UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

or

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

For the transition period from to

Commission File Number 001-39114

Galera Therapeutics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**46-1454898**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
P.O. Box 134	
Malvern, Pennsylvania	**19355**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

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, 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15-U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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

At June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $129.8 million. Solely for purposes of this disclosure, shares of common stock held by executive officers, directors and certain stockholders of the registrant as of such date have been excluded because such holders may be deemed to be affiliates.

The number of shares of registrant's Common Stock outstanding as of March 26, 2024 was 54,392,170.

DOCUMENTS INCORPORATED BY REFERENCE

None.

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical facts contained in this Annual Report on Form 10-K 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 Annual Report on Form 10-K, including without limitation statements regarding the impact of our discontinuation of the development of our product candidates; our plans to evaluate strategic alternatives; the sufficiency of our cash, cash equivalents and short-term investments and our ability to raise additional capital to fund our operations; and the plans and objectives of management for future operations and capital expenditures are forward-looking statements.

The forward-looking statements in this Annual Report on Form 10-K 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 Annual Report on Form 10-K and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the sections in this Annual Report on Form 10-K entitled "Summary Risk Factors," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Annual Report on Form 10-K.

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. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. 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. We intend the forward-looking statements contained in this Annual Report on Form 10-K to be covered by the safe harbor provisions for forward-looking statements contained in 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.

SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in Part I, Item 1A. "Risk Factors" in this Annual Report on Form 10-K. You should carefully consider these risks and uncertainties when investing in our common stock. The principal risks and uncertainties affecting our business include the following:

- We are a biopharmaceutical company with a limited operating history and have not generated any revenue from product sales. We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.
- We have currently halted clinical development of our product candidates, and there can be no assurance that we will resume such clinical development in future.
- Any financial or strategic option we pursue may not be successful.
- We are heavily dependent on the success of our lead product candidate, avasopasem manganese (avasopasem) and, because avasopasem has not received regulatory approval and we have halted all commercial preparation efforts, our business has and may continue to be harmed.
- The regulatory approval process is lengthy, expensive and uncertain, and we may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our ability to generate revenue, our business and our results of operations.
- We rely, and will continue to rely, on third parties to conduct our clinical trials for our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.
- If we are unable to establish our own sales, marketing and distribution capabilities, or enter into agreements with third parties to sell and market avasopasem or any other product candidates, we may not be successful in commercializing our product candidates if and when they are approved, and we may not be able to generate any revenue.
- We do not have our own manufacturing capabilities and will rely on third parties to produce additional clinical supplies, if needed, and commercial supplies of avasopasem and our other product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- The incidence and prevalence for target patient populations of our product candidates have not been established with precision. If the market opportunities for our product candidates are smaller than we estimate, or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability may be materially adversely affected.
- The successful commercialization of avasopasem or any other product candidates will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.
- We face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we do.
- Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, cause us to suspend or discontinue clinical trials, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Table of Contents

		Page
PART I		
Item 1.	Business	1
Item 1A.	Risk Factors	14
Item 1B.	Unresolved Staff Comments	42
Item 1C.	Cybersecurity	42
Item 2.	Properties	43
Item 3.	Legal Proceedings	43
Item 4.	Mine Safety Disclosures	44
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	44
Item 6.	[Reserved]	44
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	45
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	55
Item 8.	Financial Statements and Supplementary Data	56
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	80
Item 9A.	Controls and Procedures	80
Item 9B.	Other Information	80
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	81
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	82
Item 11.	Executive Compensation	85
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	91
Item 13.	Certain Relationships and Related Transactions, and Director Independence	93
Item 14.	Principal Accountant Fees and Services	96
PART IV		
Item 15.	Exhibits and Financial Statement Schedules	97
Item 16.	Form 10-K Summary	100

PART I

Item 1. Business.

Overview

We are a biopharmaceutical company that has historically focused on developing a pipeline of novel, proprietary therapeutics that have the potential to transform radiotherapy in cancer. Our lead product candidate, avasopasem manganese (avasopasem), is a highly selective small molecule dismutase mimetic that we have been developing for the reduction of severe oral mucositis (SOM) in patients with head and neck cancer (HNC), the reduction of esophagitis in patients with lung cancer, and the reduction of cisplatin-induced kidney damage in patients with cancer. The U.S. Food and Drug Administration (FDA) has granted Fast Track and Breakthrough Therapy designations to avasopasem for the reduction of SOM induced by radiotherapy. Our second product candidate, rucosopasem manganese (rucosopasem), has been in development to augment the anti-cancer efficacy of stereotactic body radiation therapy (SBRT) in patients with non-small cell lung cancer (NSCLC) and locally advanced pancreatic cancer (LAPC). The FDA and European Medicines Agency (EMA) have granted orphan drug designation and orphan medicinal product designation, respectively, to rucosopasem for the treatment of pancreatic cancer.

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

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

In October 2023, we halted our Phase 2b GRECO-2 trial of rucosopasem in patients with LAPC, following a futility analysis of the trial, which indicated that the trial was unlikely to succeed as designed. At the same time, we also halted our Phase 1/2 GRECO-1 trial of rucosopasem in patients with 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. Such alternatives may include a merger, sale, divestiture of assets, licensing, or other strategic transaction. If we are unable to undertake any strategic alternative, we may be required to cease operations altogether.

Disease Overviews and Our Product Candidates

Reducing Radiotherapy-Induced Toxicities in Patients with Cancer (Radioprotection)

The American Cancer Society estimates approximately two million new cancer cases will be diagnosed in the United States in 2024 and over 50% of patients with cancer will be treated with radiotherapy at some time in their treatment cycle. While radiotherapy has variable success depending on the cancer being treated, the toxicity or side effects associated with its use can limit its effectiveness. Radiotherapy causes acute and late toxicities that affect various organs and functions.

One of the most common radiotherapy-induced toxicities results in a condition referred to as mucositis which occurs when cells lining the gastro-intestinal tract, known as the mucosa, are damaged or killed. The oral mucosa is a common location for mucositis to occur, particularly for patients with HNC receiving radiotherapy.

Another common location for mucositis to occur in patients receiving radiotherapy is the esophagus, referred to as esophagitis.

Oral Mucositis

Oral mucositis (OM) occurs when radiotherapy induces the production of superoxide that attacks and breaks down the epithelial cells lining the mouth. The severity of OM is commonly measured using the WHO scale, which is also used by the FDA as a basis for product approvals. The scale consists of five Grades: Grade 0 through Grade 4. SOM is commonly defined as Grade 3 or Grade 4 OM.

Grade	WHO Scale Description
0	No OM
1	Erythema (redness) and soreness
2	Erythema and ulcers but patients can swallow solid food
3	Ulcers with extensive erythema and patients cannot swallow solid food
4	Oral alimentation (solid or liquid) is not possible

Each year in the United States, approximately 71,000 patients are diagnosed with HNC, according to the American Cancer Society and we estimate that approximately 65% will be treated with standard-of-care radiotherapy. All patients with HNC treated with radiotherapy are at risk for developing SOM. Based on observations from multiple studies, we estimate that approximately 70% will develop SOM and between 20% to 30% will develop Grade 4 OM.

Current Treatment Landscape and Limitations

There are currently no FDA-approved drugs for the treatment of OM in patients with HNC. In 2020, the Multinational Association of Supportive Care in Cancer and International Society of Oral Oncology (MASCC / ISOO), published an update to the leading clinical practice guidelines for the management of OM. These guidelines, which are summarized below, underscore how limited the existing approaches are for the management of OM in patients with HNC, and that these approaches have been largely palliative to date.

- **Basic oral care.** The guidelines suggest the use of basic oral care protocols to prevent OM across all cancer modalities; however, the guidelines indicate the clinical evidence is weak in supporting the effectiveness of this approach.

- **Anti-inflammatory agents.** The guidelines recommend the use of benzydamine mouthwash to prevent OM in patients with HNC receiving radiotherapy doses up to 50 gray without concomitant chemotherapy and suggest the use of benzydamine for patients with HNC receiving radiotherapy with chemotherapy.

- **Antimicrobials, coating agents, anesthetics, and analgesics.** The guidelines suggest the use of 0.2% morphine mouthwash to treat pain associated with OM in patients with HNC.

- **Laser and other light therapy.** The guidelines recommend the use of low-level laser therapy to prevent OM in patients with HNC receiving radiotherapy. However, some evidence suggests that low-level laser therapy may have long-term carcinogenic effects, so MASCC / ISOO advises the clinician to inform patients about the expected benefits and potential risks of this therapy.

- **Cryotherapy.** The guidelines recommend the use of 30 minutes of oral cryotherapy to prevent OM in certain cancer patients, not including those receiving radiotherapy for HNC.

- **Natural and other miscellaneous agents.** The guidelines suggest oral glutamine to prevent OM in patients with HNC receiving radiotherapy. The suggestion is made with caution because of the higher mortality rate seen in patients undergoing hematopoietic stem cell transplantation who

receive parenteral glutamine. The guidelines also suggest the use of honey to prevent OM in patients with HNC receiving radiotherapy, with or without chemotherapy.

These MASCC / ISOO guidelines demonstrate that there is a high unmet need for the treatment or prevention of OM in patients with HNC, driven by the lack of clear efficacy of the existing treatment options.

Avasopasem for Radiotherapy-Induced Severe Oral Mucositis

Avasopasem is a highly selective small molecule dismutase mimetic that we were developing for the reduction of SOM in patients with HNC. We believe avasopasem, which to date is not approved for any indication, has the potential to address shortcomings associated with current approaches and become the standard of care treatment for SOM in patients with locally advanced HNC.

Potential Benefits of Avasopasem for Severe Oral Mucositis

We believe that avasopasem has the following benefits:

- ***Mechanism of action designed to address the root cause of OM:*** Unlike existing treatment options that are largely symptomatic and reactive in nature, we believe avasopasem has the potential to address and mitigate the root cause of OM. Avasopasem is designed to rapidly convert superoxide to hydrogen peroxide, reducing mucosal damage and thereby the incidence and severity of mucositis.

- ***Compelling clinical data from two positive, randomized, double-blinded placebo-controlled trials:*** Results from our ROMAN and GT-201 trials demonstrate the potential benefits of avasopasem across multiple parameters of SOM. Avasopasem has received Fast Track and Breakthrough Therapy Designation from the FDA.

- ***Maintenance of anti-cancer efficacy of radiotherapy:*** Two-year follow-up clinical data from our ROMAN trial and GT-201 trials for avasopasem in patients with locally advanced HNC showed similar rates of tumor control and survival between avasopasem and placebo. We believe this is significant as maintenance of anti-cancer efficacy of radiotherapy is of key importance to physicians when considering new drugs to manage side effects of radiotherapy.

- ***Higher patient adherence:*** The intravenous formulation of avasopasem, administered in a clinical setting by a health care provider, promotes higher patient adherence, optimizing clinical outcomes.

Our market research surveys conducted with radiation and medical oncologists suggest avasopasem has a clinically meaningful product profile based on the safety and efficacy data from our two randomized, double-blinded placebo-controlled trials. Respondents in the various rounds of market research conducted between 2018 and 2022 projected the use of avasopasem in a range of 48% to 69% of their eligible patients, with a majority of physicians suggesting they would adopt avasopasem within the first 12 months of it becoming available.

Reducing Platinum-Induced Nephrotoxicity in Patients with Cancer (Chemoprotection)

While platinum-based chemotherapy is widely used to treat a variety of cancers, the toxicity or side effects associated with its use can limit its dosage and effectiveness. One common cisplatin-induced toxicity results in increased incidence of a condition referred to as chronic kidney disease (CKD) which occurs when cells in the renal tubules are damaged, with such damage progressing into fibrosis over time.

Chronic Kidney Disease

CKD occurs when cisplatin induces the production of superoxide that attacks and breaks down the renal tubule cells in the kidney, and the resulting injury drives a progressive fibrosis compromising kidney function. Over time in its most severe manifestations, CKD may lead to the requirement for renal replacement therapy (dialysis or

transplant) or death. Other platinum-containing therapies may also increase the rate of CKD long-term in patients treated with them.

Avasopasem for Platinum-Induced Chronic Kidney Disease

We believe avasopasem, which to date is not approved for any indication, has the potential to address, and become the standard of care treatment for, cisplatin-induced CKD in patients with locally advanced HNC and other cancers.

Potential Benefits of Avasopasem for Cisplatin-Induced CKD

We believe that avasopasem has the following benefits:

- ***Mechanism of action designed to address the root cause of platinum-induced renal tubule injury and CKD:*** There are no products approved to prevent cisplatin-induced CKD, and we believe avasopasem has the potential to address and mitigate the root cause of cisplatin-induced CKD. Avasopasem is designed to rapidly convert superoxide to hydrogen peroxide, reducing renal tubule damage by cisplatin and thereby the incidence and severity of CKD.

- ***Compelling clinical data from two positive, randomized, double-blinded placebo-controlled trials:*** Prospectively defined assessment of renal function through one-year follow-up in our ROMAN trial showed a marked reduction in the incidence of CKD in the avasopasem arm compared to the placebo arm. Retrospective analysis of our GT-201 trial showed similar results.

- ***Maintenance of anti-cancer efficacy of chemoradiotherapy:*** Our ROMAN and GT-201 trials prescribed concurrent cisplatin chemotherapy along with radiotherapy and two-year follow-up clinical data from both trials of avasopasem in patients with locally advanced HNC showed similar rates of tumor control and survival between avasopasem and placebo. We believe this is significant as maintenance of anti-cancer efficacy of cisplatin therapy is of key importance to physicians when considering new drugs to manage side effects.

Historical Clinical Development of Avasopasem and Rucosopasem

We have suspended our clinical development of and halted our commercial readiness efforts for avasopasem and rucosopasem. Below is a summary of the results of our previous clinical trials of avasopasem and rucosopasem.

ROMAN Trial (Phase 3)

In December 2021, we announced positive topline efficacy results from the ROMAN trial. We had previously announced topline results from the ROMAN trial in October 2021. Upon further analysis following the October topline data announcement, an error by the contract research organization was identified in the statistical programming. Correction of this error yielded the correct, statistically significant p-values for the primary and a key secondary endpoint. The trial was a randomized, double-blinded, multicenter, placebo-controlled trial assessing the effects of avasopasem on the incidence, duration and severity of SOM. 455 patients were enrolled in the trial and randomized 3:2 in favor of the avasopasem 90 mg treatment arm. Like our Phase 1b/2a and GT-201 trials, the eligible population was patients with locally advanced, squamous cell HNC who were eligible for seven weeks of standard-of-care radiotherapy.

The primary endpoint of the ROMAN trial was the reduction in the incidence of SOM through the radiotherapy period for patients being treated with 90 mg of avasopasem as compared to placebo received as a 60-minute intravenous infusion less than 60 minutes before radiation, Monday to Friday, for seven weeks. All patients were assessed twice weekly for OM by trained evaluators during the course of their radiotherapy treatment.

Additional endpoints included, among others, reduction in the number of days of SOM experienced by all patients and reduction in the severity of SOM, as well as the effect of treatment on tumor outcomes measured by overall survival (OS), progression-free survival (PFS), locoregional control (LRC), and distant metastasis-free (DMF), rates. Adverse events were monitored during the trial period. One-year tumor outcomes and two-year survival rates were collected.

In this trial, avasopasem demonstrated efficacy across SOM endpoints with a statistically significant 16% relative reduction on the primary endpoint of reduction in the incidence of SOM (p=0.045) and a statistically significant 56% relative reduction in the number of days of SOM (p=0.002), with a median of 18 days in the placebo arm versus 8 days in the avasopasem arm. The severity of SOM (incidence of Grade 4 OM) was reduced by 27% in the avasopasem arm compared to placebo (p=0.052).

Exploratory analyses, such as time to SOM onset and SOM incidence at various landmarks of radiotherapy delivered, also demonstrated clinical efficacy of avasopasem in reducing the burden of SOM. The median time to onset of SOM for all patients was delayed by 11 days, from 38 days in the placebo arm to 49 days in the avasopasem arm. The incidence of SOM at all radiotherapy landmarks for patients on avasopasem was reduced compared to placebo, with the relative reductions greater than the primary endpoint both earlier during the course of therapy and during the two-week observation period after radiotherapy. The gray (Gy) is the International System of Units unit of absorbed radiation dose.

In another prospectively defined exploratory analysis, after one year of post treatment follow-up, patients treated with avasopasem in combination with IMRT plus cisplatin had a 10% incidence of CKD, compared to 20% of patients in the placebo arm (p=0.0043).

We also followed patients from this trial for tumor outcomes out to one year following radiotherapy and continued to follow patients out to two years for overall survival. In the assessment of tumor outcomes and overall survival, we observed similar outcomes among patients in the avasopasem and placebo arms in OS, PFS, LRC and DMF rates, demonstrating that avasopasem protected HNC patients from SOM without affecting the treatment benefit of standard-of-care chemoradiotherapy.

Avasopasem appeared to be generally well tolerated compared to placebo.

GT-201 Trial (Phase 2b) in Patients with HNC

In December 2017, we announced positive topline data from the GT-201 trial in 223 patients with locally advanced HNC being treated with IMRT and concurrent cisplatin at multiple sites in the United States and Canada. The trial was a randomized, double-blinded, placebo-controlled trial assessing the effects of avasopasem on the median duration, incidence and severity of SOM. Patients received 30 mg of avasopasem, 90 mg of avasopasem or placebo as a 60-minute infusion less than 60 minutes before radiation, Monday to Friday, for seven weeks. All patients were assessed twice weekly for OM by trained evaluators during the course of their radiotherapy treatment. If SOM was present in a patient at the end of the course of his or her radiotherapy treatment, that patient continued to be evaluated weekly for up to eight additional weeks.

The primary endpoints of the trial were reduction in the duration of SOM in the 90 mg and 30 mg treatment arms. Duration was defined as the number of days from when a patient was first assessed with SOM until the first day that patient was assessed with Grade 2 or less OM, with no subsequent occurrences of SOM.

In this trial, the 90 mg treatment arm of avasopasem demonstrated a statistically significant reduction compared to placebo on the primary endpoint (p=0.024). The median duration of SOM in this arm was 1.5 days, a 92% reduction compared to placebo.

Secondary endpoints included reduction in the incidence and severity of SOM in each of the 90 mg and 30 mg treatment arms. For these purposes, we define the severity of SOM as the incidence of Grade 4 OM. The incidence of SOM in the 90 mg treatment arm was reduced by 36% through 60 Gy and 34% through the full course

of radiotherapy treatment compared to placebo and the severity of SOM in the 90 mg treatment arm was reduced by 47% through the full course of radiotherapy treatment compared to placebo.

In the 30 mg treatment arm, intermediate reductions compared to placebo were observed in median duration of SOM (58%), incidence of SOM through 60 Gy (31%) and through the full course of radiotherapy treatment (8%), and in severity of SOM (30%) through the full course of radiotherapy treatment.

In the trial, we also observed an apparent delay in the onset of SOM in the 90 mg treatment arm compared to placebo, reduced usage of opioids in both the 30 mg and 90 mg treatment arms compared to placebo, and reduced placement and use of gastrostomy tubes in the 90 mg treatment arm compared to placebo.

Results of this trial were published in the *Journal of Clinical Oncology* in October 2019.

We followed patients from this trial for tumor outcomes out to two years following radiotherapy. In the two-year assessment of tumor outcomes, we observed similar outcomes among the three arms in OS, PFS, LRC and DMF rates.

Tumor outcome results of this trial were published in the *International Journal of Radiation Oncology/Biology/Physics* in November 2022.

Phase 2a Trial in Patients with HNC in Europe (EUSOM)

In December 2021, we announced topline results from EUSOM, a Phase 2a multi-center trial of avasopasem in Europe evaluating avasopasem in combination with IMRT and concurrent cisplatin in patients with locally advanced HNC. This trial was conducted in twelve centers across six countries in Europe and enrolled 38 patients, of which 33 completed full treatment.

The primary objective of this trial was to assess the safety of avasopasem in combination with IMRT and concurrent cisplatin. Secondary objectives included, among others, the reduction in the incidence of SOM through the radiotherapy period.

Avasopasem appeared to be generally well tolerated. The incidence of SOM was 54.5% and the median number of days of SOM was 9 days for patients who completed treatment in the EUSOM trial, in line with the ROMAN trial, in which the incidence of SOM in the avasopasem arm was 54% and the median number of days of SOM was 8 days.

Phase 1b/2a Trial in Patients with HNC

In August 2016, we completed a Phase 1b/2a, open-label, multi-center, dose escalation trial of the safety, tolerability, pharmacodynamic and pharmacokinetic properties of avasopasem in combination with radiotherapy and concurrent cisplatin in 46 patients with locally advanced HNC. Doses ranged from 15 mg to 112 mg. The objectives of this trial were to evaluate the safety and tolerability of avasopasem in combination with IMRT and cisplatin, to determine a maximum tolerated dose and to assess the potential of avasopasem to reduce the duration, incidence and severity of SOM.

In this trial, patients were assigned to treatment duration groups based upon the dose and duration of dosing of avasopasem received and we observed that the incidence, duration, and severity of SOM through six weeks of radiotherapy (with patients receiving a cumulative radiotherapy dose of 60 Gy) decreased for patients who received six to seven weeks of avasopasem. In the group receiving six to seven weeks of avasopasem, 29% of patients experienced SOM, with a median duration of 2.5 days, and no patients experienced Grade 4 OM. Avasopasem was well tolerated and a maximum tolerated dose was not reached.

Patients in the trial were followed for tumor outcomes at one-year post-radiotherapy. The observed LRC, DMF, PFS, and OS rates in 44 patients evaluable for tumor outcome at one year were 93%, 93%, 84% and

93%, respectively. We believe these outcomes are similar to the outcomes observed in historical control studies, suggesting that avasopasem does not decrease the anti-cancer efficacy of radiotherapy.

Results of this trial were published in the *International Journal of Radiation Oncology/Biology/Physics* in February 2018.

Radiotherapy-Induced Esophagitis

Radiotherapy-induced esophagitis is a common and debilitating adverse effect that develops in patients receiving radiotherapy, most commonly for lung, esophageal, breast or head and neck cancers or for lymphoma. Radiotherapy-induced esophagitis is inflammation, edema, erythema, and erosion of the mucosal surface of the esophagus caused by radiotherapy. Esophagitis can be life-threatening, and symptoms include an inability to swallow, severe pain, ulceration, infection, bleeding and weight loss and may require hospitalization. The severity of esophagitis is graded using the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events, which is a five-point grading scale:

Grade	Description
1	Patients are asymptomatic with only clinical observations
2	Patients are symptomatic with altered eating or swallowing, with oral supplements indicated
3	Patients exhibit severely altered eating or swallowing requiring tube feeding, total parenteral nutrition or hospitalization
4	Patient requires urgent operative intervention; condition is life-threatening
5	Results in death

In lung cancer, there are approximately 235,000 new patients annually in the United States, of which approximately 50,000 are treated with radiotherapy. The overall frequency of Grade 2 or higher esophagitis in patients receiving radiotherapy for the treatment of lung cancer is approximately 50% and approximately 20-30% will experience Grade 3 or higher.

There are currently no FDA-approved drugs and no established guidelines for the treatment of radiotherapy-induced esophagitis. Treatment options are not only ineffective but also largely symptomatic in nature, with medications being administered in conjunction with a focus on adequate hydration and nutrition. These approaches, which include various analgesics such as topical lidocaine and opioids, and tube or intravenous feeding, do not treat the underlying cause of radiotherapy-induced esophagitis.

Avasopasem for Radiotherapy-Induced Esophagitis

Unlike existing treatment options that are largely palliative in nature, we believe avasopasem has the potential to address and mitigate the root cause of radiotherapy-induced esophagitis. By removing superoxide, avasopasem is designed to reduce the damage radiotherapy ordinarily causes to the patient's esophageal mucosa, and thereby reduce the incidence of radiotherapy-induced esophagitis.

Historical Clinical Development of Avasopasem for Esophagitis

Phase 2a Trial in Patients with Lung Cancer (AESOP Trial)

In May 2022, we announced topline results from an open-label, single-arm Phase 2a trial evaluating avasopasem for its potential to reduce the incidence of radiotherapy-induced esophagitis in patients with lung cancer, which we refer to as the AESOP trial. This multi-center trial enrolled 39 patients (62 screened) of which 35 completed treatment with 60 Gy of radiotherapy plus chemotherapy over six weeks. Of these 35 patients, 29 received at least five weeks of 90 mg of avasopasem on the days they underwent radiotherapy. These 29 patients were evaluated as the pre-specified per protocol population. The results demonstrated that avasopasem substantially reduced the incidence of severe esophagitis in patients with lung cancer receiving chemoradiotherapy compared to our expectations based on review of historical data in the literature. Avasopasem was generally well tolerated. The adverse events experienced are comparable to those expected with chemoradiotherapy.

Increasing Anti-Cancer Efficacy of Radiotherapy (Radiosensitization)

As cancer cells are much more sensitive than normal cells to elevated hydrogen peroxide, we believe the conversion of excess superoxide to hydrogen peroxide by our dismutase mimetics has the potential to increase the anti-cancer efficacy of radiotherapy. We were developing rucosopasem with the goal to increase the anti-cancer efficacy of high daily doses of radiotherapy.

Locally Advanced Pancreatic Cancer Overview

Pancreatic cancer is a disease in which solid tumors form in the tissues of the pancreas. The first line of treatment for patients with unresectable tumors is chemotherapy. For those patients whose tumors remain unresectable following chemotherapy, SBRT is an emerging treatment option. Even with SBRT as an option, patients with pancreatic cancer often have a poor prognosis, with a five-year survival rate of only approximately 10%. As a result, there remains a large unmet need to increase the effectiveness of disease management and ultimately improve outcomes for patients.

Non-Small Cell Lung Cancer Overview

According to the NCI, lung cancer is the leading cause of cancer-related mortality in the United States. SBRT is an established radiotherapy treatment for some forms of NSCLC. Even with current treatment options, NSCLC remains the leading cause of cancer deaths in the United States. As such, improving the effectiveness of lung cancer treatment and improving patient outcomes represents a significant unmet need.

Rucosopasem (GC4711) for Increasing Anti-Cancer Efficacy in Patients Receiving SBRT

Rucosopasem is our second product candidate. We were specifically developing rucosopasem, an analog of avasopasem, with the goal of increasing the anti-cancer efficacy of SBRT.

Phase 1 Trials

In December 2017, we completed a Phase 1 single-dose trial of intravenously administered rucosopasem in Australia. In March 2020, we completed a second Phase 1 single-ascending dose and multiple-dose trial of rucosopasem administered by 15-minute intravenous infusions to healthy volunteers in Australia.

In these trials, rucosopasem was observed to be well tolerated. There were no Grade 3, 4, or 5 adverse events, and no adverse events led to withdrawal from these trials.

Historical Clinical Development for Increasing Anti-Cancer Efficacy

Phase 1/2 Pilot Trial of Avasopasem in Patients with LAPC

In September 2021, we announced final results from a pilot Phase 1/2 safety and anti-cancer efficacy trial of avasopasem in combination with SBRT in patients with unresectable or borderline resectable LAPC. The primary objective of this trial was to determine the maximum tolerated daily dose of SBRT in conjunction with our dismutase mimetic, with secondary measures assessing, among others, OS, PFS, resectability and overall response rate compared to placebo. The trial was designed to evaluate three dose levels of SBRT, with each patient receiving five doses of SBRT. SBRT daily dose levels ranged from 10 Gy/dose to 12 Gy/dose.

The results included a minimum follow up of one year on all 42 patients enrolled in the trial. In this proof-of-concept trial, relative improvements were observed in OS, PFS, local tumor control and time to distant metastases. 46% of patients in the active arm were alive at last follow-up (11 out of 24) compared to 33% in the placebo arm (6 out of 18). 29% of patients in the active arm achieved a 30% or greater decrease in primary tumor size (partial response) compared to 11% of patients in the placebo arm. Avasopasem was well tolerated, with similar rates of early and late adverse events in the active and placebo arms. The data from this trial enabled us to select the SBRT regimen for our subsequent trial in this indication, the GRECO-2 trial, of five daily doses at 10 Gy/dose.

Results of this avasopasem trial were published in *The Lancet Oncology* in November 2023.

Phase 1/2 Trial of rucosopasem in Patients with NSCLC (GRECO-1 Trial)

In October 2020, we initiated a Phase 1/2 trial of rucosopasem in combination with SBRT in patients with NSCLC, which we refer to as the GRECO-1 trial.

The trial was designed to enroll approximately five patients with locally advanced NSCLC as part of the Phase 1 open-label safety run-in portion of the trial. Patients received 100 mg of rucosopasem with SBRT over five consecutive weekdays. Following the safety run-in cohort, up to 66 NSCLC patients with locally advanced disease will receive 100 mg of rucosopasem with SBRT or placebo with SBRT over five consecutive weekdays in the randomized, blinded, placebo-controlled Phase 2 portion of trial.

The primary objective of the trial was to assess safety with secondary measures assessing, among others, objective response rate, PFS and OS.

In June 2022, we reported interim results from the Phase 1 open-label stage of the trial with six months follow-up on all seven patients enrolled. Rucosopasem in combination with SBRT appeared to be well tolerated through the cutoff date of June 14, 2022. The most frequent adverse events were fatigue, cough, and nausea, which are common in patients with lung cancer receiving radiotherapy. Through six months, in-field partial responses were observed in three patients and stable disease was observed in three others based on RECIST criteria. These results include target tumor reductions in five patients of 61%, 58%, 33%, 29% and 27% and one patient with an 8% increase as of the cutoff date. Preservation of pulmonary lung function was also observed compared to expectations based on review of historical literature evaluating pulmonary function in a similar patient population with SBRT alone.

In October 2023, we halted the GRECO-1 trial, following the futility analysis of the GRECO-2 trial (discussed below).

Phase 2b Trial of rucosopasem in Patients with LAPC (GRECO-2 Trial)

In May 2021, we initiated a randomized, double-blinded, multicenter, placebo-controlled Phase 2b trial of rucosopasem in combination with SBRT in patients with LAPC, which we refer to as the GRECO-2 trial.

The primary objective of this trial was to determine the impact on OS of adding 100 mg of rucosopasem to SBRT following chemotherapy in patients with unresectable or borderline resectable nonmetastatic pancreatic cancer.

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.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We historically have relied on third party contract manufacturing organizations (CMOs), for the supply of current good manufacturing practice- (cGMP-) grade clinical trial materials and commercial quantities of our product candidates. We have a formal agreement with Patheon Manufacturing Services LLC (Patheon) for commercial production of avasopasem, if approved. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations-Liquidity and Capital Resources-Patheon Manufacturing Agreements” in Part II, Item 7 of this Annual Report on Form 10-K.

Competition

The biotechnology and pharmaceutical industries put significant emphasis and resources into the development of novel and proprietary therapies for cancer treatment. We have historically faced potential

competition from many different sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions.

The key competitive factors affecting the success of avasopasem and rucosopasem, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors. There are currently no FDA-approved drugs for the treatment of OM in patients with HNC and no FDA-approved drugs or established guidelines for the treatment of radiotherapy-induced esophagitis.

Intellectual Property

Our policy has historically been to seek to protect our proprietary position by, among other methods, filing or in-licensing U.S. and foreign patents and patent applications related to our product candidates and other proprietary technologies, inventions and improvements, including claims related to composition of matter and methods of use, that are important to the development and implementation of our business. We have relied on trademarks, trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position. For more information, please see "Risk Factors—Risks Related to Intellectual Property."

Patents and Patent Applications

As of December 31, 2023, our owned and currently pending and/or in-force patent portfolio consisted of approximately 18 issued U.S. patents, 12 pending U.S. patent applications, 112 issued foreign patents including 4 issued European patents that have been validated in many European countries, and 107 pending foreign applications.

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office (USPTO), in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier expiring patent. In some instances, such a patent term adjustment may result in the term of a United States patent extending beyond 20 years from the earliest filing date of a non-provisional patent application. In the United States, the term of a patent that covers a drug product may also be eligible for patent term extension when regulatory approval is granted, provided the legal requirements are met. This permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to a maximum of five years beyond the expiration of the patent if the patent is eligible for such an extension under the Hatch-Waxman Act. The length of the patent term extension is related to the length of time the drug is under regulatory review; however, it cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted. Only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and certain other jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our drug candidates receive approval by the FDA or foreign regulatory authorities, we expect to apply for patent term extensions on issued patents covering those drugs, depending upon the length of the clinical trials for each drug and other factors.

The two most advanced product candidates in our portfolio as of December 31, 2023, avasopasem and rucosopasem, are protected by issued patents with claims directed to composition of matter and method of use. Avasopasem is covered by a composition of matter patent in the United States that had a natural expiration date in March 2022. The U.S. patent family covering the method of treating OM has a natural expiration date in late 2027, and a patent term extension of up to five years may be available, if sought, depending upon the duration of clinical trials and the regulatory review process necessary for approval and subject to the FDA's decision as to the length of any extension. The U.S. patent family covering treating tissue damage resulting from radiation therapy,

chemotherapy or a combination thereof by administering high doses of avasopasem, including that tested in the ROMAN Phase 3 trial, has a natural expiration date in 2032. A patent term extension of up to five years may be available, if sought, depending upon the duration of clinical trials and the regulatory review process necessary for approval and subject to the FDA's decision as to the length of any extension. In any event, we can only extend one applicable patent for each approved drug. Rucosopasem is covered by a composition of matter patent in the United States, which also covers oral bioavailability of the product candidate, and has a natural expiration date in 2036. A patent term extension of up to five years may be available, if sought, depending upon the duration of clinical trials and the regulatory review process necessary for approval and subject to the FDA's decision as to the length of any extension. Additional pending or future patent applications may supplement or extend this patent portfolio.

However, there can be no assurance that any of our pending patent applications will issue or that we will pursue or benefit from any patent term extension or favorable adjustment to the term of any of our patents. The applicable authorities, including the FDA in the United States, may not agree with our assessment of whether such patent term extensions should be granted, and if granted, they may grant more limited extensions than we request. In all cases, the total patent life for the product with the patent extension cannot exceed 14 years from the product's approval date, or in other words, 14 years of potential marketing time. If the patent life of the product after approval has 14 or more years before expiration, the product would not be eligible for patent extension.

We also have pending patent families in the United States that cover certain combinations of our product candidates with several oncology products and therapies that may provide protection for the use of our product candidates in connection with those oncology products and therapies, which, if granted, are projected to expire between 2037 and 2043.

Trademarks and Trade Secrets

As of December 31, 2023, our owned and currently pending and/or in-force trademark portfolio consisted of 3 registered U.S. trademarks, 8 pending U.S. trademark applications, 29 registered foreign trademarks, and 16 pending foreign trademark applications.

Furthermore, we have historically relied upon trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality and invention assignment agreements with our commercial partners, collaborators, employees, and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with an employee or a third party. These agreements may be breached, and we may not have adequate resources to pursue or remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees, and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

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 (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 (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. (the Blackstone Purchaser). The Blackstone Purchaser is affiliated with Blackstone Life Sciences, successor in interest to Clarus Ventures. The Amendment increased the Royalty Purchase Price by $37.5 million to $117.5 million by increasing the fourth tranche from $20.0 million to $37.5 million and

adding a new $20.0 million tranche upon the achievement of an additional clinical enrollment milestone. We received the new $20.0 million tranche of the Amendment in June 2021, in connection with the enrollment of the first patient in the GRECO-2 trial. Also in June 2021, we completed enrollment in the ROMAN trial, thereby achieving the milestone associated with the fourth tranche, and received the associated $37.5 million in July 2021.

Pursuant to the amended Royalty Agreement, in connection with the payment of each tranche of the Royalty Purchase Price, we have agreed to sell, convey, transfer and assign to Blackstone all of our right, title and interest in a high single-digit percentage of (i) worldwide net sales of the Products and (ii) all amounts received by us or our affiliates, licensees and sublicensees with respect to Product-related damages (collectively, the Product Payments) during the Royalty Period. The Royalty Period means, on a Product-by-Product and country-by-country basis, the period of time commencing on the commercial launch of such Product in such country and ending on the latest to occur of (i) the 12th anniversary of such commercial launch, (ii) the expiration of all valid claims of our patents covering such Product in such country, and (iii) the expiration of regulatory data protection or market exclusivity or similar regulatory protection afforded by the health authorities in such country, to the extent such protection or exclusivity effectively prevents generic versions of such Product from entering the market in such country.

The amended Royalty Agreement will remain in effect until the date on which the aggregate amount of the Product Payments paid to Blackstone exceeds a fixed single-digit multiple of the actual amount of the Royalty Purchase Price received by us, unless earlier terminated pursuant to the mutual written agreement of us and Blackstone. If no Products are commercialized, we would not have an obligation to make Product Payments to Blackstone, which is the sole mechanism for repaying the liability.

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

Government Regulation

The FDA and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing and distribution of drugs, such as those we were historically developing. These agencies and other federal, state and local entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, distribution, post-approval monitoring and reporting, sampling and export and import of the product candidates that we were developing.

Data Privacy and Security Laws

Numerous state, federal and foreign laws govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information and could apply to our operations or the operations of our partners. In addition, certain foreign laws, such as the UK General Data Protection Regulation and Data Protection Act 2018 (collectively, the “UK GDPR”), govern the privacy and security of personal data, including health-related data. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Employees

As of March 26, 2024, we had 7 employees. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

Corporate Information

We were incorporated in Delaware in November 2012. Our address is 45 Liberty Blvd., Suite 230, Malvern, Pennsylvania 19355. Our common stock is listed on the Nasdaq Global Market under the symbol “GRTX.”

Available Information

Our internet website address is www.galeratx.com. In addition to the information about us and our subsidiaries contained in this Annual Report on Form 10-K, information about us can be found on our website. Our website and information included in or linked to our website are not part of this Annual Report on Form 10-K.

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission, or SEC. Additionally the SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC's website is www.sec.gov.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below 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 Complete Response Letter 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. Such alternatives may include a merger, sale, divestiture of assets, licensing, or other strategic transaction. If we are unable to undertake any suitable strategic alternative, we may be required to cease operations altogether. 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 must succeed in developing and eventually commercializing product candidates that generate significant revenue. Given that we are not currently pursuing the clinical development of our product candidates and are exploring strategic alternatives, we may never succeed in these activities 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.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek to finance our cash needs through securities offerings or debt financings, or possibly, license and collaboration agreements or research grants. The terms of any financing may adversely affect the holdings or the rights of our stockholders and our issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our common stock to decline. The sale of additional equity or convertible securities would dilute all of our stockholders, including their ownership interest. The incurrence of indebtedness would result in increased fixed or variable payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely

impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies, product candidates or future revenue streams, or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. If we raise funds through research grants, we may be subject to certain requirements, which may limit our ability to use the funds or require us to share information from our research and development. Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our stockholders and may cause the market price of our shares to decline.

Risks Related to the Discovery and Development of Our Product Candidates

We have been heavily dependent on the success of our lead product candidate, avasopasem, and because avasopasem has not received regulatory approval and we have suspended all commercial preparation efforts, our business has and may continue to be harmed.

We currently have no products that are approved for commercial sale and have suspended clinical and commercial preparation efforts, and there can be no assurance that we will resume such efforts in future.

We have not completed the development of any product candidates and we may never be able to develop marketable products. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of products are, and will remain, subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations.

Obtaining approval of a New Drug Application, or NDA, or similar regulatory approval is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or other foreign regulatory authorities may delay, limit or deny approval of any product candidates.

Clinical drug development involves a lengthy and expensive process with uncertain timelines and outcomes, and results of earlier studies and trials may not be predictive of future trial results. If development of our product candidates is unsuccessful, we may be unable to obtain required regulatory approvals and be unable to commercialize our product candidates on a timely basis, if at all.

We have currently suspended clinical development of our product candidates, and there can be no assurance that we will resume such clinical development in future. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure or delay can occur at any time during the clinical trial process. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, even after promising results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. The results of preclinical studies and clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Notwithstanding any potential promising results in earlier studies, we cannot be certain that we will not face similar setbacks. While we have currently halted clinical development, even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates.

Furthermore, we have historically relied on contract research organizations, or CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we have agreements with our CROs governing their committed activities, and the ability to audit their performance, we have limited influence over their actual performance. We have relied on third-party vendors, such as CROs, scientists and collaborators to provide us with significant data and other information related to our preclinical studies or clinical trials and our business. If such third parties provide inaccurate, misleading or incomplete data, our business, prospects and results of operations could be materially adversely affected. For example, in October 2021, we announced topline data from the Phase 3 ROMAN trial of avasopasem in SOM and reported that the trial did not achieve statistical significance on the primary endpoint. Upon further analysis of the ROMAN data, an error by the CRO was identified in the

statistical programming. Correction of this error yielded the correct, statistically significant p-values for the primary and a key secondary endpoint. We announced the correct topline results in December 2021.

Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials.

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Preclinical studies and early-stage clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in preclinical studies and early clinical trials does not ensure that later, large-scale efficacy trials will be successful, nor does it predict final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical studies and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities, such as the EMA or the competent authorities of the member states of the European Union, or EU. Results of clinical trials of our product candidates could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. To date, patients treated with our product candidates have experienced drug-related side effects including lymphopenia, nausea, fatigue, oropharyngeal pain, constipation, radiation skin injury and vomiting.

If unacceptable side effects arise in the development of our product candidates, we, the FDA, the institutional review board, or IRBs, at the institutions in which our studies are conducted, or the Data Safety Monitoring Board, or DSMB, could suspend or terminate clinical trials or the FDA or comparable foreign regulatory authorities could require clinical trials to stop or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff.

In addition, if any of our product candidates receives marketing approval in the future, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend, withdraw or limit their approval of the product, or seek an injunction against its manufacture or distribution;
- the product may be recalled or the way such product is administered to patients may be required to change;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;

- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or similar risk management measures, or create a Medication Guide outlining the risks of such side effects for distribution to patients, or implement other changes to how a product is distributed or administered;

- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;

- we could be sued and held liable for harm caused to patients; and

- the product may become less competitive.

Risks Related to Competition, Retaining Key Employees and Managing Growth

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We have a limited operating history and are highly dependent on the expertise of the principal members of our management team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. In addition, we rely on consultants and advisors. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

As we explore strategic alternatives, and particularly in light of the Workforce Reduction, we may find it difficult to maintain valuable aspects of our culture, to prevent a negative effect on employee morale or attrition beyond our planned reduction in headcount, and to retain competent personnel. If we are not able to continue to retain, on acceptable terms, the qualified personnel necessary for the continued operation of our business, we may not be able to sustain our operations.

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

In August 2023, we implemented the Workforce Reduction. The decision was based on cost-reduction initiatives intended to reduce operating expenses. We incurred a $2.3 million charge in connection with the Workforce Reduction in the third quarter of 2023, primarily consisting of severance payments, employee benefits and related costs. In connection with the Workforce Reduction, we wound down our commercial readiness efforts for avasopasem and reduced headcount across several departments.

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

Risks Related to Intellectual Property

If we are unable to adequately protect our proprietary technology and product candidates, if the scope of the patent protection obtained is not sufficiently broad, or if the terms of our patents are insufficient to protect our product candidates for an adequate amount of time, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our product candidates may be materially impaired.

We rely primarily upon a combination of patents, trademarks, trade secret protection, and other intellectual property rights as well as nondisclosure, confidentiality and other contractual agreements to protect the intellectual property related to our brands, product candidates, including avasopasem and rucosopasem, and other proprietary technologies. Our success depends on our ability to develop, manufacture, market and sell our product candidates, if approved, and use our proprietary technologies without alleged or actual infringement, misappropriation or other violation of the patents and other intellectual property rights of third parties. There have been many lawsuits and other proceedings asserting patents and other intellectual property rights in the pharmaceutical and biotechnology industries. We cannot assure you that our product candidates, including avasopasem and rucosopasem, will not infringe existing or future third-party patents. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be applications now pending of which we are unaware and which may later result in issued patents that we may infringe by commercializing our product candidates, including avasopasem and rucosopasem. There may also be issued patents or pending patent applications that we are aware of, but that we think are irrelevant to our product candidates, including avasopasem and rucosopasem, which may ultimately be found to be infringed by the manufacture, sale, or use of our product candidates, including avasopasem and rucosopasem. Moreover, we may face claims from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect. In addition, many of our product candidates, including avasopasem and rucosopasem, have a complex structure that makes it difficult to conduct a thorough search and review of all potentially relevant third-party patents. Because we have not yet conducted a formal freedom to operate analysis for patents related to our product candidates, we may not be aware of issued patents that a third party might assert are infringed by one of our current or future product candidates, which could materially impair our ability to commercialize our product candidates. Even if we diligently search third-party patents for potential infringement by our products or product candidates, including avasopasem or rucosopasem, we may not successfully find patents that our products or product candidates, including avasopasem or rucosopasem, may infringe. If we are unable to secure and maintain freedom to operate, others could preclude us from commercializing our product candidates.

The process of obtaining patent protection is expensive and time-consuming, and we may not be able to prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may choose not to seek patent protection for certain innovations or products and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope and, in any event, any patent protection we obtain may be limited. As a result, in some jurisdictions some of our products currently or in the future may not be, protected by patents. We generally apply for patents in those countries where we intend to make, have made, use, offer for sale, or sell products and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we may not accurately predict all the countries where patent protection would ultimately be desirable. If we fail to timely file a patent application in any such country or major market, we may be precluded from doing so at a later date. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities. In addition, the actual protection afforded by a patent varies on a product-by-product basis, from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Furthermore, we cannot guarantee that any patents will be issued from any pending or future owned or licensed patent applications, or that any current or future patents will provide us with any meaningful protection or competitive advantage. Even if issued, existing or future patents may be challenged, including with respect to ownership, narrowed, invalidated, held unenforceable or circumvented, any of which could limit our ability to prevent competitors and other third parties from developing and marketing similar products or limit the length of

terms of patent protection we may have for our product candidates, including avasopasem and rucosopasem, and technologies. Moreover, should we be unable to obtain meaningful patent coverage for clinically relevant dosages or infusion rates for avasopasem and rucosopasem in jurisdictions with commercially significant markets, our ability to extend and reinforce patent protection for these product candidates in those jurisdictions may be adversely impacted, which could limit our ability to prevent competitors and other third parties from developing and marketing similar products or limit the length of terms of patent protection we may have for those product candidates. Other companies may also design around technologies we have patented, licensed or developed. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our products or practicing our own patented technology.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights may be uncertain. The standards that the United States Patent and Trademark Office, or the USPTO, and its foreign counterparts use to grant patents are not always applied predictably or uniformly. Changes in either the patent laws, implementing regulations or the interpretation of patent laws may diminish the value of our rights. The legal systems of certain countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. For example, patent laws in various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than United States law does. In addition, many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to "work" the invention in that country, or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patent and other intellectual property protection, which makes it difficult to stop infringement.

Because patent applications in the United States, Europe and many other jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to conceive or reduce to practice the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or pending patent applications. We can give no assurance that all of the potentially relevant art relating to our patents and patent applications has been found; overlooked prior art could be used by a third party to challenge the validity, enforceability and scope of our patents or prevent a patent from issuing from a pending patent application. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the validity, enforceability and scope of our patents in the United States, Europe and in other countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against our competitors.

Third parties may challenge any existing patent or future patent we own or license through adversarial proceedings in the issuing offices or in court proceedings, including as a response to any assertion of our patents against them. In any of these proceedings, a court or agency with jurisdiction may find our patents invalid and/or unenforceable, or even if valid and enforceable, insufficient to provide protection against competing products and services sufficient to achieve our business objectives. We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or reexamination by the USPTO if a third party asserts a substantial question of patentability against any claim of a U.S. patent we own or license. The adoption of the Leahy-Smith America Invents Act, or the Leahy-Smith Act, in September 2011 established additional opportunities for third parties to invalidate U.S. patent claims, including inter partes review and post-grant review proceedings. Outside of the United States, patents we own or license may become subject to patent opposition or similar proceedings, which may result in loss of scope of some claims or the entire patent. In addition, such proceedings are very complex and expensive, and may divert our management's attention from our core business. If any of our patents are challenged, invalidated, circumvented by third parties or otherwise limited or expire prior to the commercialization of our products, and if we do not own or have exclusive rights to other enforceable patents protecting our products or other technologies, competitors and other third parties could market products and use processes that are substantially similar to, or superior to, ours and our business would suffer.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep a competitive advantage. For example:

- others may be able to develop products that are similar to, or better than, ours in a way that is not covered by the claims of our patents;
- we might not have been the first to conceive or reduce to practice the inventions covered by our patents or pending patent applications;
- we might not have been the first to file patent applications for our inventions;
- any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or
- we may not develop additional proprietary technologies that are patentable.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own. We currently in-license certain intellectual property from third parties to be able to use such intellectual property in our products and product candidates and to aid in our research activities. In the future, we may in-license intellectual property from additional licensors. We may rely on certain of these licensors to file and prosecute patent applications and maintain, or assist us in the maintenance of, patents and otherwise protect the intellectual property we license from them. We may have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors have been or will be conducted diligently or in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate, or support our efforts to initiate, an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe, misappropriate or otherwise violate our patents, trademarks, copyrights, trade secrets or other intellectual property, or those of our licensors. To counter infringement, misappropriation, unauthorized use or other violations, we may be required to file legal claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

We may not be able to prevent, alone or with our licensees or any future licensors, infringement, misappropriation or other violations of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party or a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates, including avasopasem and rucosopasem. Such a loss of patent protection could harm our business. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from exploiting the claimed subject matter at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from exploiting its technology on the

grounds that our patents do not cover such technology. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making, using, importing and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement, misappropriation or other intellectual property litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. We may not be able to detect or prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Our commercial success depends significantly on our ability to operate without infringing upon the intellectual property rights of third parties.

The biotechnology and pharmaceutical industries are subject to rapid technological change and substantial litigation regarding patent and other intellectual property rights. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for or obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates, including avasopasem and rucosopasem, and services. Numerous third-party patents exist in the fields relating to our products and services, and it is difficult for industry participants, including us, to identify all third-party patent rights relevant to our product candidates, including avasopasem and rucosopasem, services and technologies. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, because some patent applications are maintained as confidential for a certain period of time, we cannot be certain that third parties have not filed patent applications that cover our product candidates, including avasopasem and rucosopasem, services and technologies. Therefore, it is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies for our product candidates, including avasopasem and rucosopasem, or processes, or to obtain licenses or cease certain activities.

Patents could be issued to third parties that we may ultimately be found to infringe. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing products using our technology. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtain a license under the applicable patents, or until such patents expire or they are determined to be held invalid or unenforceable. Our failure to obtain or maintain a license to any technology that we require to develop or commercialize our current and future product candidates, including avasopasem and rucosopasem, may materially harm our business, financial condition and results of operations. Furthermore, we would be exposed to a threat of litigation.

From time to time, we may be party to, or threatened with, litigation or other proceedings with third parties, including non-practicing entities, who allege that our product candidates, including avasopasem and rucosopasem, components of our product candidates, including avasopasem and rucosopasem, services, and/or

proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. The types of situations in which we may become a party to such litigation or proceedings include:

- we or our collaborators may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our product candidates, including avasopasem and rucosopasem, or processes do not infringe those third parties' patents;
- we or our collaborators may participate at substantial cost in International Trade Commission proceedings to abate importation of third-party products that would compete unfairly with our products;
- if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference, derivation or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position;
- if third parties initiate litigation claiming that our processes or product candidates, including avasopasem and rucosopasem, infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings;
- if third parties initiate litigation or other proceedings, including inter partes reviews, oppositions or other similar agency proceedings, seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their products, services, or technologies do not infringe our patents or patents licensed to us, we will need to defend against such proceedings;
- we may be subject to ownership disputes relating to intellectual property, including disputes arising from conflicting obligations of consultants or others who were involved in developing our product candidates, including avasopasem and rucosopasem; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or product candidates, including avasopasem and rucosopasem, infringe or misappropriate its patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings.

These lawsuits and proceedings, regardless of merit, are time-consuming and expensive to initiate, maintain, defend or settle, and could divert the time and attention of managerial and technical personnel, which could materially adversely affect our business. Any such claim could also force use to do one or more of the following:

- incur substantial monetary liability for infringement or other violations of intellectual property rights, which we may have to pay if a court decides that the product candidate, service, or technology at issue infringes or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay up to treble damages and the third party's attorneys' fees;
- pay substantial damages to our customers or end users to discontinue use or replace infringing technology with non-infringing technology;
- stop manufacturing, offering for sale, selling, using, importing, exporting or licensing the product or technology incorporating the allegedly infringing technology or stop incorporating the allegedly infringing technology into such product, service, or technology;

- obtain from the owner of the infringed intellectual property right a license, which may require us to pay substantial upfront fees or royalties to sell or use the relevant technology and which may not be available on commercially reasonable terms, or at all;
- redesign our product candidates, including avasopasem and rucosopasem, services, and technology so they do not infringe or violate the third party's intellectual property rights, which may not be possible or may require substantial monetary expenditures and time;
- enter into cross-licenses with our competitors, which could weaken our overall intellectual property position;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property against others;
- find alternative suppliers for non-infringing products and technologies, which could be costly and create significant delay; or
- relinquish rights associated with one or more of our patent claims, if our claims are held invalid or otherwise unenforceable.

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us from manufacturing, marketing or otherwise commercializing our products, services and technology. Any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operation, financial condition or cash flows.

In addition, we may indemnify our customers and distributors against claims relating to the infringement of intellectual property rights of third parties related to our product candidates, including avasopasem and rucosopasem. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers or distributors, or may be required to obtain licenses for the product candidates, including avasopasem and rucosopasem, or services they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products or services.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a material adverse effect on the price of our common stock. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. The occurrence of any of these events may have a material adverse effect on our business, results of operation, financial condition or cash flows.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed.

In addition to patent and trademark protection, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Because we expect to rely on third parties to manufacture our product candidates, including avasopasem and rucosopasem, and we may collaborate with third parties on the development of our product candidates, including avasopasem and rucosopasem, we must, at times, share trade secrets with them. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them prior to disclosing our proprietary information, such as our consultants and vendors, or our former or current employees. These

agreements typically limit the rights of third parties to use or disclose our confidential information, including our trade secrets. We also enter into confidentiality and invention assignment agreements with our employees and consultants. Despite these efforts, however, any of these parties may breach the agreements and disclose our trade secrets and other unpatented or unregistered proprietary information, and once disclosed, we are likely to lose trade secret protection. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to enforce trade secret protection. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business, operating results and financial condition. Additionally, we cannot be certain that competitors will not gain access to our trade secrets and other proprietary confidential information or independently develop substantially equivalent information and techniques.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future product candidates, including avasopasem and rucosopasem, and processes.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology and pharmaceutical industries involves both technological and legal complexity, and is therefore costly, time consuming, and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith Act was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switched the United States patent system from a "first-to-invent" system to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had conceived or reduced to practice the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and pending patent applications. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

The United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act, or the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. We have received, and in the future may receive financial assistance in support of research and development activities that could result in inventions. We also partner with a number of universities, including the University of Iowa, Northwestern University, and the University of Texas Southwestern Medical Center, with

respect to certain of our research, development and manufacturing. While it is our policy to avoid engaging our university partners in projects in which there is a risk that federal funds may be commingled, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we own, co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

If we do not obtain patent term extensions in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation with respect to our product candidates, including avasopasem and rucosopasem, thereby potentially extending the term of marketing exclusivity for such product candidates, including avasopasem and rucosopasem, our business may be harmed.

In the United States, a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, including avasopasem and rucosopasem, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, which permits a patent term extension of up to a maximum of five years beyond the normal expiration of the patent if the patent is eligible for such an extension under the Hatch-Waxman Act as compensation for patent term lost during development and the FDA regulatory review process, which is limited to the approved indication (and potentially additional indications approved during the period of extension) covered by the patent. This extension is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request.

We may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such extension, the duration of such extension may be less than our request and the patent term may still expire before or shortly after we receive FDA marketing approval. If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product candidates, including avasopasem and rucosopasem, or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our own, which would have a material adverse effect on our business.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

During trademark registration proceedings, our trademark application(s) may be rejected. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties can oppose pending trademark applications and seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we propose to use with our product candidate(s), including avasopasem and rucosopasem, in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition with potential partners or customers in our markets of interest. In addition, third parties have used trademarks similar and identical to our trademarks in foreign jurisdictions and have filed or may in the future file for registration of such trademarks. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in challenging such third-party rights, we may not be able to use these trademarks to market our products in those countries. In any case, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

We may not be able to adequately protect our intellectual property rights throughout the world.

Certain of our key patent families have been filed in the United States, as well as in numerous jurisdictions outside the United States. However, our intellectual property rights in certain jurisdictions outside the United States may be less robust. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. For example, the requirements for patentability may differ in certain countries, particularly developing countries, and we may be unable to obtain issued patents that contain claims that adequately cover or protect our current or future product candidates, including avasopasem and rucosopasem. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market current or future product candidates, including avasopasem and rucosopasem. Consequently, we may not be able to prevent third parties from practicing our technology in all countries outside the United States, or from selling or importing products made using our technology in and into those other jurisdictions where we do not have intellectual property rights. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our product candidates, including avasopasem and rucosopasem, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain and enforce adequate intellectual property protection for our technology.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market our product candidates, including avasopasem and rucosopasem.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates, including avasopasem and rucosopasem, in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates, including avasopasem and rucosopasem could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates, including avasopasem and rucosopasem, or the use of our products. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates, including avasopasem and rucosopasem. We may incorrectly determine that our product candidates, including avasopasem and rucosopasem, are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates, including avasopasem and rucosopasem, and services. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates, including avasopasem and rucosopasem, and services.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates, including avasopasem and rucosopasem, that are held to be infringing. We might, if possible, also be forced to redesign products, product candidates, including avasopasem and rucosopasem, or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Patent terms may be inadequate to protect our competitive position on our product candidates, including avasopasem and rucosopasem, for an adequate amount of time.

Patents have a limited lifespan, and the protection patents afford is limited. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Even if patents covering our product candidates, including avasopasem and rucosopasem, are obtained, once the patent life has expired for patents covering a product or product candidate, we may be open to competition from competitive products and services. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Intellectual property rights do not necessarily address all potential threats to our business.

While we seek broad coverage under our existing patent applications, there is always a risk that an alteration to products or processes may provide sufficient basis for a competitor to avoid infringing our patent claims. In addition, patents, if granted, expire and we cannot provide any assurance that any potentially issued patents will adequately protect our product candidates, including avasopasem and rucosopasem. Once granted, patents may remain open to invalidity challenges including opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be

compelled to limit the scope of the allowed or granted claims thus attacked or may lose the allowed or granted claims altogether.

In addition, the degree of future protection afforded by our intellectual property rights is uncertain because even granted intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology, but that are not covered by the claims of the patents that we own or control, assuming such patents have issued or do issue;
- we or our licensors or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our product candidates, including avasopasem and rucosopasem, or technologies could use the intellectual property of others without obtaining a proper license;
- parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not develop or in-license additional proprietary technologies that are patentable;
- we may not be able to obtain and maintain necessary licenses on commercially reasonable terms, or at all; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.

We do and may employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our licensors, competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, and we are not currently subject to any claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties, we may in the future be subject to such claims.

Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or product candidates, including avasopasem and rucosopasem. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees and could result in customers seeking other sources for the technology or in ceasing from doing business with us.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while we typically require our employees, consultants and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. To the extent that we fail to obtain such assignments, such assignments do not contain a self-executing assignment of intellectual property rights or such assignment agreements are breached, we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property and this may interfere with our ability to capture the commercial value of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. We may be subject to claims that former collaborators or other third parties have an ownership interest in our patents or other intellectual property. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time-consuming. If we are unsuccessful, we could lose valuable rights in intellectual property that we regard as our own.

Other Risks Related to Our Business

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, including through civil whistleblower or qui tam actions, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes which prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician providers (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, and certified-nurse midwives) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws that require the registration of pharmaceutical sales representatives; and

- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities

will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The global economy, including credit and financial markets, has recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, rising interest and inflation rates, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including, our ability to raise additional capital when needed on acceptable terms, if at all. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws and export and import restrictions;
- employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, such as the conflict between Russia and Ukraine, terrorism, political unrest, outbreak of disease, such as the novel coronavirus, and boycotts;
- curtailment of trade, and other business restrictions;

- certain expenses including, among others, expenses for travel, translation and insurance; and

- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions or its anti-bribery provisions.

Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our business and operations may suffer in the event of information technology system failures, cyberattacks or deficiencies in our cybersecurity.

Despite the implementation of security measures, our information technology systems and those of our third-party CMOs, CROs, contractors and consultants are vulnerable to attack, interruption and damage from computer viruses and malware (e.g. ransomware), malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. There can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and information.

While we do not believe that we have experienced any significant failure or accident of our systems, from time to time, we have been the target of cybersecurity breach attempts and we expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and becoming more prevalent. We do not believe that these cybersecurity breaches have had a material impact on our operations, but future breaches may have such impact. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure or theft of confidential or proprietary information, and we could incur liabilities. Federal, state and international laws and regulations could expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties, fines and significant legal liability, if our information technology security efforts fail. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal data, such as information that we may collect in connection with clinical trials in the U.S. and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to

operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or collectively, HIPAA. HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. While we do not believe we are currently acting or regulated as a covered entity or business associate under HIPAA and thus are not directly regulated under HIPAA, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information.

Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. For example, the California Consumer Privacy Act, or CCPA, went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches has increased the likelihood of, and risks associated with data breach litigation. Further, the CPRA generally went into effect on January 1, 2023 and significantly amends the CCPA. The CPRA imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance and business process changes may be required. Similar laws have passed in Virginia, Connecticut, Utah and Colorado and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. Our activities outside the United States impose additional compliance requirements and generate additional risks of enforcement for noncompliance. In Europe, the General Data Protection Regulation, or GDPR, went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the European Economic Area, or EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease/ change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/ or civil claims (including class actions). Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States; in July 2020, the Court of Justice of the EU, or CJEU, limited how organizations could lawfully transfer personal data from the EU/EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses, or SCCs. In March 2022, the US and EU announced a new regulatory regime intended to replace the invalidated regulations; however, this new EU-US Data Privacy Framework has not been implemented beyond an executive order signed by President Biden on October 7, 2022 on Enhancing Safeguards for United States Signals Intelligence Activities. European court and regulatory decisions subsequent to the CJEU decision of July 16, 2020 have taken a restrictive approach to international data transfers. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be

used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we conduct our business, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Further, from January 1, 2021, companies have had to comply with the GDPR and also the United Kingdom GDPR, or UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability, breaches of data security or reputational damage.

Violations of or liabilities under environmental, health and safety laws and regulations could subject us to fines, penalties or other costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures, the handling, use, storage, treatment and disposal of hazardous materials and wastes and the cleanup of contaminated sites. Our operations involve the use of potentially hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We could incur substantial costs as a result of violations of or liabilities under environmental requirements in connection with our operations or property, including fines, penalties and other sanctions, investigation and cleanup costs and third-party claims. Although we generally contract with third parties for the disposal of hazardous materials and wastes from our operations, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources.

Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of changes to applicable laws and regulations and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Insurance policies are expensive and protect us only from some business risks, which leaves us exposed to uninsured liabilities.

Some of the insurance policies we currently maintain include general liability, employment practices liability, property, workers' compensation, umbrella, and directors' and officers' insurance. These policies may not adequately cover all categories of risk that our business may encounter.

Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could cause our share price to

decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the development and commercialization of any product candidates we develop. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

We also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally.

Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our product candidates or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property or result in public exposure of personal information of our employees, clinical trial patients, customers and others. Furthermore, negative posts or comments about us or our product candidates in social media could seriously damage our reputation, brand image and goodwill. Any of these events could have a material adverse effect on our business, prospects, operating results and financial condition and could adversely affect the price of our common stock.

Our employees and independent contractors, including consultants, vendors, and any third parties we may engage in connection with development and commercialization may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could harm our business.

Misconduct by our employees and independent contractors, including consultants, vendors, and any third parties we may engage in connection with development and commercialization, could include intentional, reckless or negligent conduct or unauthorized activities that violate: (i) the laws and regulations of the FDA and other comparable regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) data privacy, security, fraud and abuse and other healthcare laws and regulations; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and

reporting obligations to resolve allegations of non-compliance, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage, public health emergency, such as the novel coronavirus, or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities on which we rely, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.

In general, under Section 382 of the Code, a corporation that undergoes an "ownership change," generally defined as a greater than 50% change by value in its equity ownership over a three-year period, is subject to limitations on its ability to utilize its pre change net operating losses, or NOLs, to offset future taxable income. Our existing NOLs may be subject to limitations arising from ownership changes that we might have undergone in the past. 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 Code, further limiting our ability to utilize a material portion of the NOLs even if we attain profitability.

We are a multinational company that faces complex taxation regimes in various jurisdictions. Audits, investigations, and tax proceedings could have a material adverse effect on our business, results of operations, and financial condition.

We are subject to income and non-income taxes in multiple jurisdictions. Income tax accounting often involves complex issues, and judgment is required in determining our worldwide provision for income taxes and other tax liabilities. In particular, the jurisdictions in which we operate have detailed transfer pricing rules, which require that all transactions with non-resident related parties be priced using arm's length pricing principles within the meaning of such rules. We could be subject to tax audits involving transfer pricing issues. We believe that our tax positions are reasonable and our tax reserves are adequate to cover any potential liability. However, tax authorities in certain jurisdictions may disagree with our position, including the propriety of our related party arm's length transfer pricing policies and the tax treatment of corresponding expenses and income. If any of these tax authorities were successful in challenging our positions, we may be liable for additional income tax and penalties and interest related thereto in excess of any reserves established therefore, which may have a significant impact on our results and operations and future cash flow.

Risks Related to Our Common Stock

Our common stock may be delisted from The Nasdaq Global Market if we cannot regain compliance with Nasdaq's continued listing requirements, which could harm our business, the trading price of our common stock, our ability to raise additional capital, our ability to undertake a strategic alternative, and the liquidity of the market for our common stock.

Our common stock is currently listed on The Nasdaq Global Market. To maintain the listing of our common stock on The Nasdaq Global Market, we are required to meet certain listing requirements, including related to the price of our common stock. On September 22, 2023, we received two written notices, or the Notices, from The Nasdaq Stock Market LLC, or Nasdaq, indicating that (i) we are no longer in compliance with the minimum Market Value of Listed Securities, or MVLS, of $50.0 million required for continued listing on The Nasdaq Global Market, as set forth in Nasdaq Listing Rule 5450(b)(2)(A), or the MVLS Requirement, and (ii) for the last 30 consecutive business days, the bid price for our common stock, par value $0.001 per share, had closed below the

$1.00 per share minimum bid price requirement for continued inclusion on the Nasdaq Global Market as set forth in Nasdaq Listing Rule 5450(a)(1), or the Minimum Bid Price Requirement. In accordance with Nasdaq Listing Rule 5810(c)(3)(C), we had a period of 180 calendar days, or until March 20, 2024 to regain compliance with the MVLS Requirement and the Minimum Bid Price Requirement, respectively.

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

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

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

Our directors, officers and principal stockholders own a significant percentage of our stock and, if they choose to act together, are able to exercise influence over matters submitted to stockholders for approval.

Our officers, directors and principal stockholders each holding more than 5% of our common stock, collectively, control approximately 33% of our outstanding common stock as of March 15, 2024. Accordingly, these stockholders, if they act together, will be able to exert a significant degree of influence over our management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. The interests of these stockholders may not be the same as or may even conflict with the interests of other stockholders. For example, these stockholders could attempt to delay or prevent a change in control of us, even if such change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of us or our assets, and might affect the prevailing market price of our common stock due to investors' perceptions that conflicts of interest may exist or arise. As a result, this concentration of ownership may not be in the best interests of our other stockholders.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or JOBS Act. We will remain an emerging growth company until the earlier 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 initial public offering, or 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. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404;
- an exemption from compliance with the requirement of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements;
- providing only two years of audited financial statements in addition to any required unaudited interim financial statements and a correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. In particular, we have provided only two years of audited financial statements and have not included all of the executive compensation information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our shares price may be more volatile.

We are a "smaller reporting company" and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are considered a "smaller reporting company." We are therefore entitled to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock prices may be more volatile.

We have incurred and expect to continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we have incurred, and particularly after we are no longer an "emerging growth company," expect to continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance.

Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to

include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we have engaged in a process to document and evaluate our internal control over financial reporting, which has been both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm, as applicable, will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could cause us to need to restate our previously issued financial statements and could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions include those establishing:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and

- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers, other employees or our stockholders to us or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware, our amended and restated certificate of incorporation or our amended and restated bylaws, or (4) any action asserting a claim governed by the internal affairs doctrine. Under our amended and restated certificate of incorporation, this exclusive forum provision will not apply to claims which are vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery of the State of Delaware, or for which the Court of Chancery of the State of Delaware does not have subject matter jurisdiction. For instance, the provision would not apply to actions arising under federal securities laws, including suits brought to enforce any liability or duty created by the Securities Act, the Exchange Act, or the rules and regulations thereunder. In addition, our bylaws provide that the federal district courts of the United States are the exclusive forum for any complaint raising a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our restated certificate of incorporation and bylaws described above.

These exclusive forum provisions may have the effect of discouraging lawsuits against us and our directors, officers and other employees. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation or bylaws to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation or bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. Additionally, the proposal to pay future dividends to stockholders will effectively be at the sole discretion of our board of directors after taking into account various factors our board of directors deems relevant, including our business prospects, capital requirements, financial performance and new product development. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

General Risk Factors

New tax legislation may impact our results of operations and financial condition.

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act (the "Tax Act"), which significantly reformed the U.S. Internal Revenue Code of 1986, as amended, or the Code. Among a number of significant changes to the current U.S. federal income tax rules, the Tax Act reduced the marginal U.S. corporate income tax rate from 35% to 21%, limited the deduction for net interest expense, shifted the United States toward a more territorial tax system, and imposed new taxes to combat erosion of the U.S. federal income tax base. The financial statements contained herein reflect the effects of the Tax Act based on current guidance. However, there remain uncertainties and ambiguities in the application of certain provisions of the Tax Act, and, as a result, we made certain judgments and assumptions in the interpretation thereof. More recently, on August 16, 2022, the United States enacted the Inflation Reduction Act introducing, among other changes, a 15% corporate minimum tax on certain United States corporations and a 1% excise tax on certain stock redemptions by United States corporations. As we further analyze the impact of the Tax Act, the Inflation Reduction Act and any new tax legislation and collect relevant information to complete our computations of the related accounting impact, we may make adjustments to the provisional amounts that could materially affect our results of operations and financial condition.

An active trading market for our common stock may not be sustained.

An active public trading market for our common stock may not be sustained. The lack of an active market may impair stockholders' ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable. The lack of an active market may also reduce the fair value of our shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

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:

- developments in our exploration of strategic alternatives for our business;
- 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.

If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our shares price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. We do not have any control over the analysts or the content and opinions included in their reports. The price of our shares could decline if one or more equity research analysts downgrades our shares or issues other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause the price of our common stock or its trading volume to decline.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in dilution of the percentage ownership of our stockholders and could cause our common stock price to fall.

We will need additional capital in the future to continue our planned operations. To the extent we raise additional capital by issuing additional common stock or other equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information. Our cybersecurity risk management program includes a cybersecurity incident response plan.

We design and assess our program based on guidance from the National Institute of Standards and Technology (NIST) and other industry sources. This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use NIST publications and other sources as guides to help us identify, assess, and manage cybersecurity risks relevant to our business.

Our cybersecurity risk management program is integrated into our overall enterprise risk management program, and shares common methodologies, reporting channels and governance processes that apply across the enterprise risk management program to other legal, compliance, strategic, operational, and financial risk areas.

Our cybersecurity risk management program includes:

- risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise IT environment;
- a security team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls;
- cybersecurity awareness training of our employees, incident response personnel, and senior management;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents; and
- a third-party risk management process for service providers, suppliers, and vendors.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition.

Governance

Our board of directors considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee (Committee) oversight of cybersecurity and other information technology risks. The Committee oversees management's implementation of our cybersecurity risk management program.

The Committee receives regular reports from management on our cybersecurity risks. In addition, management updates the Committee, as necessary, regarding any material cybersecurity incidents, as well as any incidents with lesser impact potential.

The Committee reports to the full Board regarding its activities, including those related to cybersecurity. The full Board also receives briefings from management on our cyber risk management program. Board members receive presentations on cybersecurity topics from our Chief Operating Officer (COO) or external experts as part of the Board's continuing education on topics that impact public companies.

Our management team, including our COO, is responsible for assessing and managing our material risks from cybersecurity threats. The team has primary responsibility for our overall cybersecurity risk management program and supervises our retained external cybersecurity consultants.

Our management team supervises efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from external consultants engaged by us, and alerts and reports produced by security tools deployed in the IT environment.

Item 2. Properties.

Our principal office is located at 45 Liberty Blvd, Suite 230, Malvern, Pennsylvania 19355, where we lease approximately 6,900 square feet of office space under a lease that terminates on September 30, 2030.

Item 3. Legal Proceedings.

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

On May 30, 2023, we filed a lawsuit in the Court of Common Pleas in Chester County, Pennsylvania, or the Court, against Alira Health Clinical, LLC and IQVIA Biotech, LLC, or the CROs, seeking damages and alleging

breach of contract, professional negligence, and negligence related to an error by the defendants in 2021 in their statistical program for the Phase 3 ROMAN trial of avasopasem for the reduction of severe oral mucositis induced by radiotherapy in patients with locally advanced head and neck cancer (the Phase 3 ROMAN trial). In October 2023, the Court granted a joint motion to stay the lawsuit, and in March 2024 the Court granted a joint motion to continue the stay until April 22, 2024.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information and Holders

Our common stock has been publicly traded on the Nasdaq Global Market under the symbol "GRTX" since November 7, 2019. Prior to that time, there was no public market for our common stock.

On March 26, 2024, there were 12 holders of record of our common stock.

Dividends

We have never declared or paid any dividends on our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future.

Purchases of Equity Securities by the Issuer or Affiliated Purchasers

We did not repurchase any of our equity securities during the quarter ended December 31, 2023.

Recent Sales of Unregistered Securities

We did not make any sales of unregistered securities during the year ended December 31, 2023.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included elsewhere in this Form 10-K. Some of the information contained in this discussion and analysis contains forward-looking statements that involve risks and uncertainties. You should review the sections titled "Summary Risk Factors" and Part I, Item 1A. "Risk Factors" in this Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described below. Our results of operations for the year ended December 31, 2021, including a discussion of the year ended December 31, 2022 compared to the year ended December 31, 2021, has been reported previously in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 8, 2023, under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Overview

We are a biopharmaceutical company that has historically focused on developing a pipeline of novel, proprietary therapeutics that have the potential to transform radiotherapy in cancer. Our lead product candidate, avasopasem manganese (avasopasem), is a highly selective small molecule dismutase mimetic that we have been developing for the reduction of severe oral mucositis (SOM) in patients with head and neck cancer (HNC), the reduction of esophagitis in patients with lung cancer, and the reduction of cisplatin-induced kidney damage in patients with cancer. The U.S. Food and Drug Administration (FDA) has granted Fast Track and Breakthrough Therapy designations to avasopasem for the reduction of SOM induced by radiotherapy. Our second product candidate, rucosopasem manganese (rucosopasem), has been in development to augment the anti-cancer efficacy of stereotactic body radiation therapy (SBRT), in patients with non-small cell lung cancer (NSCLC), and locally advanced pancreatic cancer (LAPC). The FDA and European Medicines Agency (EMA) have granted orphan drug designation and orphan medicinal product designation, respectively, to rucosopasem for the treatment of pancreatic cancer.

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

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

In October 2023, we halted our Phase 2b GRECO-2 trial of rucosopasem in patients with LAPC, following a futility analysis of the trial, which indicated that the trial was unlikely to succeed as designed. At the same time, we also halted our Phase 1/2 GRECO-1 trial of rucosopasem in patients with 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. Such alternatives may include a merger, sale, divestiture of assets, licensing, or other strategic transaction. If we are unable to undertake any strategic alternative, we may be required to cease operations altogether.

Since our inception, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, acquiring and developing product and technology rights, and conducting research and development. We have incurred recurring losses and negative cash flows from operations and have funded our operations primarily through the sale and issuance of equity and $117.5 million of proceeds

received under the Royalty Agreement with Blackstone Life Sciences, receiving aggregate gross proceeds of $377.0 million.

Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful resumption of development and eventual commercialization of one or more of our current or future product candidates. Given that we have suspended pursuing the clinical development of our product candidates and are exploring strategic alternatives, we may never succeed in these activities and we expect to continue to incur losses for the foreseeable future. Our net loss was $59.1 million and $62.2 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had $18.3 million in cash and cash equivalents and an accumulated deficit of $437.4 million.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. We expect our existing cash and cash equivalents as of December 31, 2023 will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2025.

Nasdaq Listing Notification

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

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

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

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

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.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies are the most critical to the judgments and estimates used in the preparation of our financial statements.

Royalty Purchase Liability

Pursuant to our amended Royalty Agreement with Blackstone Life Sciences, we have received cash payments totaling $117.5 million from Blackstone based upon the achievement of specified clinical milestones, which have been recorded as long-term debt obligations. Interest expense on such obligation is imputed by estimating risk adjusted future royalty payments over the term of the amended Royalty Agreement which takes into consideration the probability of obtaining FDA approval. Other significant assumptions include adjustments to estimated gross revenues to arrive at net product sales from which a royalty payment can be estimated. The non-cash interest expense recorded increases the balance of our royalty obligation. The royalty obligation will be reduced when royalty payments are made, if any.

Actual royalty payments, however, are highly uncertain and may change depending on a number of factors, including our ability to obtain FDA approval, successfully commercialize our product candidates and the timing of future royalty payments. We impute interest expense on our royalty purchase obligations based on such factors at each reporting period. As these factors change, we will adjust our estimate of the imputed interest expense accordingly.

Given the uncertainty of obtaining future avasopasem revenue based on the FDA stating the need for a second Phase 3 trial for NDA resubmission, our inability to conduct that 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.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the development of our product candidates. We expense research and development costs as incurred.

We accrue an expense for manufacturing, 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 CMOs, CROs and clinical trial sites. We determine the estimates by reviewing contracts, vendor agreements and purchase orders, and through discussions with our internal research and development 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 these activities are highly uncertain, subject to risks and may change depending upon a number of factors, including our clinical development plan.

We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known at that time. If the actual timing of the performance of services

or the level of effort varies from the estimate, we 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.

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.

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 years ended December 31, 2023 and 2022 (in thousands):

	Year ended December 31,	
	2023	2022
Avasopasem manganese	$ 4,281	$ 9,086
Rucosopasem manganese	12,188	9,590
Other research and development expense	2,316	3,294
Personnel related and share-based compensation expense	5,330	9,042
	$ 24,115	$ 31,012

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

If we decide to resume product candidate development, the successful development of any future product candidates would be highly uncertain. We are unable to predict when, if ever, material net cash inflows would commence from sales of any future product candidates that we may develop due to the numerous risks and uncertainties associated with clinical development, including:

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

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

General and Administrative Expense

General and administrative expense consists primarily of personnel expenses, including salaries, benefits and share-based compensation expense for employees in executive, finance, accounting, legal, information technology, commercial, business development and human resource functions. General and administrative expense also includes corporate facility costs, including rent, utilities, depreciation and maintenance, not otherwise included in research and development expense, as well as legal fees related to intellectual property and corporate matters and fees for accounting and consulting services.

The process of continuing to evaluate strategic options may be costly, time-consuming and complex, and we may incur significant costs related to this continued evaluation, such as legal, accounting and advisory fees and expenses and other related charges.

Interest Income

Interest income consists of amounts earned on our cash and cash equivalents held with large institutional banks, U.S. Treasury obligations and a money market mutual fund invested in U.S. Treasury obligations, and our short-term investments in U.S. Treasury and government agency obligations.

Interest Expense

Interest expense consists of non-cash interest on proceeds received under the Royalty Agreement with Blackstone and non-cash interest expense associated with the amortization of the debt discount recorded for the Blackstone warrants.

Foreign Currency Loss

Foreign currency loss consists primarily of exchange rate fluctuations on transactions denominated in a currency other than the U.S. dollar.

Income Tax Benefit

In the year ended December 31, 2022, we recognized an income tax benefit for the revaluation of our deferred tax liability as a result of changes to the anticipated effective tax rate in certain state and local jurisdictions in which we have operations.

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 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 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 net operating loss and research and development tax credit carryforwards, given the current uncertainty over our ability to utilize such amounts.

Results of Operations for the Years Ended December 31, 2023 and 2022

The following table sets forth our results of operations for the years ended December 31, 2023 and 2022 (in thousands):

	Year ended December 31,		
	2023	2022	Change
Operating expenses:			
Research and development	$ 24,115	$ 31,012	$ (6,897)
General and administrative	22,836	20,214	2,622
Restructuring costs	2,309	—	2,309
Loss from operations	(49,260)	(51,226)	1,966
Other income (expense):			
Interest income	1,595	506	1,089
Interest expense	(11,414)	(11,571)	157
Foreign currency loss	(3)	(1)	(2)
Loss before income tax benefit	(59,082)	(62,292)	3,210
Income tax benefit	—	70	(70)
Net loss	$ (59,082)	$ (62,222)	$ 3,140

Research and Development Expense

Research and development expense decreased by $6.9 million from $31.0 million for the year ended December 31, 2022 to $24.1 million for the year ended December 31, 2023. The decrease was primarily attributable to a decrease of $4.8 million for avasopasem development costs, as the EUSOM and AESOP trials were completed in 2022 and the ROMAN trial reached completion in 2023, and decreased manufacturing expenses. Personnel related and share-based compensation expenses decreased $3.7 million due to decreased headcount and reductions in stock compensation expense and the accruals for 2023 annual bonuses. Other research and development expenses decreased $1.0 million due to reductions in regulatory expenses, costs for independent contractors and consultants, and recruiting expenses. Partially offsetting these decreases, rucosopasem development costs increased $2.6 million as enrollment increased in the GRECO-1 and GRECO-2 trials.

General and Administrative Expense

General and administrative expense increased by $2.6 million from $20.2 million for the year ended December 31, 2022 to $22.8 million for the year ended December 31, 2023, principally due to the timing of spend for avasopasem commercial preparations, which increased $5.3 million, and to professional fees, which increased $1.2 million. Partially offsetting these increases, personnel-related and share-based compensation expenses decreased $2.4 million due to decreased headcount and reductions in stock compensation expense and the accruals for 2023 annual bonuses, and insurance premiums decreased $1.5 million.

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 year ended December 31, 2023. No such costs were incurred during the year ended December 31, 2022.

Interest Income

Interest income increased by $1.1 million from $0.5 million for the year ended December 31, 2022 to $1.6 million for the year ended December 31, 2023, due to increased interest rates on invested cash and securities.

Interest Expense

We recognized $11.4 million and $11.6 million in non-cash interest expense during the years ended December 31, 2023 and 2022, respectively, in connection with the Royalty Agreement with Blackstone Life Sciences. Given the uncertainty of obtaining future avasopasem revenue based on the FDA reiterating the need for an additional Phase 3 trial for NDA resubmission, our inability to conduct an additional trial with our current resources, and our focus on exploring strategic alternatives for the development of avasopasem, coupled with our decision in October 2023 to discontinue clinical trials of rucosopasem, we suspended accreting interest on the royalty purchase liability at the end of October 2023.

Liquidity and Capital Resources

We do not currently have any approved products and have never generated any revenue from product sales. Through December 31, 2023, we have funded our operations primarily through the sale and issuance of equity and $117.5 million of proceeds received under the Royalty Agreement with Blackstone Life Sciences, receiving aggregate gross proceeds of $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 (the 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. During the year ended December 31, 2023, we sold an aggregate of 10,463,504 shares of our common stock under the Sales Agreement at a weighted average price per share of $0.20, generating aggregate net proceeds of $1.7 million after deducting fees, commissions and other expenses. The S-3 expired on December 1, 2023, and therefore as of December 31, 2023, no further sales are available under the Sales Agreement.

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

As of December 31, 2023, we had $18.3 million in cash and cash equivalents and an accumulated deficit of $437.4 million. We have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years.

Cash Flows

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

	Year ended December 31,	
	2023	2022
Net cash used in operating activities	$ (44,848)	$ (43,426)
Net cash provided by investing activities	27,293	23,994
Net cash provided by financing activities	31,496	3,889
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 13,941	$ (15,543)

Operating Activities

During the year ended December 31, 2023, we used $44.8 million of net cash in operating activities. Cash used in operating activities reflected our net loss of $59.1 million plus $6.2 million from other changes in operating assets and liabilities, partially offset by non-cash charges of $17.2 million primarily related to share-based compensation, interest expense on our Royalty Agreement with Blackstone Life Sciences and depreciation expense, and $3.2 million from the refund of the PDUFA fee. The primary use of cash was to fund our operations related to the development of our product candidates.

During the year ended December 31, 2022, we used $43.4 million of net cash in operating activities. Cash used in operating activities reflected our net loss of $62.2 million, partially offset by non-cash charges of $18.8 million related to share-based compensation, interest expense on our Royalty Agreement with Blackstone Life Sciences, depreciation and amortization expense and deferred income tax. The primary use of cash was to fund our operations related to the development of our product candidates.

Investing Activities

During the year ended December 31, 2023, investing activities provided $27.3 million, primarily from the net sales of our short-term investments.

During the year ended December 31, 2022, investing activities provided $24.0 million in cash proceeds from net sales of our short-term investments.

Financing Activities

During the year ended December 31, 2023, financing activities provided $31.5 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.

During the year ended December 31, 2022, financing activities provided $3.9 million from the sale of our common stock under the Sales Agreement with Jefferies and the exercise of stock options.

Funding Requirements

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

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

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

- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under any future collaboration agreements, if any;

- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;

- the extent to which we acquire or in-license other product candidates and technologies; and

- the costs of securing manufacturing arrangements for any future commercial production.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, any future product candidates, if approved, may not achieve commercial success.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our assessment of strategic alternatives. If we do not successfully consummate a strategic alternative, our board of directors may decide to pursue a dissolution and liquidation of our company.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Royalty Agreement with Blackstone Life Sciences (Formerly Known as Clarus Ventures)

In November 2018, we entered into the Royalty Agreement with Blackstone Life Sciences. Pursuant to the Royalty Agreement, Blackstone agreed to pay us, in the aggregate, up to $80.0 million (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 (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. (the Blackstone Purchaser). The Blackstone Purchaser is affiliated with Blackstone Life Sciences, successor in interest to Clarus Ventures. The Amendment increased the Royalty Purchase Price by $37.5 million to $117.5 million by increasing the fourth tranche from $20.0 million to $37.5 million and adding a new $20.0 million tranche upon the achievement of an additional clinical enrollment milestone. We received the new $20.0 million tranche of the Amendment in June 2021, in connection with the enrollment of the first patient in the GRECO-2 trial. Also in June 2021, we completed enrollment in the ROMAN trial, thereby achieving the milestone associated with the fourth tranche, and received the associated $37.5 million in July 2021.

Pursuant to the amended Royalty Agreement, in connection with the payment of each tranche of the Royalty Purchase Price, we have agreed to sell, convey, transfer and assign to Blackstone all of our right, title and interest in a high single-digit percentage of (i) worldwide net sales of the Products and (ii) all amounts received by us or our affiliates, licensees and sublicensees with respect to Product-related damages (collectively, the Product Payments) during the Royalty Period. The Royalty Period means, on a Product-by-Product and country-by-country basis, the period of time commencing on the commercial launch of such Product in such country and ending on the latest to occur of (i) the 12th anniversary of such commercial launch, (ii) the expiration of all valid claims of our patents covering such Product in such country, and (iii) the expiration of regulatory data protection or market exclusivity or similar regulatory protection afforded by the health authorities in such country, to the extent such protection or exclusivity effectively prevents generic versions of such Product from entering the market in such country.

The amended Royalty Agreement will remain in effect until the date on which the aggregate amount of the Product Payments paid to Blackstone exceeds a fixed single-digit multiple of the actual amount of the Royalty Purchase Price received by us, unless earlier terminated pursuant to the mutual written agreement of us and Blackstone. If no Products are commercialized, we would not have an obligation to make Product Payments to Blackstone, which is the sole mechanism for repaying the liability.

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

Patheon Manufacturing Agreements

In August 2021, we entered into a Master Manufacturing Services Agreement with Patheon (the Master Agreement). The Master Agreement governs the general terms under which Patheon, or one of its affiliates, will provide non-exclusive manufacturing services to us for the drug products specified by us from time to time. Pursuant to the Master Agreement, we have agreed to order from Patheon at least a certain percentage of our commercial requirements for a product under a related product agreement. Each product agreement that we may enter into from time to time will be governed by the terms of the Master Agreement, unless expressly modified in such product agreement.

In August 2021, we and Patheon entered into a product agreement for avasopasem (the Product Agreement), under the Master Agreement to govern the terms and conditions of Patheon's manufacture and commercial supply to us of avasopasem manganese from Patheon's Greenville, North Carolina manufacturing site.

The Master Agreement, and any related product agreement, has an initial term that expires on December 31, 2027 and includes renewal terms, as applicable. In addition, each party has the ability to terminate the Product Agreement upon the occurrence of certain customary conditions. The Master Agreement contains representations, warranties and indemnity obligations customary for agreements of this type, and the Product Agreement establishes certain pricing for avasopasem that may be adjusted as set forth in the Master Agreement.

Our obligation to purchase avasopasem under the Product Agreement is subject to certain binding forecast periods at certain established prices, which will be reviewed each year on January 1 by us and Patheon. We currently do not have any contractual commitment to purchase avasopasem under the Product Agreement.

Item 7A. 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 7A.

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm	57
Consolidated Balance Sheets as of December 31, 2023 and 2022	58
Consolidated Statements of Operations for the Years ended December 31, 2023 and 2022	59
Consolidated Statements of Comprehensive Loss for the Years ended December 31, 2023 and 2022	60
Consolidated Statements of Changes in Stockholders' Deficit for the Years ended December 31, 2023 and 2022	61
Consolidated Statements of Cash Flows for the Years ended December 31, 2023 and 2022	62
Notes to Consolidated Financial Statements	63

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Galera Therapeutics, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Galera Therapeutics, Inc. and subsidiaries (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, changes in stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2014.

Philadelphia, Pennsylvania
March 28, 2024

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

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 18,257	$ 4,266
Short-term investments	—	27,331
Restricted cash	—	50
Refundable PDUFA fee	—	3,242
Prepaid expenses and other current assets	3,372	3,646
Total current assets	21,629	38,535
Property and equipment, net	71	438
Acquired intangible asset	2,258	2,258
Goodwill	881	881
Right-of-use lease assets	1,212	43
Other assets	90	1,881
Total assets	$ 26,141	$ 44,036
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 1,375	$ 3,581
Accrued expenses	3,449	9,754
Lease liabilities	133	44
Total current liabilities	4,957	13,379
Royalty purchase liability	151,049	139,635
Lease liabilities, net of current portion	1,117	—
Deferred tax liability	203	203
Total liabilities	157,326	153,217
Commitments (Note 9)		
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 and 28,510,066 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	54	28
Additional paid-in capital	306,167	269,137
Accumulated other comprehensive loss	—	(22)
Accumulated deficit	(437,406)	(378,324)
Total stockholders' deficit	(131,185)	(109,181)
Total liabilities and stockholders' deficit	$ 26,141	$ 44,036

See accompanying notes to consolidated financial statements.

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

	Year ended December 31,	
	2023	2022
Operating expenses:		
Research and development	$ 24,115	$ 31,012
General and administrative	22,836	20,214
Restructuring costs	2,309	—
Loss from operations	(49,260)	(51,226)
Other income (expenses):		
Interest income	1,595	506
Interest expense	(11,414)	(11,571)
Foreign currency loss	(3)	(1)
Loss before income tax benefit	(59,082)	(62,292)
Income tax benefit	—	70
Net loss	(59,082)	(62,222)
Net loss per share of common stock, basic and diluted	$ (1.33)	$ (2.30)
Weighted-average shares of common stock outstanding, basic and diluted	44,549,285	27,086,664

See accompanying notes to consolidated financial statements.

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

	Year ended December 31,	
	2023	2022
Net loss	$ (59,082)	$ (62,222)
Unrealized gain (loss) on short-term investments	22	(8)
Comprehensive loss	$ (59,060)	$ (62,230)

See accompanying notes to consolidated financial statements.

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

	Common stock		Additional paid-in capital	Accumulated other comprehensive gain (loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount				
Balance at December 31, 2021	26,458,767	$ 26	$ 258,086	$ (14)	$ (316,102)	$ (58,004)
Share-based compensation expense	—	—	7,164	—	—	7,164
Exercise of stock options	68,526	—	81	—	—	81
Sale of shares under Open Market Sale Agreement, net	1,982,773	2	3,806	—	—	3,808
Unrealized loss on short-term investments	—	—	—	(8)	—	(8)
Net loss	—	—	—	—	(62,222)	(62,222)
Balance at December 31, 2022	28,510,066	28	269,137	(22)	(378,324)	(109,181)
Share-based compensation expense	—	—	5,560	—	—	5,560
Exercise of stock options	78,600	1	187	—	—	188
Exercise of common stock warrants	1,020,000	1	2,008	—	—	2,009
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
Sale of shares under Open Market Sale Agreement, net	10,463,504	10	1,691	—	—	1,701
Unrealized gain on short-term investments	—	—	—	22	—	22
Net loss	—	—	—	—	(59,082)	(59,082)
Balance at December 31, 2023	54,392,170	$ 54	$ 306,167	$ —	$ (437,406)	$ (131,185)

See accompanying notes to consolidated financial statements.

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

	Year ended December 31,	
	2023	**2022**
Operating activities:		
Net loss	$ (59,082)	$ (62,222)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	259	114
Noncash interest expense	11,414	11,571
Share-based compensation expense	5,560	7,164
Gain on disposal of property and equipment	(72)	—
Deferred tax liability	—	(70)
Changes in operating assets and liabilities:		
Refundable PDUFA fee	3,242	(3,242)
Prepaid expenses and other current assets	514	2,529
Other assets	1,932	330
Accounts payable	(2,206)	(1,463)
Accrued expenses	(6,305)	2,121
Other liabilities	(104)	(258)
Cash used in operating activities	(44,848)	(43,426)
Investing activities:		
Purchases of short-term investments	(22,643)	(59,891)
Proceeds from sales of short-term investments	49,995	83,910
Purchase of property and equipment	(59)	(25)
Cash provided by investing activities	27,293	23,994
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	1,701	3,808
Proceeds from the exercise of common stock warrants	2,009	—
Proceeds from exercise of stock options	188	81
Cash provided by financing activities	31,496	3,889
Net increase (decrease) in cash, cash equivalents and restricted cash	13,941	(15,543)
Cash, cash equivalents and restricted cash at beginning of year	4,316	19,859
Cash, cash equivalents and restricted cash at end of year	$ 18,257	$ 4,316
Supplemental schedule of non-cash investing and financing activities:		
Right-of-use asset obtained in exchange for lease obligation	$ 1,310	$ —
Sale of property and equipment in exchange for prepaid future services	$ 240	$ —

See accompanying notes to consolidated financial statements.

GALERA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and description of business

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

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

In connection with the CRL, the Company wound down its commercial readiness efforts for avasopasem, reduced headcount across several departments and began to pursue strategic alternatives. The reduction in force, which was approved by the Company's board of directors, reduced the Company's workforce by 22 employees, or approximately 70%, as of August 9, 2023 (the Workforce Reduction). The decision was based on cost-reduction initiatives intended to reduce operating expenses.

In October 2023, the Company halted its Phase 2b GRECO-2 trial of rucosopasem in patients with LAPC, following a futility analysis of the trial, which indicated that the trial was unlikely to succeed as designed. At the same time, the Company also halted its Phase 1/2 GRECO-1 trial of rucosopasem in patients with 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. Such alternatives may include a merger, sale, divestiture of assets, licensing, or other strategic transaction. If the Company is unable to undertake any strategic alternative, it may be required to cease operations altogether.

Liquidity

The Company has incurred recurring losses and negative cash flows from operations since inception and has an accumulated deficit of $437.4 million as of December 31, 2023. The Company expects its existing cash and cash equivalents as of December 31, 2023 will enable the Company to fund its operating expenses and capital expenditure requirements into the second quarter of 2025.

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

In December 2020, the Company filed an S-3 registration statement with the Securities and Exchange Commission (SEC) which covered the offering, issuance and sale of up to $200.0 million in Company securities, which included an Open Market Sale Agreement with Jefferies LLC (the Sales Agreement) covering the offering, issuance and sale of up to a maximum aggregate offering price of $50.0 million of the Company's common stock,

which could be utilized to raise funding for future operating expenses and capital expenditure requirements. During the year ended December 31, 2023, the Company sold approximately 10.5 million shares of common stock and received net proceeds of $1.7 million pursuant to the Sales Agreement. The S-3 expired on December 1, 2023, and therefore no further sales are available under the Sales Agreement.

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

2. Basis of presentation and significant accounting policies

Basis of presentation and consolidation

The accompanying consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles (U.S. GAAP). 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).

The consolidated financial statements include the accounts of Galera Therapeutics, Inc. and its wholly owned subsidiaries, Galera Therapeutics Australia Pty Ltd (Galera Australia) and Galera Labs, LLC. All intercompany accounts and transactions have been eliminated in consolidation.

The Company has determined the functional currency of Galera Australia to be the U.S. dollar. The Company records remeasurement gains and losses on monetary assets and liabilities, such as accounts payable, which are not denominated in U.S. dollars in the statements of operations.

The Company manages its operations as a single reportable segment for the purposes of assessing performance and making operating decisions.

Use of estimates

The preparation of 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 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 consolidated financial statements in the period they are determined to be necessary. Significant areas that require management's estimates include the share-based compensation assumptions, royalty purchase liability assumptions and accrued research and development expenses.

Fair value of financial instruments

Management believes that the carrying amounts of the Company's financial instruments, including accounts payable and accrued expenses, approximate fair value due to the short-term nature of those instruments. Short-term investments are recorded at their estimated fair value. The royalty purchase liability is accounted for as debt and interest is accreted over the expected repayment period. Based on the outcome from the Company's discussions with the FDA reiterating the need for an additional Phase 3 trial to support resubmission of the avasopasem NDA, the Company is exploring potential strategic alternatives for the development of avasopasem as it is not feasible to conduct an additional clinical trial with the Company's current resources. Due to the uncertainty of

obtaining regulatory approval and successful commercialization of avasopasem, it is impractical to determine the fair value of the debt.

Concentration of credit risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents and short-term investments. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash and cash equivalents. The Company had no short-term investments as of December 31, 2023.

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 December 31, 2023 and 2022 consisted of bank deposits, U.S. Treasury obligations and a money market mutual fund invested in U.S. Treasury obligations.

Restricted cash

Restricted cash represented collateral provided under a commercial credit card agreement entered into with TD Bank, N.A. during July 2022. Restricted cash was $50,000 as of December 31, 2022. The Company has recorded this deposit and accumulated interest thereon as restricted cash on its consolidated balance sheet. In October 2023, the commercial credit card agreement was terminated by the Company and the bank removed the restriction on the cash.

Refundable PDUFA fee

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

Short-term investments

Short-term investments consisted of debt securities with a maturity of greater than three months when acquired. The Company classified its short-term investments at the time of purchase as available-for-sale securities. Short-term investments were $27.3 million, net of unrealized losses of $8,000, as of December 31, 2022. Available-for-sale securities are carried at fair value. Unrealized gains and losses on available-for-sale securities are reported in accumulated other comprehensive income (loss), a component of stockholders' equity (deficit), until realized. The Company had no short-term investments as of December 31, 2023.

Property and equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over their estimated useful lives ranging from three to five years. Leasehold improvements are amortized over the shorter of their economic lives or the remaining lease term. The costs of maintenance and repairs are expensed as incurred. Improvements and betterments that add new functionality or extend the useful life of the asset are capitalized.

Impairment of long-lived assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated undiscounted future cash flows,

then an impairment charge is recognized for the amount by which the carrying value of the asset exceeds the estimated fair value of the asset. As of December 31, 2023, the Company believes that no revision of the remaining useful lives or write-down of long-lived assets is required.

Goodwill and acquired intangible asset

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

Intangible assets related to IPR&D are considered indefinite-lived intangible assets and, along with goodwill, are not amortized, but are assessed for impairment annually or more frequently if impairment indicators exist. For those compounds that reach commercialization, the IPR&D assets will be amortized over their estimated useful lives. If the associated research and development effort related to IPR&D is abandoned, the related assets will be written-off and the Company will record a noncash impairment loss on its consolidated statements of operations. For the years ended December 31, 2023 and 2022, the Company determined that there was no impairment to goodwill or IPR&D.

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

Royalty purchase liability

In November 2018, the Company entered into an Amended and Restated Purchase and Sale Agreement (the Royalty Agreement), with Clarus IV Galera Royalty AIV, L.P., Clarus IV-A, L.P., Clarus IV-B, L.P., Clarus IV-C, L.P. and Clarus IV-D, L.P. (collectively, Blackstone or Blackstone Life Sciences). Pursuant to the Royalty Agreement, Blackstone agreed to pay up to $80.0 million (the Royalty Purchase Price) in four tranches of $20.0 million each upon the achievement of specific Phase 3 clinical trial patient enrollment milestones. The Company received the first tranche of the Royalty Purchase Price in November 2018, the second tranche of the Royalty Purchase Price in April 2019, and the third tranche of the Royalty Purchase Price in February 2020, in each case in connection with the achievement of the first three milestones, respectively. The proceeds received have been recorded as long-term debt obligations. Interest expense on such obligation is imputed by estimating risk adjusted future royalty payments over the term of the Royalty Agreement which takes into consideration the probability of obtaining FDA approval. Other significant assumptions include adjustments to estimated gross revenues to arrive at net product sales from which a royalty payment can be estimated. The non-cash interest expense recorded increases the balance of the royalty obligation. The royalty obligation will be reduced when royalty payments are made, if any.

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, which was received in July 2021, and adding a new $20.0 million tranche upon the achievement of an additional clinical enrollment milestone, which was received in June 2021. 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.

Actual royalty payments are highly uncertain and may change depending on a number of factors, including the Company's ability to obtain FDA approval, successfully commercialize the Company's product candidates and the timing of future royalty payments. The Company imputes interest expense on the royalty purchase obligations based on such factors at each reporting period. As these factors change, the Company will adjust its estimate of the imputed interest expense accordingly.

Given the uncertainty of obtaining future avasopasem revenue based on the FDA reiterating the need for an additional Phase 3 trial for NDA resubmission, the Company's inability to conduct an additional trial with its current resources, and its focus on exploring strategic alternatives for the development of avasopasem, coupled with the Company's decision in October 2023 to discontinue its clinical trials of rucosopasem, the Company suspended accreting interest on the royalty purchase liability and amortizing the fees paid to the Blackstone Purchaser related to the Amendment at the end of October 2023.

Leases

At lease commencement, the Company records a lease liability based on the present value of lease payments over the expected lease term including any options to extend the lease that the Company is reasonably certain to exercise. The Company calculates the present value of lease payments using an incremental borrowing rate as the Company's leases do not provide an implicit interest rate. The Company's incremental borrowing rate for a lease is the rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms. At the lease commencement date, the Company records a corresponding right-of-use lease asset based on the lease liability, adjusted for any lease incentives received and any initial direct costs paid to the lessor prior to the lease commencement date. The Company may enter into leases with an initial term of 12 months or less (short-term leases). For short-term leases, the Company records the rent expense on a straight-line basis and does not record the leases on the balance sheet. The Company had no short-term leases as of December 31, 2023 and 2022.

After lease commencement, the Company measures its leases as follows: (i) the lease liability based on the present value of the remaining lease payments using the discount rate determined at lease commencement, and (ii) the right-of-use lease asset based on the remeasured lease liability, adjusted for any unamortized lease incentives received, any unamortized initial direct costs and the cumulative difference between rent expense and amounts paid under the lease agreement. Any lease incentives received and any initial direct costs are amortized on a straight-line basis over the expected lease term. Rent expense is recorded on a straight-line basis over the expected lease term.

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.

Share-based compensation

The Company measures share-based awards at their grant-date fair value and records compensation expense on a straight-line basis over the vesting period of the awards.

Estimating the fair value of share-based awards requires the input of subjective assumptions, including the expected life of the options and stock price volatility. The Company accounts for forfeitures of stock option awards as they occur. The Company uses the Black-Scholes option pricing model to value its stock option awards. The assumptions used in estimating the fair value of share-based awards represent management's estimate and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and management uses different assumptions, share-based compensation expense could be materially different for future awards.

The expected life of the stock options is estimated using the "simplified method," as the Company has limited historical information from which to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock option grants. The simplified method is the midpoint between the vesting period and the contractual term of the option. For stock price volatility, the Company uses comparable public companies as a basis for its expected volatility to calculate the fair value of option grants. The risk-free rate is based on the U.S. Treasury yield curve commensurate with the expected life of the option.

Employee Benefit Plan

The Company sponsors a 401(k) defined contribution plan for its employees. Employee contributions are voluntary. The Company matches employee contributions in an amount equal to 100% of the first 4% of eligible compensation, and such employer contributions are immediately vested. During each of the years ended December 31, 2023 and 2022, the Company provided matching contributions of $0.3 million.

Income taxes

The Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss and credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The Company recognizes the benefit of an uncertain tax position that it has taken or expects to take on its income tax return if such a position is more likely than not to be sustained.

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:

	December 31,	
	2023	2022
Stock options	5,739,488	5,783,185
Common stock warrants	13,850,661	550,661
	19,590,149	6,333,846

Recent Accounting Pronouncements

In August 2020, FASB issued ASU 2020-06, "Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity," which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, and it also simplifies the diluted earnings per share calculation in certain areas. This guidance is effective for fiscal years beginning after December 15, 2023, including interim periods therein. Early adoption is permitted. The Company adopted this ASU on January 1, 2023. There was no impact to the Company's consolidated financial statements.

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.

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):

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

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

There were no changes in valuation techniques during the years ended December 31, 2023 and 2022. The Company's short-term investment instruments classified using Level 1 inputs within the fair value hierarchy are classified as such because they are valued using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. The fair value of Level 2 securities is estimated based on observable inputs other than quoted prices in active markets for identical assets and liabilities, quoted prices for identical or similar assets or liabilities in inactive markets, or other inputs that are observable or can be corroborated by observable market data for substantially the full term on the assets or liabilities.

4. Prepaid expenses and other current assets

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

	December 31, 2023	December 31, 2022
Prepaid clinical expenses	$ 1,450	$ 1,359
Prepaid insurance	1,302	1,396
Other prepaid expenses and other current assets	620	891
	$ 3,372	$ 3,646

5. Property and equipment

Property and equipment consist of (amounts in thousands):

	December 31, 2023	December 31, 2022
Laboratory equipment	$ —	$ 1,398
Computer hardware and software	305	292
Leasehold improvements	46	270
Furniture and fixtures	179	179
Property and equipment, gross	530	2,139
Less: Accumulated depreciation and amortization	(459)	(1,701)
Property and equipment, net	$ 71	$ 438

Depreciation and amortization expense was $0.3 million and $0.1 million for the years ended December 31, 2023 and 2022, respectively.

In 2023, the Company wrote off $0.3 million of leasehold improvements related to the previous office space for which the lease expired in February 2023. In addition, the Company wrote off $1.4 million of laboratory equipment that was either sold, exchanged in a barter transaction for future services, or otherwise disposed of in 2023.

6. Accrued expenses

Accrued expenses consist of (amounts in thousands):

	December 31, 2023	December 31, 2022
Compensation and related benefits	$ 121	$ 2,655
Restructuring costs	443	—
Research and development expenses	2,672	6,764
Professional fees and other expenses	213	335
	$ 3,449	$ 9,754

7. Royalty purchase liability

Pursuant to the Royalty Agreement, Blackstone agreed to pay up to $80.0 million (the Royalty Purchase Price) in four tranches of $20.0 million each upon the achievement of specific Phase 3 clinical trial patient enrollment milestones. The Company received the first tranche of the Royalty Purchase Price in November 2018, the second tranche of the Royalty Purchase Price in April 2019, and the third tranche of the Royalty Purchase Price in February 2020, in each case in connection with the achievement of the first three milestones, respectively.

In May 2020, the Company entered into Amendment No. 1 to the Royalty Agreement (the Amendment) with Clarus IV Galera Royalty AIV, L.P. (the Blackstone Purchaser). The Blackstone Purchaser is affiliated with Blackstone Life Sciences, the successor in interest to Clarus Ventures. The Amendment increased the Royalty Purchase Price by $37.5 million, to $117.5 million by increasing the fourth tranche from $20.0 million to $37.5 million and adding a new $20.0 million tranche upon the achievement of an additional clinical enrollment milestone. The Company accounted for the Amendment as a debt modification and is amortizing fees paid to the Blackstone Purchaser related to the Amendment over the estimated term of the royalty purchase liability utilizing the effective-interest method. In June 2021, the Company received the new tranche ($20.0 million) 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 its 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 December 31, 2023 have been recorded as a liability on the accompanying consolidated balance sheets. Interest expense is imputed based on the estimated royalty repayment period described below, which takes into consideration the probability and timing of obtaining FDA approval and the potential future revenue from commercializing its product candidates, and which results in a corresponding increase in the liability balance. The Company updated the assumptions underlying the calculation of interest expense on the royalty purchase liability based on the CRL received from the FDA in August 2023 on the Company's NDA for avasopasem for radiotherapy-induced SOM. The Company recognized $11.4 million and $11.6 million in noncash interest expense during the years ended December 31, 2023 and 2022, respectively. 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.

Pursuant to the Royalty Agreement and the Amendment, in connection with the payment of each tranche of the Royalty Purchase Price, the Company has agreed to sell, convey, transfer and assign to Blackstone all of its right, title and interest in a high single-digit percentage of (i) worldwide net sales of avasopasem and rucosopasem (collectively, the Products) and (ii) all amounts received by the Company or its affiliates, licensees and sublicensees with respect to Product-related damages (collectively, the Product Payments) during the Royalty Period. The Royalty Period means, on a Product-by-Product and country-by-country basis, the period of time commencing on the commercial launch of such Product in such country and ending on the latest to occur of (i) the 12th anniversary of such commercial launch, (ii) the expiration of all valid claims of the Company's patents covering such Product in such country, and (iii) the expiration of regulatory data protection or market exclusivity or similar regulatory protection afforded by the health authorities in such country, to the extent such protection or exclusivity effectively prevents generic versions of such Product from entering the market in such country.

The Royalty Agreement and the Amendment will remain in effect until the date on which the aggregate amount of the Product Payments paid to Blackstone exceeds a fixed single-digit multiple of the actual amount of the Royalty Purchase Price received by the Company, unless earlier terminated pursuant to the mutual written agreement of the Company and Blackstone. If no Products are commercialized, the Company would not have an obligation to make Product Payments to Blackstone, which is the sole mechanism for repaying the liability.

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

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

The warrants are equity-classified and were valued at $4.7 million at the time of issuance using the Black-Scholes option pricing model. The warrants were recorded as a discount to the royalty purchase liability. The Company amortizes the debt discount to interest expense over the estimated term of the royalty purchase liability utilizing the effective-interest method. The Company suspended amortizing the debt discount to interest expense after October 2023, as the result of the uncertainty of any future royalties following its decision to discontinue the rucosopasem GRECO trials and that it is not feasible with its current resources for the Company to conduct another Phase 3 trial of avasopasem.

8. Leases

The Company has a non-cancelable operating lease for office and laboratory space in Malvern, Pennsylvania which, as of December 31, 2023, has a remaining lease term of approximately 6.8 years. The discount rate used to account for the Company's operating lease is the Company's estimated incremental borrowing rate of 5.4%.

Supplemental balance sheet information related to leases was as follows:

	December 31, 2023	December 31, 2022
Operating Leases		
Right-of-use lease assets	$ 1,212	$ 43
Lease liabilities, current	133	44
Lease liabilities, net of current portion	1,117	—
Total operating lease liabilities	$ 1,250	$ 44

The components of lease expense were as follows:

	Year ended December 31,	
	2023	2022
Operating lease costs		
Operating lease rental expense	$ 191	$ 267
Total operating lease expense	$ 191	$ 267

Supplemental cash flow information related to leases was as follows:

	Year ended December 31,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows for operating leases	$ 150	$ 266
Right-of-use assets obtained in exchange for lease obligation		
Operating leases	1,310	—

Our operating lease liabilities as of December 31, 2023 will mature, as follows (amounts in thousands):

2024	195
2025	217
2026	220
2027	224
2028 and after	633
Total	1,489
Less: imputed interest	(239)
	$ 1,250

9. Commitments

Executive employment agreements

The Company has entered into employment agreements with certain key executives, providing for compensation and severance in certain circumstances, such as a change in control, as described in the respective agreements.

Legal matters

The Company is subject from time to time to various claims and legal actions arising during the ordinary course of its business. Management believes that there are currently no claims or legal actions that would reasonably be expected to have a material adverse effect on the Company's results of operations, financial condition or cash flows.

10. Stockholders' Equity (Deficit)

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. During the year

ended December 31, 2023, warrants were exercised in exchange for 1,020,000 shares of common stock resulting in proceeds of $2.0 million. Warrants to purchase up to 13,300,000 shares of common stock remain unexercised as of December 31, 2023.

In December 2020, the Company entered into 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. During the years ended December 31, 2023 and 2022, 10,463,504 and 1,982,773 shares were sold under the Sales Agreement, respectively, at a weighted average price per share of $0.20 and $2.00, respectively. Net proceeds to the Company after deducting fees, commissions and other expenses related to the offering were $1.7 million and $3.8 million, respectively, for the years ended December 31, 2023 and 2022. 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 December 31, 2023 was 1,665,268.

2019 Incentive Award Plan

In connection with the Company's Initial Public Offering (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 December 31, 2023, there were 2,535,043 shares available for future issuance under the 2019 Plan, including 1,140,402 shares added pursuant to this provision effective January 1, 2023. Pursuant to this provision, the Company added an additional 2,175,686 shares to the total shares available for issuance under the 2019 Plan 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 December 31, 2023, there were 1,291,184 shares available for issuance under the ESPP, including 285,100 shares added pursuant to this provision effective January 1, 2023. Pursuant to this provision, the Company added an additional 543,921 shares to the total shares available for issuance under the ESPP effective January 1, 2024.

2023 Employment Inducement Award Plan

On April 28, 2023, the Company's 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 December 31, 2023, there were 1,500,000 shares available for issuance under the Inducement Plan.

Share-based compensation expense was as follows for the years ended December 31, 2023 and 2022 (in thousands):

	Year ended December 31,	
	2023	2022
Research and development	$ 1,675	$ 2,596
General and administrative	3,885	4,568
	$ 5,560	$ 7,164

The following table summarizes the activity related to stock option grants for the year ended December 31, 2023:

	Shares	Weighted average exercise price per share	Weighted-average remaining contractual life (years)
Outstanding at January 1, 2023	5,783,185	$ 6.86	6.8
Granted	2,424,844	2.13	
Exercised	(78,600)	2.39	
Forfeited	(2,389,941)	4.64	
Outstanding at December 31, 2023	5,739,488	$ 5.85	6.6
Vested and exercisable at December 31, 2023	3,878,156	$ 7.07	5.5
Vested and expected to vest at December 31, 2023	5,739,488	$ 5.85	6.6

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

As of December 31, 2023, the unrecognized compensation cost was $4.3 million and will be recognized over an estimated weighted-average remaining amortization period of 1.9 years. The aggregate intrinsic value of options outstanding and options exercisable as of December 31, 2023 were zero. Options granted during the years ended December 31, 2023 and 2022 had weighted-average grant-date fair values of $1.68 and $1.57 per share, respectively.

The fair value of options is estimated using the Black-Scholes option pricing model, which takes into account inputs such as the exercise price, the estimated fair value of the underlying common stock at the grant date, expected term, expected stock price volatility, risk-free interest rate and dividend yield. The fair value of stock options granted during the years ended December 31, 2023 and 2022 was determined using the methods and assumptions discussed below.

- The expected term of employee stock options with service-based vesting is determined using the "simplified" method, as prescribed in SEC's Staff Accounting Bulletin (SAB) No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to the Company's lack of sufficient historical data. The expected term of nonemployee options is equal to the contractual term.
- The expected stock price volatility is based on historical volatilities of comparable public entities within the Company's industry which were commensurate with the expected term assumption as described in SAB No. 107.
- The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the expected term.
- The expected dividend yield is 0% because the Company has not historically paid, and does not expect for the foreseeable future to pay, a dividend on its common stock.
- The Company's board of directors has determined the per share value of the Company's common stock based on the closing price as reported by the NASDAQ Global Market on the date of the grant.

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

	Year ended December 31,	
	2023	2022
Expected term (in years)	6.2	6.2
Expected stock price volatility	95.4%	92.7%
Risk-free interest rate	4.05%	2.07%
Expected dividend yield	0%	0%

11. Income Taxes

The Company's loss before income taxes for the years ended December 31, 2023 and 2022 is as follows (in thousands):

	Year ended December 31,	
	2023	2022
Domestic	$ (59,067)	$ (62,281)
Foreign	(15)	(11)
	$ (59,082)	$ (62,292)

The Company's tax benefit for the years ended December 31, 2023 and 2022 is summarized as follows (in thousands):

	Year ended December 31,	
	2023	2022
Current		
Federal	$ —	$ —
State	—	—
Foreign	—	—
	—	—
Deferred:		
Federal	—	—
State	—	(70)
Foreign	—	—
	—	(70)
Total income tax benefit	$ —	$ (70)

A reconciliation of the federal income tax rate to the Company's effective tax rate is as follows:

	Year ended December 31,	
	2023	2022
Rate reconciliation:		
Federal tax benefit at statutory rate	21.0 %	21.0 %
State tax, net of federal benefit	3.1	3.1
Net operating loss carryforwards	0.4	0.1
Change in tax rate	—	(9.6)
Sale of royalty interest	(4.1)	(3.9)
Research and development	5.2	(0.8)
Change in valuation allowance	(24.4)	(9.1)
Share-based compensation	(0.5)	(0.6)
Other	(0.7)	(0.1)
Total provision	— %	0.1 %

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and liabilities were as follows (in thousands):

	December 31,	
	2023	2022
Deferred tax assets		
Net operating loss carryforwards	$ 48,957	$ 41,697
Share-based compensation	4,518	3,731
Research and development credits	10,382	7,287
Capitalized research and development expenses	9,701	6,354
Accrued expenses and other	107	82
Gross deferred tax assets	73,665	59,151
Valuation allowance	(72,861)	(58,424)
Net deferred tax asset	804	727
Deferred tax liabilities		
Accrued expenses and other	(424)	(348)
Acquired in-process research and development	(583)	(582)
Net deferred tax liabilities	$ (203)	$ (203)

In assessing the need for a valuation allowance, the Company may utilize indefinite-lived deferred tax liabilities from an intangible asset as a future source of income. The Company's acquired IPR&D intangible asset can be utilized as a source of income arising from the future reversal of temporary difference that can be offset against post 2017 indefinite-lived net operating losses (NOLs). Therefore, the Company is permitted to offset the indefinite-lived deferred tax liability up to the 80 percent limitation for NOLs generated subsequent to January 1, 2018.

Beginning in 2022, the 2017 Tax Cuts and Jobs Act requires taxpayers to capitalize research and development expenses with amortization periods over five and fifteen years, depending on where the research is conducted. The Company has $22 million of research and development costs being capitalized in 2023. However, given the Company has a valuation allowance against its deferred tax assets, including the capitalized research and development costs, the enacted provision does not have a material impact on the consolidated financial statements.

The valuation allowance increased by $14.4 million and $5.6 million for the years ended December 31, 2023 and 2022, respectively.

The following table summarizes carryforwards of federal, state and foreign NOLs as of December 31, 2023 and 2022, respectively (in thousands):

	December 31,	
	2023	2022
Combined NOL Carryforwards:		
Federal	$ 191,315	$ 162,335
State	213,784	184,382
Foreign	1,745	1,716

As of December 31, 2023, the Company had federal and state net operating losses of $191.3 million and $213.8 million, respectively, which will begin expiring in 2032. The Company also had foreign net operating loss carryforwards of $1.7 million which do not expire. As of December 31, 2023, the Company 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.

The NOL and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. In general, under Section 382 of the Code, a corporation that undergoes an "ownership change," generally defined as a greater than 50% change by value in its equity ownership over a three-year period, is subject to limitations on its ability to utilize its pre change tax credits as well as its net operating losses (NOLs) to offset future taxable income. During 2021, the Company conducted a Section 382 study and determined that approximately $63.7 million in NOLs and $2.7 million in research and development tax credits are limited by Section 382 as of December 31, 2021. As a result of the Section 382 analysis, approximately $1.4 million of research and development tax credits are scheduled to expire unused due to the annual Section 382 limitation and therefore were written off in 2021. There has been no subsequent Section 382 analysis performed, therefore it is possible that additional limitations on the Company's NOLs and research and development tax credits may exist if an ownership change has occurred since 2021. Future changes in the Company's stock ownership, some of which might be beyond its control, could result in an ownership change under Section 382 of the Code, further limiting the Company's ability to utilize a material portion of the NOLs and research and development tax credits.

The Company will recognize interest and penalties related to uncertain tax positions as income tax expense. As of December 31, 2023, the Company had no accrued interest and penalties related to uncertain tax positions and no amounts have been recognized in the Company's statements of operations. Due to NOL and tax credit carryforwards that remain unutilized, income tax returns from 2020 through 2022 remain subject to examination by the taxing jurisdictions. The NOLs remain subject to review until utilized.

12. Related Party Transactions

IntellectMap provides IT-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 years ended December 31, 2023 and 2022 were $0.3 million and $0.2 million, respectively.

13. 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 December 31, 2023 (in thousands):

	2023
Balance, January 1	$ —
Current year restructuring costs	2,309
Payment of employee severance and related costs	(1,866)
Balance, December 31	$ 443

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2023.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control - Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that, as of December 31, 2023, our internal control over financial reporting was effective.

Attestation Report of the Independent Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

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 December 31, 2023 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

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

On March 27, 2024, our board of directors unanimously adopted amended and restated bylaws of the Company (the Amended and Restated Bylaws), effective immediately. Among other things, the Amended and Restated Bylaws:

- Enhance the existing procedural mechanics for stockholder nominations of directors and submissions of stockholder proposals (other than proposals to be included in the Company's proxy statement pursuant to Rule 14a-8 under the Securities Exchange Act of 1934, as amended (the Exchange Act)) at stockholder meetings, including, without limitation, as follows:

- To require that the nominating or proposing stockholder be a stockholder of record at the time of submitting a notice through the date of the applicable meeting;
- To require additional disclosures from nominating or proposing stockholders and proposed nominees; and
- To clarify that the number of candidates a stockholder may nominate for election at a meeting may not exceed the number of directors to be elected at such meeting and that substitute nominations are prohibited;

- Address matters relating to Rule 14a-19 under the Exchange Act (the Universal Proxy Rules) (e.g., providing the Company a remedy if a stockholder fails to satisfy the requirements of the Universal Proxy Rules, requiring nominating stockholders to make a representation as to whether they intend to use the Universal Proxy Rules, requiring stockholders intending to use the Universal Proxy Rules to provide reasonable evidence of the satisfaction of the requirements of the Universal Proxy Rules at least five business days before the applicable meeting upon the Company's request, etc.);
- Clarify that our board of directors may designate any director or officer of the Company to preside over any meeting of the stockholders and that the person presiding over any stockholder meeting may adjourn the meeting, whether or not a quorum is present;
- Modify the provisions relating to stockholder meeting adjournment procedures and lists of stockholders entitled to vote at stockholder meetings, in each case, to reflect amendments to the Delaware General Corporation Law;
- Clarify the procedures and mechanics related to the use of proxies; and
- Make various other updates, including ministerial and conforming changes.

The foregoing summary of the amendments does not purport to be complete and is qualified in its entirety by reference to the complete text of the Amended and Restated Bylaws, which are attached hereto as Exhibit 3.2 and are incorporated herein by reference.

b) Insider Trading Arrangements and Policies.

During the three months ended December 31, 2023, 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 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Directors and Executive Officers

The following table sets forth information regarding our executive officers and directors as of the date of this Annual Report on Form 10-K.

Name	Age	Position
Executive Officers		
J. Mel Sorensen, M.D.	67	President, Chief Executive Officer and Director
Christopher Degnan	44	Chief Financial Officer
Robert A. Beardsley, Ph.D.	63	Chief Operating Officer
Jennifer Evans Stacey	59	Chief Legal & Compliance Officer and Secretary
Non-Employee Directors		
Michael Powell, Ph.D.(3)	69	Chairman of the Board
Lawrence Alleva(1)(2)	74	Director
Emmett Cunningham, M.D., Ph.D., MPH	63	Director
Kevin Lokay(1)(2)(3)	67	Director
Linda West (1)(2)(3)	65	Director

(1) Member of the Audit Committee.
(2) Member of the Compensation Committee.
(3) Member of the Nominating and Corporate Governance Committee.

Executive Officers

J. Mel Sorensen, M.D. has served as Director, Chief Executive Officer and President of Galera since 2012. Dr. Sorensen serves on the boards of directors of several private companies including Esanik Therapeutics, Medsyn Biopharma and PlanetVerify Ltd. He is an advisor to the Biomarkers Consortium of the National Institutes of Health and to the Irish Cancer Society. Dr. Sorensen holds an M.B., B.Ch. and B.A.O. from University College, Dublin. Dr. Sorensen's postgraduate education and work has been in the United States, including an internal medicine residency in St. Louis and medical oncology fellowship at the Mayo Clinic, seven years at the National Cancer Institute as Senior Investigator in the Cancer Therapy Evaluation Program and four years each with Bayer and GlaxoSmithKline. Dr. Sorensen served as Director, Chief Executive Officer and President of Ascenta Therapeutics from 2004 until he joined Galera. We believe Dr. Sorensen's experience in the industry, his role as our Chief Executive Officer and President and his knowledge of the Company enable him to make valuable contributions to our board of directors.

Christopher Degnan has served as our Chief Financial Officer since October 2019 and served as our Secretary from October 2019 to October 2021. Mr. Degnan was most recently the Chief Financial Officer at Verrica Pharmaceuticals Inc., a public, late-stage biotechnology company focused on medical dermatology, from March 2018 to October 2019. Prior to Verrica, Mr. Degnan held roles of increasing responsibility at Endo International plc, a generics and specialty branded pharmaceutical company, beginning in November 2014, where he most recently served as the Vice President of Finance, Corporate FP&A and International Pharmaceuticals Segment Chief Financial Officer from December 2016 to March 2018. Prior to that, he served as the Vice President of Finance, Chief Financial Officer for Endo's U.S. Branded Pharmaceuticals segment from March 2016 to December 2016, and as the Senior Finance Director, U.S. Branded Pharmaceuticals from November 2014 to March 2016. Prior to joining Endo, Mr. Degnan held roles of increasing responsibility at AstraZeneca plc, a global biopharmaceutical company, beginning in 2004, most recently as Senior Finance Director, U.S. Commercial Finance from July 2013 to November 2014. He is a Certified Public Accountant in the State of Pennsylvania (voluntary inactive status). Mr. Degnan holds a B.B.A. degree in Accountancy from the University of Notre Dame.

Robert A. Beardsley, Ph.D., a co-founder of the Company, has served as our Chief Operating Officer since 2014, and previously served as our Executive Chair from 2012 to 2017. Prior to this, Dr. Beardsley was Chair

and Chief Executive Officer at Galera Therapeutics, LLC from 2010 to 2012, Chief Executive Officer at Metabolic Solutions Development Corporation from 2009 until 2010, and at Kereos from 2003 until 2009, and the acting Chief Executive Officer at Metaphore Pharmaceuticals, Inc. in 2002. He has also served in various management roles at Confluence Life Sciences, bioStrategies Group, Vector Securities International, Enzyme Organics and Mobil Oil. Dr. Beardsley serves on the board of Euclises, a private company, and has served on a number of boards of directors of public and private companies including Epigenetx, KemPharm, Kereos, CollaGenex Pharmaceuticals, Bioseek, and Metaphore Pharmaceuticals. Dr. Beardsley received a B.S. in Chemical Engineering, a Ph.D. in Biochemical Engineering from the University of Iowa and an M.B.A. in Finance from the University of Chicago.

Jennifer Evans Stacey, Esq. has served as our Chief Legal & Compliance Officer and Secretary since October 2021. Prior to Galera, Ms. Stacey served as Vice President, General Counsel, Secretary and Government Relations at The Wistar Institute, an international biomedical research institute focused on cancer, vaccines and infectious disease from April 2016 to October 2021. Previously, she served as Senior Vice President, General Counsel, Human Resources and Secretary at Antares Pharma, Inc. from May 2014 to July 2015. Prior to that, Ms. Stacey served as Executive Vice President, General Counsel, Human Resources, and Secretary at Auxilium Pharmaceuticals, Inc., and as Senior Vice President, Corporate Communications, General Counsel and Secretary at Aventis Behring, LLC (now CSL Behring). She began her career in life sciences at Rhône-Poulenc Rorer (now Sanofi) including two years in their Paris office. Ms. Stacey currently serves on the board of directors of Context Therapeutics, Inc. Ms. Stacey graduated with an A.B. from Princeton University and earned her J.D. from the University of Pennsylvania Law School.

Non-Employee Directors

Michael Powell, Ph.D. has served as a member of our board of directors since November 2016 and as its Chair since July 2017, and also serves as Chair of our Nominating and Corporate Governance Committee. In August 2021, Dr. Powell joined Omega Funds as an Executive Partner. Previously, he was a General Partner at Sofinnova Investments, a biopharmaceutical investment firm, from 1997 until June 2021. Dr. Powell was Group Leader of Drug Delivery at Genentech from 1990 until 1997, and Director of Product Development at Cytel from 1987 until 1990. Dr. Powell currently serves on the board of directors of Aerium Therapeutics, a private company. Until Checkmate Pharma's acquisition by Regeneron in May 2022, Dr. Powell served as the Chair of the board of directors of Checkmate Pharma and has served on the boards of directors of several private companies. He served on the Washington University board of trustees in St. Louis and was an Adjunct Professor of Pharmaceutical Chemistry at the University of Kansas. Dr. Powell holds a Ph.D. in Physical Chemistry from the University of Toronto and he completed post-doctoral studies in Bioorganic Chemistry at the University of California as a National Science and Engineering Research Council Scholar. We believe Dr. Powell is qualified to serve on our board of directors due to his extensive experience in investing in pharmaceutical companies.

Lawrence Alleva has served as a member of our board of directors since June 2019 and also serves as Chair of our Audit Committee. He is a former partner with PricewaterhouseCoopers LLP (PwC), where he worked for 39 years from 1971 until his retirement in June 2010, including 28 years' service as a partner. Mr. Alleva worked with numerous pharmaceutical and biotechnology companies as clients and, additionally, served PwC in a variety of office, regional and national practice leadership roles, most recently as the U.S. Ethics and Compliance Leader for the firm's Assurance Practice from 2006 until 2010. Mr. Alleva currently serves on the boards of directors of Bright Horizons Family Solutions, Inc., Mersana Therapeutics, Inc. and Adaptimmune Therapeutics PLC and chairs the audit committee for those companies. He previously served on the boards of directors and as chair of the audit committees of TESARO, Inc. from March 2012 to the time of its sale to GSK in January 2019, Mirna Therapeutics, Inc. from June 2015 until its merger with another company in September 2017 and of GlobalLogic, Inc. from June 2011 through the sale of the company in June 2014. Mr. Alleva is a Certified Public Accountant (inactive). He received a B.S. degree in Accounting from Ithaca College and attended Columbia University's Executive M.B.A. non-degree program. We believe Mr. Alleva is qualified to serve on our board of directors due to his finance background and industry experience, including his service on the boards of directors of other public biotechnology companies.

Emmett Cunningham, M.D., Ph.D. has served as a member of our board of directors since September 2018. Dr. Cunningham is currently a Senior Partner at HealthQuest Capital Management. He was an Executive Advisor at Blackstone Life Sciences, a life sciences investment firm, until 2023, having joined Blackstone as part of

its acquisition of Clarus in December 2018. At Blackstone, he served as Senior Managing Director from November 2018 and as an Operating Partner from January 2022 until March 2023 prior to assuming the role of Executive Advisor. Dr. Cunningham joined Clarus in 2006 as a Principal. From February 2004 to December 2005, he was Senior Vice President, Medical Strategy at Eyetech Pharmaceuticals, Inc., a pharmaceutical company. From April 2002 to February 2004, Dr. Cunningham was Vice President of Clinical Research Development and Licensing. Dr. Cunningham is also Adjunct Clinical Professor of Ophthalmology at Stanford University School of Medicine and the co-founder and Chair of the Ophthalmology Innovation Summit. Dr. Cunningham previously served on the boards of directors of Annexon Biosciences from December 2014 until February 2021, Graybug Vision from May 2016 to September 2020, and Lumos Pharma from January 2019 until February 2021, and as the Chair of the board of directors of Restoration Robotics from October 2017 to June 2018 and on the boards of two private companies, SFJ Pharmaceuticals Group and Silktech Biopharmaceuticals from June 2014 until March 2023 and from November 2017 and March 2023, respectively. Dr. Cunningham received a B.S. from Drexel University, a B.A., M.D. and M.P.H. from Johns Hopkins University and a Ph.D. in neuroscience from the University of California at San Diego. We believe Dr. Cunningham is qualified to serve on our board of directors due to his experience in research and investing in medical companies.

Kevin Lokay has served as a member of our board of directors since March 2019. Mr. Lokay served in multiple leadership roles at AstraZeneca plc, a pharmaceutical company, from August 2018 until his retirement in June 2023. Mr. Lokay most recently served as Head of Change Implementation for the U.S. Oncology Business, a position he held from April 2022 until his retirement. From November 2019 to April 2022, Mr. Lokay was Head of the U.S. Immuno-oncology Franchise at AZ, and prior to that, Mr. Lokay was the Head of the U.S. Lung Cancer Franchise at AZ from August 2018 until November 2019. Mr. Lokay served as an advisor to AbbVie Inc., a pharmaceutical company, from August 2017 until December 2017. Mr. Lokay was previously Vice President and Business Unit Head, Oncology at Boehringer Ingelheim, a pharmaceutical company, a position he held from December 2009 until December 2016. Prior to joining Boehringer Ingelheim, he was President and Chief Executive Officer of Cytogen Corporation from 2007 until 2008 and served in various positions at GlaxoSmithKline from 1997 until 2007 and at Merck & Co. from 1981 until 1997. Mr. Lokay received a B.A. in Economics from Lafayette College and a M.S. from Purdue University. We believe that Mr. Lokay is qualified to serve on our board of directors due to his extensive experience in the biopharmaceutical industry.

Linda West has served as a member of our board of directors since March 2020 and also serves as Chair of our Compensation Committee. Ms. West served in multiple leadership roles of increasing responsibility for E. I. du Pont de Nemours and Company from August 1981 until her retirement in December 2019. Ms. West most recently served as Vice President, Corporate Planning and Analyses, where she led the execution of transformational transactions from October 2009 until her retirement, including major divestitures, spin-offs, acquisitions, and the merger with The Dow Company followed by simultaneous spin-offs into three independent companies. Throughout her career with DuPont, Ms. West led early and late stage businesses including DuPont Imaging Technologies, DuPont Personal Protection, DuPont Microcircuit Materials, and DuPont Industrial Imaging. Prior to serving as Vice President, Corporate Planning and Analyses, Ms. West was the Chief Financial Officer of multiple DuPont businesses and was the Vice President, General Auditor and Chief Ethics and Compliance Officer for five years during the initial implementation of the Sarbanes-Oxley Act of 2002. Ms. West currently serves on the board of directors of Context Therapeutics. Ms. West holds a B.S. in Accounting with a minor in Business Administration from the University of Delaware. We believe that Ms. West is qualified to serve on our board of directors due to her finance background and extensive experience in business management and corporate transactions.

Board Diversity Matrix

Board Diversity Matrix (As of March 15, 2024)				
Total Number of Directors	6			
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Part I: Gender Identity				
Directors	1	5	0	0
Part II: Demographic Background				
African American or Black	0	0	0	0
Alaskan Native or Native American	0	0	0	0
Asian	0	0	0	0
Hispanic or Latinx	0	0	0	0
Native Hawaiian or Pacific Islander	0	0	0	0
White	1	5	0	0
Two or More Races or Ethnicities	0	0	0	0
LGBTQ+		0		
Did Not Disclose Demographic Background		0		

Code of Business Conduct and Ethics

We have a written Code of Business Conduct and Ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We have posted a current copy of the Code of Business Conduct and Ethics on our website, www.galeratx.com, in the "Investors" section under "Corporate Governance." In addition, we intend to post on our website all disclosures that are required by law or the rules of Nasdaq concerning any amendments to, or waivers from, any provision of the Code of Business Conduct and Ethics.

Audit Committee and Audit Committee Financial Expert

We have a separately designated standing audit committee ("Audit Committee"). The members of the Audit Committee are Lawrence Alleva, Kevin Lokey and Linda West. Mr. Alleva serves as the Chairperson of the Audit Committee. The members of our Audit Committee meet the requirements for financial literacy under the applicable Nasdaq rules. In addition, our Board of Directors has determined that Mr. Alleva qualifies as an "audit committee financial expert," as such term is defined in Item 407(d)(5) of Regulation S-K, and under the similar Nasdaq Rules requirement that the Audit Committee have a financially sophisticated member.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Item 11. Executive Compensation.

This section discusses the material components of the executive compensation program for our current and former executive officers who are named in the 2023 Summary Compensation Table below. In 2023, our "named executive officers" and their positions were as follows:

- J. Mel Sorensen, M.D., President and Chief Executive Officer;
- Christopher Degnan, Chief Financial Officer;
- Robert A. Beardsley, Ph.D., Chief Operating Officer; and
- Mark Bachleda, Pharm.D., former Chief Commercial Officer.

2023 Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers for the years presented.

Name and Principal Position	Year	Salary ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)(2)	Total ($)
J. Mel Sorensen, M.D., President and Chief Executive Officer	2023	616,505	617,628	—	16,132	1,250,265
	2022	596,860	453,096	295,446	16,045	1,361,448
Christopher Degnan, Chief Financial Officer	2023	460,845	259,684	—	13,200	733,729
	2022	432,250	231,347	159,068	12,200	834,865
Robert A. Beardsley, Ph.D., Chief Operating Officer	2023	451,389	189,499	—	13,200	654,088
	2022	446,195	128,526	171,369	11,150	757,240
Mark Bachleda, Pharm.D., former Chief Commercial Officer	2023	309,992	189,499	—	211,818	711,309
	2022	475,000	128,526	172,900	12,200	788,626

(1) Represents the grant date fair value of stock options computed in accordance with Accounting Standards Codification Topic 718, Compensation—Stock Compensation, or ASC 718, rather than the amounts paid to or realized by the named individual. We provide information regarding the assumptions used to calculate the value of the option awards in Note 10 to our consolidated financial statements included in this Annual Report on Form 10-K.

(2) The amount shown for Dr. Sorensen represents company matching contributions under our 401(k) plan and certain travel related payments under our travel policy. Amounts shown for Mr. Degnan and Dr. Beardsley represent company matching contributions under our 401(k) plan. Amount shown for Dr. Bachleda represents company matching contributions under our 401(k) plan, severance payments, and company reimbursement for COBRA medical and dental insurance premiums. See "Former Chief Commercial Officer" below for additional information.

Narrative Disclosure to Summary Compensation Table

2023 Salaries

Our named executive officers receive a base salary to compensate them for services rendered to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role, and responsibilities. The base salaries of our named executive officers are reviewed from time to time and adjusted when our Board of Directors or compensation committee determines an adjustment is appropriate.

During 2023, the compensation committee increased the annual base salary for Dr. Sorensen from $601,635 to $619,479, the annual base salary for Mr. Degnan from $438,900 to $465,234, the annual base salary for Dr. Beardsley from $447,658 to $452,135, and the annual base salary for Dr. Bachleda from $475,000 to $489,250, each effective March 2023, in recognition of the executive's individual performance and based on compensation data provided by AON/Radford.

2023 Bonuses

We maintain a discretionary bonus plan that is designed to motivate and reward our executives, including our named executive officers, for achievements relative to our goals and expectations for each fiscal year. Each named executive officer has a target bonus opportunity, expressed as a percentage of his annual base salary. Following the end of each year, our Board of Directors determines the bonuses for our executives, including our named executive officers, based on company performance against pre-established objectives and, for certain executives, individual performance, and retains discretion to allow for individual adjustments based on such factors as it deems appropriate. Bonus targets for 2023 were based 80% on achievement of corporate goals and 20% on achievement of individual goals for Mr. Degnan, Dr. Beardsley and Dr. Bachleda. Dr. Sorensen's 2023 target bonus was solely based on corporate achievement with no individual performance component.

The bonus targets for our named executive officers for 2023 were 55% for Dr. Sorensen, 40% for Mr. Degnan, 40% for Dr. Beardsley and 40% for Dr. Bachleda.

Our corporate performance objectives for 2023 included certain accomplishments in clinical and non-clinical development, regulatory and commercial, as well as financial and administrative goals. In March 2024, the Board of Directors assessed achievement against those previously established objectives and decided that since the most significant goals were not achieved and in light of the financial situation of the Company, no bonuses would be paid for 2023 performance.

Equity Compensation

We award stock options to our employees, including our named executive officers, as the long-term incentive component of our compensation program. We typically grant stock options to new hires upon their commencing employment with us. Additionally, we may grant stock options at such times as our Board of Directors determines appropriate. Generally, stock options vest over four years.

Refer to the "Outstanding Equity Awards at 2023 Fiscal Year End" table below for information regarding the stock options we granted to our named executive officers during 2023.

Retirement Plans

We currently maintain a 401(k) retirement savings plan for our employees, including our named executive officers, who satisfy certain eligibility requirements. Our named executive officers are eligible to participate in the 401(k) plan on the same terms as other full-time employees. We match 100% of contributions made by participants in the 401(k) plan up to 4% of employee contributions. These matching contributions are fully vested when made.

Employee Benefits and Perquisites

All of our full-time employees, including our named executive officers, are eligible on the same terms to participate in our health and welfare plans, including medical, dental, and vision benefits, short-term and long-term disability insurance, and accidental death and dismemberment insurance.

Outstanding Equity Awards at 2023 Fiscal Year End

The following table summarizes the number of shares of common stock underlying outstanding equity incentive plan awards for each named executive officer as of December 31, 2023.

Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
J. Mel Sorensen, M.D.	2/1/2016	338,437	—	2.43	3/2/2026
	1/18/2017	88,710	—	2.68	1/18/2027
	1/10/2019	355,972	—	7.08	1/10/2029
	1/31/2020	182,210	3,877 (1)	14.84	1/30/2030
	1/26/2021	138,541	51,459 (1)	11.99	1/25/2031
	2/28/2022	121,183	143,217 (1)	2.24	2/27/2032
	2/25/2023	91,666	348,334 (1)	1.78	2/24/2033
Christopher Degnan	10/21/2019	229,513	—	12.00	11/5/2029
	1/31/2020	72,884	1,551 (1)	14.84	1/30/2030
	1/26/2021	60,156	22,344 (1)	11.99	1/25/2031
	2/28/2022	61,875	73,125 (1)	2.24	2/27/2032
	2/25/2023	38,541	146,459 (1)	1.78	2/24/2033
Robert A. Beardsley, Ph.D.	9/17/2014	31,919	—	1.14	9/17/2024
	2/1/2016	110,779	—	2.43	3/2/2026
	1/18/2017	34,383	—	2.68	1/18/2027
	1/10/2019	227,427	—	7.08	1/10/2029
	1/31/2020	72,884	1,551 (1)	14.84	1/30/2030
	1/26/2021	54,687	20,313 (1)	11.99	1/25/2031
	2/28/2022	34,375	40,625 (1)	2.24	2/27/2032
	2/25/2023	28,125	106,875 (1)	1.78	2/24/2033
Mark Bachleda, Pharm.D (2)	—	—	—	—	—

(1) The unvested portion of the options vests in equal monthly installments until the fourth anniversary of the vesting commencement date, subject to the named executive officer's continued employment with the company through each applicable vesting date and accelerated vesting in the event the named executive officer's employment with the company is terminated by the company without cause or by the named executive officer for good reason, in either case, within 12 months following a change in control.

(2) Dr. Bachleda separated from employment with the Company in August 2023 and he held no outstanding options as of December 31, 2023.

Executive Employment Agreements

We have entered into employment agreements with each of our named executive officers. The employment agreements are for indefinite terms and entitle the named executive officers to the annual base salaries and annual target bonus opportunities, the amount of which for 2023 are described above under the headings "2023 Salaries" and "2023 Bonuses."

If we terminate a named executive officer without "good cause" or he resigns for "good reason" (each as defined below), subject to his timely executing a release of claims and his continued compliance with certain covenants, he is entitled to receive (i) base salary continuation for a period of 9 months (or 12 months for Dr. Sorensen); and (ii) direct payment of, or reimbursement for, continued health coverage pursuant to COBRA for up to 9 months (or 12 months for Dr. Sorensen) in the same percentage contributed by the Company towards the executive's health plan coverage as in effect immediately prior to the termination date.

If we terminate a named executive officer without "good cause" or he resigns for "good reason", in either case, on or within 12 months following a change in control, then, in lieu of the severance payments and benefits described above, subject to his timely executing a release of claims and his continued compliance with certain covenants, he is entitled to receive (i) a cash amount equal to one times (or 1.5 times for Dr. Sorensen) the sum of his annual base salary and his target annual bonus for the year of termination, payable over the 12 months (or 18 months for Dr. Sorensen) following his termination date; (ii) direct payment of, or reimbursement for, continued health coverage pursuant to COBRA for up to 12 months (or 18 months for Dr. Sorensen) in the same percentage contributed by the Company towards the executive's health plan coverage as in effect immediately prior to the termination date; and (iii) accelerated vesting of all unvested equity or equity-based awards held by the executive that vest solely based on the passage of time, with any such awards that vest based on the attainment of performance-vesting conditions being governed by the terms of the applicable award agreement.

The named executive officers have each agreed to refrain from (i) competing with us while employed and following his termination of employment for any reason for a period of 12 months and (ii) soliciting our employees, consultants, partners or advisors to accept employment and from soliciting our distributors, suppliers, representatives or agents to terminate or modify their relationship with the Company, in each case, while employed and following his termination of employment for any reason for a period of 12 months.

For purposes of the employment agreements, "good cause" generally means, subject to certain notice and cure rights, the executive's (i) refusal to substantially satisfy the material responsibilities and objectives reasonably assigned to him; (ii) material breach of the employment agreement or any other agreement between the executive and the Company; (iii) commission of a felony or a crime involving moral turpitude, or the commission of any other act or omission involving dishonesty or fraud with respect to the Company or its customers or suppliers; (iv) sexual harassment, unlawful discrimination or similar behavior; (v) material breach of any confidentiality or non-compete obligations; (vi) conduct that tends to bring the Company into public disgrace or disrepute; or (vii) gross negligence or willful misconduct with respect to the Company.

For purposes of the employment agreements, "good reason" generally means, subject to certain notice and cure rights, (i) the Company's failure to comply with the material terms of the employment agreement; (ii) any requirement by the Company that executive perform any act which is illegal; (iii) any material reduction in annual base salary, except in connection with across-the-board salary reductions based on the Company's financial condition or performance similarly affecting all or substantially all senior management employees; or (iv) any material reduction in executive's responsibilities, positions, duties or authority which occurs within 12 months after a change in control.

Former Chief Commercial Officer

Dr. Bachleda's position was eliminated in connection with the Workforce Reduction, and he separated from employment effective August 15, 2023. In connection with Dr. Bachleda's separation, we entered into a separation agreement with Dr. Bachleda pursuant to which he became eligible to receive the severance payments and benefits under his employment agreement with the Company, which includes base salary continuation for a period of 9 months and reimbursement for continued health coverage pursuant to COBRA for up to 9 months. The severance payments and benefits paid by the Company during 2023 are set forth in the "All Other Compensation" column of the 2023 Summary Compensation Table above.

Non-Employee Director Compensation

We maintain a compensation program for our non-employee directors under which each non-employee director was eligible to receive the following amounts for their services on our Board of Directors during 2023:

- Upon the director's initial election or appointment to our Board of Directors, an option to purchase 96,000 shares of our common stock;
- If the director has served on our Board of Directors for at least six months as of the date of an annual meeting of stockholders and will continue to serve as a director immediately following such meeting, an option to purchase shares of our common stock on the date of the annual meeting covering 64,000

shares for the chair of the Board or lead independent director or 48,000 shares for other non-employee members of the Board (other than the chair or lead independent director);

- An annual director fee of $35,000;
- If the director serves as lead independent director or chair or on a committee of our Board of Directors, an additional annual fee as follows:
  - Chair of the Board or lead independent director, $25,000;
  - Chair of the audit committee, $15,000;
  - Audit committee member other than the chair, $7,500;
  - Chair of the compensation committee, $10,000;
  - Compensation committee member other than the chair, $5,000;
  - Chair of the nominating and corporate governance committee, $8,000; and
  - Nominating and corporate governance committee member other than the chair, $4,000.

Director fees under the program are payable in arrears in four equal quarterly installments not later than the fifteenth day following the final day of each calendar quarter, provided that the amount of each payment will be prorated for any portion of a quarter that a director is not serving on our Board.

Stock options granted to our non-employee directors under the program have an exercise price equal to the fair market value of our common stock on the date of grant and expire not later than ten years after the date of grant. The stock options granted upon a director's initial election or appointment vest in 36 substantially equal monthly installments following the date of grant. The stock options granted annually to directors vest in a single installment on the earlier of the day before the next annual meeting or the first anniversary of the date of grant. In addition, all unvested stock options vest in full upon the occurrence of a change in control.

Under our director compensation program, each non-employee director may elect, on an annual basis, to receive one or more options to purchase shares of common stock in lieu of the director's annual cash fee for Board and committee service for such year. For 2023, such election was required to be made prior to May 26, 2023 and applies to cash fees earned for the period July 1, 2023 to June 30, 2024. The number of shares subject to any such option is determined by dividing the cash amount of the retainer by the Black-Scholes value of the option, computed in accordance with the terms of the director compensation program on the applicable grant date. Each such option will vest in equal quarterly installments, subject to the non-employee director's continued service as a non-employee director or on the applicable committee through each applicable vesting date.

2023 Director Compensation

The following table sets forth the compensation earned by our non-employee directors for their service on our Board during 2023.

Name	Fees Earned or Paid in Cash ($)(1)	Option Awards ($)(2)	Total ($)
Lawrence Alleva	$ 55,000	$ 148,907	$ 203,907
Emmett Cunningham, M.D., Ph.D.	35,000	121,390	156,390
Kevin Lokay	51,500	121,390	172,890
Michael Powell, Ph.D.	68,000	161,853	229,853
Linda West	56,500	149,656	206,156

(1) Represents the annual retainer earned under our director compensation program for service on our Board during 2023. Ms. West elected to receive cash director fees earned from July 1, 2022 through June 30, 2023 in the form of stock options. Accordingly, in July 2022, Ms. West was issued options to purchase 58,496 shares

(in lieu of $28,250 in cash fees for July through December 2022 and $28,250 in cash fees for January through June 2023). Mr. Alleva and Ms. West have each elected to receive cash director fees earned from July 1, 2023 through June 30, 2024 in the form of stock options. Accordingly, in July 2023, Mr. Alleva was issued options to purchase 22,762 shares (in lieu of $27,500 in cash fees for July through December 2023 and $27,500 in cash fees for January through June 2024) and Ms. West was issued options to purchase 23,382 shares (in lieu of $28,250 in cash fees for July through December 2023 and $28,250 in cash fees for January through June 2024). Each of these options vests in equal quarterly installments and has an exercise price of $1.29 for the options granted in July 2022 and an exercise price of $3.12 for the options granted in July 2023, which was the closing price per share of our stock on the applicable date of grant.

(2) Represents the grant date fair value of stock options computed in accordance with ASC 718 rather than the amounts paid to or realized by the named individual. We provide information regarding the assumptions used to calculate the value of the option awards in Note 10 to our consolidated financial statements included in this Annual Report on Form 10-K. The amounts for Mr. Alleva and Ms. West include $27,517 and $28,266, respectively, representing the excess of the grant date fair value of the options received in July 2023 in lieu of cash fees over the amount of those fees for service during 2023. The grant date fair value of these options exceeds the 2023 cash fee amount because, as described above, the options were received in lieu of cash fees otherwise payable for services performed from July 1, 2023 through June 30, 2024.

As of December 31, 2023, the aggregate number of options (exercisable and unexercisable) held by each non-employee director were as follows: Mr. Alleva: 133,812; Dr. Cunningham: 107,960; Mr. Lokay: 102,552; Dr. Powell: 130,134, and Ms. West: 183,272. None of our non-employee directors held stock awards in the Company as of December 31, 2023.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Securities Authorized for Issuance under Equity Compensation Plans

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Issuance Under Equity Compensation Plans
Equity compensation plans approved by security holders (1)	5,739,488[3]	$5.85[4]	3,826,227[5]
Equity compensation plans not approved by security holders (2)	—	—	1,500,000
Total	5,739,488	$ 5.85	5,326,227

(1) Consists of the Galera Therapeutics, Inc. Equity Incentive Plan, as amended (the "Prior Plan"), the 2019 Incentive Award Plan (the "2019 Plan") and the 2019 Employee Stock Purchase Plan (the "2019 ESPP").

(2) Consists of the Galera Therapeutics, Inc. 2023 Employment Inducement Award Plan (the "Inducement Plan"). As of the date of this Annual Report on Form 10-K, we have not granted any awards under the Inducement Plan.

(3) Consists of 1,665,268 outstanding options to purchase stock under the Prior Plan and 4,074,220 outstanding options to purchase stock under the 2019 Plan.

(4) As of December 31, 2023, the weighted-average exercise price of outstanding options under the Prior Plan was $4.66 and the weighted-average exercise price of outstanding options under the 2019 Plan was $6.33.

(5) Includes 2,535,043 shares available for future issuance under the 2019 Plan and 1,291,184 shares available for issuance under the 2019 ESPP. As of November 6, 2019, in connection with our initial public offering, no

further grants are made under the Prior Plan. The 2019 Plan provides for an annual increase to the number of shares available for issuance thereunder on the first day of each calendar year beginning on January 1, 2020 and ending on and including January 1, 2029, by an amount equal to the lesser of (i) 4% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of common stock as determined by our Board of Directors (but no more than 14,130,029 shares may be issued upon the exercise of incentive stock options). The 2019 ESPP provides for an annual increase to the number of shares available for issuance thereunder on the first day of each calendar year beginning on January 1, 2020 and ending on and including January 1, 2029, by an amount equal to the lesser of (i) 1% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of common stock as is determined by our Board of Directors, provided that no more than 3,288,886 shares of our common stock may be issued under the 2019 ESPP. As of the date of this Annual Report on Form 10-K, we have not commenced offering periods under the ESPP.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information with respect to holdings of our common stock by (i) stockholders who beneficially owned more than 5% of the outstanding shares of our common stock, and (ii) each of our directors (which includes all nominees), each of our named executive officers and all directors and executive officers as a group as of March 15, 2024, unless otherwise indicated. The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, beneficial ownership includes any shares as to which a person has sole or shared voting power or investment power. Applicable percentage ownership is based on 54,392,170 shares of common stock outstanding as of March 15, 2024. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options, or other rights held by such person that are currently exercisable or will become exercisable within 60 days of March 15, 2024 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed below is 45 Liberty Blvd, Suite 230, Malvern, Pennsylvania 19355. We believe, based on information provided to us, that each of the stockholders listed below has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% or Greater Stockholders		
Yair Schneid (1)	8,043,203	14.8
Altamont Pharmaceutical Holdings, LLC (2)	5,630,000	10.3
GSA Capital Partners LLP (3)	3,892,561	7.2
Named Executive Officers and Directors		
J. Mel Sorensen, M.D. (4)	1,727,174	3.1
Christopher Degnan (5)	508,062	*
Mark Bachleda, Pharm.D.(6)	—	*
Michael Powell, Ph.D. (7)	66,134	*
Lawrence Alleva (8)	90,490	*
Emmett Cunningham, M.D., Ph.D. (9)	59,960	*
Kevin Lokay (10)	54,552	*
Linda West (11)	189,425	*
All executive officers and directors as a group (9 persons) (12)	3,587,826	6.2

* Less than one percent.

(1) Based on Schedule 13G filed with the SEC on January 17, 2024 and Form 4 filed with the SEC on February 26, 2024. Consists of 8,043,203 shares of our common stock held of record by Yair Schneid. Mr. Schneid is deemed to have sole voting and dispositive power with regard to such shares. The mailing address of Mr. Schneid is 1 Wood Lane, Suffern, NY 10901.

(2) Based on Schedule 13G filed with the SEC on November 13, 2023 and other information known to the Company. Consists of (i) 5,280,000 shares of our common stock held of record by Altamont Pharmaceutical Holdings, LLC and (ii) warrants to purchase up to 350,000 shares of common stock. Mark Pearson is the Manager and sole Member of Altamont Pharmaceutical Holdings, LLC. As a result, Mark Pearson possesses the power to vote and dispose or direct the disposition of all the shares beneficially owned by Altamont Pharmaceutical Holdings, LLC. The business address of Altamont Pharmaceutical Holdings, LLC is 5960 Berkshire Ln, Floor 6, Dallas, TX 75225.

(3) Based solely on Schedule 13G filed with the SEC on January 2, 2024. Consists of 3,892,561 shares of our common stock held of record by GSA Capital Partners LLP. GSA Capital Partners LLP is deemed to have sole voting and dispositive power with regard to such shares. The business address of GSA Partners LLP is 5 Stratton Street, London, United Kingdom.

(4) Consists of (i) 332,044 shares of common stock and (ii) 1,395,130 shares of common stock underlying stock options exercisable within 60 days of March 15, 2024 held by Dr. Sorensen.

(5) Consists of (i) 10,000 shares of common stock and (ii) 498,062 shares of common stock underlying stock options exercisable within 60 days of March 15, 2024 held by Mr. Degnan.

(6) Dr. Bachleda's position was eliminated as part of the Workforce Reduction, and his date of termination was August 15, 2023.

(7) Consists of 66,134 shares of common stock underlying stock options exercisable within 60 days of March 15, 2024 held by Dr. Powell.

(8) Consists of (i) 2,325 shares of common stock held by Mr. Alleva directly, (ii) 8,045 shares of common stock held by a family trust for which Mr. Alleva serves as a trustee and (iii) 80,120 shares of common stock underlying stock options exercisable within 60 days of March 15, 2024 held by Mr. Alleva.

(9) Consists of 59,960 shares of common stock underlying stock options exercisable within 60 days of March 15, 2024 held by Dr. Cunningham. Dr. Cunningham is a former employee of The Blackstone Group Inc. or one of its affiliates (together, "Blackstone"). Pursuant to arrangements between Dr. Cunningham and Blackstone, Dr. Cunningham is required to transfer to Blackstone any and all compensation received in connection with his directorship for any company Blackstone invests in or advises. Dr. Cunningham is not deemed to have any beneficial ownership of these securities.

(10) Consists of 54,552 shares of common stock underlying stock options exercisable within 60 days of March 15, 2024 held by Mr. Lokay.

(11) Consists of (i) 60,000 share of common stock and (ii) 129,425 shares of common stock underlying stock options exercisable within 60 days of March 15, 2024 held by Ms. West.

(12) Consists of (i) 520,605 shares of common stock and (ii) 3,067,221 shares of common stock underlying stock options exercisable within 60 days of March 15, 2024.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Policies and Procedures for Related Person Transactions

Our Board of Directors has adopted a written Related Person Transaction Policy, setting forth the policies and procedures for the review and approval or ratification of related person transactions. Under the policy, our finance department is primarily responsible for developing and implementing processes and procedures to obtain information regarding related persons with respect to potential related person transactions and then determining, based on the facts and circumstances, whether such potential related person transactions do, in fact, constitute related person transactions requiring compliance with the policy. If our finance department determines that a transaction or relationship is a related person transaction requiring compliance with the policy, our Chief Financial

Officer is required to present to the Audit Committee all relevant facts and circumstances relating to the related person transaction. Our Audit Committee must review the relevant facts and circumstances of each related person transaction, including if the transaction is on terms comparable to those that could be obtained in arm's length dealings with an unrelated third party and the extent of the related person's interest in the transaction, take into account the conflicts of interest and corporate opportunity provisions of our Code of Business Conduct and Ethics, and either approve or disapprove the related person transaction. If advance Audit Committee approval of a related person transaction requiring the Audit Committee's approval is not feasible, then the transaction may be preliminarily entered into by management upon prior approval of the transaction by the chair of the Audit Committee subject to ratification of the transaction by the Audit Committee at the Audit Committee's next regularly scheduled meeting; provided, that if ratification is not forthcoming, management will make all reasonable efforts to cancel or annul the transaction. If a transaction was not initially recognized as a related person, then upon such recognition the transaction will be presented to the Audit Committee for ratification at the Audit Committee's next regularly scheduled meeting; provided, that if ratification is not forthcoming, management will make all reasonable efforts to cancel or annul the transaction. Our management will update the Audit Committee as to any material changes to any approved or ratified related person transaction and will provide a status report at least annually of all then current related person transactions. No director may participate in approval of a related person transaction for which he or she is a related person.

The following are certain transactions, arrangements and relationships with our directors, executive officers and stockholders owning 5% or more of our outstanding common stock, or any member of the immediate family of any of the foregoing persons, since January 1, 2022, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive and Director Compensation."

February 2023 Registered Direct Offering

On February 17, 2023, we completed a registered direct offering, which resulted in the issuance and sale of 14,320,000 shares of our common stock and warrants to purchase up to 14,320,000 shares of common stock at a combined offering price of $2.095 per share and accompanying warrant, generating gross proceeds of $30.0 million. The warrants have an exercise price of $1.97 per share of common stock, are exercisable immediately following their issuance and will expire five years from the date of issuance. We received net proceeds of approximately $27.7 million from this offering, after deducting placement agent fees and offering expenses. The following table sets forth the aggregate number of shares of our common stock and warrant shares acquired in the offering by holders of more than 5% of our common stock, including entities that became holders of more than 5% of our common stock as a result of the registered direct offering.

Participants	Shares of Common Stock	Warrant Shares	Aggregate Value
Holders of More than 5% (1)			
Armistice Capital Master Fund Ltd.	2,860,000	2,860,000	$ 5,991,700
Alyeska Master Fund, L.P.	2,500,000	2,500,000	$ 5,237,500
Deerfield Partners, L.P.	2,386,000	2,386,000	$ 4,998,670
Rosalind Advisors, Inc.	1,300,000	1,300,000	$ 2,723,500
Sectoral Asset Management, Inc.	920,000	920,000	$ 1,927,400

(1) Stockholders of more than 5% at the time of the February 17, 2023 registered direct offering.

Royalty Agreement with Clarus

In November 2018, we entered into Amended and Restated Purchase and Sale Agreement (the "Royalty Agreement"), by and among us, 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, "Clarus"), a holder of more than 5% of our capital stock. Pursuant to the Royalty Agreement, Clarus agreed to pay us, in the aggregate, up to $80.0 million (the "Royalty Purchase Price") in four tranches of $20.0 million each, upon the achievement of specified clinical milestones in our Phase 3 Reduction in Oral Mucositis with Avasopasem Manganese Trial, which we refer to as our ROMAN Trial, in exchange for all of our right, title and interest in a specified portion of the worldwide net sales of certain of our

products during a specified period of time. We achieved the first milestone under the Royalty Agreement and received the first tranche of the Royalty Purchase Price in November 2018, received the second tranche of the Royalty Purchase Price in April 2019 in connection with the achievement of the second milestone under the Royalty Agreement in March 2019, and received the third tranche of the Royalty Purchase Price in February 2020 in connection with the achievement of the third milestone under the Royalty Agreement in January 2020.

In May 2020, we 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, 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. 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.

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 Galera of the applicable specified milestone payment. The issued warrants expire six years after the initial exercise date of each respective warrant.

Investors' Rights Agreement

We are party to a second amended and restated investors' rights agreement (the "Investors' Rights Agreement"), with, among others, holders of more than 5% of our capital stock at that time and certain of our executive officers. The Investors' Rights Agreement grants the holders certain registration rights with respect to the registrable securities held by them. The registration rights terminate upon the earlier of November 12, 2024, or, with respect to the registration rights of an individual holder, when the holder can sell all of such holder's registrable securities in a three-month period without restriction under Rule 144 under the Securities Act.

Consulting Services from IntellectMap Corporation

Since February 2018, IntellectMap Corporation has provided advisory services to the Company on cybersecurity issues. The chief executive officer of IntellectMap is the brother of J. Mel Sorensen, M.D., our Chief Executive Officer and a member of our Board of Directors. We paid $0.3 million and $0.2 million in fees to IntellectMap during the fiscal years ended December 31, 2023 and 2022, respectively.

Director and Officer Indemnification and Insurance

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us or will require us to indemnify each director (and in certain cases their related venture capital funds) and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director or executive officer.

Director Independence

Lawrence Alleva, Emmett Cunningham, Kevin Lokay, Michael Powell, Ph.D. and Linda West each qualify as "independent" in accordance with the listing requirements of Nasdaq. The Nasdaq independence definition includes a series of objective tests, including that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his family members has engaged in various types of business dealings with us. In addition, as required by Nasdaq rules, our Board of Directors has made a subjective determination as to each independent director that no relationships exist, which, in the opinion of our Board of Directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our Board of Directors reviewed and discussed information provided by

the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management.

Item 14. Principal Accountant Fees and Services.

Our independent registered public accounting firm is KPMG LLP, Philadelphia, PA, Auditor Firm ID: 185. The following table summarizes the fees of KPMG LLP, billed to us for each of the last two fiscal years for audit services and billed to us in each of the last two fiscal years for other services:

Fee Category	2023	2022
Audit Fees	$ 480,000	$ 540,000
Audit Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	1,780
Total Fees	$ 480,000	$ 541,780

Audit Fees

Audit fees for the fiscal years ended December 31, 2023 and December 31, 2022 include fees for professional services rendered for the audit and quarterly review of our financial statements filed with the SEC on Form 10-K and 10-Q, and services provided in connection with SEC filings, including consents and comfort letters.

All Other Fees

All other fees for the fiscal year ended December 31, 2022 included subscription fees to the KPMG LLP Accounting Research Online tool. No subscription fees were charged for the fiscal year ended December 31, 2023.

Audit Committee Pre-Approval Policy and Procedures

The Audit Committee has adopted a policy (the "Pre-Approval Policy") that sets forth the procedures and conditions pursuant to which audit and non-audit services proposed to be performed by the independent auditor may be pre-approved. The Pre-Approval Policy generally provides that we will not engage KPMG LLP to render any audit, audit-related, tax or permissible non-audit service unless the service is either (i) explicitly approved by the Audit Committee ("specific pre-approval") or (ii) entered into pursuant to the pre-approval policies and procedures described in the Pre-Approval Policy ("general pre-approval"). Unless a type of service to be provided by KPMG LLP has received general pre-approval under the Pre-Approval Policy, it requires specific pre-approval by the Audit Committee or by a designated member of the Audit Committee to whom the committee has delegated the authority to grant pre-approvals. Any proposed services exceeding pre-approved cost levels or budgeted amounts will also require specific pre-approval. For both types of pre-approval, the Audit Committee will consider whether such services are consistent with the SEC's rules on auditor independence. The Audit Committee will also consider whether the independent auditor is best positioned to provide the most effective and efficient service, for reasons such as its familiarity with the Company's business, people, culture, accounting systems, risk profile and other factors, and whether the service might enhance the Company's ability to manage or control risk or improve audit quality. All such factors will be considered as a whole, and no one factor should necessarily be determinative. On a periodic basis, the Audit Committee reviews and generally pre-approves the services (and related fee levels or budgeted amounts) that may be provided by KPMG LLP without first obtaining specific pre-approval from the Audit Committee. The Audit Committee may revise the list of general pre-approved services from time to time, based on subsequent determinations. The Audit Committee pre-approved all services performed since the pre-approval policy was adopted.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Financial Statements.

The financial statements required by this item are listed in Item 8, “Financial Statements and Supplementary Data” herein.

(a)(2) Financial Statement Schedules.

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(a)(3) Exhibits.

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Index

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
3.1	Restated Certificate of Incorporation of Galera Therapeutics, Inc.	8-K	001-39114	3.1	11/12/2019	
3.2	Amended and Restated Bylaws of Galera Therapeutics, Inc.					*
4.1	Form of Certificate of Common Stock	S-1/A	333-234184	4.1	10/28/2019	
4.2	Description of Securities	10-K	001-39114	4.2	03/11/2021	
4.3	Second Amended and Restated Investors' Rights Agreement, dated as of August 30, 2018, by and among Galera Therapeutics, Inc. and the investors party thereto, as amended	S-1/A	333-234184	4.2	10/28/2019	
4.4	Form of Warrant to Purchase Stock, dated May 11, 2020, issued by Galera Therapeutics, Inc. to Clarus IV Galera Royalty AIV, L.P., together with a schedule of warrantholders	10-Q	001-39114	4.1	08/10/2020	
4.5	Form of Warrant to Purchase Common Stock, dated February 17, 2023, issued by Galera Therapeutics, Inc.	8-K	001-39114	4.1	02/16/2023	
10.1#	Employment Agreement, dated October 25, 2019, by and between Galera Therapeutics, Inc. and J. Mel Sorensen, M.D.	S-1/A	333-234184	10.2	10/28/2019	
10.2#	Employment Agreement, dated October 25, 2019, by and between Galera Therapeutics, Inc. and Robert A. Beardsley, Ph.D.	S-1/A	333-234184	10.3	10/28/2019	
10.3#	Employment Agreement, dated October 25, 2019 by and between Galera Therapeutics, Inc. and Christopher Degnan	S-1/A	333-234184	10.4	10/28/2019	
10.4#	Employment Agreement, dated October 25, 2019, by and between Galera Therapeutics, Inc. and Jon T. Holmlund, M.D.	S-1/A	333-234184	10.5	10/28/2019	
10.5#	Employment Agreement, dated October 7, 2021, by and between Galera Therapeutics, Inc. and Jennifer Evans Stacey	10-Q	001-39114	10.2	11/10/2021	
10.6#	Employment Agreement, dated October 7, 2021, by and between Galera Therapeutics, Inc. and Mark Bachleda and amendments to Employment Agreement, dated January 31, 2022 and September 19, 2022, by and between Galera Therapeutics, Inc. and Mark Bachleda	10-Q	001-39114	10.1	11/09/2022	
10.7#	Employment Agreement, dated July 25, 2022, by and between Galera Therapeutics, Inc. and Eugene Kennedy, M.D.	10-Q	001-39114	10.2	11/09/2022	
10.8#	Form of Indemnification Agreement between Galera Therapeutics, Inc. and its directors and officers	S-1/A	333-234184	10.8	10/28/2019	
10.9.1#	Galera Therapeutics, Inc. 2019 Incentive Award Plan	S-1/A	333-234184	10.8	10/28/2019	
10.9.2#	Form of Stock Option Award Agreement under the Galera Therapeutics, Inc. 2019 Incentive Award Plan	S-1/A	333-234184	10.10	10/28/2019	
10.9.3#	Form of Restricted Stock Award Agreement under the Galera Therapeutics, Inc. 2019 Incentive Award Plan	S-1/A	333-234184	10.11	10/28/2019	

10.9.4#	Form of Restricted Stock Unit Award Agreement under the Galera Therapeutics, Inc. 2019 Incentive Award Plan	S-1/A	333-234184	10.12	10/28/2019	
10.10#	Galera Therapeutics, Inc. 2019 Employee Stock Purchase Plan	S-1/A	333-234184	10.14	10/28/2019	
10.11#	Galera Therapeutics, Inc. Equity Incentive Plan, as amended	S-1	333-234184	10.8	10/11/2019	
10.12#	Galera Therapeutics, Inc. Non-Employee Director Compensation Policy, as amended May 5, 2022	10-Q	001-39114	10.1	08/09/2022	
10.13.1†	Amended and Restated Purchase and Sale Agreement, dated as of November 14, 2018, by and among Galera Therapeutics, Inc. and 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.	S-1	333-234184	10.1	10/11/2019	
10.13.2†	Amendment No. 1 Amended and Restated Purchase and Sale Agreement, dated May 11, 2020, by and between Galera Therapeutics, Inc. and Clarus IV Galera Royalty AIV, L.P.	10-Q	001-39114	10.1	08/10/2020	
10.14†	Warrant Purchase Agreement, dated May 11, 2020, by and between Galera Therapeutics, Inc. and Clarus IV Galera Royalty AIV, L.P.	10-Q	001-39114	10.2	08/10/2020	
10.15†	Master Manufacturing Services Agreement between Patheon Manufacturing Services LLC and Galera Therapeutics, Inc., dated August 13, 2021	8-K	001-39114	10.0	08/18/2021	
10.16	Placement Agency Agreement dated February 15, 2023, by and between Galera Therapeutics, Inc. and Piper Sandler & Co.	8-K	001-39114	10.1	02/16/2023	
10.17	Securities Purchase Agreement dated February 15, 2023 by and among Galera Therapeutics, Inc. and the purchasers named therein	8-K	001-39114	10.2	02/16/2023	
21.1	Subsidiaries of Galera Therapeutics, Inc.	S-1	333-234184	21.1	10/11/2019	
23.1	Consent of KPMG LLP					*
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.					**
97.1	Galera Therapeutics, Inc. Policy for Recovery of Erroneously Awarded Compensation, effective as of October 2, 2023					*
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 Linkbases Document	*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	*

* Filed herewith.
** Furnished herewith.
# Indicates management contract or compensatory plan.
† Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Galera Therapeutics, Inc.

Date: March 28, 2024

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

Date: March 28, 2024

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

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ J. Mel Sorensen, M.D. **J. Mel Sorensen, M.D.**	Chief Executive Officer, President and Director *(principal executive officer)*	March 28, 2024
/s/ Christopher Degnan **Christopher Degnan**	Chief Financial Officer *(principal financial and accounting officer)*	March 28, 2024
/s/ Mike Powell, Ph.D. **Michael Powell, Ph.D.**	Chairman of the Board of Directors	March 28, 2024
/s/ Lawrence Alleva **Lawrence Alleva**	Director	March 28, 2024
/s/ Emmett Cunningham, M.D., Ph.D., MPH **Emmett Cunningham, M.D., Ph.D., MPH**	Director	March 28, 2024
/s/ Linda West **Linda West**	Director	March 28, 2024
/s/ Kevin Lokay **Kevin Lokay**	Director	March 28, 2024

Exhibit 3.2

AMENDED AND RESTATED

BYLAWS

OF

GALERA THERAPEUTICS, INC.

(a Delaware corporation)

TABLE OF CONTENTS

	Page
ARTICLE I - CORPORATE OFFICES	1
1.1 REGISTERED OFFICE	1
1.2 OTHER OFFICES	1
ARTICLE II - MEETINGS OF STOCKHOLDERS	1
2.1 PLACE OF MEETINGS	1
2.2 ANNUAL MEETING	1
2.3 SPECIAL MEETING	1
2.4 ADVANCE NOTICE PROCEDURES FOR BUSINESS BROUGHT BEFORE A MEETING	2
2.5 ADVANCE NOTICE PROCEDURES FOR NOMINATIONS OF DIRECTORS	7
2.6 NOTICE OF STOCKHOLDERS' MEETINGS	12
2.7 MANNER OF GIVING NOTICE; AFFIDAVIT OF NOTICE	12
2.8 QUORUM	12
2.9 ADJOURNED MEETING; NOTICE	13
2.10 CONDUCT OF BUSINESS	13
2.11 VOTING	14
2.12 STOCKHOLDER ACTION BY WRITTEN CONSENT WITHOUT A MEETING	14
2.13 RECORD DATE FOR STOCKHOLDER NOTICE; VOTING	14
2.14 PROXIES	15
2.15 LIST OF STOCKHOLDERS ENTITLED TO VOTE	15
2.16 POSTPONEMENT, ADJOURNMENT AND CANCELLATION OF MEETING	16
2.17 INSPECTORS OF ELECTION	16
ARTICLE III - DIRECTORS	16
3.1 POWERS	16
3.2 NUMBER OF DIRECTORS	16
3.3 ELECTION, QUALIFICATION AND TERM OF OFFICE OF DIRECTORS	16
3.4 RESIGNATION AND VACANCIES	17
3.5 PLACE OF MEETINGS; MEETINGS BY TELEPHONE	17
3.6 REGULAR MEETINGS	17
3.7 SPECIAL MEETINGS; NOTICE	17
3.8 QUORUM	18

TABLE OF CONTENTS
(continued)

	Page
3.9 BOARD ACTION BY CONSENT WITHOUT A MEETING	18
3.10 FEES AND COMPENSATION OF DIRECTORS	18
3.11 REMOVAL OF DIRECTORS	19
ARTICLE IV - COMMITTEES	19
4.1 COMMITTEES OF DIRECTORS	19
4.2 COMMITTEE MINUTES	19
4.3 MEETINGS AND ACTION OF COMMITTEES	19
ARTICLE V - OFFICERS	20
5.1 OFFICERS	20
5.2 APPOINTMENT OF OFFICERS	20
5.3 SUBORDINATE OFFICERS	20
5.4 REMOVAL AND RESIGNATION OF OFFICERS	20
5.5 VACANCIES IN OFFICES	21
5.6 REPRESENTATION OF SHARES OF OTHER ENTITIES	21
5.7 AUTHORITY AND DUTIES OF OFFICERS	21
ARTICLE VI - RECORDS AND REPORTS	21
6.1 MAINTENANCE OF RECORDS	21
ARTICLE VII - GENERAL MATTERS	21
7.1 EXECUTION OF CORPORATE CONTRACTS AND INSTRUMENTS	21
7.2 STOCK CERTIFICATES; PARTLY PAID SHARES	22
7.3 MULTIPLES CLASSES OR SERIES OF STOCK	22
7.4 LOST CERTIFICATES	23
7.5 CONSTRUCTION; DEFINITIONS	23
7.6 DIVIDENDS	23
7.7 FISCAL YEAR	23
7.8 SEAL	23
7.9 TRANSFER OF STOCK	23
7.10 STOCK TRANSFER AGREEMENTS	24
7.11 REGISTERED STOCKHOLDERS	24
7.12 WAIVER OF NOTICE	24
ARTICLE VIII - NOTICE BY ELECTRONIC TRANSMISSION	24
8.1 NOTICE BY ELECTRONIC TRANSMISSION	24
8.2 DEFINITION OF ELECTRONIC TRANSMISSION	25

TABLE OF CONTENTS
(continued)

	Page
ARTICLE IX - INDEMNIFICATION AND ADVANCEMENT	25
9.1 ACTIONS, SUITS AND PROCEEDINGS OTHER THAN BY OR IN THE RIGHT OF THE CORPORATION	25
9.2 ACTIONS OR SUITS BY OR IN THE RIGHT OF THE CORPORATION	26
9.3 INDEMNIFICATION FOR EXPENSES OF SUCCESSFUL PARTY	26
9.4 NOTIFICATION AND DEFENSE OF CLAIM	27
9.5 ADVANCE OF EXPENSES	27
9.6 PROCEDURE FOR INDEMNIFICATION AND ADVANCEMENT OF EXPENSES	28
9.7 REMEDIES	28
9.8 LIMITATIONS	29
9.9 SUBSEQUENT AMENDMENT	29
9.10 OTHER RIGHTS	29
9.11 PARTIAL INDEMNIFICATION	30
9.12 INSURANCE	30
9.13 SAVINGS CLAUSE	30
9.14 DEFINITIONS	30
ARTICLE X - AMENDMENTS	30
ARTICLE XI - FORUM SELECTION; SEVERABILITY	31

AMENDED AND RESTATED BYLAWS
OF
GALERA THERAPEUTICS, INC.

ARTICLE I - CORPORATE OFFICES

1.1 REGISTERED OFFICE.

The registered office of Galera Therapeutics, Inc. (the "Corporation") shall be fixed in the Corporation's certificate of incorporation, as the same may be amended and/or restated from time to time (the "certificate of incorporation").

1.2 OTHER OFFICES.

The Corporation may have other offices at any place or places, either within or outside the State of Delaware, as the Corporation's board of directors (the "Board") shall from time to time determine or the business of the Corporation may from time to time require.

ARTICLE II - MEETINGS OF STOCKHOLDERS

2.1 PLACE OF MEETINGS.

Meetings of stockholders shall be held at any place, within or outside the State of Delaware, designated by the Board. The Board may, in its sole discretion, determine that a meeting of stockholders shall not be held at any place, but may instead be held solely by means of remote communication as authorized by Section 211(a) of the General Corporation Law of the State of Delaware (the "DGCL"). In the absence of any such designation or determination, stockholders' meetings shall be held at the Corporation's principal executive office.

2.2 ANNUAL MEETING.

The Board shall designate the date and time of the annual meeting. At the annual meeting, directors shall be elected and other proper business properly brought before the meeting in accordance with Section 2.4 of these bylaws may be transacted.

2.3 SPECIAL MEETING.

A special meeting of the stockholders may be called at any time by the Board, chairperson of the Board, chief executive officer or president (in the absence of a chief executive officer) of the Corporation, but such special meetings may not be called by any other person or persons.

No business may be transacted at such special meeting other than the business specified in such notice to stockholders. Nothing contained in this paragraph of this Section 2.3 shall be construed as limiting, fixing, or affecting the time when a meeting of stockholders called by action of the Board may be held.

2.4 ADVANCE NOTICE PROCEDURES FOR BUSINESS BROUGHT BEFORE A MEETING.

(a) At an annual meeting of the stockholders, only such business shall be conducted as shall have been properly brought before the meeting. To be properly brought before an annual meeting, business must be (i) brought before the meeting by the Corporation and specified in a notice of meeting given by or at the direction of the Board, (ii) brought before the meeting by or at the direction of the Board (or a committee thereof) or (iii) otherwise properly brought before the meeting by a stockholder who (A) is a stockholder of record of the Corporation (and, with respect to any beneficial owner, if different, on whose behalf such business is proposed, only if such beneficial owner was the beneficial owner of shares of the Corporation) at the time of giving the notice provided for in this Section 2.4 through the time of the meeting, (B) is entitled to vote at the meeting and (C) has complied with this Section 2.4 as to such business. Except for proposals properly made in accordance with Rule 14a-8 under the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder (as so amended and inclusive of such rules and regulations, the "Exchange Act"), and included in the notice of meeting given by or at the direction of the Board, the foregoing clause (iii) shall be the exclusive means for a stockholder to propose business to be brought before an annual meeting of the stockholders. Stockholders shall not be permitted to propose business to be brought before a special meeting of the stockholders, and the only matters that may be brought before a special meeting are the matters specified in the notice of meeting given by or at the direction of the person calling the meeting pursuant to Section 2.3 of these bylaws. Stockholders seeking to nominate persons for election to the Board must comply with Section 2.5 of these bylaws, and this Section 2.4 shall not be applicable to nominations except as expressly provided in Section 2.5 of these bylaws.

(b) Without qualification, for business to be properly brought before an annual meeting by a stockholder pursuant to clause (iii) of the second sentence of Section 2.4(a) of these bylaws, the stockholder must (i) provide Timely Notice (as defined below) thereof in writing and in proper form to the secretary of the Corporation and (ii) provide any updates or supplements to such notice at the times and in the forms required by this Section 2.4. To be timely, a stockholder's notice must be delivered to, or mailed and received by, the secretary of the Corporation at the principal executive offices of the Corporation not later than the close of business on the ninetieth (90th) day or earlier than the one hundred twentieth (120th) day prior to the first anniversary of the preceding year's annual meeting; *provided*, *however*, that, if the date of the annual meeting is more than thirty (30) days before or more than sixty (60) days after such anniversary date, notice by the stockholder to be timely must be so delivered, or mailed and received, not earlier than the one hundred twentieth (120th) day prior to such annual meeting and not later than the later of the close of business on the ninetieth (90th) day prior to such annual meeting and the close of business on the tenth (10th) day following the day on which public disclosure of the date of such annual meeting was first made (such notice within such time periods, "Timely Notice"). In no event shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period (or extend any time period) for the giving of Timely Notice as described above.

(c) To be in proper form for purposes of this Section 2.4, a stockholder's notice to the secretary of the Corporation shall set forth:

(i) As to each Proposing Person (as defined below), (A) the name and address of such Proposing Person (including, without limitation, if applicable, the name and address that appear on the Corporation's books and records), (B) the class or series and number of shares of the Corporation that are, directly or indirectly, owned of record or beneficially owned (within the meaning of Rule 13d-3 under the Exchange Act) by such Proposing Person, except that such Proposing Person shall in all events be deemed to beneficially own any shares of any class or series of the Corporation as to which such Proposing Person has a right to acquire beneficial ownership at any time in the future and (C) any pledge by such Proposing Person with respect to any securities of the Corporation (the disclosures to be made pursuant to the foregoing clauses (A) through (C) are referred to as "Stockholder Information");

(ii) As to each Proposing Person, (A) any derivative, swap or other transaction or series of transactions engaged in, directly or indirectly, by such Proposing Person, the purpose or effect of which is to give such Proposing Person economic risk similar to ownership of shares of any class or series of the Corporation, including, without limitation, due to the fact that the value of such derivative, swap or other transactions are determined by reference to the price, value or volatility of any shares of any class or series of the Corporation, or which derivative, swap or other transactions provide, directly or indirectly, the opportunity to profit from any increase in the price or value of shares of any class or series of the Corporation ("Synthetic Equity Interests"), which Synthetic Equity Interests shall be disclosed without regard to whether (x) the derivative, swap or other transactions convey any voting rights in such shares to such Proposing Person, (y) the derivative, swap or other transactions are required to be, or are capable of being, settled through delivery of such shares or (z) such Proposing Person may have entered into other transactions that hedge or mitigate the economic effect of such derivative, swap or other transactions, (B) any proxy (other than a revocable proxy or consent given in response to a solicitation made pursuant to, and in accordance with, Section 14(a) of the Exchange Act by way of a solicitation statement filed on Schedule 14A), agreement, arrangement, understanding or relationship pursuant to which such Proposing Person has or shares a right to vote any shares of any class or series of the Corporation, (C) any agreement, arrangement, understanding or relationship, including, without limitation, any repurchase or similar so-called "stock borrowing" agreement or arrangement, engaged in, directly or indirectly, by such Proposing Person, the purpose or effect of which is to mitigate loss to, reduce the economic risk (of ownership or otherwise) of shares of any class or series of the Corporation by, manage the risk of share price changes for, or increase or decrease the voting power of, such Proposing Person with respect to the shares of any class or series of the Corporation, or which provides, directly or indirectly, the opportunity to profit from any decrease in the price or value of the shares of any class or series of the Corporation ("Short Interests"), (D) any rights to dividends on the shares of any class or series of the Corporation owned beneficially by such Proposing Person that are separated or separable from the underlying shares of the Corporation, (E) any performance related fees (other than an asset based fee) that

such Proposing Person is entitled to based on any increase or decrease in the price or value of shares of any class or series of the Corporation, or any Synthetic Equity Interests or Short Interests, if any, (F) if such Proposing Person is not a natural person, the identity of the natural person or persons associated with such Proposing Person primarily responsible for the formulation of and decision to propose the business to be brought before the meeting (such person or persons, the "Responsible Person"), the manner in which such Responsible Person was selected, any fiduciary duties owed by such Responsible Person to the equity holders or other beneficiaries of such Proposing Person and any substantial interest of such Responsible Person in the business brought before the meeting that is not shared generally by any other record or beneficial holder of the shares of any class or series of the Corporation, (G) any significant equity interests or any Synthetic Equity Interests or Short Interests in any Principal Competitor (as defined below) held by such Proposing Person, (H) any direct or known indirect interest of such Proposing Person in any contract with the Corporation, any affiliate of the Corporation or any Principal Competitor (including, without limitation, in any such case, any employment agreement, collective bargaining agreement or consulting agreement), (I) any pending or threatened litigation in which such Proposing Person is a party involving the Corporation or any of its officers or directors, or any affiliate of the Corporation, (J) any transaction material to such Proposing Person occurring during the prior twelve months between such Proposing Person, on the one hand, and the Corporation, any affiliate of the Corporation or any Principal Competitor, on the other hand and (K) any other information relating to such Proposing Person that would be required to be disclosed in a proxy statement or other filing required to be made in connection with solicitations of proxies or consents by such Proposing Person in support of the business proposed to be brought before the meeting pursuant to Section 14(a) of the Exchange Act (the disclosures to be made pursuant to the foregoing clauses (A) through (K) are referred to as "Disclosable Interests"); *provided*, *however*, that Disclosable Interests shall not include any such disclosures with respect to the ordinary course business activities of any broker, dealer, commercial bank, trust company or other nominee who is a Proposing Person solely as a result of being the stockholder directed to prepare and submit the notice required by these bylaws on behalf of a beneficial owner; and

(iii) As to each item of business that the stockholder proposes to bring before the annual meeting, (A) a reasonably brief description of the business desired to be brought before the annual meeting, the reasons for conducting such business at the annual meeting and any material interest in such business of each Proposing Person, (B) the text of the proposal or business (including, without limitation, the text of any resolutions proposed for consideration and in the event that such business includes a proposal to amend the bylaws of the Corporation, the language of the proposed amendment), (C) a reasonably detailed description of all agreements, arrangements and understandings between or among any of the Proposing Persons or between or among any Proposing Person and any other person or entity (including, without limitation, their names) with respect to the proposal of such business by such stockholder, (D) a representation that the

stockholder is a holder of record of stock of the Corporation entitled to vote at such meeting and intends to appear in person or by proxy at the meeting to propose such business, (E) a representation whether the Proposing Person intends or is part of a group which intends (1) to deliver a proxy statement and/or form of proxy to holders of at least the percentage of the Corporation's outstanding capital stock required to approve or adopt the proposal and/or (2) otherwise to solicit proxies or votes from stockholders in support of such proposal and (F) any other information relating to such item of business that would be required to be disclosed in a proxy statement or other filing required to be made in connection with solicitations of proxies in support of the business proposed to be brought before the meeting pursuant to Section 14(a) of the Exchange Act; *provided*, *however*, that the disclosures required by this paragraph (c)(iii) shall not include any disclosures with respect to any broker, dealer, commercial bank, trust company or other nominee who is a Proposing Person solely as a result of being the stockholder directed to prepare and submit the notice required by these bylaws on behalf of a beneficial owner.

(d) For purposes of this Section 2.4, the term "Proposing Person" shall mean (i) the stockholder of record providing the notice of business proposed to be brought before an annual meeting, (ii) the beneficial owner or beneficial owners, if different, on whose behalf the notice of the business proposed to be brought before the annual meeting is made, (iii) any affiliate or associate (each within the meaning of Rule 12b-2 under the Exchange Act for the purposes of these bylaws) of such stockholder or beneficial owner and (iv) any other person or entity who is a member of a "group" (as such term is used in Rule 13d-5 under the Exchange Act) with such stockholder or beneficial owner.

(e) For purposes of this Section 2.4, the term "Principal Competitor" shall mean any competitor of the Corporation identified in Part I, Item 1 of the annual report on Form 10-K or amendment thereto most recently filed by the Corporation with the Securities and Exchange Commission or in Item 8.01 of any current report on Form 8-K filed by the Corporation with the Securities and Exchange Commission thereafter but prior to the tenth (10th) day before the deadline for a stockholder's notice under Section 2.4 or Section 2.5 these bylaws.

(f) A stockholder providing notice of business proposed to be brought before an annual meeting shall further update and supplement such notice, if necessary, so that the information provided or required to be provided in such notice pursuant to this Section 2.4 shall be true and correct as of the record date for determining stockholders entitled to notice of the annual meeting and as of the date that is ten (10) business days prior to the meeting or any adjournment or postponement thereof, and such update and supplement shall be delivered to, or mailed and received by, the secretary of the Corporation at the principal executive offices of the Corporation not later than five (5) business days after the record date for determining stockholders entitled to notice of the annual meeting (in the case of the update and supplement required to be made as of the record date), and not later than eight (8) business days prior to the date for the meeting or, if practicable, any adjournment or postponement thereof (and, if not practicable, on the first practicable date prior to the date to which the meeting has been adjourned or postponed) (in the case of the update and supplement required to be made as of ten (10) business days prior to the meeting or any adjournment or postponement thereof).

(g) Notwithstanding anything in these bylaws to the contrary and except as otherwise expressly provided in any applicable rule or regulation promulgated under the Exchange Act, no business shall be conducted at an annual meeting except in accordance with this Section 2.4. The Board or the presiding officer of an annual meeting of stockholders shall have the power and duty (a) to determine that any business was not properly brought before the meeting in accordance with this Section 2.4 (including whether the stockholder or beneficial owner, if any, on whose behalf the business proposed to be brought before the annual meeting is made, solicited (or is part of a group which solicited) or did not so solicit, as the case may be, proxies or votes in support of such stockholder's business in compliance with such stockholder's representation as required by clause (c)(iii)(E) of this Section 2.4); and (b) if any proposed business was not proposed in compliance with this Section 2.4 to declare to the meeting that any such business not properly brought before the meeting shall not be transacted.

(h) The foregoing notice requirements of this Section 2.4 shall be deemed satisfied by a stockholder with respect to business other than a nomination if the stockholder has notified the Corporation of his, her or its intention to present a proposal at an annual meeting in compliance with applicable rules and regulations promulgated under the Exchange Act and such stockholder's proposal has been included in a proxy statement that has been prepared by the Corporation to solicit proxies for such annual meeting. Nothing in this Section 2.4 shall be deemed to affect the rights of stockholders to request inclusion of proposals in the Corporation's proxy statement pursuant to Rule 14a-8 under the Exchange Act.

(i) For purposes of these bylaws, "public disclosure" shall mean disclosure in a press release issued by the Corporation and reported by a national news service or in a document publicly filed by the Corporation with the Securities and Exchange Commission pursuant to Sections 13, 14 or 15(d) of the Exchange Act.

(j) Notwithstanding the foregoing provisions of this Section 2.4, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) does not appear at the annual meeting to present proposed business, such proposed business shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the Corporation. For purposes of this Section 2.4, except as provided under Rule 14a-8 under the Exchange Act, to be considered a qualified representative of the stockholder, a person must be a duly authorized officer, manager or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the annual meeting and such person must produce such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, at the annual meeting.

(k) Notwithstanding the foregoing provisions of this Section 2.4, a stockholder shall also comply with all applicable requirements of the Exchange Act with respect to the matters set forth in this Section 2.4; provided however, that any references in these bylaws to the Exchange Act are not intended to and shall not limit any requirements applicable to proposals as to any business to be considered pursuant to this Section 2.4 (including paragraph (a)(iii) hereof), and compliance with paragraph (a)(iii) of this Section 2.4 shall be the exclusive means for a stockholder to submit business (other than business brought properly under and in compliance with Rule 14a-8 of the Exchange Act, as may be amended from time to time).

2.5 ADVANCE NOTICE PROCEDURES FOR NOMINATIONS OF DIRECTORS.

(a) Nominations of any person for election to the Board at an annual meeting or at a special meeting (but, in the case of a special meeting, only if the election of directors is a matter specified in the notice of meeting given by or at the direction of the person calling such special meeting) may be made at such meeting only (i) by or at the direction of the Board or any committee thereof, or (ii) by a stockholder who (A) is a stockholder of record of the Corporation (and, with respect to any beneficial owner, if different, on whose behalf such nomination is proposed to be made, only if such beneficial owner was the beneficial owner of shares of the Corporation) at the time of giving the notice provided for in this Section 2.5 through the time of the meeting, (B) is entitled to vote at the meeting and (C) has complied with this Section 2.5 as to such nomination. The foregoing clause (ii) shall be the exclusive means for a stockholder to make any nomination of a person or persons for election to the Board to be considered by the stockholders at an annual meeting or special meeting.

(b) Without qualification, for a stockholder to make any nomination of a person or persons for election to the Board at an annual meeting, the stockholder must (i) provide Timely Notice (as defined in Section 2.4(b) of these bylaws) thereof in writing and in proper form to the secretary of the Corporation and (ii) provide any updates or supplements to such notice at the times and in the forms required by this Section 2.5. Notwithstanding anything in this paragraph to the contrary, in the event that the number of directors to be elected to the Board at an annual meeting is increased effective after the time period for which nominations would otherwise by due under this paragraph (b) and there is no public announcement by the Corporation naming the nominees for the additional directorships at least one hundred (100) days prior to the first anniversary of the preceding year's annual meeting, a stockholder's notice required by paragraph (b) of this Section 2.5 shall also be considered timely, but only with respect to nominees for the additional directorships, if it shall be delivered to the Secretary at the principal executive offices of the Corporation not later than the close of business on the tenth (10th) day following the day on which such public announcement is first made by the Corporation. Without qualification, if the election of directors is a matter specified in the notice of meeting given by or at the direction of the person calling such special meeting, then for a stockholder to make any nomination of a person or persons for election to such position(s) as specified in the notice of the special meeting, the stockholder must (i) provide timely notice thereof in writing and in proper form to the secretary of the Corporation at the principal executive offices of the Corporation and (ii) provide any updates or supplements to such notice at the times and in the forms required by this Section 2.5. To be timely, a stockholder's notice for nominations to be made at a special meeting must be delivered to, or mailed and received by, the secretary of the Corporation at the principal executive offices of the Corporation not earlier than the close of business on the one hundred twentieth (120th) day prior to such special meeting and not later than the later of the close of business on the ninetieth (90th) day prior to such special meeting and the close of business on the tenth (10th) day following the day on which public disclosure (as defined in Section 2.4(i) of these bylaws) of the date of such special meeting was first made. In no event shall any adjournment or postponement of an annual meeting or special meeting or the announcement thereof commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above.

(c) To be in proper form for purposes of this Section 2.5, a stockholder's notice to the secretary of the Corporation shall set forth:

(i) As to each Nominating Person (as defined below), the Stockholder Information (as defined in Section 2.4(c)(i) of these bylaws) except that for purposes of this Section 2.5, the term "Nominating Person" shall be substituted for the term "Proposing Person" in all places it appears in Section 2.4(c)(i);

(ii) As to each Nominating Person, any Disclosable Interests (as defined in Section 2.4(c)(ii), except that for purposes of this Section 2.5 the term "Nominating Person" shall be substituted for the term "Proposing Person" in all places it appears in Section 2.4(c)(ii) and the disclosure in clause (L) of Section 2.4(c)(ii) shall be made with respect to the election of directors at the meeting) *provided*, *however*, that Disclosable Interests shall not include any such disclosures with respect to the ordinary course business activities of any broker, dealer, commercial bank, trust company or other nominee who is a Nominating Person solely as a result of being the stockholder directed to prepare and submit the notice required by these bylaws on behalf of a beneficial owner;

(iii) As to each person whom a Nominating Person proposes to nominate for election as a director, (A) all information with respect to such proposed nominee that would be required to be set forth in a stockholder's notice pursuant to this Section 2.5 if such proposed nominee were a Nominating Person, (B) all information relating to such proposed nominee that is required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for election of directors in a contested election pursuant to Section 14(a) under the Exchange Act (including, without limitation, such proposed nominee's written consent to being named in the proxy statement as a nominee and to serving as a director if elected), (C) a statement whether the proposed nominee, if elected, intends to tender, promptly following such person's failure to receive the required vote for election as a director at any subsequent meeting at which such person is nominated for re-election, a resignation that will become effective upon the acceptance of such resignation by the Board of Directors, (D) a description of all direct and indirect compensation and other material monetary agreements, arrangements and understandings during the past three (3) years, and any other material relationships, between or among any Nominating Person, on the one hand, and each proposed nominee and his or her respective affiliates and associates, on the other hand, including, without limitation, all information that would be required to be disclosed pursuant to Item 404 under Regulation S-K if such Nominating Person were the "registrant" for purposes of such rule and the proposed nominee were a director or executive officer of such registrant (the disclosures to be made pursuant to the foregoing clauses (A) through (D) are referred to as "Nominee Information"), (E) a representation that the Nominating Person is a holder of record of stock of the Corporation entitled to vote at such meeting and intends to appear in person or by proxy at the meeting to propose such nomination, (F) a representation whether the Nominating Person intends or is part of a group which intends (1) to deliver a

proxy statement and/or form of proxy to holders of at least the percentage of the Corporation's outstanding capital stock required to elect the nominee and/or (2) otherwise to solicit proxies or votes from stockholders in support of such nomination and (G) a completed and signed questionnaire, representation and agreement as provided in Section 2.5(g);

(iv) As to each Nominating Person, a representation from such Nominating Person as to whether such Nominating Person intends or is part of a group (as such term is used in Rule 13d-5 under the Exchange Act) that intends to (A) solicit proxies in support of the election of any proposed nominee in accordance with Rule 14a-19 under the Exchange Act or (B) engage in a solicitation (within the meaning of Exchange Act Rule 14a-1(l)) with respect to the nomination of any proposed nominee or proposed business to be considered at the meeting, as applicable, and if so, the name of each participant (as defined in Instruction 3 to Item 4 of Schedule 14A under the Exchange Act) in such solicitation; and

(v) Such other information that the Corporation may require any proposed nominee to furnish (A) as may reasonably be required by the Corporation to determine whether such proposed nominee would be deemed to be an independent director of the Corporation in accordance with the Corporation's Corporate Governance Guidelines or (B) that could be material to a reasonable stockholder's understanding of the independence or lack of independence of such proposed nominee or the suitability of such proposed nominee to serve as a director of the Corporation.

(d) For purposes of this Section 2.5, the term "Nominating Person" shall mean (i) the stockholder of record providing the notice of the nomination proposed to be made at the meeting, (ii) the beneficial owner or beneficial owners, if different, on whose behalf the notice of the nomination proposed to be made at the meeting is made, (iii) any affiliate or associate of such stockholder or beneficial owner and (iv) any other person or entity who is a member of a "group" (as such term is used in Rule 13d-5 under the Exchange Act) with such stockholder or beneficial owner.

(e) A stockholder providing notice of any nomination proposed to be made at a meeting shall further update and supplement such notice, if necessary, so that the information provided or required to be provided in such notice pursuant to this Section 2.5 shall be true and correct as of the record date for determining stockholders entitled to notice of the meeting and as of the date that is ten (10) business days prior to the meeting or any adjournment or postponement thereof, and such update and supplement shall be delivered to, or mailed and received by, the secretary of the Corporation at the principal executive offices of the Corporation not later than five (5) business days after the record date for determining stockholders entitled to notice of the meeting (in the case of the update and supplement required to be made as of the record date), and not later than eight (8) business days prior to the date for the meeting or, if practicable, any adjournment or postponement thereof (and, if not practicable, on the first practicable date prior to the date to which the meeting has been adjourned or postponed) (in the

case of the update and supplement required to be made as of ten (10) business days prior to the meeting or any adjournment or postponement thereof).

(f) Notwithstanding anything in these bylaws to the contrary, no person shall be eligible for election as a director of the Corporation unless nominated in accordance with this Section 2.5, except as otherwise expressly provided in any applicable rule or regulation promulgated under the Exchange Act. The number of proposed nominees a stockholder may include in a notice under this Section 2.5 or nominate for election at a meeting may not exceed the number of directors to be elected at such meeting, and for the avoidance of doubt, no stockholder shall be entitled to make additional or substitute nominations following the expiration of the time periods set forth in Section 2.5(b). The Board or the presiding officer at any meeting of stockholders shall have the power and duty to (a) determine that a nomination was not properly made in accordance with this Section 2.5 (including whether the stockholder or beneficial owner, if any, on whose behalf the nomination was made, solicited or is part of a group which solicited) or did not so solicit, as the case may be, proxies or votes in support of such stockholder's nomination in compliance with such stockholder's representation as required by clause (c)(iii)(E) of this Section 2.5); and (b) if any proposed nomination was not made in compliance with this Section 2.5 to declare such determination to the meeting that the defective nomination shall be disregarded.

(g) To be eligible to be a nominee for election as a director of the Corporation, the proposed nominee must deliver (in accordance with the time periods prescribed for delivery of notice under this Section 2.5) to the secretary of the Corporation at the principal executive offices of the Corporation a written questionnaire with respect to the background and qualification of such proposed nominee (which questionnaire shall be provided by the secretary within ten (10) days after receipt of a written request therefor from the Nominating Person) and a written representation and agreement (in form provided by the secretary within ten (10) days after receipt of a written request therefor from the Nominating Person) that such proposed nominee (i) is not and will not become a party to (A) any agreement, arrangement or understanding with, and has not given any commitment or assurance to, any person or entity as to how such proposed nominee, if elected as a director of the Corporation, will act or vote on any issue or question (a "Voting Commitment") that has not been disclosed to the Corporation or (B) any Voting Commitment that could limit or interfere with such proposed nominee's ability to comply, if elected as a director of the Corporation, with such proposed nominee's fiduciary duties under applicable law, (ii) is not, and will not become a party to, any agreement, arrangement or understanding with any person or entity other than the Corporation with respect to any direct or indirect compensation, reimbursement or indemnification in connection with candidacy, service or action as a director that has not been disclosed to the Corporation and (iii) in such proposed nominee's individual capacity and on behalf of the stockholder (and the beneficial owner, if different, on whose behalf the nomination is made) would be in compliance, if elected as a director of the Corporation, and will comply with applicable publicly disclosed corporate governance, conflict of interest, confidentiality and stock ownership and trading policies and guidelines of the Corporation.

(h) In addition to the requirements of this Section 2.5 with respect to any nomination proposed to be made at a meeting, each Nominating Person shall comply with all applicable requirements of the Exchange Act with respect to any such nominations.

(i) Notwithstanding the foregoing provisions of this Section 2.5, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) does not appear at the meeting to present the proposed nomination, such proposed nomination shall not be considered, notwithstanding that proxies in respect of such vote may have been received by the Corporation. For purposes of this Section 2.5, to be considered a qualified representative of the stockholder, a person must be a duly authorized officer, manager or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting of stockholders and such person must produce such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, at the meeting.

(j) Notwithstanding anything herein to the contrary, if (i) any Nominating Person provides notice pursuant to Rule 14a-19(b) under the Exchange Act with respect to any proposed nominee and (ii) (A) such Nominating Person subsequently either (1) notifies the Corporation that such Nominating Person no longer intends to solicit proxies in support of the election or reelection of such proposed nominee in accordance with Rule 14a-19(b) under the Exchange Act or (2) fails to comply with the requirements of Rule 14a-19(a)(2) or Rule 14a-19(a)(3) under the Exchange Act (or fails to timely provide reasonable evidence sufficient to satisfy the Corporation that such Nominating Person has met the requirements of Rule 14a-19(a)(3) under the Exchange Act in accordance with the following sentence) and (B) no other Nominating Person that has provided notice pursuant to Rule 14a-19(b) under the Exchange Act with respect to such proposed nominee (1) to the Corporation's knowledge based on information provided pursuant to Rule 14a-19 under the Exchange Act or these bylaws, still intends to solicit proxies in support of the election or reelection of such proposed nominee in accordance with Rule 14a-19(b) under the Exchange Act and (2) has complied with the requirements of Rule 14a-19(a)(2) and Rule 14a-19(a)(3) under the Exchange Act and the requirements set forth in the following sentence, then the nomination of such proposed nominee shall be disregarded and no vote on the election of such proposed nominee shall occur (notwithstanding that proxies in respect of such vote may have been received by the Corporation). Upon request by the Corporation, if any Nominating Person provides notice pursuant to Rule 14a-19(b) under the Exchange Act, such Nominating Person shall deliver to the secretary of the Corporation, no later than five (5) business days prior to the applicable meeting date, reasonable evidence that the requirements of Rule 14a-19(a)(3) under the Exchange Act have been satisfied.

2.6 NOTICE OF STOCKHOLDERS' MEETINGS.

Unless otherwise provided by law, the certificate of incorporation or these bylaws, the notice of any meeting of stockholders shall be given in accordance with either Section 2.7 or Section 8.1 of these bylaws not less than ten (10) nor more than sixty (60) days before the date of the meeting to each stockholder entitled to vote at such meeting as of the record date for determining the stockholders entitled to notice of the meeting. The notice shall specify the place, if any, date and hour of the meeting, the record date for determining the stockholders entitled to vote at the meeting (if such date is different from the record date for stockholders entitled to notice of the meeting), the means of remote communication, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called.

2.7 MANNER OF GIVING NOTICE; AFFIDAVIT OF NOTICE.

Notice of any meeting of stockholders shall be deemed given:

(a) if mailed, when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the Corporation's records; or

(b) if electronically transmitted, as provided in Section 8.1 of these bylaws.

An affidavit of the secretary or an assistant secretary of the Corporation or of the transfer agent or any other agent of the Corporation that the notice has been given by mail or by a form of electronic transmission, as applicable, shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

2.8 QUORUM.

Unless otherwise provided by law, the certificate of incorporation or these bylaws, the holders of a majority in voting power of the capital stock issued and outstanding and entitled to vote, present in person, or by remote communication, if applicable, or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders. A quorum, once established at a meeting, shall not be broken by the withdrawal of enough votes to leave less than a quorum. If, however, a quorum is not present or represented at any meeting of the stockholders, then either (a) the chairperson of the meeting or (b) a majority in voting power of the stockholders entitled to vote thereon, present in person, or by remote communication, if applicable, or represented by proxy, shall have power to adjourn the meeting from time to time in the manner provided in Section 2.9 of these bylaws until a quorum is present or represented. At such adjourned meeting at which a quorum is present or represented, any business may be transacted that might have been transacted at the meeting as originally noticed.

2.9 ADJOURNED MEETING; NOTICE.

When a meeting is adjourned to another time or place, unless these bylaws otherwise require, notice need not be given of the adjourned meeting if the time and place, if any, thereof, and the means of remote communication, if any, by which stockholders and proxy holders may be deemed to be present in person or represented by proxy and vote at such adjourned meeting are (a) announced at the meeting at which the adjournment is taken, (b) displayed during the time scheduled for the meeting, on the same electronic network used to enable stockholders and proxy holders to participate in the meeting by means of remote communication, or (c) set forth in the notice of meeting given in accordance with these bylaws. At the adjourned meeting, the Corporation may transact any business which might have been transacted at the original meeting. If the adjournment is for more than thirty (30) days, or if after the adjournment a new record date for determining the stockholders entitled to vote is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the adjourned meeting as of the record date for determining the stockholders entitled to notice of the adjourned meeting.

2.10 CONDUCT OF BUSINESS.

The Board may designate any director or officer of the Corporation to preside over any meeting of the stockholders and act as chairperson of the meeting. The date and time of the opening and the closing of the polls for each matter upon which the stockholders will vote at a meeting shall be announced at the meeting by the person presiding over the meeting. The Board may adopt by resolution such rules and regulations for the conduct of the meeting of stockholders as it shall deem appropriate. Except to the extent inconsistent with such rules and regulations as adopted by the Board, the person presiding over any meeting of stockholders shall have the right and authority to convene and (for any or no reason) to recess and/or adjourn the meeting (whether or not a quorum is present), to prescribe such rules, regulations and procedures (which need not be in writing) and to do all such acts as, in the judgment of such presiding person, are appropriate for the proper conduct of the meeting. Such rules, regulations or procedures, whether adopted by the Board or prescribed by the presiding person of the meeting, may include, without limitation, the following: (a) the establishment of an agenda or order of business for the meeting; (b) rules and procedures for maintaining order at the meeting and the safety of those present (including, without limitation, rules and procedures for removal of disruptive persons from the meeting); (c) limitations on attendance at or participation in the meeting to stockholders entitled to vote at the meeting, their duly authorized and constituted proxies or such other persons as the presiding person of the meeting shall determine; (d) restrictions on entry to the meeting after the time fixed for the commencement thereof; and (e) limitations on the time allotted to questions or comments by participants. The presiding person at any meeting of stockholders, in addition to making any other determinations that may be appropriate to the conduct of the meeting (including, without limitation, determinations with respect to the administration and/or interpretation of any of the rules, regulations or procedures of the meeting, whether adopted by the Board or prescribed by the person presiding over the meeting), shall, if the facts warrant, determine and declare to the meeting that a matter or business was not properly brought before the meeting and if such presiding person should so determine, such presiding person shall so declare to the meeting and any such matter or business not properly brought before the meeting shall not be transacted or considered. Unless and to the extent determined by the Board or the person presiding over the meeting, meetings of stockholders shall not be required to be held in accordance with the rules of parliamentary procedure.

2.11 VOTING.

The stockholders entitled to vote at any meeting of stockholders shall be determined in accordance with the provisions of Section 2.13 of these bylaws, subject to Section 217 (relating to voting rights of fiduciaries, pledgors and joint owners of stock) and Section 218 (relating to voting trusts and other voting agreements) of the DGCL.

Except as may be otherwise provided in the certificate of incorporation or these bylaws, each stockholder shall be entitled to one (1) vote for each share of capital stock held by such stockholder.

At all duly called or convened meetings of stockholders, at which a quorum is present, for the election of directors, a plurality of the votes cast shall be sufficient to elect a director. All other elections and questions presented to the stockholders at a duly called or convened meeting, at which a quorum is present, shall, unless a different or minimum vote is required by the

certificate of incorporation, these bylaws, the rules or regulations of any stock exchange applicable to the Corporation, or any law or regulation applicable to the Corporation or its securities, in which case such different or minimum vote shall be the applicable vote on the matter, be decided by the affirmative vote of the holders of a majority in voting power of the votes cast affirmatively or negatively (excluding abstentions) at the meeting by the holders entitled to vote thereon.

2.12 STOCKHOLDER ACTION BY WRITTEN CONSENT WITHOUT A MEETING.

Any action required or permitted to be taken by the stockholders of the Corporation must be effected at a duly called annual or special meeting of stockholders of the Corporation and may not be effected by any consent in writing by such stockholders.

2.13 RECORD DATE FOR STOCKHOLDER NOTICE; VOTING.

In order that the Corporation may determine the stockholders entitled to notice of any meeting of stockholders or any adjournment thereof, the Board may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board, and which record date shall, unless otherwise required by law, not be more than sixty (60) nor less than ten (10) days before the date of such meeting. If the Board so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination. If no record date is fixed by the Board, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; *provided*, *however*, that the Board may fix a new record date for determination of stockholders entitled to vote at the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance herewith at the adjourned meeting.

In order that the Corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board may fix a record date, which shall not be more than sixty (60) days prior to such other action. If no such record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board adopts the resolution relating thereto.

2.14 PROXIES.

Each stockholder entitled to vote at a meeting of stockholders may authorize another person or persons to act for such stockholder by proxy, but no such proxy shall be voted or acted

upon after one (1) year from its date, unless the proxy provides for a longer period. The revocability of a proxy that states on its face that it is irrevocable shall be governed by the provisions of Section 212 of the DGCL. A proxy may be in the form of a telegram, cablegram or other means of electronic transmission which sets forth or is submitted with information from which it can be determined that the telegram, cablegram or other means of electronic transmission was authorized by the stockholder. Any stockholder directly or indirectly soliciting proxies from other stockholders may use any proxy card color other than white, which shall be reserved for exclusive use of the Board.

2.15 LIST OF STOCKHOLDERS ENTITLED TO VOTE.

The Corporation shall prepare, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting (*provided*, *however*, if the record date for determining the stockholders entitled to vote is less than ten (10) days before the date of the meeting, the list shall reflect the stockholders entitled to vote as of the tenth day before the date of the meeting), arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. The Corporation shall not be required to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting for a period of at least ten (10) days prior to the meeting: (a) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (b) during ordinary business hours, at the Corporation's principal executive office. In the event that the Corporation determines to make the list available on an electronic network, the Corporation may take reasonable steps to ensure that such information is available only to stockholders of the Corporation. Except as otherwise provided by law, the stock ledger shall be the only evidence as to the identity of the stockholders entitled to vote in person or by proxy and the number of shares held by each of them, and as to the stockholders entitled to examine the list of stockholders.

2.16 POSTPONEMENT, ADJOURNMENT AND CANCELLATION OF MEETING.

Any previously scheduled annual or special meeting of the stockholders may be postponed or adjourned, and any previously scheduled annual or special meeting of the stockholders may be canceled, by resolution of the Board.

2.17 INSPECTORS OF ELECTION.

Before any meeting of stockholders, the Board shall appoint an inspector or inspectors of election to act at the meeting or its adjournment or postponement and make a written report thereof. The number of inspectors shall be either one (1) or three (3). If any person appointed as inspector fails to appear or fails or refuses to act, then the chairperson of the meeting may, and upon the request of any stockholder or a stockholder's proxy shall, appoint a person to fill that vacancy. Unless otherwise required by law, inspectors may be officers, employees or agents of the Corporation. Such inspectors shall have the duties prescribed by law. Each inspector, before entering upon the discharge of his or her duties, shall take and sign an oath to execute faithfully the duties of inspector with strict impartiality and according to the best of his or her ability. If there are three (3) inspectors of election, the decision, act or certificate of a majority is effective

in all respects as the decision, act or certificate of all. Any report or certificate made by the inspectors of election is prima facie evidence of the facts stated therein.

ARTICLE III - DIRECTORS

3.1 POWERS.

Subject to the provisions of the DGCL and any limitations in the certificate of incorporation, the business and affairs of the Corporation shall be managed and all corporate powers shall be exercised by or under the direction of the Board.

3.2 NUMBER OF DIRECTORS.

The authorized number of directors shall be determined from time to time by resolution of the Board, provided the Board shall consist of at least one (1) member. No reduction of the authorized number of directors shall have the effect of removing any director before that director's term of office expires.

3.3 ELECTION, QUALIFICATION AND TERM OF OFFICE OF DIRECTORS.

Except as provided in Section 3.4 of these bylaws, each director, including, without limitation, a director elected to fill a vacancy, shall hold office until the expiration of the term for which elected and until such director's successor is elected and qualified or until such director's earlier death, resignation or removal. Directors need not be stockholders unless so required by the certificate of incorporation or these bylaws. The Corporation may also have, at the discretion of the Board, a chairperson of the Board and a vice chairperson of the Board. The certificate of incorporation or these bylaws may prescribe other qualifications for directors.

3.4 RESIGNATION AND VACANCIES.

Any director may resign at any time upon notice given in writing or by electronic transmission to the chairperson of the Board or the Corporation's chief executive officer, president or secretary. When one or more directors so resigns and the resignation is effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each director so chosen shall hold office as provided in this section in the filling of other vacancies.

Unless otherwise provided in the certificate of incorporation or these bylaws, vacancies and newly created directorships resulting from any increase in the authorized number of directors shall, unless the Board determines by resolution that any such vacancies or newly created directorships shall be filled by stockholders, be filled only by a majority of the directors then in office, although less than a quorum, or by a sole remaining director. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified. A vacancy in the Board shall be deemed to exist under these bylaws in the case of the death, removal or resignation of any director.

3.5 PLACE OF MEETINGS; MEETINGS BY TELEPHONE.

The Board may hold meetings, both regular and special, either within or outside the State of Delaware.

Unless otherwise restricted by the certificate of incorporation or these bylaws, members of the Board, or any committee designated by the Board, may participate in a meeting of the Board, or any committee, by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting pursuant to this bylaw shall constitute presence in person at the meeting.

3.6 REGULAR MEETINGS.

Regular meetings of the Board may be held without notice at such time and at such place as shall from time to time be determined by the Board; *provided* that any director who is absent when such determination is made shall be given notice of the determination. A regular meeting of the Board may be held without notice immediately after and at the same place as the annual meeting of stockholders.

3.7 SPECIAL MEETINGS; NOTICE.

Special meetings of the Board for any purpose or purposes may be called at any time by the chairperson of the Board, the chief executive officer, the president, the secretary or a majority of the authorized number of directors.

Notice of the time and place of special meetings shall be:

(a) delivered personally by hand, by courier or by telephone;

(b) sent by United States first-class mail, postage prepaid;

(c) sent by facsimile; or

(d) sent by electronic mail, electronic transmission or other similar means,

directed to each director at that director's address, telephone number, facsimile number or electronic mail or other electronic address, as the case may be, as shown on the Corporation's records.

If the notice is (a) delivered personally by hand, by courier or by telephone, (b) sent by facsimile or (c) sent by electronic mail or electronic transmission, it shall be delivered or sent at least twenty-four (24) hours before the time of the holding of the meeting. If the notice is sent by United States mail, it shall be deposited in the United States mail at least four (4) days before the time of the holding of the meeting. Any oral notice may be communicated to the director. The notice need not specify the place of the meeting (if the meeting is to be held at the Corporation's principal executive office) nor the purpose of the meeting.

3.8 QUORUM.

The greater of (a) a majority of the directors at any time in office and (b) one-third of the number of directors established by the Board pursuant to Section 3.2 of these bylaws shall constitute a quorum of the Board for the transaction of business. The vote of a majority of the directors present at any meeting at which a quorum is present shall be the act of the Board, except as may be otherwise specifically provided by statute, the certificate of incorporation or these bylaws. If a quorum is not present at any meeting of the Board, then the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present.

3.9 BOARD ACTION BY CONSENT WITHOUT A MEETING.

Unless otherwise restricted by the certificate of incorporation or these bylaws, any action required or permitted to be taken at any meeting of the Board, or of any committee thereof, may be taken without a meeting if all members of the Board or committee, as the case may be, consent thereto in writing or by electronic transmission and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the Board or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

3.10 FEES AND COMPENSATION OF DIRECTORS.

Unless otherwise restricted by the certificate of incorporation or these bylaws, the Board shall have the authority to fix the compensation of directors.

3.11 REMOVAL OF DIRECTORS.

Subject to the rights of the holders of the shares of any series of preferred stock of the Corporation, the Board or any individual director may be removed from office only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock of the Corporation entitled to vote thereon.

ARTICLE IV - COMMITTEES

4.1 COMMITTEES OF DIRECTORS.

The Board may designate one (1) or more committees, each committee to consist of one (1) or more of the directors of the Corporation. The Board may designate one (1) or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the Board or in these bylaws, shall have and may exercise all the powers and authority of the Board in the management of the business and affairs of the Corporation, and may authorize the seal of the Corporation to be affixed to all papers that may require it; but no such committee shall have the

power or authority to (a) approve or adopt, or recommend to the stockholders, any action or matter (other than the election or removal of directors) expressly required by the DGCL to be submitted to stockholders for approval, or (b) adopt, amend or repeal any bylaw of the Corporation.

4.2 COMMITTEE MINUTES.

Each committee shall keep regular minutes of its meetings and report the same to the Board when required.

4.3 MEETINGS AND ACTION OF COMMITTEES.

Meetings and actions of committees shall be governed by, and held and taken in accordance with, the provisions of:

(a) Section 3.5 of these bylaws (place of meetings and meetings by telephone);

(b) Section 3.6 of these bylaws (regular meetings);

(c) Section 3.7 of these bylaws (special meetings and notice);

(d) Section 3.8 of these bylaws (quorum);

(e) Section 7.12 of these bylaws (waiver of notice); and

(f) Section 3.9 of these bylaws (action without a meeting),

with such changes in the context of those bylaws as are necessary to substitute the committee and its members for the Board and its members. However:

(i) the time of regular meetings of committees may be determined either by resolution of the Board or by resolution of the committee;

(ii) special meetings of committees may also be called by resolution of the Board; and

(iii) notice of special meetings of committees shall also be given to all alternate members, who shall have the right to attend all meetings of the committee. The Board may adopt rules for the governance of any committee not inconsistent with the provisions (or any part thereof) of these bylaws.

ARTICLE V - OFFICERS

5.1 OFFICERS.

The officers of the Corporation shall be a president and a secretary. The Corporation may also have, at the discretion of the Board, a chief executive officer, a chief financial officer or treasurer, one (1) or more vice presidents, one (1) or more assistant vice presidents, one (1) or more assistant treasurers, one (1) or more assistant secretaries, and any such other officers as

may be appointed in accordance with the provisions of these bylaws. Any number of offices may be held by the same person.

5.2 APPOINTMENT OF OFFICERS.

The Board shall appoint the officers of the Corporation, except such officers as may be appointed in accordance with the provisions of Section 5.3 of these bylaws, subject to the rights, if any, of an officer under any contract of employment.

5.3 SUBORDINATE OFFICERS.

The Board may appoint, or empower the chief executive officer or, in the absence of a chief executive officer, the president, to appoint, such other officers and agents as the business of the Corporation may require. Each of such officers shall hold office for such period, as is provided in these bylaws or as the Board may from time to time determine.

5.4 REMOVAL AND RESIGNATION OF OFFICERS.

Subject to the rights, if any, of an officer under any contract of employment, any officer may be removed, either with or without cause, by the Board at any regular or special meeting of the Board or, except in the case of an officer chosen by the Board, by any officer upon whom such power of removal may be conferred by the Board.

Any officer may resign at any time by giving written notice to the Corporation. Any resignation shall take effect at the date of the receipt of that notice or at any later time specified in that notice. Unless otherwise specified in the notice of resignation, the acceptance of the resignation shall not be necessary to make it effective. Any resignation is without prejudice to the rights, if any, of the Corporation under any contract to which the officer is a party.

5.5 VACANCIES IN OFFICES.

Any vacancy occurring in any office of the Corporation shall be filled by the Board or as provided in Section 5.3 of these bylaws.

5.6 REPRESENTATION OF SHARES OF OTHER ENTITIES.

The chairperson of the Board, the president, any vice president, the treasurer, the secretary or assistant secretary of this Corporation, or any other person authorized by the Board or the president or a vice president, is authorized to vote, represent and exercise on behalf of this Corporation all rights incident to any and all securities of any other entity or entities standing in the name of this Corporation. The authority granted herein may be exercised either by such person directly or by any other person authorized to do so by proxy or power of attorney duly executed by such person having the authority.

5.7 AUTHORITY AND DUTIES OF OFFICERS.

All officers of the Corporation shall respectively have such authority and perform such duties in the management of the business of the Corporation as may be designated from time to

time by the Board and, to the extent not so provided, as generally pertain to their respective offices, subject to the control of the Board.

ARTICLE VI - RECORDS AND REPORTS

6.1 MAINTENANCE OF RECORDS.

Subject to applicable law, the Corporation shall, either at its principal executive office or at such place or places as designated by the Board, keep a record of its stockholders listing their names and addresses and the number and class of shares held by each stockholder, a copy of these bylaws as amended to date, accounting books and other records.

ARTICLE VII - GENERAL MATTERS

7.1 EXECUTION OF CORPORATE CONTRACTS AND INSTRUMENTS.

The Board, except as otherwise provided in these bylaws, may authorize any officer or officers, or agent or agents, to enter into any contract or execute any instrument in the name of and on behalf of the Corporation; such authority may be general or confined to specific instances. Unless so authorized or ratified by the Board or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the Corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

7.2 STOCK CERTIFICATES; PARTLY PAID SHARES.

The shares of the Corporation shall be represented by certificates provided that the Board may provide by resolution or resolutions that some or all of any or all classes or series of stock shall be uncertificated shares. Certificates for the shares of stock, if any, shall be in such form as is consistent with the certificate of incorporation and applicable law. Every holder of stock represented by a certificate shall be entitled to have a certificate signed by, or in the name of the Corporation by any two authorized officers of the Corporation representing the number of shares registered in certificate form. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate has ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if he were such officer, transfer agent or registrar at the date of issue.

The Corporation may issue the whole or any part of its shares as partly paid and subject to call for the remainder of the consideration to be paid therefor. Upon the face or back of each stock certificate issued to represent any such partly paid shares, or upon the books and records of the Corporation in the case of uncertificated partly paid shares, the total amount of the consideration to be paid therefor and the amount paid thereon shall be stated. Upon the declaration of any dividend on fully paid shares, the Corporation shall declare a dividend upon partly paid shares of the same class, but only upon the basis of the percentage of the consideration actually paid thereon.

7.3 MULTIPLES CLASSES OR SERIES OF STOCK.

If the Corporation is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate that the Corporation shall issue to represent such class or series of stock; *provided*, *however*, that, except as otherwise provided in Section 202 of the DGCL, in lieu of the foregoing requirements, there may be set forth on the face or back of the certificate that the Corporation shall issue to represent such class or series of stock a statement that the Corporation will furnish without charge to each stockholder who so requests the powers, the designations, the preferences and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Within a reasonable time after the issuance or transfer of uncertificated stock, the Corporation shall send to the registered owner thereof a written notice containing the information required to be set forth or stated on certificates pursuant to the DGCL or a statement that the Corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

7.4 LOST CERTIFICATES.

Except as provided in this Section 7.4, no new certificates for shares shall be issued to replace a previously issued certificate unless the latter is surrendered to the Corporation in accordance with applicable law. The Corporation may issue a new certificate of stock or uncertificated shares in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the Corporation may require the owner of the lost, stolen or destroyed certificate, or such owner's legal representative, to give the Corporation a bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares.

7.5 CONSTRUCTION; DEFINITIONS.

Unless the context requires otherwise, the general provisions, rules of construction and definitions in the DGCL shall govern the construction of these bylaws. Without limiting the generality of this provision, the singular number includes the plural, the plural number includes the singular, and the term "person" includes both a corporation and a natural person.

7.6 DIVIDENDS.

The Board, subject to any restrictions contained in either (a) the DGCL or (b) the certificate of incorporation, may declare and pay dividends upon the shares of its capital stock. Dividends may be paid in cash, in property or in shares of the Corporation's capital stock.

The Board may set apart out of any of the funds of the Corporation available for dividends a reserve or reserves for any proper purpose and may abolish any such reserve. Such

purposes shall include but not be limited to equalizing dividends, repairing or maintaining any property of the Corporation, and meeting contingencies.

7.7 FISCAL YEAR.

The fiscal year of the Corporation shall be fixed by resolution of the Board and may be changed by the Board.

7.8 SEAL.

The Corporation may adopt a corporate seal, which shall be adopted and which may be altered by the Board. The Corporation may use the corporate seal by causing it or a facsimile thereof to be impressed or affixed or in any other manner reproduced.

7.9 TRANSFER OF STOCK.

Shares of the Corporation shall be transferable in the manner prescribed by law and in these bylaws. Shares of stock of the Corporation shall be transferred on the books of the Corporation only by the holder of record thereof or by such holder's attorney duly authorized in writing, upon surrender to the Corporation of the certificate or certificates representing such shares endorsed by the appropriate person or persons (or by delivery of duly executed instructions with respect to uncertificated shares), with such evidence of the authenticity of such endorsement or execution, transfer, authorization and other matters as the Corporation may reasonably require, and accompanied by all necessary stock transfer stamps. To the fullest extent permitted by law, no transfer of stock shall be valid as against the Corporation for any purpose until it shall have been entered in the stock records of the Corporation by an entry showing the names of the persons from and to whom it was transferred.

7.10 STOCK TRANSFER AGREEMENTS.

The Corporation shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the Corporation to restrict the transfer of shares of stock of the Corporation of any one or more classes owned by such stockholders in any manner not prohibited by the DGCL.

7.11 REGISTERED STOCKHOLDERS.

The Corporation, to the fullest extent permitted by law,:

(a) shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends and to vote as such owner;

(b) shall be entitled to hold liable for calls and assessments the person registered on its books as the owner of shares; and

(c) shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of another person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.

7.12 WAIVER OF NOTICE.

Whenever notice is required to be given under any provision of the DGCL, the certificate of incorporation or these bylaws, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time of the event for which notice is to be given, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders need be specified in any written waiver of notice or any waiver by electronic transmission unless so required by the certificate of incorporation or these bylaws.

ARTICLE VIII - NOTICE BY ELECTRONIC TRANSMISSION

8.1 NOTICE BY ELECTRONIC TRANSMISSION.

Without limiting the manner by which notice otherwise may be given effectively to stockholders pursuant to the DGCL, the certificate of incorporation or these bylaws, any notice to stockholders given by the Corporation under any provision of the DGCL, the certificate of incorporation or these bylaws shall be effective if given by a form of electronic transmission consented to by the stockholder to whom the notice is given. Any such consent shall be revocable by the stockholder by written notice to the Corporation. Any such consent shall be deemed revoked if:

(a) the Corporation is unable to deliver by electronic transmission two (2) consecutive notices given by the Corporation in accordance with such consent; and

(b) such inability becomes known to the secretary or an assistant secretary of the Corporation or to the transfer agent, or other person responsible for the giving of notice.

However, the inadvertent failure to treat such inability as a revocation shall not invalidate any meeting or other action.

Any notice given pursuant to the preceding paragraph shall be deemed given:

(a) if by facsimile telecommunication, when directed to a number at which the stockholder has consented to receive notice;

(b) if by electronic mail, when directed to an electronic mail address at which the stockholder has consented to receive notice;

(c) if by a posting on an electronic network together with separate notice to the stockholder of such specific posting, upon the later of (i) such posting and (ii) the giving of such separate notice; and

(d) if by any other form of electronic transmission, when directed to the stockholder.

An affidavit of the secretary or an assistant secretary of the Corporation or of the transfer agent or other agent of the Corporation that the notice has been given by a form of electronic transmission shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

8.2 DEFINITION OF ELECTRONIC TRANSMISSION.

For the purposes of these bylaws, an "electronic transmission" means any form of communication, not directly involving the physical transmission of paper, that creates a record that may be retained, retrieved and reviewed by a recipient thereof, and that may be directly reproduced in paper form by such a recipient through an automated process.

ARTICLE IX - INDEMNIFICATION AND ADVANCEMENT

9.1 ACTIONS, SUITS AND PROCEEDINGS OTHER THAN BY OR IN THE RIGHT OF THE CORPORATION.

The Corporation shall indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the Corporation) by reason of the fact that he or she is or was, or has agreed to become, a director or officer of the Corporation, or, while a director or officer of the Corporation, is or was serving, or has agreed to serve, at the request of the Corporation, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including, without limitation, any employee benefit plan) (all such persons being referred to hereafter as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including, without limitation, attorneys' fees), liabilities, losses, judgments, fines (including, without limitation, excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974), and amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if Indemnitee acted in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that Indemnitee did not act in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that his or her conduct was unlawful.

9.2 ACTIONS OR SUITS BY OR IN THE RIGHT OF THE CORPORATION.

The Corporation shall indemnify any Indemnitee who was or is a party to or threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the Corporation to procure a judgment in its favor by reason of the fact that Indemnitee is or was, or has agreed to become, a director or officer of the Corporation, or, while a director or officer of the Corporation, is or was serving, or has agreed to serve, at the request of the Corporation, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another

corporation, partnership, joint venture, trust or other enterprise (including, without limitation, any employee benefit plan), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including, without limitation, attorneys' fees) actually and reasonably incurred by or on behalf of Indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if Indemnitee acted in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, except that no indemnification shall be made under this Section 9.2 in respect of any claim, issue or matter as to which Indemnitee shall have been adjudged to be liable to the Corporation, unless, and only to the extent, that the Court of Chancery of Delaware or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of such liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnity for such expenses (including, without limitation, attorneys' fees) which the Court of Chancery of Delaware or such other court shall deem proper.

9.3 INDEMNIFICATION FOR EXPENSES OF SUCCESSFUL PARTY.

Notwithstanding any other provisions of this Article IX, to the extent that an Indemnitee has been successful, on the merits or otherwise, in defense of any action, suit or proceeding referred to in Sections 9.1 and 9.2 of these bylaws, or in defense of any claim, issue or matter therein, or on appeal from any such action, suit or proceeding, Indemnitee shall be indemnified to the fullest extent permitted by law against all expenses (including, without limitation, attorneys' fees) actually and reasonably incurred by or on behalf of Indemnitee in connection therewith.

9.4 NOTIFICATION AND DEFENSE OF CLAIM.

As a condition precedent to an Indemnitee's right to be indemnified, such Indemnitee must notify the Corporation in writing as soon as practicable of any action, suit, proceeding or investigation involving such Indemnitee for which indemnity will or could be sought. With respect to any action, suit, proceeding or investigation of which the Corporation is so notified, the Corporation will be entitled to participate therein at its own expense and/or to assume the defense thereof at its own expense, with legal counsel reasonably acceptable to Indemnitee. After notice from the Corporation to Indemnitee of its election so to assume such defense, the Corporation shall not be liable to Indemnitee for any legal or other expenses subsequently incurred by Indemnitee in connection with such action, suit, proceeding or investigation, other than as provided below in this Section 9.4. Indemnitee shall have the right to employ his or her own counsel in connection with such action, suit, proceeding or investigation, but the fees and expenses of such counsel incurred after notice from the Corporation of its assumption of the defense thereof shall be at the expense of Indemnitee unless (a) the employment of counsel by Indemnitee has been authorized by the Corporation, (b) counsel to Indemnitee shall have reasonably concluded that there may be a conflict of interest or position on any significant issue between the Corporation and Indemnitee in the conduct of the defense of such action, suit, proceeding or investigation or (c) the Corporation shall not in fact have employed counsel to assume the defense of such action, suit, proceeding or investigation, in each of which cases the fees and expenses of counsel for Indemnitee shall be at the expense of the Corporation, except as otherwise expressly provided by this Article IX. The Corporation shall not be entitled, without the consent of Indemnitee, to assume the defense of any claim brought by or in the right of the

Corporation or as to which counsel for Indemnitee shall have reasonably made the conclusion provided for in clause (b) above. The Corporation shall not be required to indemnify Indemnitee under this Article IX for any amounts paid in settlement of any action, suit, proceeding or investigation effected without its written consent. The Corporation shall not settle any action, suit, proceeding or investigation in any manner which would impose any penalty or limitation on Indemnitee without Indemnitee's written consent. Neither the Corporation nor Indemnitee will unreasonably withhold or delay its consent to any proposed settlement.

9.5 ADVANCE OF EXPENSES.

Subject to the provisions of Sections 9.4 and 9.6 of these bylaws, in the event of any threatened or pending action, suit, proceeding or investigation of which the Corporation receives notice under this Article IX, any expenses (including, without limitation, attorneys' fees) incurred by or on behalf of Indemnitee in defending an action, suit, proceeding or investigation or any appeal therefrom shall be paid by the Corporation in advance of the final disposition of such matter to the fullest extent permitted by law; *provided*, *however*, that, to the extent required by law, the payment of such expenses incurred by or on behalf of Indemnitee in advance of the final disposition of such matter shall be made only upon receipt of an undertaking by or on behalf of Indemnitee to repay all amounts so advanced in the event that it shall ultimately be determined by final judicial decision from which there is no further right to appeal that Indemnitee is not entitled to be indemnified by the Corporation as authorized in this Article IX or otherwise; and *provided further* that no such advancement of expenses shall be made under this Article IX if it is determined (in the manner described in Section 9.6 of these bylaws) that (a) Indemnitee did not act in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the Corporation, or (b) with respect to any criminal action or proceeding, Indemnitee had reasonable cause to believe his or her conduct was unlawful. Such undertaking shall be accepted without reference to the financial ability of Indemnitee to make such repayment.

9.6 PROCEDURE FOR INDEMNIFICATION AND ADVANCEMENT OF EXPENSES.

In order to obtain indemnification or advancement of expenses pursuant to Section 9.1, 9.2, 9.3 or 9.5 of these bylaws, an Indemnitee shall submit to the Corporation a written request. Any such advancement of expenses shall be made promptly, and in any event within 60 days after receipt by the Corporation of the written request of Indemnitee, unless (a) the Corporation has assumed the defense pursuant to Section 9.4 of these bylaws (and none of the circumstances described in Section 9.4 of these bylaws that would nonetheless entitle the Indemnitee to indemnification for the fees and expenses of separate counsel have occurred) or (b) the Corporation determines within such 60-day period that Indemnitee did not meet the applicable standard of conduct set forth in Section 9.1, 9.2 or 9.5 of these bylaws, as the case may be. Any such indemnification, unless ordered by a court, shall be made with respect to requests under Section 9.1 or 9.2 of these bylaws only as authorized in the specific case upon a determination by the Corporation that the indemnification of Indemnitee is proper because Indemnitee has met the applicable standard of conduct set forth in Section 9.1 or 9.2 of these bylaws, as the case may be. Such determination shall be made in each instance (a) by a majority vote of the directors of the Corporation consisting of persons who are not at that time parties to the action, suit or

proceeding in question ("disinterested directors"), whether or not a quorum, (b) by a committee of disinterested directors designated by majority vote of disinterested directors, whether or not a quorum, (c) if there are no disinterested directors, or if the disinterested directors so direct, by independent legal counsel (who may, to the extent permitted by law, be regular legal counsel to the Corporation) in a written opinion or (d) by the stockholders of the Corporation.

9.7 REMEDIES.

To the fullest extent permitted by law, the right to indemnification or advancement of expenses as granted by this Article IX shall be enforceable by Indemnitee in any court of competent jurisdiction. Neither the failure of the Corporation to have made a determination prior to the commencement of such action that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Corporation pursuant to Section 9.6 of these bylaws that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct. In any suit brought by Indemnitee to enforce a right to indemnification or advancement, or brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Corporation shall have the burden of proving that Indemnitee is not entitled to be indemnified, or to such advancement of expenses, under this Article IX. Indemnitee's expenses (including, without limitation, attorneys' fees) reasonably incurred in connection with successfully establishing Indemnitee's right to indemnification or advancement, in whole or in part, in any such proceeding shall also be indemnified by the Corporation to the fullest extent permitted by law. Notwithstanding the foregoing, in any suit brought by Indemnitee to enforce a right to indemnification hereunder it shall be a defense that the Indemnitee has not met any applicable standard for indemnification set forth in the DGCL.

9.8 LIMITATIONS.

Notwithstanding anything to the contrary in this Article IX, except as set forth in Section 9.7 of these bylaws, the Corporation shall not indemnify an Indemnitee pursuant to this Article IX in connection with a proceeding (or part thereof) initiated by such Indemnitee unless the initiation thereof was approved by the Board. Notwithstanding anything to the contrary in this Article IX, the Corporation shall not indemnify (or advance expenses to) an Indemnitee to the extent such Indemnitee is reimbursed (or advanced expenses) from the proceeds of insurance, and in the event the Corporation makes any indemnification (or advancement) payments to an Indemnitee and such Indemnitee is subsequently reimbursed from the proceeds of insurance, such Indemnitee shall promptly refund indemnification (or advancement) payments to the Corporation to the extent of such insurance reimbursement.

9.9 SUBSEQUENT AMENDMENT.

No amendment, termination or repeal of this Article IX or of the relevant provisions of the DGCL or any other applicable laws shall adversely affect or diminish in any way the rights of any Indemnitee to indemnification or advancement of expenses under the provisions hereof with respect to any action, suit, proceeding or investigation arising out of or relating to any

actions, transactions or facts occurring prior to the final adoption of such amendment, termination or repeal.

9.10 OTHER RIGHTS.

The indemnification and advancement of expenses provided by this Article IX shall not be deemed exclusive of any other rights to which an Indemnitee seeking indemnification or advancement of expenses may be entitled under any law (common or statutory), agreement or vote of stockholders or disinterested directors or otherwise, both as to action in Indemnitee's official capacity and as to action in any other capacity while holding office for the Corporation, and shall continue as to an Indemnitee who has ceased to be a director or officer, and shall inure to the benefit of the estate, heirs, executors and administrators of Indemnitee. Nothing contained in this Article IX shall be deemed to prohibit, and the Corporation is specifically authorized to enter into, agreements with officers and directors providing indemnification and advancement rights and procedures different from those set forth in this Article IX. In addition, the Corporation may, to the extent authorized from time to time by the Board, grant indemnification and advancement rights to other employees or agents of the Corporation or other persons serving the Corporation and such rights may be equivalent to, or greater or less than, those set forth in this Article IX.

9.11 PARTIAL INDEMNIFICATION.

If an Indemnitee is entitled under any provision of this Article IX to indemnification by the Corporation for some or a portion of the expenses (including, without limitation, attorneys' fees), liabilities, losses, judgments, fines (including, without limitation, excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974, as amended) or amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with any action, suit, proceeding or investigation and any appeal therefrom but not, however, for the total amount thereof, the Corporation shall nevertheless indemnify Indemnitee for the portion of such expenses (including, without limitation, attorneys' fees), liabilities, losses, judgments, fines (including, without limitation, excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974, as amended) or amounts paid in settlement to which Indemnitee is entitled.

9.12 INSURANCE.

The Corporation may purchase and maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Corporation or another corporation, partnership, joint venture, trust or other enterprise (including, without limitation, any employee benefit plan) against any expense, liability or loss incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the DGCL.

9.13 SAVINGS CLAUSE.

If this Article IX or any portion hereof shall be invalidated on any ground by any court of competent jurisdiction, then the Corporation shall nevertheless indemnify each Indemnitee as to any expenses (including, without limitation, attorneys' fees), liabilities, losses, judgments, fines

(including, without limitation, excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974, as amended) and amounts paid in settlement in connection with any action, suit, proceeding or investigation, whether civil, criminal or administrative, including, without limitation, an action by or in the right of the Corporation, to the fullest extent permitted by any applicable portion of this Article IX that shall not have been invalidated and to the fullest extent permitted by applicable law.

9.14 DEFINITIONS.

Terms used in this Article IX and defined in Section 145(h) and Section 145(i) of the DGCL shall have the respective meanings assigned to such terms in such Section 145(h) and Section 145(i).

ARTICLE X - AMENDMENTS

Subject to the limitations set forth in Section 9.9 of these bylaws or the provisions of the certificate of incorporation, the Board is expressly empowered to adopt, amend or repeal the bylaws of the Corporation. The stockholders also shall have power to adopt, amend or repeal the bylaws of the Corporation; *provided*, *however*, that, in addition to any vote of the holders of any class or series of stock of the Corporation required by law or by the certificate of incorporation, such action by stockholders shall require the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock of the Corporation entitled to vote thereon.

ARTICLE XI - FORUM SELECTION; SEVERABILITY

11.1 FORUM SELECTION.

Unless the Corporation consents in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. Any person or entity purchasing or otherwise acquiring or holding any interest in shares of capital stock of the Corporation shall be deemed to have notice of and consented to the provisions of this Article XI.

11.2 SEVERABILITY.

To the extent any provision of these bylaws would be, in the absence of this Section 11.2, invalid, illegal or unenforceable for any reason whatsoever, such provision shall be severable from the other provisions of these bylaws, and all provisions of these bylaws shall be construed so as to give effect to the intent manifested by these bylaws, including, to the maximum extent possible, the provision that would be otherwise invalid, illegal or unenforceable.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (No. 333-251061) on Form S-3 and (Nos. 333-234607 and 333-271837) on Form S-8 of our report dated March 28, 2024, with respect to the consolidated financial statements of Galera Therapeutics, Inc.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 28, 2024

Exhibit 31.1

CERTIFICATIONS

I, J. Mel Sorensen, certify that:

1. I have reviewed this Annual Report on Form 10-K 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: March 28, 2024

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

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

Exhibit 31.2

CERTIFICATIONS

I, Christopher Degnan, certify that:

1. I have reviewed this Annual Report on Form 10-K 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: March 28, 2024

By: /s/ Christopher Degnan

Christopher Degnan
Chief Financial Officer
(principal financial officer)

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of Galera Therapeutics, Inc. (the "Company") for the year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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

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

March 28, 2024

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

J. Mel Sorensen, M.D.
Chief Executive Officer, President and Director
(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 Annual Report on Form 10-K of Galera Therapeutics, Inc. (the "Company") for the year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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

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

March 28, 2024

/s/ Christopher Degnan

Christopher Degnan
Chief Financial Officer
(principal financial officer)

Exhibit 97.1

GALERA THERAPEUTICS, INC. POLICY FOR RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

Galera Therapeutics, Inc. (the "***Company***") has adopted this Policy for Recovery of Erroneously Awarded Compensation (the "***Policy***"), effective as of October 2, 2023 (the "***Effective Date***"). Capitalized terms used in this Policy but not otherwise defined herein are defined in Section 11.

1. Persons Subject to Policy

This Policy shall apply to current and former Officers of the Company. Each Officer shall be required to sign an acknowledgment pursuant to which such Officer will agree to be bound by the terms of, and comply with, this Policy; however, any Officer's failure to sign any such acknowledgment shall not negate the application of this Policy to the Officer.

2. Compensation Subject to Policy

This Policy shall apply to Incentive-Based Compensation received on or after the Effective Date. For purposes of this Policy, the date on which Incentive-Based Compensation is "received" shall be determined under the Applicable Rules, which generally provide that Incentive-Based Compensation is "received" in the Company's fiscal period during which the relevant Financial Reporting Measure is attained or satisfied, without regard to whether the grant, vesting or payment of the Incentive-Based Compensation occurs after the end of that period.

3. Recovery of Compensation

In the event that the Company is required to prepare a Restatement, the Company shall recover, reasonably promptly, the portion of any Incentive-Based Compensation that is Erroneously Awarded Compensation, unless the Committee has determined that recovery would be Impracticable. Recovery shall be required in accordance with the preceding sentence regardless of whether the applicable Officer engaged in misconduct or otherwise caused or contributed to the requirement for the Restatement and regardless of whether or when restated financial statements are filed by the Company. For clarity, the recovery of Erroneously Awarded Compensation under this Policy will not give rise to any person's right to voluntarily terminate employment for "good reason," or due to a "constructive termination" (or any similar term of like effect) under any plan, program or policy of or agreement with the Company or any of its affiliates.

4. Manner of Recovery; Limitation on Duplicative Recovery

The Committee shall, in its sole discretion, determine the manner of recovery of any Erroneously Awarded Compensation, which may include, without limitation, reduction or cancellation by the Company or an affiliate of the Company of Incentive-Based Compensation or Erroneously Awarded Compensation, reimbursement or repayment by any person subject to this Policy of the Erroneously Awarded Compensation, and, to the extent permitted by law, an offset of the Erroneously Awarded Compensation against other compensation payable by the Company

or an affiliate of the Company to such person. Notwithstanding the foregoing, unless otherwise prohibited by the Applicable Rules, to the extent this Policy provides for recovery of Erroneously Awarded Compensation already recovered by the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 or Other Recovery Arrangements, the amount of Erroneously Awarded Compensation already recovered by the Company from the recipient of such Erroneously Awarded Compensation may be credited to the amount of Erroneously Awarded Compensation required to be recovered pursuant to this Policy from such person.

5. Administration

This Policy shall be administered, interpreted and construed by the Committee, which is authorized to make all determinations necessary, appropriate or advisable for such purpose. The Board of Directors of the Company (the "***Board***") may re-vest in itself the authority to administer, interpret and construe this Policy in accordance with applicable law, and in such event references herein to the "Committee" shall be deemed to be references to the Board. Subject to any permitted review by the applicable national securities exchange or association pursuant to the Applicable Rules, all determinations and decisions made by the Committee pursuant to the provisions of this Policy shall be final, conclusive and binding on all persons, including the Company and its affiliates, equityholders and employees. The Committee may delegate administrative duties with respect to this Policy to one or more directors or employees of the Company, as permitted under applicable law, including any Applicable Rules.

6. Interpretation

This Policy will be interpreted and applied in a manner that is consistent with the requirements of the Applicable Rules, and to the extent this Policy is inconsistent with such Applicable Rules, it shall be deemed amended to the minimum extent necessary to ensure compliance therewith.

7. No Indemnification; No Liability

The Company shall not indemnify or insure any person against the loss of any Erroneously Awarded Compensation pursuant to this Policy, nor shall the Company directly or indirectly pay or reimburse any person for any premiums for third-party insurance policies that such person may elect to purchase to fund such person's potential obligations under this Policy. None of the Company, an affiliate of the Company or any member of the Committee or the Board shall have any liability to any person as a result of actions taken under this Policy.

8. Application; Enforceability

Except as otherwise determined by the Committee or the Board, the adoption of this Policy does not limit, and is intended to apply in addition to, any other clawback, recoupment, forfeiture or similar policies or provisions of the Company or its affiliates, including any such policies or provisions of such effect contained in any employment agreement, bonus plan, incentive plan, equity-based plan or award agreement thereunder or similar plan, program or agreement of the Company or an affiliate or required under applicable law (the "***Other Recovery Arrangements***"). The remedy specified in this Policy shall not be exclusive and shall be in addition to every other

right or remedy at law or in equity that may be available to the Company or an affiliate of the Company.

9. Severability

The provisions in this Policy are intended to be applied to the fullest extent of the law; provided, however, to the extent that any provision of this Policy is found to be unenforceable or invalid under any applicable law, such provision will be applied to the maximum extent permitted, and shall automatically be deemed amended in a manner consistent with its objectives to the extent necessary to conform to any limitations required under applicable law.

10. Amendment and Termination

The Board or the Committee may amend, modify or terminate this Policy in whole or in part at any time and from time to time in its sole discretion. This Policy will terminate automatically when the Company does not have a class of securities listed on a national securities exchange or association.

11. Definitions

"***Applicable Rules***" means Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder, the listing rules of the national securities exchange or association on which the Company's securities are listed, and any applicable rules, standards or other guidance adopted by the Securities and Exchange Commission or any national securities exchange or association on which the Company's securities are listed.

"***Committee***" means the committee of the Board responsible for executive compensation decisions comprised solely of independent directors (as determined under the Applicable Rules), or in the absence of such a committee, a majority of the independent directors serving on the Board.

"***Erroneously Awarded Compensation***" means the amount of Incentive-Based Compensation received by a current or former Officer that exceeds the amount of Incentive-Based Compensation that would have been received by such current or former Officer based on a restated Financial Reporting Measure, as determined on a pre-tax basis in accordance with the Applicable Rules.

"***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

"***Financial Reporting Measure***" means any measure determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including GAAP, IFRS and non-GAAP/IFRS financial measures, as well as stock or share price and total equityholder return.

"***GAAP***" means United States generally accepted accounting principles.

"***IFRS***" means international financial reporting standards as adopted by the International Accounting Standards Board.

"***Impracticable***" means (a) the direct costs paid to third parties to assist in enforcing recovery would exceed the Erroneously Awarded Compensation; provided that the Company (i) has made reasonable attempts to recover the Erroneously Awarded Compensation, (ii) documented such attempt(s), and (iii) provided such documentation to the relevant listing exchange or association, (b) to the extent permitted by the Applicable Rules, the recovery would violate the Company's home country laws pursuant to an opinion of home country counsel; provided that the Company has (i) obtained an opinion of home country counsel, acceptable to the relevant listing exchange or association, that recovery would result in such violation, and (ii) provided such opinion to the relevant listing exchange or association, or (c) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and the regulations thereunder.

"***Incentive-Based Compensation***" means, with respect to a Restatement, any compensation that is granted, earned, or vested based wholly or in part upon the attainment of one or more Financial Reporting Measures and received by a person: (a) after beginning service as an Officer; (b) who served as an Officer at any time during the performance period for that compensation; (c) while the issuer has a class of its securities listed on a national securities exchange or association; and (d) during the applicable Three-Year Period.

"***Officer***" means each person who serves as an executive officer of the Company, as defined in Rule 10D-1(d) under the Exchange Act.

"***Restatement***" means an accounting restatement to correct the Company's material noncompliance with any financial reporting requirement under securities laws, including restatements that correct an error in previously issued financial statements (a) that is material to the previously issued financial statements or (b) that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Three-Year Period***" means, with respect to a Restatement, the three completed fiscal years immediately preceding the date that the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare such Restatement, or, if earlier, the date on which a court, regulator or other legally authorized body directs the Company to prepare such Restatement. The "Three-Year Period" also includes any transition period (that results from a change in the Company's fiscal year) within or immediately following the three completed fiscal years identified in the preceding sentence. However, a transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of nine to 12 months shall be deemed a completed fiscal year.

* * * * *

ACKNOWLEDGMENT AND CONSENT TO
POLICY FOR RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

The undersigned has received a copy of the Policy for Recovery of Erroneously Awarded Compensation (the "Policy") adopted by Galera Therapeutics, Inc. (the "Company").

For good and valuable consideration, the receipt of which is acknowledged, the undersigned agrees to the terms of the Policy and agrees that compensation received by the undersigned may be subject to reduction, cancellation, forfeiture and/or recoupment to the extent necessary to comply with the Policy, notwithstanding any other agreement to the contrary. The undersigned further acknowledges and agrees that the undersigned is not entitled to indemnification in connection with any enforcement of the Policy and expressly waives any rights to such indemnification under the Company's organizational documents or otherwise.

_____ _____

Date Signature

_____

Name

_____

Title