per share	Weighted- average remaining contractual life (years)
Outstanding at January 1, 2024	5,739,488	\$ 5.85	6.6
Forfeited	(168,525)	5.21	
Outstanding at March 31, 2024	<u>5,570,963</u>	<u>\$ 5.87</u>	<u>6.4</u>
Vested and exercisable at March 31, 2024	<u>3,924,473</u>	<u>\$ 7.02</u>	<u>5.5</u>
Vested and expected to vest at March 31, 2024	<u>5,570,963</u>	<u>\$ 5.87</u>	<u>6.4</u>

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 March 31, 2024, the unrecognized compensation cost was \$3.3 million and will be recognized over an estimated weighted-average amortization period of 1.8 years. The aggregate intrinsic value of options outstanding and of options exercisable as of March 31, 2024 were zero. Options granted during the three months ended March 31, 2023 had weighted-average grant-date fair values of \$1.41 per share. There were no options granted during the three months ended March 31, 2024.

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 granted during the three months ended March 31, 2023 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.

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The grant date fair value of each option grant was estimated throughout the three months ended March 31, 2023 using the Black-Scholes option-pricing model using the following weighted-average assumptions. There were no options granted during the three months ended March 31, 2024.

	Three months ended March 31, 2023
Expected term (in years)	6.2
Expected stock price volatility	94.9 %
Risk-free interest rate	4.13 %
Expected dividend yield	0 %

**10. Related party transactions**

IntellectMap provides information technology advisory services to the Company. The chief executive officer of IntellectMap is the brother of the Company's chief executive officer. Fees incurred by the Company with respect to IntellectMap during the three months ended March 31, 2024 and 2023 were \$55,000 and \$70,000, respectively.

**11. Restructuring charges**

On August 9, 2023, the Company announced a plan to reduce expenses and extend its cash runway. In connection with this plan, the Company's board of directors approved the Workforce Reduction. The decision was based on cost-reduction initiatives intended to reduce operating expenses. The Company incurred a \$2.3 million charge in the third quarter of 2023 in connection with the Workforce Reduction, primarily consisting of severance payments, employee benefits and related costs.

The following table summarizes the restructuring balances at March 31, 2024 (in thousands):

	2024
Balance, January 1, 2024	\$ 443
Current year restructuring costs	—
Payment of employee severance and related costs	(299)
Balance, March 31, 2024	\$ 144

**12. Subsequent events**

On May 3, 2024, the Company entered into a Stockholder Rights Agreement with Equiniti Trust Company, LLC, as rights agent (the Rights Agreement). Pursuant to the Rights Agreement, the board of directors declared a dividend of one preferred share purchase right (each a Right) for each outstanding share of Company common stock to stockholders of record at the close of business on May 20, 2024. Each Right entitles its holder, subject to the terms of the Rights Agreement, to purchase from the Company one one-thousandth of a share of Series A Junior Participating Preferred Stock, par value \$0.001 per share, of the Company at an exercise price of \$1.50 per Right, subject to adjustment. Rights will attach to any shares of common stock that become outstanding after May 20, 2024 and prior to the earlier of the Distribution Time, as defined in the Rights Agreement, and the redemption or expiration of the Rights, and in certain other circumstances described in the Rights Agreement.

## 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, 2023, filed with the SEC on March 28, 2024, or the 2023 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 biopharmaceutical company that has historically focused on developing a pipeline of novel, proprietary therapeutics that have the potential to transform radiotherapy in cancer. Our lead product candidate, avasopasem manganese (avasopasem), is a highly selective small molecule dismutase mimetic that we have been developing for the reduction of severe oral mucositis (SOM) in patients with head and neck cancer (HNC), the reduction of esophagitis in patients with lung cancer, and the reduction of cisplatin-induced kidney damage in patients with cancer. 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. Our second product candidate, rucosopasem manganese (rucosopasem), has been in 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 and European Medicines Agency (EMA) have granted orphan drug designation and orphan medicinal product designation, respectively, to rucosopasem for the treatment of pancreatic cancer.

In August 2023, we announced receipt of a Complete Response Letter (CRL) from the FDA regarding our New Drug Application (NDA) for avasopasem for radiotherapy-induced SOM in patients with HNC undergoing standard-of-care treatment. In the CRL, the FDA communicated that results from an additional clinical trial will be required for resubmission. During the Type A meeting held in September 2023, and in the subsequently received meeting minutes, the FDA reiterated the need for a second Phase 3 trial to support resubmission of the NDA. With our current resources it is not feasible to conduct this additional trial. We continue to explore appropriate development paths for avasopasem, including in radiotherapy-induced SOM.

In connection with the avasopasem CRL, we wound down our commercial readiness efforts for avasopasem, reduced headcount across several departments and began to pursue strategic alternatives. The reduction in force, which was approved by our Board of Directors, reduced our workforce by 22 employees, or approximately 70%, as of August 9, 2023. The decision was based on cost-reduction initiatives intended to reduce operating expenses.

In October 2023, we halted our Phase 2b GRECO-2 trial of rucosopasem in patients with LAPC, following a futility analysis of the trial, which indicated that the trial was unlikely to succeed as designed. At the same time, we also halted our Phase 1/2 GRECO-1 trial of rucosopasem in patients with NSCLC.

In October 2023, we also announced that we had engaged Stifel, Nicolaus & Company, Inc., as our financial advisor, to assist in reviewing strategic alternatives with the goal of maximizing value for our stockholders. Such alternatives may include a merger, sale, divestiture of assets, licensing, or other strategic transaction. There can be no assurance that this process will result in us pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms. Should a strategic alternative be implemented, we anticipate using available net proceeds to discharge our liabilities and outstanding obligations, distribute the remainder, if any, to stockholders and wind down our operations. Should we be unable to identify and implement a meaningful strategic alternative in a timely manner, our board of directors is likely to consider dissolution and liquidation of the Company.

### Nasdaq Listing Notification

On September 22, 2023, we received two written notices (the Notices) from The Nasdaq Stock Market LLC (Nasdaq) indicating that (i) we are no longer in compliance with the minimum Market Value of Listed Securities (MVLS) of \$50.0 million required for continued listing on The Nasdaq Global Market, as set forth in Nasdaq Listing Rule 5450(b)(2)(A) (the MVLS Requirement), and (ii) for the last 30 consecutive business days, the bid price for our common stock, par value \$0.001 per share, had closed below the \$1.00 per share minimum bid price requirement for continued inclusion on the Nasdaq Global Market as set forth in Nasdaq Listing Rule 5450(a)(1) (the Minimum Bid Price Requirement). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), we had a period of 180 calendar days, or until March 20, 2024 to regain compliance with the MVLS Requirement and the Minimum Bid Price Requirement, respectively.

On September 25, 2023, we received an additional written notice (the Additional Notice) from Nasdaq, indicating that we are no longer in compliance with the minimum Market Value of Publicly Held Shares (MVPHS) of \$15.0 million required for continued listing on The Nasdaq Global Market, as set forth in Nasdaq Listing Rule 5450(b)(2)(C) (the MVPHS Requirement). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), we had a period of 180 calendar days, or until March 25, 2024 to regain compliance with the MVPHS Requirement.

We did not regain compliance with the Minimum Bid Price Requirement or the MVLS Requirement by March 20, 2024, and on March 21, 2024 we received a notice of delisting from Nasdaq. In addition, we did not regain compliance with the MVPHS Requirement by March 25, 2024 and on March 26, 2024, we received a notice of delisting from Nasdaq. On March 28, 2024, we requested a hearing before a Nasdaq Hearings Panel (Panel) to appeal Nasdaq's delisting determinations. There can be no assurance that our appeal will be successful. Our hearing request stayed the suspension of trading and delisting of our common stock pending the conclusion of the hearing process. Consequently, we expect our common stock will remain listed on The Nasdaq Global Market at least until the Panel renders a decision following the hearing.

Delisting from the Nasdaq Global Market or any Nasdaq market could make trading our common stock more difficult for investors, potentially leading to declines in our share price and liquidity. In addition, without a Nasdaq market listing, stockholders may have a difficult time getting a quote for the sale or purchase of our common stock, the sale or purchase of our common stock would likely be made more difficult and the trading volume and liquidity of our common stock could decline. Delisting from Nasdaq could also make it more difficult for us to raise additional capital. The absence of such a listing may adversely affect the acceptance of our common stock as currency or the value accorded by other parties. If our common stock is delisted by Nasdaq, our common stock may be eligible to trade on an over-the-counter quotation system, such as the OTCQB market, where an investor may find it more difficult to sell our common stock or obtain accurate quotations as to the market value of our common stock. We cannot assure that our common stock, if delisted from Nasdaq, will be listed on another national securities exchange or quoted on an over-the counter quotation system. See "Risk Factors" in Part I, Item 1A of the 2023 Form 10-K.

### **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 2023 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 three months ended March 31, 2024 there were no material changes to our critical accounting policies from those discussed in the 2023 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 (CROs), as well as investigative sites and consultants that conduct our preclinical studies and clinical trials;

- expenses incurred under agreements with contract manufacturing organizations (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 months ended March 31, 2024 and 2023 (in thousands):

	Three months ended March 31,	
	2024	2023
Avasopasem manganese	\$ (147)	\$ 1,866
Rucosopasem manganese	643	2,925
Other research and development expense	320	572
Personnel related and share-based compensation expense	672	1,909
	<u>\$ 1,488</u>	<u>\$ 7,272</u>

We have ceased all clinical trial activity and have suspended the clinical development of our product candidates.

If we decide to resume product candidate development, the successful development of any future product candidates would be highly uncertain. We are unable to predict when, if ever, material net cash inflows would commence from sales of any future product candidates that we may develop due to the numerous risks and uncertainties associated with clinical development, 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 on the initiation and completion of our preclinical studies, clinical trials and manufacturing scale-up.

We may never succeed in achieving regulatory approval for any future product candidates we may develop.

### ***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.

The process of continuing to evaluate strategic options may be costly, time-consuming and complex, and we may incur significant costs related to this continued evaluation, such as legal, accounting and advisory fees and 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, 2023, we had federal and state tax net operating loss carryforwards (NOLs) of \$191.3 million and \$213.8 million, respectively, which will 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, 2023, we also had federal, state and foreign research and development tax credit carryforwards of \$10.4 million. The federal and state research and development tax credit carryforwards will begin to expire in 2032 and 2037, 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. In addition, future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Internal Revenue Code, further limiting our ability to utilize a material portion of the NOLs and credits. We have recorded a valuation allowance on substantially all of our deferred tax assets, including our deferred tax assets related to our NOLs 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 Months Ended March 31, 2024 and 2023***

The following table sets forth our results of operations for the three months ended March 31, 2024 and 2023 (in thousands):

	Three months ended March 31,		Change
	2024	2023	
<b>Operating expenses:</b>			
Research and development	\$ 1,488	\$ 7,272	\$ (5,784)
General and administrative	3,089	6,609	(3,520)
Loss from operations	(4,577)	(13,881)	9,304
<b>Other income (expense):</b>			
Interest income	196	395	(199)
Interest expense	—	(4,223)	4,223
Foreign currency loss	—	(1)	1
<b>Net loss</b>	<b>\$ (4,381)</b>	<b>\$ (17,710)</b>	<b>\$ 13,329</b>

#### *Research and Development Expense*

Research and development expense decreased by \$5.8 million from \$7.3 million for the three months ended March 31, 2023 to \$1.5 million for the three months ended March 31, 2024. Avasopasem development costs decreased by \$2.0 million as the ROMAN trial was completed, manufacturing activities ceased, and we recorded a \$0.4 million credit for the release of an accrual for the ROMAN trial. Rucosopasem development costs decreased \$2.3 million as we halted the GRECO-1 and GRECO-2 clinical trials. Personnel related and share-based compensation expense decreased \$1.2 million, primarily due to the Workforce Reduction, and other research and development expenses decreased \$0.3 million. As noted above, we have ceased all clinical trial activity and have suspended the clinical development of our product candidates.

#### *General and Administrative Expense*

General and administrative expense decreased by \$3.5 million from \$6.6 million for the three months ended March 31, 2023 to \$3.1 million for the three months ended March 31, 2024, principally due to the cessation of avasopasem commercial preparations and medical affairs activities and reduced personnel related and share-based compensation expenses due to the Workforce Reduction.

#### *Interest Income*

Interest income decreased from \$0.4 million for the three months ended March 31, 2023 to \$0.2 million for the three months ended March 31, 2024, due to the reduction in investable cash and securities.

#### *Interest Expense*

We recognized \$4.2 million in non-cash interest expense during the three months ended March 31, 2023 in connection with the Royalty Agreement with Blackstone Life Sciences. Given the uncertainty of obtaining future avasopasem revenue based on the FDA reiterating the need for an additional Phase 3 trial for NDA resubmission, our inability to conduct an additional trial with our current resources, and our focus on exploring strategic alternatives for the development of avasopasem, coupled with our decision in October 2023 to discontinue clinical trials of rucosopasem, we suspended accreting interest on the royalty purchase liability at the end of October 2023.

### **Liquidity and Capital Resources**

We do not currently have any approved products and have never generated any revenue from product sales. Through March 31, 2024, 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 \$377.0 million. In November 2019, we completed our IPO, which resulted in the issuance and sale of 5,000,000 shares of common stock at a public offering price of \$12.00 per share, generating net proceeds of \$53.0 million after deducting underwriting discounts and other offering costs. On December 9, 2019, in connection with the partial exercise of the over-allotment option granted to the underwriters of our IPO, 445,690 additional shares of common stock were sold at the IPO price of \$12.00 per share, generating net proceeds of approximately \$5.0 million after deducting underwriting discounts and other offering costs.

In December 2020, we entered into an Open Market Sale Agreement (Sales Agreement) with Jefferies LLC (Jefferies) as sales agent, pursuant to which we could, 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 our Registration Statement on Form S-3 (File No. 333-251061) filed with the SEC

on December 1, 2020. Sales of common stock pursuant to the Sales Agreement were 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. The S-3 expired on December 1, 2023, and therefore as of December 31, 2023, no further sales are available under the Sales Agreement.

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. We received net proceeds of approximately \$27.6 million from this offering, after deducting placement agent fees and offering expenses.

As of March 31, 2024, we had \$13.5 million in cash and cash equivalents and an accumulated deficit of \$441.8 million. We expect our existing cash and cash equivalents as of March 31, 2024 will enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2025. 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):

	Three months ended March 31,	
	2024	2023
Net cash used in operating activities	\$ (4,791)	\$ (11,666)
Net cash provided by investing activities	—	5,305
Net cash provided by financing activities	—	27,782
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ (4,791)</u>	<u>\$ 21,421</u>

### *Operating Activities*

During the three months ended March 31, 2024, we used \$4.8 million of net cash in operating activities. Cash used in operating activities reflected our net loss of \$4.4 million and \$1.3 million from other changes in operating assets and liabilities, partially offset by non-cash charges of \$0.9 million related to share-based compensation and depreciation expense. The primary use of cash was to fund our operations as we reviewed strategic alternatives.

During the three months ended March 31, 2023, we used \$11.7 million of net cash in operating activities. Cash used in operating activities reflected our net loss of \$17.7 million, partially offset by non-cash charges of \$5.7 million related to share-based compensation, interest expense on our Royalty Agreement with Blackstone Life Sciences and depreciation expense, and \$0.3 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 three months ended March 31, 2023, investing activities provided \$5.3 million in cash proceeds from the net sales of our short-term investments.

### *Financing Activities*

During the three months ended March 31, 2023, financing activities provided \$27.8 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 stock options.



## ***Funding Requirements***

Our future success is dependent on our ability to identify and ultimately consummate a strategic transaction. Potential strategic alternatives to be explored and evaluated during the review process may include a merger, the sale of our company, acquisition or other business combination, a strategic partnership with one or more parties, or the licensing, sale or divestiture of some of our proprietary technologies. We are actively working with a financial advisor in this process. If we are unable to undertake any strategic alternative, we may be required to cease operations altogether.

Our future funding requirements will depend on many factors, including:

- the outcome and timing of the process we have initiated to review strategic alternatives, which may include a merger, sale of our company, acquisition or other business combination, a strategic partnership with one or more parties, or the licensing, sale or divestiture of some of our proprietary technologies;
- the scope, progress, results and costs of any future preclinical studies and clinical trials;
- the scope, prioritization and number of any future research and development programs;
- the costs, timing and outcome of regulatory review of any future product candidates;
- our ability to establish and maintain any future 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 any future 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; and
- the costs of securing manufacturing arrangements for any future commercial production.

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.

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 stockholders' 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 are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our assessment of strategic alternatives. If we do not successfully consummate a strategic alternative, our board of directors may decide to pursue a dissolution and liquidation of our company.

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 March 31, 2024.

*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 March 31, 2024 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, or the Court, against Alira Health Clinical, LLC and IQVIA Biotech, LLC, or the CROs, seeking damages and alleging breach of contract, professional negligence, and negligence related to an error by the defendants in 2021 in their 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). In October 2023, the Court granted a joint motion to stay the lawsuit. As of the filing of this Quarterly Report on Form 10-Q, the stay continues.

### 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, 2023, filed with the SEC on March 28, 2024. There have been no material changes to the risk factors described in that report. The occurrence of any of the events or developments described in our Risk Factors could adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.*

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

None.

### Item 3. Defaults Upon Senior Securities.

None.

### Item 4. Mine Safety Disclosures.

Not applicable.

### Item 5. Other Information.

a) *Disclosure in lieu of reporting on a Current Report on Form 8-K.*

None.

b) *Material changes to the procedures by which security holders may recommend nominees to the board of directors.*

None.

c) *Insider trading arrangements and policies.*

During the three months ended March 31, 2024, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

**Item 6. Exhibits.**

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

<b>Exhibit Number</b>	<b>Description</b>	<b>Form</b>	<b>File No.</b>	<b>Exhibit</b>	<b>Filing Date</b>	<b>Filed/ Furnished Herewith</b>
3.1	Restated Certificate of Incorporation of Galera Therapeutics, Inc.	<a href="#">8-K</a>	001-39114	<a href="#">3.1</a>	11/12/2019	
3.2	Certificate of Designation of the Series A Junior Participating Preferred Stock of the Company, dated May 3, 2024	<a href="#">8-A</a>	001-39114	<a href="#">3.1</a>	5/3/2024	
3.3	Amended and Restated Bylaws of Galera Therapeutics, Inc.	<a href="#">10-K</a>	001-39114	<a href="#">3.2</a>	3/28/2024	
4.1	Stockholder Rights Agreement, dated as of May 3, 2024 by and between the Company and Equiniti Trust Company, LLC, as rights agent (which includes the Form of Rights Certificate as Exhibit B thereto)	<a href="#">8-K</a>	001-39114	<a href="#">4.1</a>	5/3/2024	
31.1	<a href="#">Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>					*
31.2	<a href="#">Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>					*
32.1	<a href="#">Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>					**
32.2	<a href="#">Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>					**
101.INS	Inline XBRL Instance Document - the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document					*
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					*

\* Filed herewith.

\*\* Furnished herewith.



## 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: May 13, 2024

By: \_\_\_\_\_

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

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

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**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 March 31, 2024 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: May 13, 2024

By:

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

J. Mel Sorensen, M.D.

Chief Executive Officer and President  
(principal executive officer)

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