

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, 2025

or

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

For the transition period from _____ to _____

Commission File Number 001-39114

Galera Therapeutics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

101 Lindenwood Drive, Suite 225

Malvern, Pennsylvania

(Address of principal executive offices)

46-1454898

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

19355

(Zip Code)

(610) 725-1500

(Registrant's telephone number, including area code)

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	OTCQB 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

Non-accelerated filer

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, 2025, 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 \$1.5 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 16, 2026 was 75,462,390.

DOCUMENTS INCORPORATED BY REFERENCE

None.

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”) and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). 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 are forward-looking statements, including without limitation statements regarding our acquisition of and integration with Nova Pharmaceuticals, Inc.; the impact of our discontinuation of the development of all but one of our product candidates; the sufficiency of our cash, cash equivalents and short-term investments and our ability to raise additional capital to fund our operations; and the plans and objectives of management for future operations.

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 and Section 21E of 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.
- Our ability to continue as a going concern is dependent on obtaining additional funding, and failure to secure such funding could significantly impair our operations.
- We previously halted clinical development of all but one of our product candidates, and those product candidates for which development was halted were subsequently included in the asset sale to Biossil.
- Any financial or strategic option we pursue may not be successful.
- Our common stock is currently quoted on the OTCQB Market, which may have an unfavorable impact on our stock price and liquidity.
- We are heavily dependent on the success of our product candidate, which has not received regulatory approval. The regulatory approval process is lengthy, expensive and uncertain, and we may be unable to obtain regulatory approval for our product candidate under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidate 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 candidate, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.
- We do not have our own manufacturing capabilities and will rely on third parties to produce additional clinical supplies, if needed. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidate or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- We may not receive any royalty, milestone, contingent value or other payments under any current or future license or collaboration agreements, including our agreement with Biossil, Inc.
- The incidence and prevalence for target patient populations of our product candidate have not been established with precision. If the market opportunities for our product candidate 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 our product candidate 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 candidate, 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 candidate may cause undesirable side effects or have other properties that could delay or prevent its 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.

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PART I

Item 1. Business.

Overview

We are a biopharmaceutical company that historically was focused on developing a portfolio of small molecule superoxide dismutase (SOD) mimetics to improve radiotherapy in cancer, primarily by reducing one of the most common side effects of radiotherapy, severe oral mucositis (SOM). In October 2025 we sold our assets related to avasopasem and rucosopasem and all other dismutase mimetics assets to Bioasil, Inc. (Bioasil), a privately-held company based in Toronto, Canada. In connection with selling these assets, we assigned and Bioasil assumed all rights and obligations under the Royalty Agreement with Blackstone Life Sciences (Blackstone), as described below. We received consideration from Bioasil in the form of an upfront payment of \$3.5 million and are eligible to receive further payments upon the achievement of future regulatory and commercial milestones and we received contingent value rights of up to \$105.0 million in the aggregate.

On December 30, 2024, we completed the acquisition of Nova Pharmaceuticals, Inc. (Nova), a privately-held biotechnology company advancing a pan-inhibitor of nitric oxide synthase (NOS). With that acquisition, we have shifted our strategic focus to developing a product candidate to treat certain types of advanced breast cancer, including metaplastic breast cancer (MpBC) and other refractory subsets of triple-negative breast cancer (TNBC). In support of the acquisition, a syndicate of investors led by Ikarian Capital invested \$2.9 million to purchase Galera common stock and pre-funded warrants. The Company continues as Galera Therapeutics, Inc., and our common stock is listed on the Over-The-Counter Quote Bulletin Board – Venture Market (OTCQB: GRTX).

Following the sale to Bioasil, our portfolio is now comprised of a pan-NOS inhibitor. Our lead program is a Phase 1/2 trial of the pan-NOS inhibitor in combination with nab-paclitaxel and alpelisib for MpBC. This is an investigator-sponsored trial that is funded by a National Institutes of Health (NIH) grant to investigators at the Methodist Hospital in Houston, Texas (Houston Methodist), including the drug supply for the trial. In 2025, the Phase 2a portion of the trial was reached and two additional sites were added: the University of Texas MD Anderson Cancer Center and the National Institutes of Health (NIH) Clinical Center. Assuming we are successful in securing additional capital, a second trial for this agent is being planned in TNBC in collaboration with the I-SPY 2 consortium.

As of December 31, 2025, the Company had 3 employees. Galera's cash balance as of December 31, 2025 is anticipated to fund operations through the first quarter of 2027. With its limited resources, Galera continues to concentrate on developing therapies for breast cancer with toxicity reducing indications. Galera also continues to consider partnerships and alternative ways for advancing these indications. Details of development can be found below.

Disease Overviews and Our Product Candidate

Forms of Breast Cancer that are the Focus of Galera's Research and Development

Breast cancer is the most common cancer in women, accounting for ~31% of all female cancers. While most of these cancers are curable and well managed with surgery, radiotherapy and conventional chemotherapeutic regimens, over 42,000 women still die of breast cancer each year in the United States. These deaths are disproportionately due to more aggressive and resistant subsets of breast cancer, such as TNBC, which is the most aggressive large subtype of breast cancer, accounting for 15-20% of diagnoses, defined by the absence of estrogen (ER) and progesterone (PR) receptors and human epidermal growth factor receptor 2 (Her2) expression.

Metaplastic breast cancer (MpBC) is a particularly aggressive form of TNBC that has no satisfactory or approved treatment today and is the target of Galera's lead product and an ongoing investigator-sponsored trial at the Methodist Hospital in Houston, Texas (Houston Methodist). It accounts for around 5-7% of TNBC and is particularly resistant to chemotherapy or immunotherapy. It is heterogeneous histologically, with squamous or spindle cell features, or Epithelial-to-Mesenchymal Transition (EMT). EMT is a biological process in which epithelial cells lose their characteristics (such as cell-cell adhesion and polarity) and gain mesenchymal properties

(such as increased motility and invasiveness). Metastases occur more easily than in other forms of TNBC and it has a worse prognosis, with a survival rate of 8 months or less in patients with metastatic disease. MpBC patients predominately have aberrations in both the PI3K and iNOS pathways.

Investigators at Houston Methodist discovered a new cancer gene, ribosomal protein L39 (RPL39), that is associated with chemoresistance and lung metastases in TNBC and MpBC. RPL39 promotes the production of nitric oxide by regulating the function of NOS. Elevated expressions of RPL39 and NOS in MpBC are poor prognostic indicators. These investigators demonstrated that NOS inhibition with the pan-NOS inhibitor NG-monomethyl-L-arginine (L-NMMA) decreased tumor cell proliferation, mammosphere formation, and migration in vitro, and reduced tumor development and growth as well as lung metastasis in TNBC patient-derived xenograft (PDX) models.

The Houston Methodist team conducted a phase I/II clinical trial of L-NMMA plus taxane for treating patients with chemorefractory, locally advanced breast cancer (LABC) or metastatic TNBC. The treatment achieved an overall response rate of 45.8% (82% for LABC, 9/11), with no grade ≥ 3 toxicities attributed to L-NMMA. Of the 35 TNBC patients enrolled on this trial, 15 had MpBC. The Company's subsidiary, Nova, has a worldwide license agreement with Houston Methodist that gives Nova the exclusive rights to certain Houston Methodist patents related to L-NMMA for use in the field of oncology, and non-exclusive rights to certain Houston Methodist know-how for use in connection with the licensed patents.

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 historical product candidates. We previously had a formal agreement with Patheon Manufacturing Services LLC (Patheon) for production of avasopasem, which was assumed by Biossil.

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 our products, 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.

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 candidate 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, 2025, Galera has exclusively licensed from Houston Methodist currently pending patent applications and in-force patents related to tilarginine consisting of 2 issued U.S. patents, 1 pending PCT application, 2 pending U.S. patent applications, 14 issued foreign patents, including 1 issued European patent that has been validated in a number of European countries, and 4 pending foreign applications. Galera also has a pending

U.S. provisional patent application related to the use of tilarginine in oncology therapies. Any issuing patents from this provisional patent application are estimated to expire in 2046.

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 Patent Term Extension (PTE) application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year while a PTE application is pending and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. To grant the interim extension, 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. In the U.S., only one patent applicable to an approved drug product 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 product. 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, PTE-eligible patents covering those drug products.

Galera has one pan-NOS inhibitor (L-NMMA or tilarginine) that has reached clinical development as of December 31, 2025. Tilarginine has been studied in hundreds of patients for non-oncologic conditions and in a few Phase I/II trials in patients with cancer. Those trials were conducted by Houston Methodist Hospital, who then exclusively licensed their rights to tilarginine to Nova Pharmaceuticals, which was acquired by Galera on December 30, 2024. We have pending and/or in force patent families including U.S. and foreign patents and applications that cover certain combinations of tilarginine with oncology products and therapies that may provide protection for the use of our product candidate in connection with the protocols used in these clinical trials, which are estimated to expire between 2035 and 2045.

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.

Trademarks and Trade Secrets

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 our dismutase mimetics (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 in April 2019, and the third tranche in February 2020.

In May 2020, we entered into Amendment No. 1 to the Royalty Agreement (Amendment No. 1) 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. Amendment No. 1 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, and received the \$37.5 million tranche in July 2021. As partial consideration for Amendment No. 1, 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 and expire six years after the initial exercise date of each respective warrant.

In August 2025, the Company entered into the Second Amendment to the Royalty Agreement (the Second Amendment) with the Blackstone Purchaser. The Second Amendment reduced the royalty payable to Blackstone on (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) from a high single-digit percentage to four percent (4%).

In connection with the 2025 sale of our dismutase mimetics assets to Biossil, we assigned and Biossil assumed all rights and obligations under the amended Royalty Agreement, and Blackstone acknowledged that it would look solely to Biossil to pay and perform the obligations and liabilities under the amended Royalty Agreement.

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 candidate that we are developing.

Review and Approval of Drugs in the United States

In the United States, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. The failure to comply with applicable requirements under the FDCA and other applicable laws at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution,

injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or other governmental entities.

An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance, as applicable, with the Animal Welfare Act and FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND, which must take effect before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, and other applicable regulations to establish the safety and efficacy of the proposed drug product for each proposed indication;
- manufacturing, packaging, labelling, and distribution of drug substances and drug products consistent with the FDA's cGMP regulations which are utilized in the GLP non-clinical and GCP clinical studies to investigate the drug candidate;
- development of product label, package inserts, and prescriber information that is intended to be used and included with the commercial product;
- preparation and submission to the FDA of an NDA;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees, if appropriate, and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies, or REMS, and post-approval studies required by the FDA.

Preclinical Studies

Preclinical studies include laboratory evaluations of product chemistry, toxicity and formulation, as well as *in vitro* and *in vivo* animal studies to assess the safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. Some long-term preclinical testing, such as long-term repeat-dose toxicology studies, may continue after the IND is submitted.

Companies usually must complete some long-term preclinical testing, such as long-term repeat-dose toxicology studies, and must also develop additional information about the chemistry and physical characteristics of

the investigational product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the candidate product and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the candidate product does not undergo unacceptable deterioration over its shelf life.

The IND and IRB Processes

An IND is an exemption from the FDCA that allows an unapproved drug to be shipped in interstate commerce for use in an investigational clinical trial. In support of a request for an IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, the results of preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. An IND goes into effect 30 days after its filing, unless during this 30-day period the FDA raises concerns or questions and imposes a clinical hold.

A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed. The FDA may also place a clinical hold or partial clinical hold on a trial after a clinical trial has begun.

A sponsor may choose, but is not required, to conduct a foreign clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical trial is not conducted under an IND, the sponsor must ensure that the trial complies with certain FDA regulatory requirements in order to use the trial as support for an IND or application for marketing approval, including that such trials must be conducted in accordance with GCP, including review and approval by an independent ethics committee, or IEC, and obtaining informed consent from patients. The GCP requirements in the final rule encompass both ethical and data integrity standards for clinical studies. The FDA's regulations are intended to help ensure the protection of human patients enrolled in non-IND foreign clinical studies, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies.

In addition, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must exercise continuing supervision over the trial. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to trial patients. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the trial. Suspension or termination of development during any phase of clinical trials can occur if it is determined that the participants or patients are being exposed to an unacceptable health risk. Other reasons for suspension or termination may be made based on evolving business objectives and/or competitive climate.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on its ClinicalTrials.gov website.

Human Clinical Trials in Support of an NDA

Clinical trials involve the administration of the investigational product to human patients or healthy volunteers under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research patients provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written trial protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the trial, the tests to be conducted on study participants, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

Human clinical trials are typically conducted in 3 sequential phases, but the phases may overlap.

- *Phase 1.* The drug is initially introduced into healthy human subjects or, in certain indications such as cancer, patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.
- *Phase 2.* The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- *Phase 3.* The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

Reports detailing activities under, and the status of, an IND must be submitted at least annually to the FDA. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Sponsors may reach an SPA agreement with respect to the design of clinical trials. The FDA's SPA process is designed to facilitate the FDA's review and approval of drugs and biologics by allowing the FDA to evaluate the proposed design and size of certain clinical or animal studies, including clinical trials that are intended to form the primary basis for determining a product candidate's efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding protocol design and scientific and regulatory requirements. The FDA aims to complete SPA reviews within 45 days of receipt of the request. The FDA ultimately assesses whether specific elements of the protocol design of the trial, such as entry criteria, dose selection, endpoints and/or planned analyses, are acceptable to support regulatory approval of the product with respect to the effectiveness of the indication studied. All exchanges between the FDA and the sponsor regarding an SPA must be clearly documented in an SPA letter or the minutes of a meeting between the sponsor and the FDA.

Although the FDA may agree to an SPA, an SPA agreement does not guarantee approval of a product. Even if the FDA agrees to the design, execution, and analysis proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement in certain circumstances. In particular, an SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, the sponsor company fails to comply with

the agreed upon trial protocols, or the relevant data, assumptions or information provided by the sponsor in a request for the SPA change or are found to be false or omit relevant facts.

In addition, even after an SPA agreement is finalized, the SPA agreement may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol. Generally, such modification is intended to improve the study. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement. Moreover, if the FDA revokes or alters its agreement under the SPA, or interprets the data collected from the clinical trial differently than we do, the FDA may not deem the data sufficient to support an application for regulatory approval.

Concurrent with clinical trials, companies often complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality, purity, and potency of the final drug. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Submission of an NDA to the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is subject to an application user fee. The sponsor of an approved NDA is also subject to an annual prescription drug program fee. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for drugs with orphan designation and a waiver for certain small businesses. The FDA conducts a preliminary review of an NDA within 60 days of its receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing, and the sponsor receives a Refuse to File Notice. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to certain performance goals in the review process of NDAs. The goal for review of most standard applications is within 10 months from the date of filing, and for "priority review" products the review goal is within 6 months of filing. The review process may be extended by the FDA to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections, or PAIs, may cover all facilities associated with an NDA submission, including drug component manufacturing (such as active pharmaceutical ingredients), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications at the commercial scale. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

In addition, as a condition of approval, the FDA may require an applicant to develop a Risk Evaluation and Mitigation Strategies, or REMS. REMS uses risk minimization strategies to ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, physician communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may require a REMS at the time of approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of a product.

The FDA may refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Fast Track, Breakthrough Therapy, and Priority Review Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are referred to as fast-track designation, breakthrough therapy designation, and priority review designation.

Specifically, the FDA may designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a Fast Track application does not begin until the last section of the application is submitted. In addition, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, a product may be designated as a Breakthrough Therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to Breakthrough Therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; and assigning a cross-disciplinary project lead for the review team.

Third, the FDA may designate a product for Priority Review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from 10 months to 6 months.

The FDA's Decision on an NDA

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter, or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA may issue an approval letter. The FDA has committed to reviewing such resubmissions in 2 or 6 months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies,

including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting (such as annual reports and quarterly safety reports for the first 3 years), product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements for any marketed products, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. All promotional materials must be submitted to FDA prior to the time of their first use. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drug samples at the federal level and sets minimum

standards for the registration and regulation of drug sample distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Section 505(b)(2) NDAs

NDAs for most new drug products are based on two adequate and well-controlled clinical trials which must contain substantial evidence of the safety and efficacy of the proposed new product. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the applicant to rely, in part, on the FDA's previous findings of safety and efficacy for a similar product, or published literature. Specifically, Section 505(b)(2) of the FDCA applies to an NDA for a drug for which the investigations to show whether the drug is safe and effective and relied upon by the applicant for approval of the application "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted."

Thus, Section 505(b)(2) authorizes the FDA to approve an NDA based in part on safety and effectiveness data that were not developed by the applicant. Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the Section 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain preclinical studies or clinical trials of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference-listed drug, or RLD.

Specifically, in order for an ANDA to be approved, the FDA generally must find that the generic version is a duplicate to the RLD with respect to the active ingredients, the route of administration, the dosage form, conditions of use and the strength of the drug. The FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is required to be bioequivalent to an RLD.

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, also referred to as the Orange Book. Clinicians and pharmacists often consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing clinicians or patient.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. For the purposes of this provision, a new chemical entity, or "NCE", is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period applies to the condition(s) of use for which the new clinical investigation was conducted, and often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product.

Hatch-Waxman Patent Certification and the 30-Month Stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, the applicant must certify with respect to each patent that: (1) the required patent information has not been filed, (2) the listed patent has expired, (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired (other than method of use patents involving indications for which the applicant is not seeking approval).

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. As a result, approval of a Section 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of an NCE, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

505(b)(2) and NCE Data Exclusivity in U.S.

In the United States, the Hatch-Waxman Act provides a 3-year period of non-patent data exclusivity within the United States to the first applicant to gain approval through a 505(b)(2) application seeking regulatory approval of, for example, a new indication, dosage, or strength of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigation and does not prohibit the FDA from approving an ANDA for drugs containing the original active agent.

In the United States, the Hatch-Waxman Act provides period of 5-years of non-patent data exclusivity for a new drug containing a new chemical entity. For the purposes of this provision, a new chemical entity, or “NCE”, is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the Food and Drug Administration Safety and Innovation Act or FDASIA, in 2012, sponsors must also submit pediatric trial plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric trial or studies the applicant plans to conduct, including trial objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA’s internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional 6 months to the term of any patent or regulatory exclusivity, including orphan exclusivity. This 6-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA’s request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, the latest statutory or regulatory period of exclusivity or patent covering the product is extended by 6 months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug product as an “orphan drug” if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting an NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve any other applications for the same product for the same indication for 7 years, except in certain limited circumstances. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to 5 years for patent term lost during product development and the FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The U.S. Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Pharmaceutical Coverage and Reimbursement

Our ability to successfully commercialize our product candidate in the event we may receive regulatory approval will depend in significant part on the availability of coverage and reimbursement from third-party payors, including governmental healthcare programs, such as the Medicare and Medicaid programs in the U.S., private health insurers, managed care organizations, and other entities. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include our product candidate. Third-party payors, together with regulators and others, are increasingly challenging the prices charged for pharmaceutical products and related services, in addition to their cost-effectiveness, safety and efficacy.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Interim reimbursement amounts for new drugs, if applicable, may also be insufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Coverage and reimbursement policies for drug products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third party payors in the U.S. Third party payors in the U.S. often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies.

Moreover, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval will be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. We cannot be certain that our product candidate will be considered cost-effective by third-party payors. This process could delay the market acceptance of any product candidate for which we may receive approval and could have a negative effect on our future revenues and operating results.

Additionally, individual states in the U.S. have become increasingly active in passing laws and implementing regulations designed to control pharmaceutical product pricing, including reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. It is likely that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for a pharmaceutical manufacturer's products or additional pricing pressure.

Other U.S. Healthcare Laws and Compliance Requirements

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of pharmaceutical products that are granted marketing approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable federal and state fraud and abuse laws, anti-kickback

laws, false claims laws, laws requiring reporting of payments to physicians and teaching physicians and other healthcare providers, and other healthcare laws and regulations that may constrain business and/or financial arrangements. Restrictions under applicable healthcare laws and regulations include, but are not limited to, the following:

- 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 or bribe), 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, 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. Private individuals, commonly known as “whistleblowers,” can bring False Claims Act qui tam actions on behalf of the government and may share in amounts paid by the defendant to the government in recovery or settlement. 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; Moreover, manufacturers can be held liable under the False Claims Act even though they, in most cases, do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims;
- 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, among others, to track and report annually to the government information related to all payments and other transfers of value made to U.S.-licensed physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, and certified-nurse midwives and U.S. teaching hospitals, as well as track and report ownership and investment interests held in such manufacturers, among others, by U.S.-licensed physicians and their immediate family members, unless an exception applies;
- analogous U.S. state laws and regulations, including, but not limited to: 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 and that 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.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, individual imprisonment, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, possible exclusion from participation in federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Healthcare Reform

The U.S. and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access.

In the U.S. there have been, and continue to be, proposals by the federal government, state governments, regulators and third-party payors to control or manage the costs of health care and, more generally, to reform the U.S. healthcare system. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA) was enacted, which included significant changes to the coverage and payment for pharmaceutical products under government health care programs. This law was designed to expand access to health insurance coverage for uninsured and underinsured individuals while containing overall healthcare costs. The ACA and certain of its provisions have been subject to judicial challenges as well as legislative and regulatory efforts to repeal or replace them or to alter their interpretation or implementation. For example, on June 17, 2021, the U.S. Supreme Court dismissed a lawsuit challenging the constitutionality of certain aspects of the ACA without ruling on the merits of the constitutionality arguments.

Other legislative changes designed to reduce healthcare expenditures have been proposed and adopted in the U.S. since the ACA was enacted. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through the first eleven months of FY 2032, unless additional Congressional action is taken (with the exception of a temporary suspension due to the COVID-19 pandemic from May 1, 2020 through March 31, 2022 and a subsequent reduction to 1% from April 1, 2022 until June 30, 2022). In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, there have been several recent U.S. Congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to pharmaceutical and biological product pricing, reduce the cost of prescription drugs and biological products under Medicare, and reform government program reimbursement methodologies for drug and biological products. For example, in August 2022, former President

Biden signed into law the Inflation Reduction Act (IRA), which implements substantial changes to the Medicare program, including drug pricing reforms and changes to the Medicare Part D benefit design. Among other reforms, the IRA imposes inflation rebates on drug and biological product manufacturers for products reimbursed under Medicare Parts B and D if the prices of those products increase faster than inflation; implements changes to the Medicare Part D benefit that cap benefit annual out-of-pocket spending at \$2,000 (adjusted annually for inflation), with new discount obligations for pharmaceutical manufacturers; and establishes a “maximum fair price” for a fixed number of pharmaceutical and biological products covered under Medicare Parts B and D following a price negotiation process with the Centers for Medicare and Medicaid Services (CMS). CMS continues to take steps to implement the IRA, including: negotiating and publishing “maximum fair prices” for drugs selected under the IRA’s price negotiation framework and releasing quarterly lists of Medicare Part B products and annual lists of Medicare Part D products that are subject to adjusted coinsurance rates based on the inflationary rebate provisions of the IRA. While it remains to be seen how the drug pricing provisions imposed by the IRA will affect the broader pharmaceutical industry, several pharmaceutical manufacturers and other industry stakeholders have challenged the law, including through lawsuits brought against the U.S. Department of Health and Human Services (HHS), the Secretary of HHS, CMS, and the CMS Administrator challenging the constitutionality and administrative implementation of the IRA’s drug price negotiation provisions. Additionally, when originally enacted, the IRA explicitly excluded from price negotiation orphan drugs designated for only one rare disease or condition and for which the only active approved indication is for such disease or condition. However, the One Big Beautiful Bill Act (OBBBA) signed into law on July 4, 2025 amended the applicable statute to broaden the orphan drug exclusion such that products with more than one orphan designation and more than one approved indication will remain exempt from price negotiation, so long as each approved indication is for a rare disease or condition. The OBBBA also postpones the start of price negotiation requirements for drugs and biologics with orphan designations until the product receives approval for a non-orphan indication.

The current presidential administration has also signaled its intent to pursue additional healthcare reform measures, including those aimed at reducing prescription drug prices, through various means, including presidential executive orders and agency action. These efforts include, among other things, proposals to establish a “most favored nation” drug pricing policy that would tie U.S. drug prices to the prices paid for drugs in other countries. It remains to be seen how these drug pricing initiatives will affect the broader pharmaceutical industry.

At the state level, individual states in the U.S. have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosures and transparency measures, and, in some cases, laws designed to encourage importation from other countries and bulk purchasing. Some third-party payors also require pre-approval of coverage for new or innovative devices or therapies before they will reimburse healthcare providers that use such therapies. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize any product that is ultimately approved. In addition, several state laws require disclosures related to state agencies and/or commercial purchasers with respect to certain price increases and new product launches that exceed certain pricing thresholds as identified in the relevant statutes. Some of these laws and regulations contain ambiguous requirements that government officials have not yet clarified. Given the lack of clarity in the laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations. Some states have also established prescription drug affordability boards that are tasked with identifying certain high-cost prescription products that may pose affordability challenges for consumers and payers, conducting cost reviews on such products, and, in some circumstances, imposing upper payment limits on such products.

We expect that these initiatives and other healthcare reform measures that may be adopted in the future, as well as the trend toward managed healthcare and increasing influence of managed care organizations, may result in more rigorous coverage criteria and lower reimbursement, leading to additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of current and future cost containment measures or other healthcare reforms may adversely affect our operations and prevent us from being able to generate revenue, attain profitability or commercialize our drug candidates.

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.

Human Capital

As of March 16, 2026, we had 3 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 101 Lindenwood Drive, Suite 225, Malvern, Pennsylvania 19355. Our common stock is listed on the Over-The-Counter Quote Bulletin Board - Venture 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

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

We incurred losses in each year since our inception in 2012 through 2024, driven by expenses for research and development and our ongoing operations. None of our clinical products have been approved for commercialization, and after the sale to Biossil only one product candidate remains. Historically, we invested substantially all of our efforts and financial resources in identifying, acquiring, in-licensing and developing our historical product candidates, including commencing and conducting clinical trials and providing general and administrative support for these operations. Our net loss for the year ended December 31, 2024 was \$19.0 million. During the year ended December 31, 2025 we recorded a \$151.0 million non-cash gain from the extinguishment of the royalty purchase liability on our consolidated balance sheet, as the result of the assumption by Biossil of our obligations under the Royalty Agreement with Blackstone. As a result, our net income for the year ended December 31, 2025 was \$149.0 million. Despite this net income for the 2025 fiscal year, we anticipate incurring losses for the foreseeable future. As of December 31, 2025, we had an accumulated deficit of \$307.3 million.

To become consistently profitable, we must succeed in developing and eventually commercializing a product candidate that generates significant revenue. 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 candidate.

We may seek to finance our cash needs through securities offerings, debt financings and/or private placements, which may possibly be undertaken in conjunction with a merger or reverse merger. 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, our product candidate 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 Candidate

We are heavily dependent on the success of our product candidate, tilarginine, which has not received regulatory approval. If development of our product candidate is unsuccessful, we may be unable to obtain required regulatory approvals and be unable to commercialize our product candidate on a timely basis, if at all.

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. We have suffered significant and unexpected setbacks in certain of our clinical trials with respect to our historical product candidates. These kind of setbacks can potentially recur in the future due to, 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 candidate may not be predictive of the results of later-stage clinical trials. A product candidate 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 again in the future. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidate.

We rely, and will continue to rely, on third parties to conduct our clinical trials for our product candidate, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

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 may 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, which has occurred in one prior instance with regard to a former product candidate, our business, prospects and results of operations could be materially adversely affected.

We and/or our partners or potential partners may in the future rely on foreign CROs and contract manufacturing organizations, or CMOs. Such foreign CROs and CMOs may be subject to U.S. legislation, sanctions, tariffs, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us or our partners or potential partners, delay the procurement or supply of such material or have an adverse effect on our or our partners' or potential partners' ability to secure significant commitments from governments to purchase potential therapies. For example, President Trump recently signed into law the National Defense Authorization Act of 2026, which includes Section 851 regarding "prohibition on contracting with certain biotechnology providers" (the BIOSECURE Act), which restricts federal government contracts, grants, and loans from being issued to companies that use biotechnology equipment or services from any designated "biotechnology company of concern," as part of such companies' performance of those agreements with the U.S. government. Once fully implemented through issuance of regulations, the BIOSECURE Act may ultimately limit certain U.S. biotechnology companies from using equipment or services produced or provided by Chinese biotechnology companies that meet the designation criteria of the new law, or certain affiliated entities.

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 our product candidate 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 candidate 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 candidate 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 candidate 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 candidate could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

If unacceptable side effects arise in the development of our product candidate, 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 candidate 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 our product candidate 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.

The biopharmaceutical industries are subject to extensive regulatory obligations and policies that may be subject to significant and abrupt change, including due to judicial challenges, election cycles, and resulting regulatory updates and changes in policy priorities.

On June 28, 2024, the U.S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act (APA) “must exercise their independent judgment” and “may

not defer to an agency interpretation of the law simply because a statute is ambiguous.” The decision may have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by HHS, CMS, FDA and other agencies with significant oversight of the biopharmaceutical industries. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies will be subject to increased litigation and judicial scrutiny.

In addition, federal agency activities, priorities, leadership, policies, rulemaking, communications, spending, and staffing may be significantly impacted by election cycles and legislative developments. For example, the current presidential administration has signaled its continued commitment to significantly reduce government spending through cuts to federal healthcare programs and reductions in the workforces of key government agencies, such as HHS, FDA, and CMS. Efforts by the current administration to further limit federal agency budgets or personnel may result in reductions to agency budgets, employees, and operations. The administration and agencies have also made abrupt announcements about new or changed regulatory policies, such as policies related to the use of artificial intelligence to review product applications. And, the recent federal government shutdown may prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, and may significantly impact the ability of the FDA to timely review and process our regulatory submissions. These developments may lead to greater uncertainty regarding FDA policies, slower response times and longer review periods, potentially affecting our ability to progress development of our product candidate or obtain regulatory approval for our product candidate.

The National Institutes of Health (NIH) may also be significantly impacted by election cycles and legislative developments, and has experienced instability impacting biomedical research, including the termination of certain research grants and workforce reductions. Any future decrease in the amount of, or delay in the approval of, appropriations to the NIH (and associated decreases in grants provided by the NIH) could result in fewer grants benefiting life sciences research. These reductions or delays could also result in a decrease in the aggregate amount of grants awarded for life sciences research or the redirection of existing funding to other projects or priorities, any of which in turn could affect our current or future clinical trials.

There are also a number of healthcare-related legislative and regulatory initiatives and reforms in the United States that significantly affect the biopharmaceutical industry. For example, there has been heightened governmental scrutiny in the U.S. of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. Any resulting changes in regulation may result in unexpected delays, increased costs, or other negative impacts on our business that are difficult to predict.

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 few 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.

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.

Risks Related to Intellectual Property

If we are unable to adequately protect our proprietary technology and product candidate, 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 candidate 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 candidate 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 candidate, and other proprietary technologies. Our success depends on our ability to develop, manufacture, market and sell our product candidate, 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 candidate 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 candidate. There may also be issued patents or pending patent applications that we are aware of, but that we think are irrelevant to our product candidate, which may ultimately be found to be infringed by the manufacture, sale, or use of our product candidate. 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, our product candidate has 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 candidate, 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 candidate. Even if we diligently search third-party patents for potential infringement by our products or product candidate, we may not successfully find patents that our products or product candidate, may infringe. If we are unable to secure and maintain freedom to operate, others could preclude us from commercializing our product candidate.

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 candidate and technologies. Moreover, should we be unable to obtain meaningful patent coverage for clinically relevant dosages or infusion rates for our product candidate in jurisdictions with commercially significant markets, our ability to extend and reinforce patent protection for this

product candidate 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 our product candidate. 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.

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 candidate 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. 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 candidate 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 candidate, services and technologies. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidate 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 candidate, 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 candidate 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 candidate, 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 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 candidate, components of our product candidate, 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 candidate 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 candidate 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 candidate; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or product candidate 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 us 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 candidate, 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.

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 candidate, and we may collaborate with third parties on the development of our product candidate, 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 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 candidate, thereby potentially extending the term of marketing exclusivity for such product candidate, 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 candidate, 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 candidate 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 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. 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. 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 candidate, 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 candidate.

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 candidate 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 candidate 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 candidate 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 candidate. We may incorrectly determine that our product candidate is 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 candidate and services. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidate 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 our product candidate that are held to be infringing. We might, if possible, also be forced to redesign products, product candidate 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 candidate 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 candidate 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 candidate. 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 candidate 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 candidate. 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.

Risks Related to the Nova Acquisition

Our stockholders may not realize a benefit from our acquisition (the "Nova Acquisition") of Nova Pharmaceuticals, Inc. ("Nova") commensurate with the ownership dilution they may experience in connection with the Nova Acquisition upon conversion of preferred stock issued in connection therewith.

In the event we are unable to realize the strategic benefits currently anticipated from the Nova Acquisition, our stockholders will potentially have experienced substantial dilution of their ownership interest without receiving any commensurate benefit. We have devoted and will continue to devote significant management attention and resources to integrate the two companies and we may not manage these processes successfully. Delays in this process could adversely affect the combined company's business, financial results, financial condition and stock price. Even if we are able to integrate the business operations successfully, there can be no assurance that this integration will result in the realization of the full benefits anticipated. It is also possible that undisclosed, contingent or other liabilities or problems in connection with the acquired company may arise in the future of which we were previously unaware. These undisclosed liabilities could have an adverse effect on our business, financial condition and prospects. Additionally, in the event of any liquidation, holders of Series B Preferred Stock would be entitled to receive two-times the amount that a holder of common stock would receive had such shares of Series B Preferred Stock been converted, which could disincentivize further purchases of our common stock.

Other Risks Related to Our Business

The successful commercialization of our product candidate will depend in part on the extent to which third-party payors, including governmental authorities and private health insurers, provide coverage and adequate reimbursement levels, as well as implement pricing policies favorable for our product candidate.

Our ability to successfully commercialize our product candidate for which we may receive regulatory approval will depend in significant part on the availability of coverage and reimbursement from third-party payors, including governmental healthcare programs, such as the Medicare and Medicaid programs in the U.S., private health insurers, managed care organizations, and other entities. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include our product candidate. Third-party payors, together with regulators and others, are increasingly challenging the prices charged for pharmaceutical products and related services, in addition to their cost-effectiveness, safety, and efficacy.

Moreover, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval will be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. We cannot be certain that our product candidate will be considered cost-effective by third-party payors. This process could delay the market acceptance of our product candidate for which we may receive approval and could have a negative effect on our future revenues and operating results.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations, customers and others will be subject to applicable healthcare regulatory laws, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations, customers and others 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 candidate, if approved. See Part I, Item 1, Government Regulation, "Other

U.S. Healthcare Laws and Compliance Requirements” for additional details on applicable federal and state healthcare laws and regulations that may affect our business.

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 U.S. and 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 U.S. and global economy and in the U.S. and global financial markets. The global economy, including credit and financial markets, has 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 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.

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. Some of these vulnerabilities have increased with the widespread use of artificial intelligence technology. 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 candidate 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 candidate, 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.

While we do not currently have any operations outside the United States, should we have any in the future our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. 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 former 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, workers' compensation, umbrella, and directors' and officers' liability insurance. These policies may not adequately cover all categories of risk that our business may encounter.

Insurance coverage may become more expensive over time 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 certain losses. We do not currently maintain product liability insurance. 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 also do not carry specific biological or hazardous waste insurance coverage, and our 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 do not know 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.

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 is 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 tax attributes (net operating losses, or NOLs, and research and development tax credits) to offset future taxable income. Our existing tax attributes are subject to limitations arising from ownership changes that we have undergone in the past.

Risks Related to Our Common Stock

Our common stock is currently quoted on the OTCQB Market, which may have an unfavorable impact on our stock price and liquidity.

Our common stock is currently quoted on the OTCQB. The quotation of our shares on the OTCQB may result in a less liquid market available for existing and potential stockholders to trade shares of our common stock, could depress the trading price of our common stock and could have a long-term adverse impact on our ability to raise capital in the future. When fewer shares of a security are being traded on the OTCQB, volatility of prices may increase and price movement may outpace the ability to deliver accurate quote information. Due to lower trading volumes in shares of our common stock, there may be a lower likelihood that orders for shares of our common stock will be executed, and current prices may differ significantly from the price that was quoted at the time of entry of the order.

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 48% of our outstanding common stock as of March 16, 2026. Accordingly, these stockholders, if they act together, are 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 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.

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.

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.

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

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

- the listing of our common stock on the OTCQB Market;
- delays in the commencement, enrollment and the ultimate completion of clinical trials;
- discontinuation of clinical trials;
- the results and potential impact of competitive products or technologies;
- our ability to manufacture and successfully produce our product candidate;
- 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.

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. This dilution would be in addition to the anticipated dilution resulting from the conversion of our Series B Preferred Stock. 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 recognize the critical importance of securing our information systems and protecting the confidentiality, integrity, and availability of our data. To achieve this, we have developed and implemented a comprehensive cybersecurity risk management program designed to identify, assess, and mitigate risks to our critical systems and data, including risks resulting from cybersecurity threats associated with our use of third-party service providers.

Our cybersecurity strategy is integrated into the company’s broader enterprise risk management framework, ensuring that cybersecurity considerations are an integral part of decision-making at all levels of the organization. We collaborate with external experts, including cybersecurity assessors and vendors, to continuously evaluate and enhance our security posture and conduct regular risk assessments, penetration testing, and security audits.

Monitoring, Training and Incident Response

We continuously monitor our information systems for potential cybersecurity threats. Our cybersecurity incident response plan outlines specific procedures for responding to incidents, minimizing damage, and recovering swiftly. We have implemented a comprehensive cybersecurity training program for all employees to ensure they are fully equipped to handle cybersecurity responsibilities. The training emphasizes making cybersecurity an integral part of our corporate culture. It covers a wide range of topics, including understanding the different types of malware and how to avoid them, recognizing social engineering tactics like phishing and pretexting, and the importance of creating strong passwords while using multi-factor authentication. Additionally, the program addresses the unique security risks associated with remote work, mobile device usage, and Wi-Fi connections, as well as best practices for securing email communications and ensuring physical security of devices. Employees also

learn about the importance of information classification, securing sensitive data, and safeguarding mobile devices and USB drives from unauthorized access or attacks. The program highlights the risks associated with the dark web and emphasizes how employees can protect themselves and the organization from information exposure. Furthermore, the training ensures that employees understand how to effectively respond to cybersecurity incidents, including how to recognize, report, and address security threats in a timely manner. This training is regularly updated to reflect the latest security threats and trends, ensuring employees are always aware of evolving risks. Employee understanding is assessed through quizzes, and executive leadership plays a key role in reinforcing cybersecurity as a top priority by modeling strong security behaviors and emphasizing ongoing vigilance.

Cybersecurity Risks

We have not experienced or identified risks from 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

The Board of Directors (the Board), with oversight from the Audit Committee, is responsible for the governance of cybersecurity risks. The Audit Committee receives regular updates from management on cybersecurity risks and incidents, ensuring that the Board is kept informed. Management, led by the Chief Executive Officer (the “CEO”), is responsible for implementing the cybersecurity program, monitoring the company’s risk posture, and reporting to the Audit Committee and the Board regarding cybersecurity-related risks. The CEO works closely with external consultants and vendors, including IntellectMap, to ensure that we stay current with industry standards and best practices.

Item 2. Properties.

Our principal office is located at 101 Lindenwood Drive, Suite 225, Malvern, Pennsylvania 19355, where we lease office space under a month-to-month lease.

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.

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 was publicly traded on the Nasdaq Global Market under the symbol “GRTX” from November 7, 2019 until September 16, 2024. Prior to November 7, 2019, there was no public market for our common stock. Our common stock is now quoted under its existing symbol “GRTX” on the Over-The-Counter Quote Bulletin Board – Venture Market (OTCQB).

On March 16, 2026, there were 15 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.

Item 6. [Reserved]

Not applicable.

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, 2023, including a discussion of the year ended December 31, 2024 compared to the year ended December 31, 2023, has been reported previously in our Annual Report on Form 10-K for the year ended December 31, 2024, filed with the SEC on March 31, 2025, under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

Overview

We are a biopharmaceutical company that historically was focused on developing a portfolio of small molecule superoxide dismutase (SOD) mimetics to improve radiotherapy in cancer, primarily by reducing one of the most common side effects of radiotherapy, severe oral mucositis (SOM). In October 2025 we sold our assets related to avasopasem and rucosopasem and all other dismutase mimetics assets to Biossil, Inc. (Biossil), a privately-held company based in Toronto, Canada. In connection with selling these assets, we assigned and Biossil assumed all rights and obligations under the Royalty Agreement with Blackstone Life Sciences (Blackstone), as described below. We received consideration from Biossil in the form of an upfront payment of \$3.5 million and are eligible to receive further payments upon the achievement of future regulatory and commercial milestones and received contingent value rights of up to \$105.0 million in the aggregate.

On December 30, 2024, we completed the acquisition of Nova Pharmaceuticals, Inc., a privately-held biotechnology company advancing a pan-inhibitor of nitric oxide synthase (NOS). Nitric oxide (NO) plays a critical role in the tumor microenvironment (TME), in the initiation, progression and metastasis of many cancers and in the immune responses to cancer. Specifically, NOS has been shown to be over-expressed in TNBC and especially in the rare subset of triple-negative breast cancer (TNBC) known as metaplastic breast cancer (MpBC) that today has no effective or regulatory approved therapy. Initial clinical data with our pan-NOS inhibitor in these patients, when combined with a taxane, have been promising. With that acquisition, we have shifted our strategic focus to developing a product candidate to treat certain types of advanced breast cancer, including MpBC and other refractory subsets of TNBC. In support of the acquisition, a syndicate of investors led by Ikarian Capital invested \$2.9 million to purchase Galera common stock and pre-funded warrants. The Company continues as Galera Therapeutics, Inc., and our common stock is listed on the Over-The-Counter Quote Bulletin Board – Venture Market (OTCQB:GRTX).

In November 2025, our subsidiary Nova Pharmaceuticals, Inc. was merged into another subsidiary, Grape Merger Sub II, LLC, and the surviving entity was renamed Nova Pharmaceuticals Operating, LLC (Nova).

Following the sale to Biossil, our portfolio is now comprised of a pan-NOS inhibitor. Our lead program is a Phase 1/2 trial of the pan-NOS inhibitor in combination with nab-paclitaxel and alpelisib for MpBC. This is an investigator-sponsored trial that is funded by a National Institutes of Health (NIH) grant to investigators at the Methodist Hospital in Houston, Texas (Houston Methodist), including the drug supply for the trial. Assuming we are successful in securing additional capital, a second trial for this agent is being planned in TNBC in collaboration with the I-SPY 2 consortium.

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, \$117.5 million of proceeds received under the Royalty Agreement with Blackstone, and \$3.5 million received from the sale to Biossil, receiving aggregate gross proceeds of \$383.4 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. We may never succeed in these activities and we expect to continue to incur losses for the foreseeable future. We had net income of \$149.0 million for the year ended December 31, 2025, primarily resulting from a \$151.0 million non-cash gain from the derecognition of the royalty purchase liability on our consolidated balance sheet, as the result of the assumption by Biossil of our obligations under the Royalty Agreement with Blackstone. Our net loss was \$19.0 million for the year ended December 31, 2024. As of December 31, 2025, we had \$6.4 million in cash and cash equivalents and an accumulated deficit of \$307.3 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, 2025 will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months from the date of filing of this Annual Report on Form 10-K. Future capital requirements will depend on our strategic alternatives, which may include pursuit of a strategic transaction, a voluntary dissolution, or the continued operation of product development. Our anticipated operating expenses involve significant risks and uncertainties and are dependent on our current assessment of the extent and costs of activities required to advance our product candidate. In the future, we anticipate that we will need to raise substantial additional financing to fund our operations through equity or debt financings, or through strategic transactions. To meet these requirements, we may seek to sell equity or convertible securities in public or private transactions that may result in significant dilution to our stockholders. We may offer and sell shares of our common stock under any registration statement we may file in the future. If we raise additional funds through the issuance of convertible securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. We may also defer certain operating expenses unless and until additional capital is received. However, there can be no assurance that we will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to us, or that we will be successful in deferring certain operating expenses. If we are unable to raise sufficient additional capital or defer sufficient operating expenses, we may be unable to further develop our product candidate.

Our Common Stock is now quoted under its existing symbol “GRTX” on the Over-The-Counter Quote Bulletin Board – Venture Market.

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

Prior to the assignment and assumption of our Royalty Agreement with Blackstone to Biossil in October 2025, we accounted for the \$117.5 million in aggregate proceeds received under the Royalty Agreement as debt, and imputed our interest expense, when applicable, based on royalty repayment period amounts we estimated, which took into consideration the probability and timing of obtaining approval from the U.S. Food and Drug Administration (FDA) and the potential future revenue from commercializing our product candidate. In October 2023, following our decisions to discontinue the rucosopasem GRECO trials and not conduct another Phase 3 trial of avasopasem, we suspended imputing any interest expense related to our royalty purchase liability. Accordingly, no interest expense was recognized during the years ended December 31, 2025 and 2024.

Upon our assignment of all further rights and obligations associated with the Royalty Agreement to Biossil in October 2025, inclusive of Blackstone's acknowledgement of the assignment, we determined the outstanding royalty purchase obligation of \$151.0 million met the extinguishment criteria under the applicable accounting standards. The extinguishment of this royalty purchase obligation was recorded as gain on extinguishment of debt within our consolidated statement of operations for the year ended December 31, 2025.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the development of our product candidate. 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.

Components of Results of Operations

Acquired in-process research and development expenses

Acquired in-process research and development expenses consist of a non-cash expense related to the acquisition of research and development programs that had no alternative future use at the time of acquisition which requires immediate expense recognition.

Research and Development Expense

Research and development expenses consist primarily of costs incurred in connection with the discovery and development of our current and past 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, 2025 and 2024 (in thousands):

	Year ended December 31,	
	2025	2024
Avasopasem manganese.....	\$ 61	\$ (318)
Rucosopasem manganese.....	—	696
Pan-NOS inhibitor.....	5	—
Other research and development expense.....	264	607
Personnel related and share-based compensation expense.....	19	2,166
	<u>\$ 349</u>	<u>\$ 3,151</u>

We have ceased all clinical trial activity directly funded by the Company, and had suspended the clinical development of our dismutase mimetics product candidates prior to their sale to Biossil.

The successful development of our product candidate is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the development of our product candidate. We are unable to predict when, if ever, material net cash inflows will 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 candidate 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 candidate;
- 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, and accounting functions. General and administrative expense also includes legal fees related to intellectual property and corporate matters, director fees, fees for accounting and consulting services, insurance expense, and rent.

Assuming we are successful in securing additional capital, we expect that our expenses will increase in the future to support our continued research and development activities and to expand our operations.

Interest Income

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

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, 2024, the impairment of our acquired intangible asset and goodwill resulted in an income tax benefit of \$0.2 million due to the tax effect of the reduction in the deferred tax liability associated with the asset.

Net Operating Loss and Research and Development Tax Credit Carryforwards

As of December 31, 2025, we had federal and state tax net operating loss carryforwards of \$157.8 million and \$12.6 million, respectively, which will begin to expire in 2044 unless previously utilized. In connection with the Section 382 study performed in 2025, the federal research and development tax credit carryforwards have been written off.

Results of Operations for the Years Ended December 31, 2025 and 2024

The following table sets forth our results of operations for the years ended December 31, 2025 and 2024 (in thousands):

	Year ended December 31,		Change
	2025	2024	
Operating expenses:			
Acquired in-process research and development....	\$ —	\$ 3,843	\$ (3,843)
Research and development.....	349	3,151	(2,802)
General and administrative	5,693	11,002	(5,309)
Gain on sale of dismutase mimetics assets	(3,500)	—	(3,500)
Write-off of acquired intangible asset.....	—	2,258	(2,258)
Write-off of goodwill.....	—	881	(881)
Gain on litigation settlement.....	—	(975)	975
Loss from operations.....	(2,542)	(20,160)	17,618
Other income (expense):			
Interest income.....	248	554	(306)
Gain on extinguishment of debt.....	151,049	—	151,049
Change in fair value of warrant liability.....	294	452	(158)
Foreign currency loss.....	—	(6)	6
Income (loss) before income tax benefit.....	149,049	(19,160)	168,209
Income tax benefit.....	—	203	(203)
Net income (loss).....	<u>\$ 149,049</u>	<u>\$ (18,957)</u>	<u>\$ 168,006</u>

Acquired In-Process Research and Development Expense

In connection with the acquisition of Nova, we recognized a non-cash in-process research and development expense of \$3.8 million during the year ended December 31, 2024 related to the acquired anti-cancer therapeutics programs that had no alternative future use at the time of acquisition, which requires immediate expense recognition.

Research and Development Expense

Research and development expense decreased by \$2.9 million from \$3.2 million for the year ended December 31, 2024 to \$0.3 million for the year ended December 31, 2025. Personnel-related and share-based compensation expense decreased \$2.1 million, as our remaining research and development personnel were terminated during the year ended December 31, 2024, which included \$0.8 million of severance charges, and their stock options forfeited. Rucosopasem development costs decreased by \$0.7 million as we wound up the GRECO-1 and GRECO-2 clinical trials in 2024. Other research and development expenses decreased \$0.3 million, which was offset by a \$0.4 million increase in avasopasem development costs since the year ended December 31, 2024 included a \$0.4 million credit for previously estimated CRO expenses following a legal settlement.

General and Administrative Expense

General and administrative expense decreased by \$5.3 million from \$11.0 million for the year ended December 31, 2024 to \$5.7 million for the year ended December 31, 2025. Personnel related and share-based compensation expenses decreased \$2.9 million due to reduced headcount, severance expense during the year ended December 31, 2024 for two officers terminated in August 2024, stock options forfeited by terminated employees, and stock options that became fully vested during 2024. In addition, legal and professional fees decreased \$1.2 million, insurance expense decreased \$0.6 million, and facilities costs decreased \$0.6 million because the year ended December 31, 2024 included a \$0.5 million charge for expenses incurred to terminate our office lease.

Gain on Sale of Dismutase Mimetics Assets

We recognized a gain on sale of assets of \$3.5 million during the year ended December 31, 2025 in connection with the sale of our dismutase mimetics assets to Biossil, the amount of the cash consideration received in October 2025.

Write-off of Acquired Intangible Asset and Goodwill

In August 2024, our board of directors approved the Plan of Dissolution, under which future development of our historical product candidates would no longer continue. In connection with this decision, we concluded that the related IPR&D asset and related goodwill were each impaired in their entirety, and as such recognized non-cash impairment charges of \$2.3 million for the IPR&D and \$0.9 million for the goodwill during the year ended December 31, 2024.

Gain on Litigation Settlement

We recognized a \$1.0 million gain during the year ended December 31, 2024 in connection with the settlement of certain litigation, which was recorded in operating expenses.

Interest Income

Interest income decreased by \$0.4 million from \$0.6 million for the year ended December 31, 2024 to \$0.2 million for the year ended December 31, 2025, due to the reduction in investable cash and securities and reduced interest rates.

Gain on Extinguishment of Debt

As discussed above, we assigned all further rights and obligations associated with the Royalty Agreement to Biossil in connection with the October 2025 sale of our dismutase mimetics assets, including avasopasem and rucosopasem, resulting in recognition of a \$151.0 million gain during the year ended December 31, 2025 in connection with extinguishment of the \$151.0 million royalty purchase liability.

Change in Fair Value of Warrant Liability

During the years ended December 31, 2025 and 2024 we recognized gains of \$0.3 million and \$0.5 million, respectively, for changes in fair value of the warrant liability as a result of the change in the price of our common stock. The warrant liability was reclassified to equity as of March 31, 2025.

Income Tax Benefit

During the year ended December 31, 2024, the impairment of our acquired intangible asset and goodwill resulted in an income tax benefit of \$0.2 million due to the tax effect of the reduction in the deferred tax liability associated with the asset.

Liquidity and Capital Resources

We do not have any products approved for sale, and we do not expect to generate any revenue from product sales unless and until we successfully complete development and obtain regulatory approval for our product candidate, which will not be for many years, if ever. Through December 31, 2025, we have funded our operations primarily through the sale and issuance of equity, \$117.5 million of proceeds received under the Royalty Agreement with Blackstone Life Sciences, and \$3.5 million from the sale to Biossil, receiving aggregate gross proceeds of \$383.4 million.

On October 15, 2025, we entered into, and subsequently amended, an Asset Purchase and Sale Agreement with Biossil, pursuant to which Biossil agreed to acquire all of our right, title and interest in and to our

assets related to avasopasem and rucosopasem and all other dismutase mimetic assets. In connection with acquiring these assets, we assigned and Biossil assumed all rights and obligations under the Royalty Agreement with Blackstone. We received consideration from Biossil in the form of an upfront payment of \$3.5 million and are eligible to receive further payments upon the achievement of future regulatory and commercial milestones and received contingent value rights of up to \$105.0 million in the aggregate.

In December 2024, we completed a private placement with a group of investors led by Ikarian Capital. We issued approximately 21.1 million shares of common stock plus pre-funded warrants exercisable for approximately 23.0 million shares of common stock at an offering price of \$0.065 per share or pre-funded warrant. As a result of the private placement, we received net proceeds of approximately \$2.9 million.

In February 2023, we completed a registered direct offering, which resulted in the issuance and sale of 14,320,000 shares of our common stock and warrants to purchase up to 14,320,000 shares of common stock at a combined offering price of \$2.095 per share and accompanying warrant, 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, 2025, we had \$6.4 million in cash and cash equivalents and an accumulated deficit of \$307.3 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. We expect our existing cash and cash equivalents as of December 31, 2025 will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months from the date of filing of this Annual Report on Form 10-K. Future capital requirements will depend on our strategic alternatives, which may include pursuit of a strategic transaction, a voluntary dissolution, or the continued operation of product development.

Cash Flows

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

	Year ended December 31,	
	2025	2024
Net cash used in operating activities.....	\$ (6,049)	\$ (12,145)
Net cash provided by (used in) investing activities.....	3,500	(46)
Net cash provided by financing activities.....	635	2,223
Net decrease in cash, cash equivalents and restricted cash.....	<u>\$ (1,914)</u>	<u>\$ (9,968)</u>

Operating Activities

During the year ended December 31, 2025, we used \$6.0 million of net cash in operating activities. Cash used in operating activities reflected our net income of \$149.0 million less net non-cash gains and charges of \$154.4 million, primarily attributable to the gain on sale of our dismutase mimetics assets and gain on extinguishment of debt, and \$0.7 million from other changes in operating assets and liabilities. The primary use of cash was to fund our operations.

During the year ended December 31, 2024, we used \$12.2 million of net cash in operating activities. Cash used in operating activities reflected our net loss of \$19.0 million plus \$2.1 million from other changes in operating assets and liabilities, partially offset by non-cash charges of \$8.9 million related to acquired in-process research and development, the write-off of the acquired intangible asset and goodwill, deferred tax benefit, share-based compensation, depreciation expense, and loss from disposal of property and equipment. The primary use of cash was to fund our operations as we reviewed strategic alternatives and completed the acquisition of Nova.

Investing Activities

During the year end December 31, 2025, we received proceeds of \$3.5 million from the sale of our dismutase mimetics assets. During the year ended December 31, 2024, investing activities used \$46,000, primarily cash paid for the acquisition of Nova.

Financing Activities

During the year ended December 31, 2025, financing activities provided \$0.6 million from the sale of our common stock in a private placement in December 2024, some proceeds of which were received in January 2025.

During the year ended December 31, 2024, financing activities provided \$2.2 million from the sale of our common stock and pre-funded warrants in a private placement in December 2024.

Funding Requirements

We expect our existing cash and cash equivalents as of December 31, 2025 will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months from the date of filing of this Annual Report on Form 10-K. Future capital requirements will depend on our strategic alternatives, which may include pursuit of a strategic transaction, a voluntary dissolution, or the continued operation of product development. Our anticipated operating expenses involve significant risks and uncertainties and are dependent on our current assessment of the extent and costs of activities required to advance our product candidate. In the future, we anticipate that we will need to raise substantial additional financing to fund our operations through equity or debt financings, or through strategic transactions. To meet these requirements, we may seek to sell equity or convertible securities in public or private transactions that may result in significant dilution to our stockholders. We may offer and sell shares of our common stock under an existing registration statement or any registration statement we may file in the future. If we raise additional funds through the issuance of convertible securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. We may also defer certain operating expenses unless and until additional capital is received. However, there can be no assurance that we will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to us, or that we will be successful in deferring certain operating expenses. If we are unable to raise sufficient additional capital or defer sufficient operating expenses, we may be compelled to reduce the scope of our operations and planned capital expenditures and may decide to delay or discontinue certain activities, including planned research and development activities, hiring plans, manufacturing activities and commercial preparation efforts.

Because of the numerous risks and uncertainties associated with research, development and commercialization of our product candidate, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on, and could increase significantly as a result of, many factors, including:

- the 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 candidate and technologies;
- the costs of securing manufacturing arrangements for any future commercial production; and
- the costs of scaling-up or contracting for sales and marketing capabilities as we prepare for the potential commercialization of our product candidate.

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 certain activities, including planned research and development activities or hiring plans.

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.

Key Agreements

Asset Purchase Agreement with Biossil

On October 15, 2025, the Company and Biossil, Inc. entered into an Asset Purchase and Sale Agreement, as amended (the Purchase Agreement), whereby Biossil agreed to acquire all of the Company's right, title and interest in and to its assets related to avasopasem (GC4419) and rucosopasem (GC4711) and all other dismutase mimetic assets (the Assets).

In connection with the purchase of the Assets, Biossil agreed to assume all further rights and obligations of the Company under the Amended and Restated Purchase and Sale Agreement, dated November 14, 2018, by and among the Company, Clarus IV Galera Royalty AIV, L.P., and the other parties thereto, as amended from time to time. Clarus IV Galera Royalty AIV, L.P. is affiliated with Blackstone Life Sciences (Blackstone).

The purchase price for the Assets consists of (i) an upfront payment of \$3,500,000, and (ii) potential future regulatory milestones, commercial milestones and contingent value rights of up to \$105,000,000 in the aggregate.

The Purchase Agreement contains customary representations, warranties and covenants related to the Assets and the business of the Company. Certain provisions, including confidentiality, indemnification, and payment obligations, survive the closing of the Transaction in certain circumstances as set forth in the Purchase Agreement.

Methodist Hospital License Agreement

The Company's subsidiary, Nova, has a worldwide license agreement (the License) with Houston Methodist. The License was executed in January 2024 and gives Nova the exclusive rights to certain Houston

Methodist patents for use in the field of oncology, and non-exclusive rights to certain Houston Methodist know-how for use in connection with the licensed patents.

As consideration for the License, Nova paid Houston Methodist an initial license fee of \$300,000, approximately \$147,000 as reimbursement for patent costs incurred prior to the date of the license, and a \$100,000 deposit for future patent costs incurred by Houston Methodist to the extent they are not paid by Nova. Under a separate patent prosecution agreement, fees of the law firm maintaining the licensed patents are billed to and payable directly by Nova.

The License includes due diligence requirements for Nova to submit an Investigational New Drug (IND) application by January 31, 2028, and thereafter to initiate Phase 1, 2 and 3 clinical trials and file a Biologics License Application (BLA) by specified dates. If Nova receives FDA approval for a product covered by the License, fees are payable upon attainment of certain commercial milestones, and low-to-mid single digit royalties are payable on net sales. Fees are also payable on any sublicense revenue that Nova receives.

As additional consideration for the License, Nova made an initial issuance of shares of Nova common stock to Houston Methodist, and subsequently issued additional shares such that Houston Methodist maintained an agreed percentage of Nova outstanding shares. On December 30, 2024, the Houston Methodist shares in Nova were exchanged for approximately 7,323 shares of the Company's Series B Preferred Stock. Refer to Notes 3 and 12 to our consolidated financial statements included in this Annual Report on Form 10-K.

Unless earlier terminated, the License expires on the later of January 31, 2044, or the end of the patent term for the last licensed patent to expire, after which the license continues on a nonexclusive, royalty-free basis.

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.

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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, 2025 and 2024, the related consolidated statements of operations, changes in redeemable convertible preferred stock and stockholders' equity (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, 2025 and 2024, 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Extinguishment of the royalty purchase liability

As discussed in Notes 1, 2, 4, and 9 to the consolidated financial statements, in October 2025 the Company entered into an asset purchase agreement with Biossil, Inc. (Biossil) pursuant to which the Company sold its dismutase mimetics assets and assigned its royalty purchase agreement with Blackstone Life Sciences (Blackstone) to Biossil. In connection with this transaction, Biossil assumed all rights and obligations under the royalty purchase agreement, and Blackstone executed a notice of assignment releasing the Company from further obligations. As a result, the Company extinguished the royalty purchase liability of

approximately \$151.0 million and recorded a gain on extinguishment of debt during the year ended December 31, 2025.

We identified the evaluation of the extinguishment of the royalty purchase liability as a critical audit matter. Significant auditor judgment was required to evaluate the Company's conclusion that the assignment of the royalty purchase agreement resulted in a legal defeasance and extinguishment of the liability under applicable accounting guidance. This evaluation involved assessing whether the Company was legally released as the primary obligor, which required careful consideration of complex contractual provisions. A different conclusion regarding whether the liability had been legally extinguished would have resulted in a significant difference in the Company's reported liabilities and results of operations.

The following are the primary procedures we performed to address this critical audit matter. We tested the Company's conclusion that the royalty purchase liability was legally defeased by:

- reading and evaluating management's accounting memorandum regarding the extinguishment of the royalty purchase liability and gain on extinguishment of debt, including management's application of the relevant accounting guidance
- inspecting the royalty purchase agreement with Blackstone and related amendments, the asset purchase agreement with Biossil, and the notice of assignment to evaluate whether the contractual terms permitted assignment and release of the Company as the primary obligor
- inspecting the legal opinion obtained by management from external counsel and evaluating the competence and objectivity of the legal specialist, and assessing whether the opinion supported the Company's conclusion that the transaction resulted in a legal defeasance
- corroborating our understanding of the transaction through inquiry of management and inspection of board of directors' minutes and other governance documentation related to the approval of the transaction

/s/ KPMG LLP

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

Philadelphia, Pennsylvania
March 19, 2026

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

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents.....	\$ 6,375	\$ 8,289
Subscription receivable	—	635
Prepaid expenses and other current assets.....	720	1,077
Total current assets.....	7,095	10,001
Other assets.....	101	100
Total assets	\$ 7,196	\$ 10,101
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable.....	\$ 265	\$ 1,275
Accrued expenses.....	380	391
Total current liabilities	645	1,666
Royalty purchase liability.....	—	151,049
Warrant liability.....	—	1,055
Total liabilities.....	645	153,770
Commitments and contingencies (Note 11)		
Series B redeemable convertible preferred stock, \$0.001 par value: 10,000,000 shares authorized; 119,318 shares issued and outstanding at December 31, 2025 and 2024.....	2,577	4,372
Stockholders' equity (deficit):		
Common stock, \$0.001 par value: 200,000,000 shares authorized; 75,462,390 shares issued and outstanding at December 31, 2025 and 2024	75	75
Additional paid-in capital.....	311,213	308,247
Accumulated deficit.....	(307,314)	(456,363)
Total stockholders' equity (deficit).....	3,974	(148,041)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit).....	\$ 7,196	\$ 10,101

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,	
	2025	2024
Operating expenses:		
Acquired in-process research and development.....	\$ —	\$ 3,843
Research and development.....	349	3,151
General and administrative.....	5,693	11,002
Gain on sale of dismutase mimetics assets.....	(3,500)	—
Write-off of acquired intangible asset.....	—	2,258
Write-off of goodwill	—	881
Gain on litigation settlement	—	(975)
Loss from operations.....	(2,542)	(20,160)
Other income (expenses):		
Interest income	248	554
Gain on extinguishment of debt	151,049	—
Change in fair value of warrant liability	294	452
Foreign currency loss	—	(6)
Income (loss) before income tax benefit.....	149,049	(19,160)
Income tax benefit.....	—	203
Net income (loss).....	\$ 149,049	\$ (18,957)
Net income (loss) attributable to common stockholders, basic and diluted.....	\$ 63,524	\$ (18,733)
Weighted-average shares of common stock outstanding, basic and diluted.....	98,503,430	54,633,215
Net income (loss) per share of common stock, basic and diluted.....	\$ 0.64	\$ (0.34)
Net income (loss) attributable to Series B redeemable convertible preferred stockholders, basic and diluted.....	\$ 76,948	\$ (224)
Weighted-average shares of Series B redeemable convertible preferred stock outstanding, basic and diluted.....	119,318	652
Net income (loss) per share of Series B redeemable convertible preferred stock, basic and diluted	\$ 644.89	\$ (342.89)

See accompanying notes to consolidated financial statements.

GALERA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY
(DEFICIT)
(IN THOUSANDS EXCEPT SHARE AMOUNTS)

	Redeemable convertible preferred stock		Common stock		Additional paid-in capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at December 31, 2023.....	—	\$ —	54,392,170	\$ —	306,167	(437,406)	\$ (131,185)
Share-based compensation expense.....	—	—	—	—	2,545	—	2,545
Issuance of Series B convertible preferred stock in asset acquisition.....	119,318	2,577	—	—	—	—	—
Accretion of redeemable convertible preferred stock to redemption value.....	—	1,795	—	—	(1,795)	—	(1,795)
Sale of common stock and common stock warrants in private placement, net of issuance costs of \$27	—	—	21,070,220	—	1,330	—	1,351
Net loss.....	—	—	—	—	—	(18,957)	(18,957)
Balance at December 31, 2024.....	119,318	4,372	75,462,390	—	308,247	(456,363)	(148,041)
Share-based compensation expense.....	—	—	—	—	410	—	410
Amortization of redeemable convertible preferred stock to redemption value	—	(1,795)	—	—	1,795	—	1,795
Reclassification of pre-funded stock warrants.....	—	—	—	—	761	—	761
Net income	—	—	—	—	—	149,049	149,049
Balance at December 31, 2025.....	119,318	2,577	75,462,390	\$ —	311,213	(307,314)	\$ 3,974

See accompanying notes to consolidated financial statements.

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

	Year ended December 31,	
	2025	2024
Operating activities:		
Net income (loss)	\$ 149,049	\$ (18,957)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Acquired in-process research and development	—	3,843
Depreciation and amortization	—	20
Share-based compensation expense	410	2,545
Write-off of acquired intangible asset	—	2,258
Write-off of goodwill	—	881
Deferred tax benefit	—	(203)
Change in fair value of warrants	(294)	(452)
Gain on sale of dismutase mimetics assets	(3,500)	—
Gain on extinguishment of debt	(151,049)	—
Loss on disposal of property and equipment	—	48
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	357	2,295
Other assets	(1)	89
Accounts payable	(1,010)	(1,416)
Accrued expenses	(11)	(3,058)
Other liabilities	—	(38)
Cash used in operating activities	(6,049)	(12,145)
Investing activities:		
Cash paid for acquisition of Nova	—	(50)
Proceeds from sale of property and equipment	—	4
Proceeds from sale of dismutase mimetics assets	3,500	—
Cash provided by (used in) investing activities	3,500	(46)
Financing activities:		
Proceeds from the sale of common stock and common stock warrants in private placement, net of issuance costs	635	2,223
Cash provided by financing activities	635	2,223
Net decrease in cash and cash equivalents	(1,914)	(9,968)
Cash and cash equivalents at beginning of year	8,289	18,257
Cash and cash equivalents at end of year	\$ 6,375	\$ 8,289
Supplemental schedule of non-cash investing and financing activities:		
Extinguishment of royalty purchase liability upon sale of dismutase mimetics assets	\$ 151,049	\$ —
Issuance of Series B redeemable convertible preferred stock in asset acquisition	\$ —	\$ 2,577
Accretion (amortization) of redeemable convertible preferred stock to redemption value	\$ (1,795)	\$ 1,795
Subscription receivable in connection with private placement	\$ —	\$ 635
Derecognition of lease liability and right-of-use asset due to lease termination	\$ —	\$ 1,212
Acquisition costs in accounts payable	\$ —	\$ 869
Reclassification of warrant liability to additional paid-in capital	\$ 761	\$ —

See accompanying notes to consolidated financial statements.

GALERA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and description of business

Galera Therapeutics, Inc. (the Company, or Galera) is a biopharmaceutical company that historically was focused on developing a portfolio of small molecule dismutase (SOD) mimetics to improve radiotherapy in cancer, primarily by reducing one of the most common side effects of radiotherapy, severe oral mucositis (SOM). The Company sold its assets related to avasopasem and rucosopasem and all other dismutase mimetics assets to Bioasil, Inc. (Bioasil), a privately-held company based in Toronto, Canada, in October 2025. Galera received consideration from Bioasil in the form of an upfront payment of \$3.5 million and is eligible to receive further payments upon the achievement of future regulatory and commercial milestones and received contingent value rights of up to \$105.0 million in the aggregate. In addition, Bioasil assumed all rights and obligations associated with the Company's royalty purchase obligation (Note 9), resulting in a gain on sale of assets of \$3.5 million and a gain on extinguishment of debt of \$151.0 million related to the extinguishment of the outstanding royalty purchase liability that was assumed by Bioasil.

Galera's clinical portfolio now is comprised of a pan-inhibitor of nitric oxide synthase (NOS) that was acquired in December 2024 through the acquisition of Nova Pharmaceuticals, Inc. (Nova) (Note 3). Galera's lead program is now an investigator-sponsored Phase 1/2 trial of the pan-NOS inhibitor in combination with nab-paclitaxel and alpelisib for MpBC, which is being conducted at Methodist Hospital in Houston, Texas (Houston Methodist) with funding by a grant from the National Institutes of Health.

Liquidity

The Company has incurred recurring losses and negative cash flows from operations since inception and has an accumulated deficit of \$307.3 million as of December 31, 2025. The Company expects its existing cash and cash equivalents as of December 31, 2025 will enable the Company to fund its operating expenses, which are currently at a limited level, for at least twelve months from the date these consolidated financial statements were issued.

In December 2024, the Company completed a private placement with a group of investors led by Ikarian Capital. The Company issued 21,070,220 shares of common stock plus pre-funded warrants exercisable for 23,041,040 shares of common stock at an offering price of \$0.065 per share or pre-funded warrant. The Company received net proceeds of approximately \$2.9 million after deducting issuance costs of approximately \$27,000, of which \$0.6 million was received in January 2025. The pre-funded warrants have an exercise price of \$0.001 per share, are exercisable immediately following their issuance and never expire.

As stated above, in October 2025 the Company received \$3.5 million from the sale of its dismutase mimetics assets to Bioasil.

The Company does not currently have sufficient cash to adequately fund the development of its product candidate. In order to continue research and development, the Company will need to raise additional financing to fund its operations, which could be through equity or debt financing or through strategic transactions. Future capital requirements will depend on what, if any, strategic alternatives are available to the Company, which may include pursuit of a strategic transaction, a voluntary dissolution, or the continued operation of product development.

2. Basis of presentation and significant accounting policies

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).

GALERA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The consolidated financial statements include the accounts of Galera Therapeutics, Inc. and its wholly owned subsidiaries, Nova Pharmaceuticals Operating, LLC, Galera Therapeutics Australia Pty Ltd (Galera Australia), and Galera Labs, LLC. Galera Australia was deregistered in November 2024. In December 2024, the Company acquired Nova Pharmaceuticals, Inc. as a wholly owned subsidiary, which was merged into another wholly owned subsidiary, Grape Merger Sub II, LLC in November 2025, with the surviving entity renamed Nova Pharmaceuticals Operating, LLC (see Note 3). 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.

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.

Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker (CODM) in making decisions regarding resource allocation and assessing performance.

The Company's Chief Executive Officer (CEO), as the CODM, manages the Company's business activities as a single operating and reportable segment at the consolidated level. Accordingly, the CEO uses consolidated income (loss) from operations as well as consolidated net income (loss) to measure segment profit or loss, allocate resources, and assess performance. The measure of segment assets is reported on the balance sheet as total assets.

Significant expenses within income (loss) from operations, as well as within net income (loss), include research and development and general and administrative expenses, which are each separately presented on the Company's consolidated statements of operations. Other segment items within net income (loss) include acquired in-process research and development, write-offs of the acquired intangible asset and goodwill, a gain on litigation settlement, a gain on sale of dismutase mimetics assets, a gain on extinguishment of debt, interest income, interest expense, the change in fair value of warrant liability, foreign currency loss, and income tax benefit.

GALERA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The table below summarizes the significant expense categories reviewed by the CEO for the years ended December 31, 2025 and 2024:

	Year ended December 31,	
	2025	2024
Research and Development		
Personnel.....	\$ 1	\$ 1,476
Stock-based compensation.....	18	690
Program expenses	66	378
Other unallocated expenses.....	264	607
Total research and development	<u>349</u>	<u>3,151</u>
General and Administrative		
Personnel.....	1,197	2,607
Stock-based compensation.....	392	1,855
Professional fees	2,876	4,060
Other general and administrative.....	1,228	2,480
Total general and administrative.....	<u>5,693</u>	<u>11,002</u>
Other segment items	(155,091)	4,804
Net income (loss).....	<u>\$ 149,049</u>	<u>\$ (18,957)</u>

Asset acquisitions

Acquisitions of assets or a group of assets that do not meet the definition of a business are accounted for as asset acquisitions, with a cost accumulation model used to determine the cost of the acquisition. Common stock issued as consideration in an acquisition of assets is generally measured based on the acquisition date fair value of the equity interests issued. Direct transaction costs are recognized as part of the cost of an acquisition of assets. Intangible assets that are acquired in an asset acquisition for use in research and development activities that have an alternative future use are capitalized as in-process research and development (IPR&D). Acquired IPR&D that has no alternative future use is expensed immediately in the consolidated statements of operations.

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. The royalty purchase liability was accounted for as debt and interest was accreted over the expected repayment period until the extinguishment of the royalty purchase liability following the sale to Biossill. 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 New Drug Application (NDA), it was not feasible to conduct an additional clinical trial with the Company's resources. Due to the uncertainty of obtaining regulatory approval and successful commercialization of avasopasem, it was impractical to determine the fair value of the debt. The pre-funded warrants were measured at fair value on a recurring basis and carried at their estimated fair value until their reclassification to equity at March 31, 2025.

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, 2025 or 2024.

GALERA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2025 and 2024 consisted of bank deposits and a money market mutual fund invested in U.S. Treasury obligations. The Company maintains a portion of its cash and cash equivalents in accounts with major financial institutions, and its deposits at these institutions exceed insured limits.

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. The Company had no property and equipment as of December 31, 2025 or 2024.

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, 2025, 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

Intangible assets related to IPR&D are considered indefinite-lived intangible assets and, along with goodwill, are not amortized, but are assessed for impairment annually or more frequently if impairment indicators exist. For those compounds that reach commercialization, the IPR&D assets will be amortized over their estimated useful lives. If the associated research and development effort related to IPR&D is abandoned, the related assets will be written-off and the Company will record a noncash impairment loss on its consolidated statements of operations.

In August 2024, the Company's board of directors approved a plan of complete liquidation and dissolution (Plan of Dissolution), under which future development of the Company's historical product candidates would no longer continue. In connection with this decision, the Company concluded that the related IPR&D asset and related goodwill were each impaired in their entirety, and as such recognized non-cash impairment charges of \$2.3 million for the IPR&D and \$0.9 million for the goodwill during the year ended December 31, 2024. The impairment also resulted in an income tax benefit of \$0.2 million due to the tax effect of the reduction in the deferred tax liability associated with the IPR&D asset. The Plan of Dissolution ultimately did not receive approval by the Company's shareholders.

Royalty purchase liability

In November 2018, the Company entered into an Amended and Restated Purchase and Sale Agreement (as subsequently amended, the Royalty Agreement) with Clarus IV Galera Royalty AIV, 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). Proceeds from the Royalty Agreement are accounted as debt. Interest expense is imputed based on the estimated royalty repayment period and considers the probability and timing of obtaining regulatory approvals and potential future revenue from commercial net product sales. Changes in estimates, if any, are made prospectively. Amendments to royalty purchase arrangements are evaluated for extinguishment and modification accounting treatment at the time of each amendment. Royalty purchase liabilities are derecognized when they are deemed to be extinguished, which is determined when the Company has paid the liability in its entirety and is relieved of its obligation, or when the Company is legally released from being the primary obligor under the liability, either judicially or by the creditor.

GALERA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In connection with the sale of the Company's dismutase mimetics assets to Biossil, the Company assigned and Biossil assumed all rights and obligations under the Royalty Agreement, and Blackstone acknowledged that it would look solely to Biossil to pay and perform the obligations and liabilities under the Royalty Agreement. The Company extinguished its outstanding royalty purchase liability at the time of the assignment and assumption with Biossil.

Warrant Liability

The pre-funded warrants issued in conjunction with the private placement in December 2024 (See Note 1) were classified as liabilities on the balance sheet at December 31, 2024, as they contained terms for redemption of the underlying security that were outside the Company's control. The warrant liability was initially recorded at fair value upon the date of issuance and subsequently remeasured to fair value at each reporting date, with changes recognized in the consolidated statements of operations. In March 2025 the pre-funded warrants were amended, and were thereafter deemed to qualify for equity classification. The Company recognized a final change in the fair value of the liability classified warrants immediately prior to the reclassification (See Note 5).

Redeemable Convertible Preferred Stock

The Company records shares of redeemable convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs. The Company has applied the guidance in ASC 480-10-S99-3A, SEC Staff Announcement: Classification and Measurement of Redeemable Securities, and has therefore classified the redeemable convertible preferred stock outside of stockholders' equity (deficit) because, if conversion to common stock is not approved by the stockholders, the redeemable convertible preferred stock will be redeemable at the option of the holders for cash equal to the closing price of the common stock on the last trading day prior to the holder's redemption request. The Company determined that the conversion and redemption are outside of the Company's control. Additionally, the Company determined the conversion and redemption features did not require bifurcation as derivatives.

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. As of December 31, 2025, the Company had one short-term lease. The Company had no short-term leases as of December 31, 2024.

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

GALERA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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. The Company provided matching contributions of approximately \$31,000 and \$78,000 during the years ended December 31, 2025 and 2024, respectively.

Gain on litigation settlement

On May 30, 2023, the Company filed a lawsuit in the Court of Common Pleas in Chester County, Pennsylvania, or the Court, against Alira Health Clinical, LLC and IQVIA Biotech, LLC (the CROs), seeking damages and alleging breach of contract, professional negligence, and negligence related to an error by the defendants in 2021 in their statistical program for the Phase 3 ROMAN trial of avasopasem for the reduction of SOM induced by radiotherapy in patients with locally advanced head and neck cancer (the Phase 3 ROMAN trial) (the Litigation). On August 2, 2024, the Company and the CROs entered into an agreement to settle the Litigation, pursuant to which, in exchange for mutual releases, the CROs paid to the Company the amount of \$975,000, and the parties terminated the contracts between the Company and the CROs, with no further obligations under the parties' contracts. On August 8, 2024, the Company filed a Praecipe to Settle, Discontinue, and End the Litigation. During

GALERA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

the year ended December 31, 2024, the Company recorded the \$975,000 as gain on litigation settlement within operating expenses on its consolidated statement of operations.

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.

The budget and tax legislation signed into law on July 4, 2025 includes changes to U.S. federal tax law, which may be subject to further clarification and the issuance of interpretive guidance. The Company has assessed the legislation and its effect on its consolidated financial statements. Due to the existence of a full valuation allowance against the Company's U.S. federal deferred tax assets, the Company does not expect the enactment of this law to have a material impact on its consolidated financial statements.

Under Internal Revenue Code section 382, if a corporation undergoes a specified change in ownership, the corporation's ability to use its pre-change net operating loss (NOL) carryforwards and other pre-change tax attributes to offset its post-change income may be limited. Such limitation may result in the expiration of the NOL carryforwards generated before 2018 and other pre-change tax attributes prior to their utilization. During the year ended December 31, 2025 the Company performed a section 382 study and determined that an ownership change occurred on December 30, 2024 upon the completion of the acquisition of Nova. The Company calculated the section 382 annual limitation and evaluated the corporation's ability to use its NOL carryforwards and other pre-change tax attributes in future periods and determined that a portion of them would likely expire before being utilized. Consequently, \$62.6 million of pre-2018 federal NOLs, \$230.2 million of state NOLs and \$9 million of federal research and development tax credits were written off during the year. However, as the Company had previously recorded a full valuation allowance on all deferred tax assets, these write-offs resulted in no impact to the net deferred tax position or net income during the year.

Net income (loss) per share

Income (loss) per common share requires consideration of the two-class method when an entity has participating securities. The Company's outstanding warrants from the February 2023 registered direct offering (Note 12) entitle the holders to receive dividends on a basis equivalent to the dividends paid to holders of common stock, participating pro-rata in the earnings of the Company as if the warrant was converted into common shares of the Company. As a result, the February 2023 warrants meet the definition of a participating security, and the Company is required to apply the two-class method. Under the two-class method, earnings available to common shareholders, including both distributed and undistributed earnings, are allocated to each class of common stock and participating securities according to dividends declared and participating rights in undistributed earnings. Since the February 2023 warrants do not have contractual obligations that require participation in the Company's losses, the two-class method is not required for periods in which Company has a net loss.

For purposes of basic and diluted net income or loss per share, shares of the Series B redeemable convertible preferred stock (Series B) have the same characteristics as common stock and have no material preferential rights over common stock, and accordingly have been considered as a second class of common stock in the computation of basic and diluted net income or loss per share regardless of their legal form. Income and losses are allocated between the common shares and the Series B on a pro rata basis as they share equally in income, losses and residual net assets on an as-converted basis.

Basic income (loss) per share of common stock is computed by dividing net income (loss) available to common stockholders, which excludes the income allocated to participating security holders, by the weighted-average number of shares of common stock outstanding during each period, including pre-funded warrants. The pre-

GALERA THERAPEUTICS, INC.
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funded warrants to purchase common stock are included in the calculation of basic and diluted net income (loss) per share as the exercise price of \$0.001 per share is non-substantive and is virtually assured.

Diluted income (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. A reconciliation of the Company's basic and diluted income (loss) per common share is as follows:

	Year ended December 31,	
	2025	2024
<u>Numerator:</u>		
Net income (loss).....	\$ 149,049	\$ (18,957)
Less: Allocation of undistributed income to participating security (February 2023 Warrants).....	(8,577)	—
Less: Allocation of undistributed income or loss to Series B.....	(76,948)	224
Undistributed income (loss) available to common stockholders, basic and diluted.....	\$ 63,524	\$ (18,733)
<u>Denominator:</u>		
Weighted average shares of common stock outstanding, basic and diluted.....	98,503,430	54,633,215
Net income (loss) per share of common stock, basic and diluted.....	\$ 0.64	\$ (0.34)
Net income (loss) attributable to Series B redeemable convertible preferred stockholders, basic and diluted.....	\$ 76,948	\$ (224)
Weighted average shares of Series B redeemable convertible preferred stock outstanding, basic and diluted.....	119,318	652
Net income (loss) per share of Series B redeemable convertible preferred stock, basic and diluted.....	\$ 644.89	\$ (342.89)

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding, as they would be anti-dilutive:

	December 31,	
	2025	2024
Stock options	10,969,734	4,384,108
Common stock warrants	550,661	13,850,661
	11,520,395	18,234,769

Recent Accounting Pronouncements

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, with early adoption permitted. The Company adopted this ASU on December 31, 2025, and applied the new disclosure requirements using a prospective approach. The adoption did not have a material impact on the Company's consolidated financial statements. See Note 13 Income Taxes.

In September 2025, FASB issued ASU 2025-07, "Derivatives and Hedging (Topic 815) and Revenue from Contracts with Customers (Topic 606): Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract" (ASU 2025-07). ASU 2025-07 clarifies the application of derivative accounting to certain contracts and refines the guidance for share-based noncash consideration received from customers. Specifically, ASU 2025-07 introduces a scope exception for contracts that are not exchange-traded and whose underlying is tied to operations or activities specific to one party. It also clarifies that share-based noncash consideration from a customer should initially be accounted for under ASC 606 until the right to receive or retain such consideration becomes unconditional, at which point financial instruments guidance

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may apply. ASU 2025-07 is effective for fiscal years beginning after December 15, 2026 and interim periods within those fiscal years. Early adoption is permitted. The Company early adopted this ASU in the fourth quarter of 2025 on a prospective basis and applied this ASU in accounting for the sale of assets to Biossil.

Recent Accounting Pronouncements Not Yet Adopted

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

In November 2024, the FASB issued ASU 2024-04, “ASC 470- Debt with Conversion and Other Options, Induced Conversions of Convertible Debt Instruments,” (ASU 2024-04) which clarifies whether or not a settlement of a convertible debt instrument is subject to the induced conversion guidance. The guidance is effective for the Company’s annual reporting period beginning on January 1, 2026, including interim periods. Early adoption is permitted and the respective amendments in ASU 2024-04 may be applied on a prospective or retrospective basis. The Company does not expect the adoption to have a material impact on its consolidated financial statements.

In September 2025, the FASB issued ASU 2025-06, “Intangibles – Goodwill and Other – Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software.” The updated guidance changes the accounting for internal-use software by eliminating references to sequential project stages. Eligible software development cost capitalization will begin when: (1) management has authorized and committed to funding the software project and (2) it is probable that the software will be completed and used as intended. The guidance is effective for annual periods beginning after December 15, 2027, and interim periods within those annual periods, with early adoption permitted. The guidance may be applied using a prospective transition method, a retrospective transition method or a modified prospective transition method. The Company is assessing the impact of adopting this guidance on its consolidated financial statements.

In December 2025, the FASB issued ASU 2025-11, “Interim Reporting - Narrow Scope Improvements,” (ASU 2025-11) which is intended to improve the navigability of the guidance in ASC 270, Interim Reporting, and clarify when it applies. Under the amendments, an entity is subject to ASC 270 if it provides interim financial statements and notes in accordance with GAAP. ASU 2025-11 also addresses the form and content of such financial statements, interim disclosures requirements, and establishes a principle under which an entity must disclose events since the end of the last annual reporting period that have a material impact on the entity. ASU 2025-11 is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027, and early adoption is permitted. The Company is assessing the impact of adopting this guidance on its consolidated financial statements.

3. Asset acquisition

On December 30, 2024, the Company acquired Nova Pharmaceuticals, Inc. (Nova), in accordance with the terms of an Agreement and Plan of Merger, dated December 30, 2024 (Merger Agreement), pursuant to which the Company acquired Nova’s tilarginine programs and assumed certain liabilities associated with the acquired assets. The upfront consideration included the issuance of 119,318 shares of Series B at an aggregate fair value of \$2.6 million.

Each share of Series B is convertible into 1,000 shares of common stock, subject to the Beneficial Ownership Limitation (defined below). The fair value of the shares issued to Nova was based on the closing stock price of the Company’s common stock on December 30, 2024, of \$0.027, less a discount of 20.0% related to unregistered share restrictions of the preferred shares. The fair value measurement for the Series B is classified as Level 3 within the fair value hierarchy.

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The Company accounted for the transaction as an asset acquisition as the Company acquired inputs and no substantive processes or outputs. The assets acquired in the transaction were measured based on the estimated fair value of the consideration paid of \$3.5 million, which included direct transactions costs of \$0.9 million.

The consideration paid and the relative values of the assets acquired, and liabilities assumed were as follows:

Consideration transferred:	
Fair value of Series B Preferred Stock issued	\$ 2,577
Transaction costs paid	919
Total consideration paid	<u>\$ 3,496</u>
Assets acquired:	
Other assets.....	\$ 100
In-process research and development.....	3,843
Total assets acquired	<u>\$ 3,943</u>
Liabilities assumed:	
Accounts payable and accrued expenses.....	447
Total liabilities assumed.....	447
Net assets acquired	<u>\$ 3,496</u>

As the Nova IPR&D assets acquired have no alternative future use to the Company, the Company charged \$3.8 million to Acquired IPR&D expense within its consolidated statement of operations for the year ended December 31, 2024.

The Merger Agreement was unanimously approved by the Board of Directors of both companies and by the stockholders of Nova. The Board of Directors includes three current Galera board members, and two additional board members selected by Nova. On March 17, 2026, the Company's subsidiary, Nova Pharmaceuticals Operating, LLC, waived the Company's obligations to hold a meeting of the Company's stockholders to vote on (i) the approval of the conversion of the Series B into shares of Common Stock; (ii) the approval of an amendment to Galera's certificate of incorporation to effect a reverse stock split and/or increase the number of authorized shares of common stock to such amount as determined by the Board following the closing; and (iii) the approval of one or more adjournments of the Stockholders' Meeting to solicit additional proxies if there are not sufficient votes cast in favor of the foregoing matters (the Waiver). These obligations were waived following the filing of a Certificate of Amendment (the Certificate of Amendment) to the Certificate of Designation of Preferences, Rights, and Limitations of Series B Non-Voting Convertible Preferred Stock (Certificate of Designation) with the Secretary of State of the State of Delaware on February 12, 2026. Pursuant to this amendment, in the sole discretion of the Board, the Company may elect to convert, in whole or in part, outstanding shares of Series B into shares of Common Stock calculated based on the Conversion Ratio (one share of Series B convertible into 1,000 shares of common stock, as defined in the Certificate of Designation). The Waiver and the Certificate of Amendment were each approved by the Board, and the Certificate of Amendment was further approved by the unanimous written consent of the holders of the Series B.

4. Sale of assets

In October 2025, the Company entered into an Asset Purchase and Sale Agreement, as amended (APA) with Biossil, Inc (Biossil), pursuant to which Biossil acquired all of the Company's right, title and interest in and to its assets related to avasopasem and rucosopasem and all other dismutase mimetics assets (the Transaction). The assets consisted of intellectual property rights related to dismutase mimetics and inventory of avasopasem and rucosopasem; there was no carrying value for these assets. Biossil assumed the Company's existing agreements related to these assets.

The Company received consideration from Biossil in the form of an upfront payment in October 2025 of \$3.5 million, and is eligible to receive further payments upon the achievement of future regulatory and commercial milestones of up to \$75.0 million, and received contingent value rights of up to \$30.0 million should

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change in fair value of the warrant liabilities for the year ended December 31, 2025 is as follows (amounts in thousands):

Balance at December 31, 2024.....	\$	1,055
Additions		—
Change in fair value		(294)
Reclassification to equity		(761)
Balance at December 31, 2025.....	<u>\$</u>	<u>—</u>

6. Prepaid expenses and other current assets

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

	<u>December 31,</u> <u>2025</u>	<u>December 31,</u> <u>2024</u>
Prepaid insurance	\$ 490	\$ 795
Other prepaid expenses and other current assets	230	282
	<u>\$ 720</u>	<u>\$ 1,077</u>

7. Property and equipment

In connection with the termination of its office lease in August 2024, the Company wrote off its remaining fixed assets during the third quarter of 2024. Depreciation and amortization expense was \$20,000 for the year ended December 31, 2024. There was no depreciation expense for the year ended December 31, 2025.

8. Accrued expenses

Accrued expenses consist of (amounts in thousands):

	<u>December 31,</u> <u>2025</u>	<u>December 31,</u> <u>2024</u>
Compensation and related benefits	\$ 20	\$ 48
Research and development expenses	20	31
Late filing of S-1 registration statement	115	—
Professional fees and other expenses.....	225	312
	<u>\$ 380</u>	<u>\$ 391</u>

9. Royalty purchase liability

Pursuant to the Company's Royalty Agreement with Blackstone, the Company has received \$117.5 million in aggregate proceeds. Proceeds from the Royalty Agreement were accounted as debt on the accompanying consolidated balance sheets. Interest expense was imputed based on the estimated royalty repayment period, which took into consideration the probability and timing of obtaining approval from the U.S. Food and Drug Administration (FDA) and the potential future revenue from commercializing its historical product candidates, and which resulted in a corresponding increase in the liability balance.

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 was not feasible with its current resources for the Company to conduct another Phase 3 trial of avasopasem. Accordingly, no interest was recognized during the years ended December 31, 2025 and 2024.

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In August 2025, the Royalty Agreement was amended, which reduced the royalty rate on net sales of avasopasem and rucosopasem to four percent (4%). The amendment was accounted for as a modification of debt to which no immediate gain or loss is recognized.

In connection with the sale of the Company’s dismutase mimetics assets to Biossil in October 2025, the Company assigned and Biossil assumed all rights and obligations under the amended Royalty Agreement, and Blackstone acknowledged that it would look solely to Biossil to pay and perform the obligations and liabilities under the amended Royalty Agreement. Accordingly, the Company has extinguished the royalty purchase liability from its consolidated balance sheet, recording a \$151.0 million noncash gain on the extinguishment in its consolidated statement of operations for the year ended December 31, 2025.

10. Leases

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

In January 2025 the Company entered into a new operating lease agreement for office space in Malvern, Pennsylvania. The lease commencement date was February 1, 2025, and the lease term was 12 months, after which it continues on a month-to-month basis, with 90 days’ notice required for cancellation.

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

	Year ended December 31,	
	2025	2024
Operating lease costs		
Operating lease rental expense.....	\$ 14	\$ 559
Total operating lease expense	\$ 14	\$ 559

Supplemental cash flow information related to leases was as follows (amounts in thousands):

	Year ended December 31,	
	2025	2024
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows for operating leases.....	\$ 14	\$ 597
Derecognition of lease liability and right-of-use asset due to lease termination		
Operating leases	—	1,212

11. Commitments and contingencies

License agreement

The Company’s subsidiary, Nova, has a worldwide license agreement (the License) with Houston Methodist. The License was executed in January 2024 and gives Nova the exclusive rights to certain Houston Methodist patents for use in the field of oncology, and non-exclusive rights to certain Houston Methodist know-how for use in connection with the licensed patents. Under a separate patent prosecution agreement, fees of the law firm maintaining the licensed patents are billed to and payable directly by Nova.

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The License includes due diligence requirements for Nova to submit an Investigational New Drug (IND) application by January 31, 2028, and thereafter to initiate Phase 1, 2 and 3 clinical trials and file a Biologics License Application (BLA) by specified dates. If Nova receives FDA approval for a product covered by the License, fees are payable upon attainment of certain commercial milestones, and low-to-mid single digit royalties are payable on net sales. Fees are also payable on any sublicense revenue that Nova receives.

As additional consideration for the License, Nova made an initial issuance of shares of Nova common stock to Houston Methodist, and subsequently issued additional shares such that Houston Methodist maintained an agreed percentage of Nova outstanding shares. On December 30, 2024, the Houston Methodist shares in Nova were exchanged for approximately 7,323 shares of the Company's Series B (See Notes 3 and 12).

Unless earlier terminated, the License expires on the later of January 31, 2044, or the end of the patent term for the last licensed patent to expire, after which the license continues on a nonexclusive, royalty-free basis.

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.

12. Convertible Preferred Stock and Stockholders' Equity (Deficit)

Shareholder Rights Agreement

On May 3, 2024, the Company entered into a Stockholder Rights Agreement with Equiniti Trust Company, LLC, as rights agent (the Rights Agreement). Pursuant to the Rights Agreement, the board of directors declared a dividend of one preferred share purchase right (each a Right) for each outstanding share of Company common stock to stockholders of record at the close of business on May 20, 2024. Each Right entitled its holder, subject to the terms of the Rights Agreement, to purchase from the Company one one-thousandth of a share of Series A Junior Participating Preferred Stock, par value \$0.001 per share, of the Company at an exercise price of \$1.50 per Right, subject to adjustment. Rights attached to any shares of common stock that become outstanding after May 20, 2024 and prior to the earlier of the Distribution Time, as defined in the Rights Agreement, and the redemption or expiration of the Rights, and in certain other circumstances described in the Rights Agreement. Pursuant to the terms of the Rights Agreement, the Rights terminated upon closing of the acquisition of Nova. The Company intends to file a Certificate of Elimination eliminating from its Certificate of Incorporation, as amended, the designation of certain shares of its preferred stock as Series A Junior Participating Preferred Stock, which had been designated for potential use in connection with the Rights Agreement. Upon such filing, all 200,000 shares of preferred stock previously designated as Series A Junior Participating Preferred Stock will be eliminated and returned to the status of authorized but unissued shares of preferred stock, without designation.

Equity offerings

December 2024 Private Placement

In December 2024, the Company completed a private placement with a group of investors led by Ikarian Capital. The Company issued 21,070,220 shares of common stock plus pre-funded warrants exercisable for 23,041,040 shares of common stock at an offering price of \$0.065 per share (or, in the case of certain of the investors who also received pre-funded warrants in lieu of shares, \$0.065 per pre-funded warrant), generating net

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proceeds of approximately \$2.9 million after offering costs of approximately \$27,000, of which \$0.6 million was received in January 2025. The pre-funded warrants have an exercise price of \$0.001 per share, are exercisable immediately following their issuance, and never expire.

The Company considered the appropriate accounting guidance and concluded that the pre-funded warrants qualified for liability treatment, and therefore, recorded the warrant liability at fair value \$1.5 million. The remainder of the net proceeds were allocated to the common stock issued and recorded as a component of equity.

In connection with the December 2024 Private Placement, the Company entered into a registration rights agreement with the group of investors (as amended, the “Registration Rights Agreement”), pursuant to which the Company agreed to file with the SEC, a registration statement for the resale of the shares of common stock issued in the private placement. The Company agreed to use commercially reasonable efforts to have such registration statement declared effective within 30 days of such filing (or within 60 days should the SEC provide written comments on the registration statement) and to maintain the effectiveness of such registration statement until all relevant securities are sold or can be freely traded without restrictions. As of the filing date of this Form 10-K, the Company has not filed a registration statement with the SEC and the deadline for such registration has passed under the Registration Rights Agreement. The Company may request a further extension of the time to file the registration statement from the investors. Should it fail to receive such an extension, or should it receive the extension but fail to file the registration statement by the expiration date of the extension, the Company would be subject to penalties up to 5% of the amount received in the private placement, a maximum of approximately \$145,000.

December 2024 Series B Preferred Stock

Under the terms of the Merger Agreement, 119,318.285 shares of Series B were issued to the securityholders of Nova, each share of which is convertible into 1,000 shares of the Company’s common stock. Conversion of the shares of Series B is subject to approval at a subsequent meeting of the Company’s common stockholders to be held no earlier than twelve (12) months, but no later than eighteen (18) months, following the December 30, 2024 closing.

The following is a summary of the rights, preferences, and terms of the Series B:

Dividends

The holders of Series B are entitled to receive cash dividends, on an as-if-converted-to-common-stock basis, equal to and in the same form and manner as dividends actually paid on shares of common stock, when and if such dividends are paid. As of December 31, 2025, there were no unpaid Series B dividends.

Voting Rights

The holders of the Series B generally have no voting rights, except as required by law or outlined in the Certificate of Designation. However, a majority vote of the outstanding shares of Series B Non-Voting Preferred Stock is required to approve certain actions that could adversely affect their rights, issue additional shares, or undertake specific mergers or fundamental transactions.

Liquidation Preference

The Series B participates pari passu with the common stock in the distribution of assets upon a liquidation, dissolution, or winding up of the corporation. Distributions to holders of Series B are weighted to reflect two times the amount that would be received if the shares were fully converted into common stock.

Conversion

At any time after approval by the Company’s common shareholders, at the option of the holder, each share of Series B is convertible into 1,000 shares of common stock, subject to certain antidilution adjustments.

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Pursuant to an amendment to the Certificate of Designation approved by the Series B holders in February 2026, the Company's board of directors, at its sole discretion, can elect to convert the Series B into common stock (a Mandatory Conversion). If not converted by 24 months after the issuance date, upon request by a holder of Series B, the Company will pay in cash the fair value, as defined, of the common stock into which the Series B would otherwise be converted.

Beneficial Ownership Limitation

A holder of Series B is prohibited from converting shares of Series B into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 19.9% of the total number of shares of common stock issued and outstanding immediately after giving effect to such conversion. The beneficial ownership limitation does not apply in the case of a Mandatory Conversion.

Redemption

Shares of Series B are generally not redeemable. However, in the event the Series B is not converted within 24 months after the initial issuance of the Series B, each holder of Series B may elect, at the holder's option, to have the shares of Series B be redeemed by the Company at an amount equal to the last reported closing trading price of the common stock at such time on an as-converted to common stock basis, as further described in the Certificate of Designation relating to the Series B.

The Company recognized accretion of \$1.8 million to reflect the estimated fair value at redemption as of December 31, 2024. This accretion was reversed during the year ended December 31, 2025 as a result of the decrease in the common stock price, and as of December 31, 2025 the Series B was recorded at its initial fair value of approximately \$2.6 million.

Protective Provisions

Approval of holders of a majority of the Series B is required for certain significant corporate actions.

February 2023 Registered Direct Offering

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, 2025.

Warrants

The following table summarizes the Company's outstanding warrants:

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	As of December 31,		
	Number of shares	Exercise Price	Expiration Date
Warrants issued in connection with Amendment to Royalty Agreement	293,686	\$ 13.62	6/6/2027
	256,975	\$ 13.62	7/18/2027
Warrants issued pursuant to February 2023 Registered Direct Offering	13,300,000	\$ 1.97	2/17/2028
Pre-funded warrants issued pursuant to December 2024 Private placement.....	23,041,040	\$ 0.001	No expiration

As of December 31, 2025, all of the warrants are equity-classified.

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, 2025 was 943,133.

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, 2025, there were 2,498,979 shares available for future issuance under the 2019 Plan, including 3,018,496 shares added pursuant to this provision effective January 1, 2025. Pursuant to this provision, the Company added an additional 3,018,496 shares to the total shares available for issuance under the 2019 Plan effective January 1, 2026. 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, 2025, there were 2,589,729 shares available for issuance under the ESPP, including

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754,624 shares added pursuant to this provision effective January 1, 2025. Pursuant to this provision, the Company added an additional 754,624 shares to the total shares available for issuance under the ESPP effective January 1, 2026.

2023 Employment Inducement Award Plan

On April 28, 2023, the Board of Directors adopted the Galera Therapeutics, Inc. 2023 Employment Inducement Award Plan (Inducement Plan), which became effective on such date without stockholder approval pursuant to Rule 5635(c)(4) of The Nasdaq Stock Market LLC listing rules (Rule 5635(c)(4)). The Inducement Plan provides for the grant of nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units, and other stock-based awards. In accordance with Rule 5635(c)(4), awards under the Inducement Plan may only be granted to persons who (a) were not previously an employee or director of the Company, or (b) are commencing employment with the Company following a bona fide period of non-employment, in either case as an inducement material to the individual's entering into employment with the Company. A total of 1,500,000 shares of common stock was reserved for issuance under the Inducement Plan. Any shares subject to awards previously granted under the Inducement Plan that expire, terminate or are otherwise surrendered, canceled, or forfeited, in a manner that results in the Company (i) acquiring the shares covered by the award at a price not greater than the price (as adjusted to reflect any equity restructuring) paid by the participant for such shares or (ii) not issuing any shares covered by the award, the unused shares covered by such awards will again be available for award grants under the Inducement Plan. As of December 31, 2025, there were 1,500,000 shares available for issuance under the Inducement Plan.

Share-based Compensation

Share-based compensation expense was as follows for the years ended December 31, 2025 and 2024 (in thousands):

	Year ended December 31,	
	2025	2024
Research and development	\$ 18	\$ 690
General and administrative	392	1,855
	\$ 410	\$ 2,545

The following table summarizes the activity related to stock option grants for the year ended December 31, 2025:

	Shares	Weighted average exercise price per share	Weighted- average remaining contractual life (years)
Outstanding at January 1, 2025	4,384,108	\$ 6.01	4.0
Granted	8,488,000	0.02	
Forfeited	(1,902,374)	6.60	
Outstanding at December 31, 2025	10,969,734	\$ 1.27	8.2
Vested and exercisable at December 31, 2025	3,578,651	\$ 3.77	6.0
Vested and expected to vest at December 31, 2025	10,969,734	\$ 1.27	8.2

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, 2025, the unrecognized compensation cost was \$0.4 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, 2025 were zero. Options granted during the year

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ended December 31, 2025 had weighted-average grant-date fair values of \$0.02 per share. There were no options granted during the year ended December 31, 2024.

The fair value of options is estimated using the Black-Scholes option pricing model, which takes into account inputs such as the exercise price, the estimated fair value of the underlying common stock at the grant date, expected term, expected stock price volatility, risk-free interest rate and dividend yield. The fair value of stock options granted during the year ended December 31, 2025 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 the Company as well as 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. There were no options granted during the year ended December 31, 2024.

	Year ended December 31,
	2025
Expected term (in years).....	6.2
Expected stock price volatility	112.3%
Risk-free interest rate	3.93%
Expected dividend yield.....	0%

13. Income Taxes

The Company’s income (loss) before income taxes for the years ended December 31, 2025 and 2024 is as follows (in thousands):

	Year ended December 31,	
	2025	2024
Domestic.....	\$ 149,049	\$ (25,306)
Foreign.....	—	6,349
	\$ 149,049	\$ (18,957)

The Company’s tax provision (benefit) for the years ended December 31, 2025 and 2024 is summarized as follows (in thousands):

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	Year ended December 31,	
	2025	2024
Current		
Federal.....	\$ —	\$ —
State.....	—	—
Foreign.....	—	—
Deferred:		
Federal.....	—	(90)
State.....	—	(113)
Foreign.....	—	—
	—	(203)
Total income tax benefit.....	\$ —	\$ (203)

The table below provides the updated requirements of ASU 2023-09 for 2025.

A reconciliation of the federal income tax rate to the Company's effective tax rate is as follows (dollars in thousands):

	Year ended December 31, 2025	
Rate reconciliation:		
Provision for incomes taxes at U.S. Federal Statutory rate.....	\$ 31,300	21.0 %
Effect of changes in tax laws or rates enacted in the current period...	—	—
Federal:		
Tax Credits:		
Research and development credits	8,998	6.0
Change in valuation allowance.....	(21,980)	(14.7)
Non-taxable or non-deductible items:		
Share-based compensation	148	0.1
Gain on debt extinguishment.....	(31,720)	(21.3)
Other Non-deductible items	(38)	—
Adjustment to prior period provision	198	0.1
Other:		
Net Operating Losses	13,143	8.8
State and local incomes taxes, net of federal benefit (1).....	(49)	—
Total provision.....	\$ —	— %

(1) State taxes in Pennsylvania made up the majority (greater than 50%) of the tax effect in this category.

The Company did not pay any federal or state income taxes in 2025.

As previously disclosed for the years ended December 31, 2024, prior to the adoption of ASU 2023-09, the reconciliation of the federal income tax rate to the Company's effective tax rate is as follows:

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	<u>Year ended December 31, 2024</u>
Rate reconciliation:	
Federal tax benefit at statutory rate	21.0 %
State tax, net of federal benefit.....	4.4
Net operating loss carryforwards...	(2.7)
Change in tax rate.....	(0.5)
Sale of royalty interest.....	—
Difference in foreign rate	(3.6)
Research and development.....	(6.8)
Change in valuation allowance.....	(15.3)
Share-based compensation	(2.6)
Investment in Galera Australia.....	9.9
IPR&D.....	(3.4)
Other.....	0.7
Total provision.....	<u>1.1 %</u>

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

	<u>December 31,</u>	
	<u>2025</u>	<u>2024</u>
Deferred tax assets		
Net operating loss carryforwards	\$ 33,630	\$ 52,962
Share-based compensation.....	4,576	4,628
Research and development credits.....	—	8,998
Capitalized research and development expenses	5,199	7,773
Capital loss carryforward	1,554	1,554
Accrued expenses and other.....	82	37
Gross deferred tax assets.....	45,041	75,952
Valuation allowance.....	(44,900)	(75,754)
Net deferred tax asset.....	141	198
Deferred tax liabilities		
Accrued expenses and other.....	(141)	(198)
Net deferred tax liabilities.....	<u>\$ —</u>	<u>\$ —</u>

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. As of December 2024, the Company wrote off the remaining IPR&D intangible asset and, as such, the Company is now in a full valuation allowance position.

For tax years beginning after December 31, 2024, the 2025 tax legislation signed into law in July 2025 amends Internal Revenue Code Section 174 (IRC 174) by making permanent the option of expensing domestic research and development expenditures. For tax years 2025 and forward, taxpayers have the option to deduct all remaining unamortized research and development expenditures capitalized after December 31, 2021 and before December 31, 2024 either (i) on their 2025 tax return, (ii) ratably over the 2025 and 2026 tax years, or (iii) continue amortizing the costs over the remainder of the applicable five-year period. The Company will continue to expense the \$31.2 million of unamortized research and development expenditures over the applicable five year period on its tax return, expensing \$10.3 million for the period ending December 31, 2025.

The valuation allowance decreased by \$30.9 million for the year ended December 31, 2025 and increased by \$2.9 million for the year ended December 31, 2024.

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The following table summarizes carryforwards of federal, state and foreign NOLs as of December 31, 2025 and 2024, respectively (in thousands):

	December 31,	
	2025	2024
Combined NOL Carryforwards:		
Federal	\$ 157,773	\$ 209,474
State	12,642	231,939
Foreign	—	—

As of December 31, 2025, the Company had federal and state NOLs of \$157.8 million and \$12.6 million, respectively, which will begin expiring in 2044. In connection with the Section 382 study performed in 2025, the federal research and the development tax credit carryforwards have been written off.

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 NOLs to offset future taxable income. During 2025, the Company conducted a Section 382 study and determined that approximately \$441.4 million in NOLs and \$9.0 million in research and development tax credits were limited by Section 382 as of December 31, 2024. As a result of the Section 382 analysis, approximately \$62.6 million of pre-2018 federal NOLs and \$230.2 million of state NOLs will expire unused due to the annual Section 382 limitation and were written off. In addition, \$9.0 million of research and development tax credits are scheduled to expire unused due to the annual Section 382 limitation and were also written off. As the Company had previously recorded a full valuation allowance on all deferred tax assets, these write-offs resulted in no impact to the net deferred tax position or net income during the year ended December 31, 2025.

The Company will recognize interest and penalties related to uncertain tax positions as income tax expense. As of December 31, 2025, 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 2022 through 2024 remain subject to examination by the taxing jurisdictions. The NOLs remain subject to review until utilized.

14. Related Party Transactions

IntellectMap Advisory Services

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 each of the years ended December 31, 2025 and 2024 were \$0.2 million.

Nova Acquisition

In connection with the acquisition of Nova, Dr. Chang and Mr. Friedman, now members of the Company's Board, received 1,841.92 and 8,326.269 shares of the Company's Series B, respectively, in exchange for shares of common stock of Nova held immediately prior to the closing of such acquisition. When the Company's board of directors elects the conversion of Series B into shares of common stock, and such conversion is effected by the Company, these shares of Series B will be convertible into 1,841,920 and 8,326,269 shares of common stock, respectively. In addition to her shares of Series B, Dr. Chang also purchased, and was issued, 7,644,932 shares of common stock upon the closing of the December 2024 private placement.

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Friedman Independent Contractor Agreement

In March 2025 the Company entered into an Independent Contractor Agreement with Mr. Friedman (the Contractor Agreement) to provide corporate and business development services, with an effective date of January 1, 2025. Mr. Friedman will be paid \$10,000 per month for the duration of the Contractor Agreement. The Contractor Agreement has a one-year term, with automatic renewals for successive one-year terms unless earlier terminated. The Contractor Agreement can be terminated by either party upon 30 days' prior notice. Fees incurred by the Company with respect to Mr. Friedman during the year ended December 31, 2025 were \$0.1 million.

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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 Accounting 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 Accounting Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2025.

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, 2025, our internal control over financial reporting was effective.

Attestation Report of the Independent Registered Public Accounting Firm

Effective December 31, 2024, we lost our status as an "emerging growth company," meaning we can no longer rely on certain exemptions from various public company reporting requirements, including having an extended transition period to comply with new or revised accounting standards applicable to public companies. We maintained our status as a smaller reporting company; thus, our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting.

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, 2025 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Insider Trading Arrangements and Policies.

During the three months ended December 31, 2025, 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.

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Waiver of Certain Provisions of the Nova Merger Agreement

On March 17, 2026, Nova Pharmaceuticals Operating, LLC, a Delaware limited liability company formerly known as Grape Merger Sub II (Surviving Company), executed the Waiver with respect to that certain Agreement and Plan of Merger, dated December 30, 2024, by and among Galera, Grape Merger Sub I, Inc., the Surviving Company, and Nova Pharmaceuticals, Inc. (Merger Agreement). Pursuant to the Waiver, the Surviving Company waived Galera's obligations under the Merger Agreement to hold a meeting of stockholders to vote on (i) the approval of the conversion of Galera's Series B Non-Voting Convertible Preferred Stock, par value \$0.001 per share, into shares of Galera's common stock, par value \$0.001 per share; (ii) the approval of an amendment to Galera's certificate of incorporation to effect a reverse stock split and/or increase the number of authorized shares of common stock to such amount as determined by Galera's Board of Directors following the closing; and (iii) the approval of one or more adjournments of such stockholders' meeting to solicit additional proxies if there are not sufficient votes cast in favor of the foregoing matters. The Waiver was approved by the Board of Directors of each of Galera and the Surviving Company.

The foregoing summary of the Waiver is not complete and is qualified in its entirety by reference to the full text of the Waiver, a copy of which is filed as Exhibit 2.1.1 to this Annual Report on Form 10-K and incorporated by reference.

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.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Executive Officers		
J. Mel Sorensen, M.D.....	69	President, Chief Executive Officer and Chairman of the Board
Joel Sussman	77	Chief Accounting Officer, Treasurer and Secretary
Non-Employee Directors		
Lawrence Alleva(1)(2)(3).....	76	Director
Kevin Lokay(1)(2)(3).....	69	Director
Michael Friedman	48	Director
Nancy T. Chang, PhD	76	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, and as Chairman of the Board starting in January 2025. Dr. Sorensen serves on the boards of directors of several private companies including Esanik Therapeutics, Inc., Medsyn Biopharma, LLC and PlanetVerify Ltd. 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 a 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.

Joel Sussman has served as our Chief Accounting Officer and Treasurer since April 2019, and served as our Chief Financial Officer and Treasurer from December 2012 to April 2019. He has also served as our Secretary since September 2024. From 2002 to 2019, Mr. Sussman provided consulting services as a Chief Financial Officer for various private life sciences companies. Before his consulting career, he held CFO and Treasurer roles at several public and private companies. Mr. Sussman received a B.A. from Yale University and an M.B.A. from the Wharton School of the University of Pennsylvania. Mr. Sussman is a licensed certified public accountant.

Non-Employee Directors

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., and Adaptimmune Therapeutics PLC and chairs the audit committee for those companies. He currently serves as the Chair of Adaptimmune's board. 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, Mersana Therapeutics, Inc. from 2018 through its acquisition in early 2026, 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.

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.

Michael Friedman was appointed to the Board on December 30, 2024. He is a principal and executive in residence at Emerald Bioventures, a life science incubator and venture capital firm. At Emerald Bioventures, Mr. Friedman handles company formation, corporate finance and operations within the portfolio. Mr. Friedman has over 20 years of investment banking experience, specializing in healthcare mergers and acquisitions, leveraged finance and capital markets at firms such as Bank of America Corporation, Merrill Lynch, Jefferies and Ladenburg. Mr. Friedman has worked on venture rounds, private investment in public equity transactions, licensing transactions, sell-side and buy-side mergers and acquisitions, initial public offerings, debt financings, asset sales and divestitures. Mr. Friedman has an M.B.A from the University of Chicago and a B.B.A from the University of Wisconsin. Mr. Friedman previously served on the board of Akari Therapeutics Plc (formerly known as Peak Bio). We believe that Mr. Friedman is qualified to serve on our board of directors due to his extensive experience in the finance industry.

Nancy T. Chang, PhD, was appointed to the Board on December 30, 2024. She completed her undergraduate studies at Taiwan National Tsing Hua University and attended the Ph. D. program at the Division of Medical Sciences at Harvard Medical School. Dr. Chang joined the founding team at Centocor, where she served as director of research and worked on the development of monoclonal antibody as therapeutics and to the HIV field including the development of the first HIV diagnosis assay. In 1986, Dr. Chang joined the Baylor College of Medicine, where she served as Associate Professor of Virology until 1991. During this tenure, Dr. Chang co-founded Tanox, a company that focused on the treatment of immunological diseases including allergy, asthma, and inflammation by using antibodies as a therapeutic agent. From 1995 to 2000, Dr. Chang also served on the Texas Higher Education Coordinate Board under Governor George W. Bush. After 2007, Dr. Chang led OrbiMed's Asia fund as the chairman, founder and senior managing director. She served on the board of directors for various institutes including the Federal Reserve Bank in Houston, BioHouston, Biotechnology Innovation Organization (Bio), Charles River Laboratories, and several biotech companies. Currently, Dr. Chang serves on the board of directors of Ansun Biopharma, where she is Chairperson, Immix Biopharma and W&T Offshore, is an advisor to ViRx at Stanford and to Baylor College of Medicine, and is president of Apex Enterprise Inc. and the Tang Family Foundation. We believe that Dr. Chang is qualified to serve on our board of directors due to her extensive experience in the biopharmaceutical industry.

Mr. Friedman and Dr. Chang were each appointed pursuant to the terms of an Agreement and Plan of Merger (the “Merger Agreement”), dated December 30, 2024, by and between Galera and Nova Pharmaceuticals, Inc. (“Nova”), pursuant to which Galera acquired Nova’s Houston Methodist license and assumed certain liabilities associated with the acquired assets. The upfront consideration included the issuance of 119,318 shares of Series B Non-Voting Convertible Preferred Stock at an aggregate fair value of \$2.6 million. Under the terms of the Merger Agreement, Galera’s board of directors must consist of five members, three designated by Galera, at least two of whom must be independent, and two of whom are to be designated by Nova. Nova appointed each of Mr. Friedman and Dr. Chang.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our officers and directors, and persons who own more than 10 percent of a registered class of our equity securities (“Reporting Persons”), to file with the SEC reports of ownership and reports of changes in ownership of our common stock and our other equity securities. Reporting Persons are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file. Based solely on our review of such reports received or written representations from certain Reporting Persons, the Company believes that during the fiscal year ended December 31, 2025, all Reporting Persons complied with all applicable requirements.

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 concerning any amendments to, or waivers from, any provision of the Code of Business Conduct and Ethics.

Insider Trading Policy

We have adopted an Insider Trading Policy governing the purchase, sale, and/or other dispositions of our securities by our directors, officers, and employees, and have implemented processes for the Company that we believe are reasonably designed to promote compliance with insider trading laws, rules and regulations. Our Insider Trading Policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

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 and Kevin Lokay. Mr. Alleva serves as the Chairperson of the Audit Committee. While our common stock no longer trades on the Nasdaq Global Market, the members of our Audit Committee continue to 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.

The following is a discussion and analysis of compensation arrangements of our named executive officers. Because we qualify as a “smaller reporting company” under the SEC rules, we have elected to prepare this annual report and other periodic reports as a “smaller reporting company” consistent with rules of the SEC. Under the scaled disclosure obligations applicable to smaller reporting companies, we are not required to provide, among

other things, a Compensation Discussion and Analysis and certain other tabular and narrative disclosures relating to executive compensation.

In 2025, our “named executive officers” and their positions were as follows:

- J. Mel Sorensen, M.D., President and Chief Executive Officer; and
- Joel Sussman, Chief Accounting Officer, Treasurer and Secretary

2025 Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers for the years ended December 31, 2025 and 2024.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)(1)	Non-Equity			Total (\$)
				Option Awards (\$)(2)	Incentive Plan Compensation (\$)	All Other Compensation (\$)(3)	
J. Mel Sorensen, M.D., President and Chief Executive Officer	2025	619,479	—	114,342	—	14,000	747,821
	2024	619,479	—	—	—	13,800	633,279
Joel Sussman, Chief Accounting Officer, Treasurer and Secretary	2025	336,000	20,000	38,114	—	14,000	408,114
	2024	336,000	—	—	—	13,440	349,440

- (1) The amount reflected for Mr. Sussman in 2025 represents a discretionary bonus paid to him in May 2025.
- (2) 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 executive officer. We provide information regarding the assumptions used to calculate the value of the option awards in Note 12 to our consolidated financial statements included in this Annual Report on Form 10-K.
- (3) Represents company matching contributions under our 401(k) plan.

Narrative Disclosure to Summary Compensation Table

2025 Salaries and Bonus Compensation

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 2025, there were no increases in the base salaries of the named executive officers.

In prior years, we maintained a discretionary bonus plan that was designed to motivate and reward our executives, including our named executive officers, for achievements relative to our goals and expectations for each fiscal year. In light of the Company’s financial situation, the Company did not establish a 2025 or 2024 bonus plan, but Mr. Sussman was awarded a \$20,000 discretionary bonus in May 2025.

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. In 2025, we granted stock options to Dr. Sorensen and Mr. Sussman with respect to 6,000,000 shares and 2,000,000 shares, respectively, which vest in 48 quarterly installments over four years, subject to their continued employment through each applicable vesting date.

Refer to the “Outstanding Equity Awards at 2025 Fiscal Year End” table below for information regarding the stock options held by our named executive officers as of December 31, 2025.

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.

Equity Grant Practices

While the Company does not have a formal grant policy, we have not timed the release of material non-public information (“MNPI”) based on equity grant dates. In 2025, we did not grant stock options to our named executive officers during any period beginning four business days before the filing or furnishing of a periodic report or current report disclosing MNPI and ending one business day after the filing or furnishing of such report with the SEC.

Outstanding Equity Awards at 2025 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, 2025.

<u>Name</u>	<u>Vesting Commencement Date</u>	<u>Number of Securities Underlying Unexercised Options (#) Exercisable</u>	<u>Number of Securities Underlying Unexercised Options (#) Unexercisable (1)</u>	<u>Option Exercise Price (\$)</u>	<u>Option Expiration Date</u>
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	186,087	—	14.84	1/30/2030
	1/26/2021	190,000	—	11.99	1/25/2031
	2/28/2022	253,383	11,017	2.24	2/27/2032
	2/25/2023	311,666	128,334	1.78	2/24/2033
	5/1/2025	875,000	5,125,000	0.02	4/30/2035
Joel Sussman	2/1/2016	32,238	—	2.43	3/2/2026
	1/18/2017	21,429	—	2.68	1/18/2027
	1/10/2019	5,932	—	7.08	1/10/2029
	4/1/2019	35,155	—	9.26	3/29/2029
	1/31/2020	49,623	—	14.84	1/30/2030
	1/26/2021	50,000	—	11.99	1/25/2031
	2/28/2022	57,500	2,500	2.24	2/27/2032
	2/25/2023	46,041	18,959	1.78	2/24/2033
5/1/2025	291,666	1,708,334	0.02	4/30/2035	

- (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.

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 2025 are described above under the headings "2025 Salaries and Bonus Compensation".

Following the termination of a named executive officer's employment for any reason, such named executive officer will be entitled to receive any earned but unpaid bonus for the year prior to the year in which the termination occurs. In addition, if we terminate a named executive officer without "good cause" or he resigns for "good reason" (each as defined below), subject to the executive's timely executing a release of claims and his continued compliance with certain covenants, the executive is entitled to receive (i) base salary continuation for a period of 12 months; and (ii) direct payment of, or reimbursement for, continued health coverage pursuant to COBRA for up to 12 months 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 the executive 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 the executive's timely executing a release of claims and the executive's

continued compliance with certain covenants, the executive is entitled to receive (i) a cash amount equal to one times (or 1.5 times for Dr. Sorensen) the sum of the executive's annual base salary and target annual bonus for the year of termination, payable over the 12 months (or 18 months for Dr. Sorensen) following the executive's 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 the executive's 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 the executive's 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 the executive; (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) with respect to Dr. Sorensen's employment agreement only, any requirement by the Company that the 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 the executive's responsibilities, positions, duties or authority which is not consented to by the named executive officer (and, with respect to Dr. Sorensen's employment agreement only, which occurs within 12 months after a change in control).

Narrative Disclosure to 2025 Non-Employee Director Compensation Table

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 2025:

- 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:
 - o Chair of the Board or lead independent director, \$25,000;
 - o Chair of the audit committee, \$15,000;
 - o Audit committee member other than the chair, \$7,500;
 - o Chair of the compensation committee, \$10,000;
 - o Compensation committee member other than the chair, \$5,000;
 - o Chair of the nominating and corporate governance committee, \$8,000; and
 - o 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.

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. 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.

2025 Director Compensation

The following table sets forth the compensation earned by our non-employee directors for their service on our Board during 2025. Dr. Sorensen also serves on our Board but is not separately compensated for such service. Please see the “2025 Summary Compensation Table” for the compensation received by Dr. Sorensen with respect to 2025.

Name	Fees Earned or Paid in Cash \$(1)	Option Awards \$(2)	Total (\$)
Lawrence Alleva	\$ 63,000	\$ 1,649	\$ 64,649
Nancy Chang, Ph.D.....	35,000	3,335	38,335
Michael Friedman	35,000	3,335	38,335
Kevin Lokay.....	56,500	1,649	58,149

- (1) Represents the annual retainer earned under our director compensation program for service on our Board during 2025.
- (2) 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 non-employee director. We provide information regarding the assumptions used to calculate the value of the option awards in Note 12 to our consolidated financial statements included in this Annual Report on Form 10-K. As of December 31, 2025, the aggregate number of options (exercisable and unexercisable) held by each non-employee director were as follows: Mr. Alleva: 181,812; Dr. Chang: 96,000; Mr. Friedman: 96,000; and Mr. Lokay: 150,552. None of our non-employee directors held stock awards with respect to shares of Company common stock as of December 31, 2025.

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 Pri ce 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).....	10,969,734 ⁽³⁾	\$ 1.27 ⁽⁴⁾	5,088,708 ⁽⁵⁾
Equity compensation plans not approved by security holders (2).....	—	—	1,500,000
Total.....	<u>10,969,734</u>	<u>\$ 1.27</u>	<u>6,588,708</u>

- (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 943,133 outstanding options to purchase stock under the Prior Plan and 10,026,601 outstanding options to purchase stock under the 2019 Plan.
- (4) As of December 31, 2025, the weighted-average exercise price of outstanding options under the Prior Plan was \$4.81 and the weighted-average exercise price of outstanding options under the 2019 Plan was \$0.94.
- (5) Includes 2,498,979 shares available for future issuance under the 2019 Plan and 2,589,729 shares available for issuance under the 2019 ESPP. As of November 6, 2019, in connection with our initial public offering, no further grants may be 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. 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, 2026, 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 75,462,390 shares of common stock outstanding as of March 15, 2026. 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, 2026 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 101 Lindenwood Drive, Suite 225, 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)(2).....	10,823,610	14.3
Rochel Soffer (1)(2).....	5,928,137	7.9
GSA Capital Partners LLP (3).....	3,892,561	5.2
Affiliates of Ikarian Capital, LLC (4).....	30,579,731	9.9
Named Executive Officers and Directors		
J. Mel Sorensen, M.D. (5)	3,128,531	4.0
Joel Sussman (6).....	773,597	1.0
Nancy Chang, Ph.D. (7).....	7,687,598	10.2
Lawrence Alleva (8).....	192,182	*—
Michael Friedman (9).....	42,666	*—
Kevin Lokay (10).....	150,552	*—
All executive officers and directors as a group (6 persons) (11).....	11,975,126	15.0

* Less than one percent.

- (1) Based on Schedule 13G/A filed with the SEC on May 16, 2024. Consists of 10,823,610 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. Does not include 3,178,137 shares of common stock held by Rochel Soffer individually and 2,750,000 shares of common stock held by Alpha Pharma Investments LLC. Rochel Soffer is the spouse of Mr. Schneid and is also the sole member of Alpha Pharma Investments LLC. Rochel Soffer has voting and dispositive power of Alpha Pharma Investments LLC and is therefore deemed the beneficial owner of such securities. Mr. Schneid disclaims beneficial ownership of all securities owned by Rochel Soffer and Alpha Pharma Investments LLC, except to the extent of their pecuniary interest therein, if any. The mailing address of Mr. Schneid is 1 Wood Lane, Suffern, NY 10901.
- (2) Based on Schedule 13G filed with the SEC on May 16, 2024. Consists of 3,178,137 shares of our common stock held of record by Rochel Soffer and 2,750,000 shares of our common stock held of record by Alpha Pharma Investments LLC. Rochel Soffer is the sole member of Alpha Pharma Investments LLC and is therefore deemed the beneficial owner of such securities. Ms. Soffer is the spouse of Yair Schneid. Ms. Soffer disclaims beneficial ownership of all securities owned by Yair Schneid, except to the extent of their pecuniary interest therein, if any. The mailing address of Ms. Soffer is 9559 Collins Avenue, #1009S, Miami, FL 33154.
- (3) Based 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) Based in part on Schedule 13G filed with the SEC on February 14, 2025. Consists of: (i) 5,361,517 shares of common stock and 16,386,788 pre-funded warrants held by Ikarian Healthcare Master Fund LP; (ii) 1,620,818 shares of common stock and 4,953,824 pre-funded warrants held by Boothbay Absolute Return Strategies LP; and (iii) 556,356 shares of common stock and 1,700,428 pre-funded warrants held by Boothbay Diversified Alpha Master Fund LP. However, the warrants cannot be exercised in an amount that would cause these entities to collectively hold over 9.99% of the Company's capital stock. The business address of Ikarian Healthcare Master Fund LP is 100 Crescent Court, Suite 1620, Dallas, TX 75201. The business address of each of Boothbay Absolute Return Strategies LP and Boothbay Diversified Alpha Master Fund LP is 140 E. 45th Street, 14FL, New York, NY 10017.
- (5) Consists of 195,029 shares of our common stock and 2,933,502 shares of our common stock underlying stock options exercisable within 60 days of March 15, 2026.
- (6) Consists of 773,597 shares of our common stock underlying stock options exercisable within 60 days of March 15, 2026.

- (7) Consists of 7,644,932 shares of our common stock and 42,666 shares of our common stock underlying stock options exercisable within 60 days of March 15, 2026.
- (8) Consists of 10,370 shares of our common stock and 181,812 shares of our common stock underlying stock options exercisable within 60 days of March 15, 2026.
- (9) Consists of 42,666 shares of our common stock underlying stock options exercisable within 60 days of March 15, 2026.
- (10) Consists of 150,552 shares of our common stock underlying stock options exercisable within 60 days of March 15, 2026.
- (11) Consists of 7,850,331 shares of our common stock and 4,124,795 shares of our common stock underlying stock options exercisable within 60 days of March 15, 2026.

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, 2023, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive and Director Compensation."

December 2024 Private Placement

In December 2024, the Company completed a private placement with a group of investors led by Ikarian Capital. The Company issued approximately 21.1 million shares of common stock plus pre-funded warrants exercisable for approximately 23.0 million shares of common stock at an offering price of \$0.065 per share or pre-funded warrant. As a result of the private placement, the Company received net proceeds of approximately \$2.9 million after deducting issuance costs of approximately \$27,000, of which \$0.6 million was received in January

2025. The pre-funded warrants have an exercise price of \$0.001 per share, are exercisable immediately following their issuance and never expire.

Nova Acquisition

Mr. Friedman and Dr. Chang were each appointed to our board of directors pursuant to the terms of an Agreement and Plan of Merger, dated December 30, 2024, by and between Galera and Nova, pursuant to which Galera acquired Nova's Houston Methodist license and assumed certain liabilities associated with the acquired assets. Mr. Friedman and Dr. Chang received 8,326.269 and 1,841.92 shares of our Series B Non-Voting Convertible Preferred Stock, respectively, which are convertible into 8,326,269 and 1,841,920 shares of our common stock, respectively. The other independent members of our board of directors have unanimously determined that ownership of our Series B Non-Voting Convertible Preferred Stock does not compromise the independent judgment of Dr. Chang.

Consulting Agreement with Mr. Friedman

Michael Friedman, a member of our Board, entered into an Independent Contractor Agreement with the Company, effective January 1, 2025 (the "Contractor Agreement"). Pursuant to the Contractor Agreement, Mr. Friedman will provide corporate and business development services to the Company as an independent contractor. As compensation for his services, the Company will pay to Mr. Friedman a cash amount equal to \$10,000 per month. Additionally, the Company will reimburse Mr. Friedman for reasonable out-of-pocket expenses incurred in connection with his services, subject to certain conditions. The Company has also agreed to indemnify and hold Mr. Friedman harmless from any third-party claims, losses, or legal expenses arising from services performed under the Contractor Agreement, except in cases of intentional misconduct or gross negligence. Following termination of the Contractor Agreement, Mr. Friedman will be prohibited from soliciting the Company's employees, clients, or customers for a period of one year from such termination. The Contractor Agreement has a one-year term, with automatic renewals for successive one-year terms unless terminated by either party with 30 days' advance notice. The Contractor Agreement can be terminated by either the Company or Mr. Friedman with or without cause upon 30 days' prior notice.

Royalty Agreement with Clarus

Refer to Part II, Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, "Key Agreements."

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 \$0.2 million in fees to IntellectMap during each of the fiscal years ended December 31, 2025 and 2024.

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, Kevin Lokay and Dr. Chang each qualify as "independent" in accordance with the listing requirements of Nasdaq. While the Company's stock is no longer listed with the Nasdaq Stock Market, the

Board continues to refer to Nasdaq listing guidelines to inform its independence analysis. 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, 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	2025	2024
Audit Fees	\$ 485,000	\$ 613,068
Audit Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total Fees	\$ 485,000	\$ 613,068

Audit Fees

Audit fees for the fiscal years ended December 31, 2025 and 2024 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.

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	Exhibit	Filing Date
2.1	Agreement and Plan of Merger, dated as of December 30, 2024 by and among Galera, Grape Merger Sub I, Inc., Grape Merger Sub II, LLC and Nova	8-K	2.1	12/31/2024
2.1.1*	Waiver of Certain Provisions of Agreement and Plan of Merger			
3.1	Restated Certificate of Incorporation of Galera Therapeutics, Inc.	8-K	3.1	11/12/2019
3.2	Certificate of Designation of Series A Junior Participating Preferred Stock	8-A	3.1	05/3/2024
3.3	Certificate of Designation of Series B Non-Voting Preferred Stock	8-K	3.1	12/31/2024
3.3.1	Certificate of Amendment to Certificate of Designation of Series B Non-Voting Preferred Stock	8-K	3.1	02/18/2026
3.4	Amended and Restated Bylaws of Galera Therapeutics, Inc.	10-K	3.2	03/28/2024
4.1	Form of Certificate of Common Stock	S-1/A	4.1	10/28/2019
4.2*	Description of Securities			
4.3	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 warrant holders	10-Q	4.1	08/10/2020
4.4	Form of Warrant to Purchase Common Stock, dated February 17, 2023, issued by Galera Therapeutics, Inc.	8-K	4.1	02/16/2023
4.5	Form of Pre-Funded Common Stock Purchase Warrant	8-K	4.1	12/31/2024
4.6	Amendment to Pre-Funded Common Stock Purchase Warrant	10-Q	10.3	05/15/2025
10.1#	Employment Agreement, dated October 25, 2019, by and between Galera Therapeutics, Inc. and J. Mel Sorensen, M.D.	S-1/A	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	10.3	10/28/2019
10.2.1#	Letter re: Separation Agreement, dated June 4, 2024, by and between Galera Therapeutics, Inc. and Robert A. Beardsley, Ph.D.	10-Q	10.1	08/14/2024
10.3#	Employment Agreement, dated October 25, 2019 by and between Galera Therapeutics, Inc. and Christopher Degnan	S-1/A	10.4	10/28/2019
10.3.1#	Letter re: Separation Agreement, dated August 28, 2024, by and between Galera Therapeutics, Inc. and Christopher Degnan	10-Q	10.1	12/13/2024
10.4#	Employment Agreement, dated October 25, 2019, by and between Galera Therapeutics, Inc. and Jon T. Holmlund, M.D.	S-1/A	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	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	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	10.2	11/09/2022
10.8#	Form of Indemnification Agreement between Galera Therapeutics, Inc. and its directors and officers	S-1/A	10.8	10/28/2019
10.9.1#	Galera Therapeutics, Inc. 2019 Incentive Award Plan	S-1/A	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	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	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	10.12	10/28/2019
10.10#	Galera Therapeutics, Inc. 2019 Employee Stock Purchase Plan	S-1/A	10.14	10/28/2019
10.11#	Galera Therapeutics, Inc. Equity Incentive Plan, as amended	S-1	10.8	10/11/2019
10.12#	Galera Therapeutics, Inc. Non-Employee Director Compensation Program, effective as of February 11, 2021 and as amended on May 5, 2022 and April 28, 2023	10-Q	10.1	05/11/2023
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	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	10.1	08/10/2020
10.13.3	Second Amendment to Amended and Restated Purchase and Sale Agreement, dated August 27, 2025, by and between Galera Therapeutics, Inc. and Clarus IV Galera Royalty AIV, L.P.	10-Q	10.3	11/13/2025
10.13.4	Notice of Assignment to Blackstone, dated as of October 20, 2025	8-K	10.1	10/27/2025
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	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	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	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	<u>8-K</u>	10.2	02/16/2023
10.18	Securities Purchase Agreement, dated as of December 30, 2024, by and among Galera and each purchaser identified on Annex A thereto	<u>8-K</u>	10.1	12/31/2024
10.19	Form of Registration Rights Agreement	<u>8-K</u>	10.2	12/31/2024
10.19.1	Form of First Amendment to Registration Rights Agreement	<u>8-K</u>	10.1	04/02/2025
10.19.2	Form of Second Amendment to Registration Rights Agreement	<u>10-Q</u>	10.1	08/13/2025
10.20#	Employment Agreement, dated April 1, 2019, by and between Galera Therapeutics, Inc. and Joel Sussman	<u>10-K</u>	<u>10.20</u>	03/31/2025
10.21#	Consulting Agreement, dated January 1, 2025, by and between Galera Therapeutics, Inc. and Michael Friedman.	<u>10-K</u>	<u>10.21</u>	03/31/2025
10.22	Asset Purchase and Sale Agreement, dated as of October 15, 2025, by and among the Company, Galera Labs, LLC, and Biossil Inc.	<u>10-Q</u>	<u>10.1</u>	11/13/2025
10.22.1	Amendment and Mutual Release, dated as of October 15, 2025, by and between the Company and Biossil Inc.	<u>10-Q</u>	<u>10.2</u>	11/13/2025
10.22.2*	Second Amendment to Asset Purchase and Sale Agreement, dated as of October 27, 2025, by and between the Company and Biossil Inc.			
19.1	Galera Therapeutics, Inc. Policy on Insider Trading	<u>10-K</u>	<u>19.1</u>	03/31/2025
21.1*	Subsidiaries of Galera Therapeutics, Inc.			
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 10-K 97.1 03/28/2024
- 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.

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