Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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	**46-1454898**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
45 Liberty Blvd, Suite 230 **Malvern, Pennsylvania**	**19355**
(Address of principal executive offices)	**(Zip Code)**

(610) 725-1500
(Registrant's telephone number, including area code)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	GRTX	OTC Pink 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 December 12, 2024, the registrant had 54,392,170 shares of common stock, $0.001 par value per share, outstanding.

Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. All statements other than statements of historical fact contained in this Quarterly Report, including without limitation statements regarding our plans and expectations regarding alternatives available for the future of our company in light of our discontinued business activities and lack of resources following the failure to obtain stockholder approval for the Plan of Dissolution (defined herein); the impact of our discontinuation of the development of our product candidates; the amount of proceeds, if any, that might be realized from the sale or other disposition of any of our remaining assets; cash, cash runway and future cash position, including the availability, timing and amount of liquidating distributions, the amounts that will need to be set aside by us, and the adequacy of such reserves to satisfy our obligations; the pursuit of strategic alternatives that are not currently contemplated; 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; the listing of our common stock on the OTC Pink Market; 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; our ability to receive stockholder approval of the Plan of Dissolution, if we seek such approval in the future; our ability to sell or otherwise dispose of any of our remaining assets or enter into a strategic transaction; our ability to make liquidating distributions and the timing thereof, if we pursue liquidation in the future; the impact of general economic conditions on our business and operations; 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)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 8,455	$ 18,257
Prepaid expenses and other current assets	444	3,372
Total current assets	8,899	21,629
Property and equipment, net	—	71
Acquired intangible asset	—	2,258
Goodwill	—	881
Right-of-use lease assets	—	1,212
Other assets	2	90
Total assets	$ 8,901	$ 26,141
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 296	$ 1,375
Accrued expenses	618	3,449
Lease liabilities	—	133
Total current liabilities	914	4,957
Royalty purchase liability	151,049	151,049
Lease liabilities, net of current portion	—	1,117
Deferred tax liability	—	203
Total liabilities	151,963	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 September 30, 2024 and December 31, 2023	54	54
Additional paid-in capital	308,316	306,167
Accumulated deficit	(451,432)	(437,406)
Total stockholders' deficit	(143,062)	(131,185)
Total liabilities and stockholders' deficit	$ 8,901	$ 26,141

See accompanying notes to unaudited interim consolidated financial statements.

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

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 305	$ 6,093	$ 3,223	$ 20,926
General and administrative	3,439	4,994	9,307	20,849
Write-off of acquired intangible asset	2,258	—	2,258	—
Write-off of goodwill	881	—	881	—
Gain on litigation settlement	(975)	—	(975)	—
Restructuring costs	—	2,309	—	2,309
Loss from operations	(5,908)	(13,396)	(14,694)	(44,084)
Other income (expenses):				
Interest income	126	411	471	1,300
Interest expense	—	(2,087)	—	(10,709)
Foreign currency loss	(2)	(1)	(6)	(2)
Loss before income tax benefit	(5,784)	(15,073)	(14,229)	(53,495)
Income tax benefit	203	—	203	—
Net loss	(5,581)	(15,073)	(14,026)	(53,495)
Net loss per share of common stock, basic and diluted	$ (0.10)	$ (0.33)	$ (0.26)	$ (1.30)
Weighted-average shares of common stock outstanding, basic and diluted	54,392,170	45,477,952	54,392,170	41,234,679

See accompanying notes to unaudited interim consolidated financial statements.

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

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Net loss	$(5,581)	$(15,073)	$(14,026)	$(53,495)
Unrealized gain (loss) on short-term investments	—	(5)	—	22
Comprehensive loss	$(5,581)	$(15,078)	$(14,026)	$(53,473)

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	54,392,170	54	307,042	—	(441,787)	(134,691)
Share-based compensation expense	—	—	723	—	—	723
Net loss	—	—	—	—	(4,064)	(4,064)
Balance at June 30, 2024	54,392,170	54	307,765	—	(445,851)	(138,032)
Share-based compensation expense	—	—	551	—	—	551
Net loss	—	—	—	—	(5,581)	(5,581)
Balance at September 30, 2024	54,392,170	$ 54	$308,316	$ —	$ (451,432)	$ (143,062)

	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	42,906,833	43	298,362	16	(396,034)	(97,613)
Share-based compensation expense	—	—	1,525	—	—	1,525
Exercise of common stock warrants	920,000	1	1,811	—	—	1,812
Unrealized loss on short-term investments	—	—	—	(11)	—	(11)
Net loss	—	—	—	—	(20,712)	(20,712)
Balance at June 30, 2023	43,826,833	44	301,698	5	(416,746)	(114,999)
Share-based compensation expense	—	—	1,390	—	—	1,390
Exercise of stock options	1,833	—	4	—	—	4
Exercise of common stock warrants	100,000	—	197	—	—	197
Sales of shares under Open Market Sale Agreement, net	9,805,457	10	1,923	—	—	1,933
Unrealized loss on short-term investments	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	(15,073)	(15,073)
Balance at September 30, 2023	53,734,123	$ 54	$305,212	$ —	$ (431,819)	$ (126,553)

See accompanying notes to unaudited interim consolidated financial statements.

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

	Nine months ended September 30,	
	2024	2023
Operating activities:		
Net loss	$(14,026)	$(53,495)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	20	44
Noncash interest expense	—	10,709
Share-based compensation expense	2,149	4,373
Write-off of acquired intangible asset	2,258	—
Write-off of goodwill	881	—
Deferred tax benefit	(203)	—
Loss (gain) on disposal of property and equipment	48	(72)
Changes in operating assets and liabilities:		
Refundable PDUFA fee	—	3,242
Prepaid expenses and other current assets	2,928	1,133
Other assets	88	37
Accounts payable	(1,079)	134
Accrued expenses	(2,832)	(970)
Other liabilities	(38)	(68)
Cash used in operating activities	(9,806)	(34,933)
Investing activities:		
Purchases of short-term investments	—	(22,627)
Proceeds from sales of short-term investments	—	45,995
Proceeds from sale of property and equipment	4	—
Purchase of property and equipment	—	(50)
Cash provided by investing activities	4	23,318
Financing activities:		
Proceeds from the sale of common stock and common stock warrants in registered direct offering, net of issuance costs	—	27,598
Proceeds from the sale of common stock under the Open Market Sale Agreement, net of issuance costs	—	1,933
Proceeds from the exercise of common stock warrants	—	2,009
Proceeds from exercise of stock options	—	188
Cash provided by financing activities	—	31,728
Net increase (decrease) in cash and cash equivalents	(9,802)	20,113
Cash and cash equivalents at beginning of period	18,257	4,316
Cash and cash equivalents at end of period	$ 8,455	$ 24,429
Supplemental schedule of non-cash investing and financing activities:		
Derecognition of lease liability and right-of-use asset due to lease termination	$ 1,212	$ —
Right-of-use asset obtained in exchange for lease obligation	$ —	$ 1,310
Sale of property and equipment in exchange for prepaid future services	$ —	$ 319

See accompanying notes to unaudited interim consolidated financial statements.

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. As of September 30, 2024, the Company had 3 employees.

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 NCSLC.

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.

Following the conclusion of its review of strategic alternatives, on August 8, 2024 the Company's board of directors approved the Company's dissolution and liquidation (Dissolution), pursuant to a plan of complete liquidation and dissolution (Plan of Dissolution), subject to stockholder approval. The Plan of Dissolution contemplated an orderly wind down of the Company's business and operations in accordance with the provisions of Delaware law. At a special meeting of stockholders held on October 17, 2024 the Plan of Dissolution was not approved by the Company's stockholders.

As the Company's stockholders did not approve the Dissolution, the Company's board of directors and management will continue to explore what, if any, other alternatives are available for the future of the Company in light of its discontinued business activities and lack of resources. Such alternatives may include a merger, sale, divestiture of assets, licensing or other strategic transaction. It is also possible that the Company would seek voluntary dissolution at a later time, potentially with further diminished assets. In addition, the Company could cease operations, make an assignment for the benefit of creditors, turn the Company over to a third-party management company or liquidator or file for bankruptcy protection.

It is possible that our board of directors may consider or decide to pursue another strategic alternative that is not currently contemplated.

Liquidity

The Company has incurred recurring losses and negative cash flows from operations since inception and has an accumulated deficit of $451.4 million as of September 30, 2024. The Company expects its existing cash and cash equivalents as of September 30, 2024 will enable the Company to fund its operating expenses for at least twelve months from the date these consolidated financial statements were issued.

Future capital requirements will depend on what, if any, strategic alternatives are available to the Company, which may include pursuit of a strategic transaction, a voluntary dissolution, or the continued operation of product development.

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.

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). These unaudited interim consolidated financial statements do not include any adjustments relating to the recovery of recorded assets or the classification of the liabilities that might be necessary under the liquidation basis of accounting or should the Company be unable to continue as a going concern.

In the opinion of management, the accompanying interim consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's financial position as of September 30, 2024 and its results of operations for the three and nine months ended September 30, 2024 and 2023, and statements of changes in stockholders' deficit and cash flows for the nine months ended September 30, 2024 and 2023. Operating results for the three and nine months ended September 30, 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 September 30, 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 was 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.

In August 2024, the Company's board of directors approved the Plan of Dissolution, under which future development of the Company's product candidates would no longer continue. In connection with this decision, the Company concluded that the related IPR&D asset and related goodwill were each impaired in their entirety, and as such recognized non-cash impairment charges of $2.3 million for the IPR&D and $0.9 million for the goodwill during the three and nine months ended September 30, 2024. The impairment also resulted in an income tax benefit of $0.2 million due to the tax effect of the reduction in the deferred tax liability associated with the IPR&D asset. There was no impairment to goodwill or IPR&D during the three and nine months ended September 30, 2023.

Research and development expenses

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

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

Gain on litigation settlement

On May 30, 2023, the Company 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 (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 SOM induced by radiotherapy in patients with locally advanced HNC (the Phase 3 ROMAN trial) (the Litigation). On August 2, 2024, the Company and the CROs entered into an agreement to settle the Litigation, pursuant to which, in exchange for mutual releases, the CROs paid to the Company the amount of $975,000, and the parties terminated the contracts between the Company and the CROs, with no further obligations under the parties' contracts. On August 8, 2024, the Company filed a Praecipe to Settle, Discontinue, and End the Litigation. During the three months ended September 30, 2024, the Company recorded the $975,000 as gain on litigation settlement within operating expenses on its consolidated statements of operations.

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 September 30, 2024, none of the total restructuring-related charges remain unpaid.

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:

	September 30,	
	2024	2023
Stock options	5,345,910	6,387,121
Common stock warrants	13,850,661	13,850,661
	19,196,571	20,237,782

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 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.

In November 2024, the FASB issued ASU 2024-03, "Income Statement–Reporting Comprehensive Income–Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses," which requires the disaggregation of certain expenses in the notes of the financials, to provide enhanced transparency into the expense captions presented on the face of the income statement. The guidance is effective for annual reporting periods beginning after December 15, 2026 and interim periods beginning after December 15, 2027 and may be applied either prospectively or retrospectively. 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):

	September 30, 2024		
	(Level 1)	(Level 2)	(Level 3)
Assets			
Money market funds and U.S. Treasury obligations (included in cash equivalents)	$ 8,119	$ —	$ —

	December 31, 2023		
	(Level 1)	(Level 2)	(Level 3)
Assets			
Money market funds and U.S. Treasury obligations (included in cash equivalents)	$17,964	$ —	$ —

There were no changes in valuation techniques during the nine months ended September 30, 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):

	September 30, 2024	December 31, 2023
Prepaid clinical expenses	$ —	$ 1,450
Prepaid insurance	151	1,302
Other prepaid expenses and other current assets	293	620
	$ 444	$ 3,372

5. Property and equipment

Property and equipment consist of (amounts in thousands):

	September 30, 2024	December 31, 2023
Computer hardware and software	$ —	$ 305
Leasehold improvements	—	46
Furniture and fixtures	—	179
Property and equipment, gross	—	530
Less: Accumulated depreciation and amortization	—	(459)
Property and equipment, net	$ —	$ 71

In connection with the termination of its office lease in August 2024, the Company wrote off its remaining fixed assets during the third quarter of 2024. Depreciation and amortization expense was $20,000 and $44,000 for the nine months ended September 30, 2024 and 2023, respectively.

6. Accrued expenses

Accrued expenses consist of (amounts in thousands):

	September 30, 2024	December 31, 2023
Compensation and related benefits	$ 151	$ 121
Restructuring costs	—	443
Research and development expenses	201	2,672
Professional fees and other expenses	266	213
	$ 618	$ 3,449

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 September 30, 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 radiotherapy-induced SOM. The Company recognized $10.7 million in noncash interest expense during the nine months ended September 30, 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 nine months ended September 30, 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. Pursuant to the terms of the Royalty Agreement and the Amendment, the Royalty Agreement and the Amendment remain in effect and any future purchaser or licensor of the Products will be bound by the terms of the Royalty Agreement and the Amendment, unless otherwise agreed by Blackstone.

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 had a non-cancelable operating lease for office space in Malvern, Pennsylvania. On August 8, 2024, the Company entered into a Lease Termination Agreement with its landlord. In return for an early termination fee of $0.4 million, the office lease was terminated as of August 31, 2024, and the Company has no further obligations with regard to the office lease. The Company's total cost to exit the office lease was $0.5 million, including a broker fee and other costs. The discount rate used to account for the Company's operating leases was the Company's estimated incremental borrowing rate of 5.4%.

Supplemental balance sheet information related to leases was as follows:

	September 30, 2024	December 31, 2023
Operating Leases		
Right-of-use lease assets	$ —	$ 1,212
Lease liabilities, current	—	133
Lease liabilities, net of current portion	—	1,117
Total operating lease liabilities	$ —	$ 1,250

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 September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Operating lease costs				
Operating lease rental expense	$ 451	$ 54	$ 559	$ 138
Total operating lease expense	$ 451	$ 54	$ 559	$ 138

Supplemental cash flow information related to leases was as follows:

	Nine months ended September 30,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows for operating leases	$ 597	$ 97
Right-of-use assets obtained in exchange for lease obligation		
Operating leases	—	1,310
Derecognition of lease liability and right-of-use asset due to lease termination		
Operating leases	1,212	—

9. Equity

Shareholder Rights Agreement

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.

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 September 30, 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.

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 September 30, 2024 was 1,504,215.

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 September 30, 2024, there were 5,104,307 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 September 30, 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 September 30, 2024, there were 1,500,000 shares available for issuance under the Inducement Plan.

Share-based Compensation

Share-based compensation expense was as follows for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Research and development	$ 190	$ 415	$ 652	$ 1,315
General and administrative	361	975	1,497	3,058
	$ 551	$ 1,390	$ 2,149	$ 4,373

The following table summarizes the activity related to stock option grants for the nine months ended September 30, 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	(393,578)	4.09	
Outstanding at September 30, 2024	5,345,910	$ 5.98	5.4
Vested and exercisable at September 30, 2024	4,434,256	$ 6.67	4.8
Vested and expected to vest at September 30, 2024	5,345,910	$ 5.98	5.4

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 September 30, 2024, the unrecognized compensation cost was $1.8 million and will be recognized over an estimated weighted-average amortization period of 1.6 years. The aggregate intrinsic value of options outstanding and of options exercisable as of September 30, 2024 were zero. Options granted during the nine months ended September 30, 2023 had weighted-average grant-date fair values of $1.66 per share. There were no options granted during the nine months ended September 30, 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 nine months ended September 30, 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.

The grant date fair value of each option grant was estimated throughout the nine months ended September 30, 2023 using the Black-Scholes option-pricing model using the following weighted-average assumptions. There were no options granted during the nine months ended September 30, 2024.

	Nine months ended September 30, 2023
Expected term (in years)	6.2
Expected stock price volatility	95.3%
Risk-free interest rate	4.05%
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 nine months ended September 30, 2024 and 2023 were $0.1 million and $0.2 million, 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 September 30, 2024 (in thousands):

	2024
Balance, January 1, 2024	$ 443
Current year restructuring costs	—
Payment of employee severance and related costs	(443)
Balance, September 30, 2024	$ —

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 unaudited 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

Until recently, we have operated as 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 may 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. As of September 30, 2024, the Company had 3 employees.

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 NCSLC.

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.

Following the conclusion of our review of strategic alternatives, on August 8, 2024 our board of directors approved our dissolution and liquidation (Dissolution), pursuant to a plan of complete liquidation and dissolution (Plan of Dissolution), subject to stockholder approval. The Plan of Dissolution contemplated an orderly wind down of our business and operations in accordance with the provisions of Delaware law. At the special meeting held on October 17, 2024 the Plan of Dissolution was not approved by the Company's stockholders.

As our stockholders did not approve the Dissolution, our board of directors and management will continue to explore what, if any, other alternatives are available for the future of the Company in light of its discontinued business activities and lack of resources. Such alternatives may include a merger, sale, divestiture of assets, licensing or other strategic transaction. It is also possible that we would seek voluntary dissolution at a later time, potentially with further diminished assets. In addition, we could cease operations, make an assignment for the benefit of creditors, turn the Company over to a third-party management company or liquidator or file for bankruptcy protection.

We caution that trading in the Company's securities is highly speculative and poses substantial risks. Trading prices for the Company's securities may bear little or no relationship to the actual value realized, if any, by holders of the Company's securities. Accordingly, the Company urges extreme caution with respect to existing and future investments in its securities.

Nasdaq Delisting Notification

On May 31, 2024, we received written notice (the Notice) from the Office of General Counsel of The Nasdaq Stock Market (Nasdaq) indicating that the Nasdaq Hearings Panel had determined to delist our shares from Nasdaq due to our failure to meet Nasdaq's continued listing standards. As previously disclosed, we were in violation of the requirements to maintain a minimum average market value of listed securities, as set forth in Nasdaq Listing Rule 5450(b)(2)(A), the minimum bid price requirement, as set forth in Nasdaq Listing Rule 5450(a)(1), and the minimum market value of publicly held shares, as set forth in Listing Rule 5450(b)(2)(C). The Notice indicated that trading in our shares of common stock (the Common Stock) on Nasdaq was to be suspended effective at the open of trading on June 4, 2024. On September 6, 2024, Nasdaq filed a Form 25 which removed our Common Stock from listing. Our Common Stock is now quoted under its existing symbol "GRTX" on the Pink Market operated by OTC Markets Group Inc.

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 nine months ended September 30, 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 and nine months ended September 30, 2024 and 2023 (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Avasopasem manganese	$ (10)	$ 1,108	$ (159)	$ 4,491
Rucosopasem manganese	27	3,417	687	9,670
Other research and development expense	120	478	567	1,830
Personnel related and share-based compensation expense	168	1,090	2,128	4,935
	$ 305	$ 6,093	$ 3,223	$ 20,926

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.

We expect to incur additional costs related to the pursuit of any available strategic alternatives, such as legal 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 and Nine Months Ended September 30, 2024 and 2023

The following table sets forth our results of operations for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,			Nine months ended September 30,		
	2024	2023	Change	2024	2023	Change
Operating expenses:						
Research and development	$ 305	$ 6,093	$(5,788)	$ 3,223	$ 20,926	$(17,703)
General and administrative	3,439	4,994	(1,555)	9,307	20,849	(11,542)
Write-off of acquired intangible asset	2,258	—	2,258	2,258	—	2,258
Write-off of goodwill	881	—	881	881	—	881
Gain on litigation settlement	(975)	—	(975)	(975)	—	(975)
Restructuring costs	—	2,309	(2,309)	—	2,309	(2,309)
Loss from operations	(5,908)	(13,396)	7,488	(14,694)	(44,084)	29,390
Other income (expense):						
Interest income	126	411	(285)	471	1,300	(829)
Interest expense	—	(2,087)	2,087	—	(10,709)	10,709
Foreign currency loss	(2)	(1)	(1)	(6)	(2)	(4)
Loss before income tax benefit	(5,784)	(15,073)	9,289	(14,229)	(53,495)	39,266
Income tax benefit	203	—	203	203	—	203
Net loss	$(5,581)	$(15,073)	$ 9,492	$(14,026)	$(53,495)	$ 39,469

Research and Development Expense

Research and development expense decreased by $5.8 million from $6.1 million for the three months ended September 30, 2023 to $0.3 million for the three months ended September 30, 2024. Avasopasem development costs decreased by $1.1 million as the ROMAN trial was completed and manufacturing activities ceased. Rucosopasem development costs decreased $3.4 million as we halted the GRECO-1 and GRECO-2 clinical trials. Personnel related and share-based compensation expense decreased $0.9 million, primarily due to the Workforce Reduction, and other research and development expenses decreased $0.4 million. As noted above, we have ceased all clinical trial activity and have suspended the clinical development of our product candidates.

Research and development expense decreased by $17.7 million from $20.9 million for the nine months ended September 30, 2023 to $3.2 million for the nine months ended September 30, 2024. Avasopasem development costs decreased by $4.7 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 $9.0 million as we halted the GRECO-1 and GRECO-2 clinical trials. Personnel related and share-based compensation expense decreased $2.8 million, primarily due to the Workforce Reduction, and other research and development expenses decreased $1.3 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 $1.6 million from $5.0 million for the three months ended September 30, 2023 to $3.4 million for the three months ended September 30, 2024, principally due to the cessation of avasopasem commercial preparations and medical affairs activities, and reduced share-based compensation and legal expenses, partially offset by $0.7 million of severance charges recorded in the period.

General and administrative expense decreased by $11.5 million from $20.8 million for the nine months ended September 30, 2023 to $9.3 million for the nine months ended September 30, 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, partially offset by $0.7 million of severance charges recorded in the period.

Write-off of Acquired Intangible Asset and Goodwill

In August 2024, our board of directors approved the Plan of Dissolution, under which future development of our product candidates would no longer continue. In connection with this decision, we concluded that the related IPR&D asset and related goodwill were each impaired in their entirety, and as such recognized non-cash impairment charges of $2.3 million for the IPR&D and $0.9 million for the goodwill during the three and nine months ended September 30, 2024.

Gain on Litigation Settlement

We recognized a $1.0 million gain during the three and nine months ended September 30, 2024 in connection with the settlement of the Litigation, as discussed below, which was recorded in operating expenses.

Restructuring Costs

In connection with the CRL announcement, we restructured our operations and reduced our workforce by 22 employees, or approximately 70%, as of August 9, 2023. As a result of these restructuring initiatives, we incurred total restructuring-related charges of $2.3 million during the three and nine months ended September 30, 2023. No such costs were incurred during the three and nine months ended September 30, 2024.

Interest Income

Interest income decreased from $0.4 million for the three months ended September 30, 2023 to $0.1 million for the three months ended September 30, 2024 and decreased from $1.3 million for the nine months ended September 30, 2023 to $0.5 million for the nine months ended September 30, 2024, primarily due to the reduction in investable cash and securities.

Interest Expense

We recognized $2.1 million and $10.7 million in non-cash interest expense during the three and nine months ended September 30, 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.

Income Tax Benefit

During the three and nine months ended September 30, 2024, the impairment of our acquired intangible asset and goodwill resulted in an income tax benefit of $0.2 million due to the tax effect of the reduction in the deferred tax liability associated with the asset.

Liquidity and Capital Resources

We do not currently have any approved products and have never generated any revenue from product sales. Through September 30, 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 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 September 30, 2024, we had $8.5 million in cash and cash equivalents and an accumulated deficit of $451.4 million. We expect our existing cash and cash equivalents as of September 30, 2024 will enable us to fund our operating expenses for at least twelve months from the date of filing of this Quarterly Report on Form 10-Q. Future capital requirements will depend on our strategic alternatives, which may include pursuit of a strategic transaction, a voluntary dissolution, or the continued operation of product development. 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, financial position and any strategic transaction we pursue.

We have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years.

Cash Flows

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

	Nine months ended September 30,	
	2024	2023
Net cash used in operating activities	$(9,806)	$(34,933)
Net cash provided by investing activities	4	23,318
Net cash provided by financing activities	—	31,728
Net increase (decrease) in cash and cash equivalents	$(9,802)	$ 20,113

Operating Activities

During the nine months ended September 30, 2024, we used $9.8 million of net cash in operating activities. Cash used in operating activities reflected our net loss of $14.0 million and $0.9 million from other changes in operating assets and liabilities, partially offset by non-cash charges of $5.1 million related to the write-off of the acquired intangible asset and goodwill, deferred tax benefit, share-based compensation, depreciation expense, and loss from disposal of property and equipment. The primary use of cash was to fund our operations as we reviewed strategic alternatives.

During the nine months ended September 30, 2023, we used $34.9 million of net cash in operating activities. Cash used in operating activities reflected our net loss of $53.5 million, partially offset by non-cash charges of $15.1 million primarily related to share-based compensation, interest expense on our Royalty Agreement with Blackstone Life Sciences and depreciation expense, $3.2 million from the refund of the Prescription Drug User Fee Act (PDUFA) fee that was paid to the FDA in December 2022 in conjunction with the filing of our NDA for avasopasem, and $0.3 million from other changes in operating assets and liabilities. The primary use of cash was to fund our operations related to the development of our product candidates.

Investing Activities

During the nine months ended September 30, 2024, investing activities provided $4,000 in cash proceeds from the sale of property and equipment. During the nine months ended September 30, 2023, investing activities provided $23.3 million in cash proceeds, primarily from the net sales of our short-term investments.

Financing Activities

During the nine months ended September 30, 2023, financing activities provided $31.7 million from the sale of our common stock and common stock warrants in our registered direct offering in February 2023, from the sale of our common stock under the Sales Agreement with Jefferies, and from the exercise of common stock warrants and stock options during the period.

Funding Requirements

Our future capital requirements will depend on the results of any strategic alternative we may pursue and are able to implement. Other strategic alternatives may include pursuit of a strategic transaction, a voluntary dissolution, or the continued operation of product development. In the event we resume product candidate development, our future capital requirements will depend on many factors, including:

- 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.

If we are not able to identify and implement a strategic transaction or a dissolution, until such time, if ever, as we can generate substantial product revenues, our options to finance our cash needs in addition to existing cash may include 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 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 (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. Pursuant to the terms of the Royalty Agreement and the Amendment, the Royalty Agreement and the Amendment remains in effect and any future purchaser or licensor of the Products will be bound by the terms of the Royalty Agreement and the Amendment, unless otherwise agreed by Blackstone.

In May 2020, as partial consideration for the Amendment, we issued two warrants to the Blackstone Purchaser to purchase an aggregate of 550,661 shares of our common stock at an exercise price equal to $13.62 per share, each of which 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 principal executive officer and principal 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 principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 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 September 30, 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), or the Litigation. On August 2, 2024, we and the CROs entered into an agreement to settle the Litigation, pursuant to which, in exchange for mutual releases, the CROs paid to us the amount of $975,000, and the parties terminated the contracts between Galera and the CROs, with no further obligations under the parties' contracts. On August 8, 2024, we filed a Praecipe to Settle, Discontinue, and End the Litigation.

Item 1A. Risk Factors.

Particularly as a result of the failure to receive stockholder approval of the Dissolution, trading in our securities is highly speculative and poses substantial risks. Trading prices for our securities may bear little or no relationship to the actual value realized, if any, by holders of our securities. Accordingly, we urge extreme caution with respect to existing and future investments in our securities.

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, except as noted below. The occurrence of any of the events or developments described in our Risk Factors could adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Financial Position and Capital Needs

Any financial or strategic option we pursue may not be successful.

In August 2023, in connection with the CRL announcement, we initiated a process to explore potential strategic alternatives. We engaged Stifel, Nicolaus & Company, Inc., as our financial advisor, to assist in reviewing strategic alternatives with the goal of maximizing value for our stockholders. After an extensive review of strategic alternatives, we have been unable to identify and enter into a viable transaction with a merger partner or purchaser of our company or our assets and sought stockholder approval of the Plan of Dissolution. Because our stockholders did not approve the Dissolution, the board of directors will continue to explore what, if any, alternatives are available for the future of the Company in light of its discontinued business activities. Such alternatives may include a merger, sale, divestiture of assets, licensing, or other strategic transaction. In addition, we may seek voluntary dissolution at a later time with potentially diminished assets or seek bankruptcy protection (should our net assets decline to levels that would require such action). It is unlikely that these alternatives would result in greater stockholder value than the proposed Plan of Dissolution and the Dissolution. The process of continuing to evaluate these 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. There can be no assurance of completion of any particular course of action or a defined timeline for completion, and we can provide no assurance that any strategic alternative we pursue will have a positive impact on our results of operations or financial condition.

We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

We have incurred losses in each year since our inception in 2012, related to expenses for research and development and our ongoing operations, and we anticipate incurring losses for the foreseeable future. Historically, we invested substantially all of our efforts and financial resources in identifying, acquiring, in-licensing and developing our product candidates, including commencing and conducting clinical trials and providing general and administrative support for these operations. Our net losses for the years ended December 31, 2023 and 2022 were $59.1 million and $62.2 million, respectively. As of December 31, 2023, we had an accumulated deficit of $437.4 million.

To become and remain profitable, we would have to succeed in developing and eventually commercializing product candidates that generate significant revenue. Given that we are not currently pursuing and have no plans to pursue the clinical development of our product candidates, we do not expect to succeed in the activities required to generate a profit and we expect to continue to incur losses for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Risks Related to Our Common Stock

Our common stock is eligible for quotation on the OTC Pink Market, which may have an unfavorable impact on our stock price and liquidity.

Our common stock is eligible for quotation on the Pink Market operated by OTC Markets Group Inc. The Pink Market is a regulated quotation service that displays real-time quotes, last sale prices and volume information in over-the-counter securities. The Pink Market is not an issuer listing service, market, or exchange. The requirements for quotation on the Pink Market are considerably lower and less regulated than those of an exchange such as The Nasdaq Stock Market LLC, on which we were previously listed. Because of this, it is possible that fewer brokers or dealers will be interested in making a market in our common stock because the market for such securities is more limited, the stocks are more volatile, and the risk to investors is greater, which may impact the liquidity of our common stock. We cannot assure you that an active public market for our common stock will ever develop. Even if an active market begins to develop in our common stock, the quotation of our common stock on the Pink Market may result in a less liquid market available for existing and potential stockholders to trade common stock, could depress the trading price of our common stock and could have a long-term adverse impact on our ability to raise capital in the future. If an active market is never developed for our common stock, it will be difficult or impossible for you to sell any common stock you purchase. Until our common stock is listed on a national securities exchange, regarding which we can provide no assurance, we expect that it will continue to be listed on the OTC Pink Market.

General Risk Factors

The price of our common stock is likely to be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

Our share price is likely to be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, stockholders may not be able to sell their common stock at a price that they consider reasonable. The market price for our common stock may be influenced by many factors, including:

- the failure to obtain stockholder approval for our Dissolution;
- any other developments in our exploration of other strategic alternatives for our business;
- the listing of our common stock on the OTC Pink Market;

- delays in the commencement, enrollment and the ultimate completion of clinical trials;
- discontinuation of clinical trials;
- the results and potential impact of competitive products or technologies;
- our ability to manufacture and successfully produce our product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- financing or other corporate transactions, or inability to obtain additional funding;
- failure to meet or exceed expectations of the investment community;
- regulatory or legal developments in the United States and other countries;
- the recruitment or departure of key personnel;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions;
- changes in voting control of our executive officers and certain other members of our senior management or affiliates who hold our shares; and
- the other factors described in this “Risk Factors” section and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on March 28, 2024, and our Quarterly Report on Form 10-Q for the period ended June 30, 2024, filed with the SEC on August 14, 2024.

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.

Item 2.06 Material Impairments.

In August 2024, the Company's board of directors approved the Plan of Dissolution, under which future development of the Company's product candidates would no longer continue. In connection with this decision, on December 11, 2024, the audit committee of the Company's board of directors concluded that the related IPR&D asset and related goodwill were each impaired in their entirety, and as such recognized non-cash impairment charges of $2.3 million for the IPR&D and $0.9 million for the goodwill during the three and nine months ended September 30, 2024.

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 September 30, 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.

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
3.1	Restated Certificate of Incorporation of Galera Therapeutics, Inc.	8-K	001-39114	3.1	11/12/2019	
3.2	Certificate of Designation of the Series A Junior Participating Preferred Stock of the Company, dated May 3, 2024	8-A	001-39114	3.1	5/3/2024	
3.3	Amended and Restated Bylaws of Galera Therapeutics, Inc.	10-K	001-39114	3.2	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)	8-K	001-39114	4.1	5/3/2024	
10.1	Separation Agreement and General Release, dated August 31, 2024, between the Company and Chris Degnan					*
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					*
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					**
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					**
101.INS	Inline XBRL Instance Document—the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document					*
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					*

* Filed herewith.
** Furnished herewith.

SIGNATURES

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

Galera Therapeutics, Inc.

Date: December 13, 2024

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

Date: December 13, 2024

By: /s/ Joel Sussman
Joel Sussman
Chief Accounting Officer
(principal financial officer and principal accounting officer)

Exhibit 10.1

GALERA THERAPEUTICS, INC.

August 28, 2024

Chris Degnan

Re: Separation Agreement

Dear Chris:

This letter sets forth the terms of the separation agreement (this "**Agreement**") that Galera Therapeutics, Inc. (the "**Company**") is offering to you to aid in your employment transition from the Company.

1. Separation Date. You agree and acknowledge that your Company employment will terminate by way of mutual agreement on August 31, 2024 (the "**Separation Date**"). As of and following the Separation Date, (a) you will no longer be employed by the Company, and (b) you will no longer hold any other employment, director, manager, or officer positions with the Company, its direct and indirect parents, and/or its direct and indirect subsidiaries (the Company, along with its direct and indirect parents and subsidiaries, the "**Company Group**"). Following the Separation Date, the Company will pay you all amounts earned and owing pursuant to the terms and conditions of Sections 4.5(a)(i), (iii), (iv) and (v) of the Employment Agreement (as defined in Section 2 below).

2. Severance Benefits. As consideration for this Agreement, your employment termination will be deemed to be a termination under Section 4.5(b) of your Employment, Confidentiality, Noncompete and Invention Rights Agreement, dated as of October 25, 2019 (the "**Employment Agreement**"). As such, pursuant to the terms and conditions of the Employment Agreement (as modified and enhanced by this Agreement), if: (i) you remain a Company employee in good standing through and including the Separation Date and your employment terminates on the Separation Date; (ii) on or within twenty-one (21) calendar days following the Separation Date, you sign, date, and return to the Company (without alteration), the General Release of Claims attached hereto as ***Exhibit A*** (the "**General Release**"); (iii) you allow the General Release to become effective in accordance with its terms; and (iv) you comply with the terms of and your obligations under this Agreement and your other Continuing Obligations owed to the Company Group as detailed in Section 5 below (collectively, clauses (i) through (v), the "**Obligations**"), the Company Group will provide you with the following "**Termination Benefits**":

(a) Termination Payments. Termination pay in the form of a lump sum cash payment equal to your final monthly base salary for a period of nine (9) months following the Separation Date (totaling $348,925.50) (the "**Termination Payments**"). The Termination Payments will be paid to you on September 15, 2024, subject to required payroll deductions and withholdings. For the avoidance of doubt, you acknowledge and agree that you will not receive, and are forfeiting, any additional payments related to the Target Bonus (as defined in the Employment Agreement) subject to Section 3 below.

(b) Continuation Coverage. If you timely elect continuation coverage pursuant to COBRA for you and your eligible dependents, the Company will pay your COBRA group health insurance premiums for you and your eligible dependents (e.g., the full COBRA premium cost in effect at the time of such payment) (the "**COBRA Premiums**") until the earlier of (i) a period of nine (9) months from the Separation Date or (ii) the date upon which you and/or your eligible dependents become covered under similar plans (the "**COBRA Payment Period**"). If you become eligible for health insurance coverage under another employer's group health plan or through self-employment, or if you otherwise cease to be

eligible for COBRA coverage, you must immediately notify the Company, and the Company's obligation to pay the COBRA Premiums shall cease. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA Premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company instead shall provide you with taxable monthly payments in an amount equal to the COBRA Premium amount for the first month of your COBRA coverage, and such monthly payments shall be made through the remainder of the COBRA Payment Period.

(c) Equity. In accordance with the terms of the Company's 2019 Incentive Award Plan, you will have ninety (90) days after the Separation Date to exercise any vested options.

(d) Independent Contractor Agreement. Nothing in this Agreement or in the General Release shall release the Company from its obligations under the Independent Contractor Agreement dated August 31, 2024 (the "**Independent Contractor Agreement**"), between you and the Company.

3. Change in Control. In the event that there is a Change in Control (as defined in the Employment Agreement) between the Separation Date and nine-month anniversary of the Separation Date, (i) you shall receive 1 times your Target Bonus within thirty (30) days of the Change in Control; (ii) "Section 4.5(b) of your Employment, Confidentiality, Noncompete and Invention Rights Agreement, dated as of October 25, 2019" in Section 2 hereof shall be replaced with "Section 4.5(c) of your Employment, Confidentiality, Noncompete and Invention Rights Agreement, dated as of October 25, 2019 (the '**Employment Agreement**');" (iii) "nine (9) months" in Sections 2(a) and 2(b) hereof shall be replaced with "twelve (12) months;" and (iv) the first two sentences of Section 2(a) hereof shall be replaced with "Termination pay in the form of a lump sum cash payment equal to your final monthly base salary for a period of twelve (12) months following the Separation Date (totaling $465,234.00) (the "**Termination Payments**"). The Termination Payments will be paid to you upon the closing of the transaction that effects the Change in Control, subject to required payroll deductions and withholdings, less any portion of the Termination Payments paid on September 15, 2024."

4. No Other Compensation or Benefits. You agree and acknowledge that, except as expressly provided in this Agreement, you have not earned and will not receive from the Company Group any additional compensation (including base salary, bonus, incentive compensation, commissions, severance, or equity) or benefits prior to, on, or after the Separation Date other than any benefits to which you are entitled under broad-based employee benefit plans of the Company Group in which you participate.

5. Continuing Obligations. You acknowledge and reaffirm your continuing obligations owed to the Company Group, including without limitation, pursuant to: (a) the Employment Agreement (including Sections 5 – 22 of the Employment Agreement), and (b) any other similar agreement entered into by you and which benefits or may be enforced by the Company or any other member of the Company Group, each of which agreements and obligations remain in full force and effect in accordance with their terms during the Transition Period and following the Separation Date.

6. Confidentiality. The existence and terms of, and amount paid under, this Agreement will be held in strictest confidence by you, and will not be publicized or disclosed in any manner whatsoever; provided, however, that: (a) you may disclose this Agreement in confidence to your immediate family; (b) you may disclose this Agreement in confidence to your attorneys, accountants, auditors, tax preparers, and financial advisors; and (c) you may disclose this Agreement insofar as such disclosure may be necessary to enforce its terms or as otherwise required by law. In particular, and without limitation, you agree, either directly or indirectly (including through third parties), not to disclose the existence or terms of, or amounts paid under, this Agreement to any current or former Company employee, contractor or consultant.

7. No Admissions. The promises and payments in consideration of this Agreement are not and shall not be construed to be an admission of any liability or obligation by either party to the other party, and neither party makes any such admission.

8. Cooperation. From and after the date of this Agreement, you agree to cooperate fully with the Company Group, or any member thereof, in connection with its or their actual or contemplated defense, prosecution, or investigation of any claims or demands by or against third parties, or in connection with other matters arising from events, acts, or failures to act that occurred during the period of your employment by the Company; provided, that such cooperation will not unreasonably burden you or unreasonably interfere with your subsequent employment or other business or personal affairs. Such cooperation includes making yourself available to the Company Group upon reasonable notice, without subpoena, to provide complete, truthful and accurate information in witness interviews, depositions, and trial testimony. The Company will reimburse you for reasonable and pre-approved out-of-pocket expenses you incur in connection with any such cooperation, excluding forgone wages, salary, or other compensation, and will accommodate your scheduling needs.

9. Choice of Law. This Agreement will be governed and interpreted by and under the laws of the State of Delaware without giving effect to any conflicts of laws principles that require the application of the law of a different state. The parties agree to, and agree not to challenge, the exclusive jurisdiction and exclusive venue of the state and federal courts in Delaware, in any action or proceeding arising out of or relating to this Agreement or the transactions contemplated hereby, and further irrevocably agree that all claims in any such action or proceeding shall be heard and determined exclusively in the state or federal courts located in Delaware.

10. General. This Agreement, ***Exhibit A***, the Employment Agreement (as modified by this Agreement) and the Continuing Obligations in Section 5 above (which obligations shall remain in full force and effect in accordance with their terms following the Separation Date), constitutes the complete, final and exclusive embodiment of the entire agreement between you and the Company Group with regard to the subject matter hereof. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes and terminates any other agreements, promises, warranties or representations by and between you, the Company and all other members of the Company Group concerning its subject matter. This Agreement may not be modified or amended except in a writing signed by both you and the Company's Board of Directors. This Agreement will bind the heirs, personal representatives, successors and assigns of both you and the Company, and inure to the benefit of both you and the Company, their heirs, successors and assigns. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination shall not affect any other provision of this Agreement and the provision in question shall be modified so as to be rendered enforceable in a manner consistent with the intent of the parties insofar as possible under applicable law. Any ambiguity in this Agreement shall not be construed against either party as the drafter. Any waiver of a breach of this Agreement, or rights hereunder, shall be in writing and shall not be deemed to be a waiver of any successive breach or rights hereunder. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act or other applicable law) or other transmission method and any counterpart so delivered will be deemed to have been duly and validly delivered and be valid and effective for all purposes.

[***Signature Page to Follow***]

If this Agreement is acceptable to you, please sign below on or within seven (7) business days from the Separation Date and then promptly return the fully signed original to me. The Company's offer contained herein will automatically expire if we do not receive the fully signed Agreement from you within this timeframe.

We wish you the best in your future endeavors.

Sincerely,

Galera Therapeutics, Inc.

By: /s/ Mel Sorensen
Name: Mel Sorensen
Title: Chief Executive Officer

Agreed and Acknowledged:

/s/ Chris Degnan
Chris Degnan

Date: August 31, 2024

Exhibit A – General Release of Claims

EXHIBIT A

GENERAL RELEASE OF CLAIMS
(TO BE SIGNED ON OR WITHIN 21 CALENDAR DAYS OF THE SEPARATION DATE)

If I choose to sign and return this General Release of Claims (the "**General Release**"), and allow it to become effective by its terms, the Company Group will provide me with the Termination Benefits set forth in Section 2 of the Separation Agreement between me and the Company dated August 28, 2024 (the "**Agreement**"). I understand that I am not entitled to the Termination Benefits unless I sign and return this General Release to the Company on or within twenty-one (21) calendar days following the Separation Date, and allow it to become effective by its terms. Capitalized terms used in this General Release that are not defined herein shall have the meaning as defined in the Agreement.

1. I understand that any payments or benefits paid or granted to me under Section 3 of the Agreement represent, in part, consideration for signing this General Release and are not salary, wages or benefits to which I was already entitled. I understand and agree that I will not receive the payments and benefits specified in Section 3 of the Agreement unless I execute this General Release and do not revoke this General Release within the time period permitted hereafter or breach this General Release. I also acknowledge and represent that I have received all payments and benefits that I am entitled to receive (as of the date hereof) by virtue of my employment with the Company.

2. Except as provided in Section 4 and Section 5 below and except for the provisions of the Agreement that expressly survive the termination of my employment with the Company, I knowingly and voluntarily (for myself, my heirs, executors, administrators and assigns) release and forever discharge the Company and the other Released Parties from any and all claims, suits, controversies, actions, causes of action, cross-claims, counter-claims, demands, debts, compensatory damages, liquidated damages, punitive or exemplary damages, other damages, claims for costs and attorneys' fees, or liabilities of any nature whatsoever in law and in equity, both past and present (through the date I execute this General Release) and whether known or unknown, suspected, or claimed against the Company or any of the Released Parties which I, my spouse, or any of my heirs, executors, administrators or assigns, may have, which arise out of or are connected with my employment with, or my separation or termination from, the Company (including, but not limited to, any allegation, claim or violation, arising under: Title VII of the Civil Rights Act of 1964, as amended; the Civil Rights Act of 1991; the Age Discrimination in Employment Act of 1967, as amended (including the Older Workers Benefit Protection Act); the Equal Pay Act of 1963, as amended; the Americans with Disabilities Act of 1990; the Family and Medical Leave Act of 1993; the Worker Adjustment Retraining and Notification Act; the Employee Retirement Income Security Act of 1974; any applicable Employee Order Programs; the Fair Labor Standards Act; or their state or local counterparts; the Pennsylvania Human Relations Act; the Pennsylvania Whistleblower Law; the Pennsylvania Public Employee Relations Act; the Philadelphia Fair Practices Ordinance; or under any other federal, state or local civil or human rights law, or under any other local, state, or federal law, regulation or ordinance; or under any public policy, contract or tort, or under common law; or arising under any policies, practices or procedures of the Company; or any claim for wrongful discharge, breach of contract, infliction of emotional distress, defamation; or any claim for costs, fees, or other expenses, including attorneys' fees incurred in these matters) (all of the foregoing are collectively referred to herein as the "Claims").

3. I represent that I have made no assignment or transfer of any right, claim, demand, cause of action or other matter covered by Section 2 above.

4. This General Release does not release claims that cannot be released as a matter of law, including, but not limited to, my right to report possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation, my right to file a charge with or participate in a charge, investigation or proceeding by the Equal Employment Opportunity Commission, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company (with the understanding that my release of claims herein bars me from recovering monetary or other individual relief from the Company or any Released Parties in connection with any charge, investigation or proceeding, or any related complaint or lawsuit, filed by me or by anyone else on my behalf before the federal Equal Employment Opportunity Commission or a comparable state or local agency), claims for unemployment compensation or any state disability insurance benefits pursuant to the terms of applicable state law, claims to continued participation in certain of the Company's group benefit plans pursuant to the terms and conditions of COBRA, claims to exercise rights I may have under Section 7 of the U.S. National Labor Relations Act, such as the right to engage in concerted activity, including collective action or discussion concerning wages or working conditions, claims to any benefit entitlements vested as the date of separation of my employment, pursuant to written terms of any employee benefit plan of the Company or its affiliates, my rights or remedies in connection with my ownership of vested equity securities of the Company, my right to indemnification by the Company or any of its affiliates pursuant to contract or applicable law, and my rights under applicable law.

5. I further agree that this General Release does not waive or release any rights or claims that I may have under the Age Discrimination in Employment Act of 1967 which arise after the date I execute this General Release. I acknowledge and agree that my separation from employment with the Company in compliance with the terms of the Agreement shall not serve as the basis for any claim or action (including, without limitation, any claim under the Age Discrimination in Employment Act of 1967).

6. In signing this General Release, I acknowledge and intend that it shall be effective as a bar to each and every one of the Claims hereinabove mentioned or implied. I expressly consent that this General Release shall be given full force and effect according to each and all of its express terms and provisions, including those relating to unknown and unsuspected Claims (notwithstanding any state statute that expressly limits the effectiveness of a general release of unknown, unsuspected and unanticipated Claims), if any, as well as those relating to any other Claims hereinabove mentioned or implied. I acknowledge and agree that this waiver is an essential and material term of this General Release and that without such waiver the Company would not have agreed to the terms of the Agreement. I further agree that in the event I should bring a Claim seeking damages against the Company, or in the event I should seek to recover against the Company in any Claim brought by a governmental agency on my behalf, this General Release shall serve as a complete defense to such Claims. I further agree that I am not aware of any pending charge or complaint of the type described in Section 2 above as of the execution of this General Release. Notwithstanding the foregoing, although I am releasing claims under the Age Discrimination in Employment Act of 1967, as amended, I may challenge the knowing and voluntary nature of this Agreement under such law before a court, the Equal Employment Opportunity Commission, or other agency; provided, however, nothing herein shall limit the court or agency's ability to offset any money awarded to me upon such a challenge by the amount of consideration received under this Agreement or from awarding the Company attorney fees or costs that may be authorized under applicable law.

7. I agree that neither this General Release, nor the furnishing of the consideration for this General Release, shall be deemed or construed at any time to be an admission by the Company, any Released Party or myself of any improper or unlawful conduct.

8. I agree that I will forfeit all amounts payable by the Company pursuant to Section 3 of the Agreement if I challenge the validity of this General Release; provided that this forfeiture shall not apply with respect to challenges regarding the validity of any waiver or release under the Age Discrimination in Employment Act of 1967. I also agree that if I violate this General Release by suing the Company or the other Released Parties, I will pay all costs and expenses of defending against the suit incurred by the Released Parties, including reasonable attorneys' fees, and return all payments received by me pursuant to Section 3 of the Agreement.

9. I agree not to criticize, denigrate or otherwise disparage the Company, its past and present investors, officers, directors or employees or its affiliates, *provided*, that nothing in this Section 9 shall limit my response to questions on any and all such subjects from the Company's Chief Executive Officer, members of its board of directors, its legal counsel or my own legal counsel, or as otherwise required by law. I further agree to keep all confidential and proprietary information about the past or present business affairs of the Company and its affiliates confidential unless a prior written release from the Company is obtained. I further agree that as of the date hereof, I have returned to the Company any and all property, tangible or intangible, relating to its business, which I possessed or had control over at any time (including, but not limited to, company-provided credit cards, building or office access cards, keys, computer equipment, manuals, files, documents, records, software, customer data base and other data) and that I shall not retain any copies, compilations, extracts, excerpts, summaries or other notes of any such manuals, files, documents, records, software, customer data base or other data. In addition, the Defend Trade Secrets Act of 2016 provides the following immunity rights: (a) an individual shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made either (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law, or (ii) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal; and (b) an individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the employer's trade secret to the attorney of the individual and use the trade secret information in the court proceeding if the individual files any document containing the trade secret under seal and does not disclose the trade secret, except pursuant to court order.

   Notwithstanding anything in this General Release to the contrary, this General Release shall not relinquish, diminish, or in any way affect any rights or claims arising out of any action or inaction by the Company or by any Released Party after the date hereof.

10. I recognize and agree that the restraints contained in the Agreement (both separately and in total) are reasonable and enforceable and I agree to abide by the terms of those sections.

11. Whenever possible, each provision of this General Release shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this General Release is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other provision or its validity and enforceability in any other jurisdiction, but this General Release shall be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provision had never been contained herein.

12. This General Release does not waive or release any rights or claims that I may have under the Independent Contractor Agreement.

BY SIGNING THIS GENERAL RELEASE, I REPRESENT AND AGREE THAT:

1. I HAVE READ IT CAREFULLY;
2. I UNDERSTAND ALL OF ITS TERMS AND KNOW THAT I AM GIVING UP IMPORTANT RIGHTS, INCLUDING BUT NOT LIMITED TO, RIGHTS UNDER THE AGE DISCRIMINATION IN EMPLOYMENT ACT OF 1967, AS AMENDED, TITLE VII OF THE CIVIL RIGHTS ACT OF 1964, AS AMENDED; THE EQUAL PAY ACT OF 1963, THE AMERICANS WITH DISABILITIES ACT OF 1990; AND THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974, AS AMENDED;
3. I VOLUNTARILY CONSENT TO EVERYTHING IN IT;
4. I HAVE BEEN ADVISED TO CONSULT WITH AN ATTORNEY BEFORE EXECUTING IT AND I HAVE DONE SO OR, AFTER CAREFUL READING AND CONSIDERATION, I HAVE CHOSEN NOT TO DO SO OF MY OWN VOLITION;
5. I HAVE HAD AT LEAST 21 DAYS FROM THE DATE OF MY RECEIPT OF THIS GENERAL RELEASE TO CONSIDER IT, AND ANY CHANGES MADE SINCE SUCH DATE WILL NOT RESTART THE REQUIRED 21-DAY PERIOD;
6. I UNDERSTAND THAT I HAVE SEVEN DAYS AFTER THE EXECUTION OF THIS GENERAL RELEASE TO REVOKE IT AND THAT THIS GENERAL RELEASE SHALL NOT BECOME EFFECTIVE OR ENFORCEABLE UNTIL THE REVOCATION PERIOD HAS EXPIRED;
7. I HAVE SIGNED THIS GENERAL RELEASE KNOWINGLY AND VOLUNTARILY AND WITH THE ADVICE OF ANY COUNSEL RETAINED TO ADVISE ME WITH RESPECT TO IT; AND
8. I AGREE THAT THE PROVISIONS OF THIS GENERAL RELEASE MAY NOT BE AMENDED, WAIVED, CHANGED OR MODIFIED EXCEPT BY AN INSTRUMENT IN WRITING SIGNED BY AN AUTHORIZED REPRESENTATIVE OF THE COMPANY AND BY ME.

DATE: August 31, 2024

SIGNED: /s/ Chris Degnan
Chris Degnan

Exhibit 31.1

CERTIFICATION

I, J. Mel Sorensen, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: December 13, 2024

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

Exhibit 31.2

CERTIFICATION

I, Joel Sussman, 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: December 13, 2024

By: /s/ Joel Sussman
Joel Sussman
Chief Accounting Officer
(principal financial officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Galera Therapeutics, Inc. (the "Company") for the period ended September 30, 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: December 13, 2024

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

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Galera Therapeutics, Inc. (the "Company") for the period ended September 30, 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: December 13, 2024

By: /s/ Joel Sussman
Joel Sussman
Chief Accounting Officer
(principal financial officer)