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 001-40034

GRI BIO, INC.

(Exact name of registrant as specified in its charter)

Delaware	**82-4369909**
(State or other jurisdiction of incorporation and organization)	(I.R.S. Employer Identification No.)
2223 Avenida de la Playa, #208, La Jolla, CA 92037	(619) 400-1170
(Address of principal executive offices, including zip code)	**(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, par value $0.0001 per share	GRI	The Nasdaq Capital 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 Section 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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

Indicate by check mark whether the registrant 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 Act). Yes ☐ No ☒

As of June 30, 2025 (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the registrant's common stock held by non-affiliates was approximately $1.5 million based on the last reported sale price of the registrant's common stock on The Nasdaq Capital Market on June 30, 2025.

As of January 29, 2026, 1,445,029 shares of the Registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the fiscal year ended December 31, 2025 (Annual Report) contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. Some of the statements in the sections captioned "*Item 1. Business*," "*Item 1A. Risk Factors*," "*Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations*," and elsewhere in this Annual Report contain forward-looking statements. In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would" or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our history of losses and need for additional capital to fund our operations, our inability to obtain additional capital on acceptable terms, or at all, our ability to continue as a going concern and to continue our operations, the failure of which could result in our stockholders receiving no value for their investment;
- our ability to remain listed on The Nasdaq Capital Market and to maintain compliance with applicable continued listing requirements;
- our ability to remediate material weaknesses in our internal controls over financial reporting or to maintain effective internal controls over financial reporting and our evaluations regarding the effectiveness of any compensating controls;
- our limited operating history and the difficulties encountered by a small developing company;
- the timing of initiation of planned clinical trials;
- the timing of any planned Investigational New Drug (INDs) or New Drug Applications (NDAs);
- plans to research, develop, and commercialize current and future product candidates;
- the ability to enter into new collaborations, and to fulfill obligations under any such collaboration agreements;
- the clinical utility, potential benefits and market acceptance of product candidates;
- commercialization, marketing and manufacturing capabilities and strategy;
- the ability to identify additional products or product candidates with significant commercial potential;
- developments and projections relating to our competitors and their industries;
- the impact of government laws and regulations;
- our ability to protect our intellectual property position and to obtain patent extensions;
- estimates regarding future revenue, expenses, capital requirements and need for additional financing;
- any statements about the effect, or potential effect, of the reverse stock splits, including the January 2026 Reverse Stock Split (as defined below), on the price or trading of our common stock, par value $0.0001 per share (Common Stock), on The Nasdaq Capital Market; and
- statements of belief and any statement of assumptions underlying any of the foregoing.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part I, Item 1A. "*Risk Factors*" and elsewhere in this Annual Report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Annual Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report to conform these statements to new information, actual results or to changes in our expectations, except as required by law.

You should read this Annual Report and the documents that we reference in this Annual Report and have filed with the U.S. Securities and Exchange Commission (the SEC) as exhibits to the Annual Report with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

As used in this Annual Report, unless the context requires otherwise, the "Company," "GRI Bio," "we," "us" and "our" refer to GRI Bio, Inc., including its wholly-owned subsidiary, GRI Bio Operations, Inc.

RISK FACTOR SUMMARY

The following is a summary of the principal risks described below in Part I, Item 1A. "*Risk Factors*" in this Annual Report. We believe that the risks described in the "*Risk Factors*" section are material to investors, but other factors not presently known to us or that we currently believe are immaterial may also adversely affect us. The following summary should not be considered an exhaustive summary of the material risks facing us, and it should be read in conjunction with the "*Risk Factors*" section and the other information contained in this Annual Report.

Risks Related to Our Financial Position and Need for Additional Capital

- We have incurred significant net losses since inception, and we expect to continue to incur significant net losses for the foreseeable future. We have never been, and may never be, profitable.
- We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs, future commercialization efforts or other operations or cease operations entirely. In particular, we will require substantial additional capital or resources to complete a Phase 2b clinical trial of GRI-0621.
- We may utilize our cash and available resources faster than we expect and our estimate regarding the length of time for which our resources will support our planned operations only includes the cost of certain preliminary work towards the initiation of a Phase 2b trial of GRI-0621; this estimate does not include the costs of completing a Phase 2b trial of GRI-0621, which is subject to obtaining substantial additional capital or resources.
- Our management has expressed substantial doubt about our ability to continue as a going concern, and the reports of our independent auditors contain explanatory paragraphs regarding this uncertainty.

Risks Related to Research and Development and the Pharmaceutical Industry

- Our business is highly dependent on the success of our product candidates, GRI-0621 and GRI-0803, and any other product candidates that we may advance into clinical development. All of our product candidates will require significant additional development before we may be able to seek regulatory approval and launch a product commercially.
- Clinical development involves a lengthy, complex and expensive process, with an uncertain outcome. In addition, the results of preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials.
- Interim, topline and preliminary data from our clinical trials (including topline data from our recently completed Phase 2a trial for GRI-0621) that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

Risks Related to Commercialization of Our Product Candidates

- Failure to obtain or maintain adequate reimbursement or insurance coverage for our approved product candidates, if any, could limit our ability to market those product candidates and decrease our ability to generate revenue.
- Even if we obtain U.S. Food and Drug Administration (FDA) approval of any of our product candidates, if any, we may never obtain approval or commercialize these product candidates outside of the United States, which could limit our ability to realize their full market potential.
- We may enter, or attempt to enter, into collaborations with third parties for the development and commercialization of our product candidates, and these collaboration would be important to our business. If we are unable to enter into collaborations that we deem beneficial, or if these collaborations are not successful, our business could be adversely affected.

Risks Related to Our Intellectual Property

- Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.
- If we do not obtain patent term extension and data exclusivity or similar protections to extend the term of patent protection covering any product candidates which we may develop, our business may be materially harmed.

Risks Related to Our Reliance on Third Parties

- We rely on third parties to conduct our clinical trials, manufacture our product candidates and perform other services. If these third parties do not successfully carry out their contractual duties, meet expected timelines or otherwise conduct the trials as required or perform and comply with regulatory or contractual requirements, we may not be able to successfully complete clinical development, obtain regulatory approval or commercialize our product candidates when expected or at all, and our business could be substantially harmed.

Risks Related to Managing Our Business and Operations

- If we lose key management personnel, or if we fail to recruit and retain additional highly skilled personnel, our ability to develop current product candidates or identify and develop new product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.
- We may be unable to adequately protect our internal information systems, or those used by our contract research organizations (CROs), clinical sites or other contractors or consultants upon which we rely, from cyberattacks, compromises, cybersecurity incidents or other disruptions, which could result in the compromise of confidential, sensitive or proprietary information, lead to operational or service interruption, harm our reputation and subject us to litigation, fines and other significant financial and legal exposure and other material and adverse consequences.

Risks Related to Financing, our Common Stock and Capital Requirements

- Future sales and issuances of our securities could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.
- The January 2026 Reverse Stock Split may have caused or cause our stock price to decline relative to its value before the split and has likely reduced the liquidity of shares of our Common Stock.
- We will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives.
- Management has determined that our internal controls were not effective as of December 31, 2024, March 31, 2025, June 30, 2025, September 30, 2025 and December 31, 2025 due to material weaknesses. We have remediated one material weakness and, resources permitting, plan to implement a plan to remediate the remaining material weakness. However, our efforts at remediation may be unsuccessful and the implementation of additional remediation is dependent upon additional resources and funding being available to us. If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

MARKET, INDUSTRY AND OTHER DATA

This Annual Report contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates, including data regarding the estimated size of such markets and the incidence of certain medical conditions. We obtained the industry, market and similar data set forth in this Annual Report from our internal estimates and research and from independent industry publications, governmental publications, reports by market research firms or other independent sources that we believe to be reliable sources. In some cases, we do not expressly refer to the sources from which this data is derived. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our internal data and estimates are based upon information obtained from trade and business organizations and other contacts in the industry in which we operate, and our management's understanding of industry conditions. While we believe our internal research is reliable, it has not been verified by an independent source. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. The third-party information presented in this Annual Report, and, in particular, any estimates in this Annual Report, as those estimates may relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section entitled "*Item 1A. Risk Factors*" in this Annual Report, and elsewhere in this Annual Report.

PART I

Item 1. BUSINESS.

Overview

We are a clinical-stage biopharmaceutical company focused on discovering, developing, and commercializing innovative therapies that target serious diseases associated with dysregulated immune responses leading to inflammatory, fibrotic and autoimmune disorders. Our goal is to be an industry leader in developing therapies to treat these diseases and to improve the lives of patients suffering from such diseases.

Our product candidate, GRI-0621, is an oral inhibitor of type 1 invariant Natural Killer T (iNKT) cells. The active pharmaceutical ingredient in GRI-0621, tazarotene, is a synthetic retinoid acid receptor-beta and gamma selective agonist. Tazarotene is approved in the United States for topical treatment of psoriasis and acne. While there are no approved oral formulations of tazarotene, as of December 31, 2025, it has been evaluated in over 1,700 patients as an oral product for up to 52-weeks. We are developing GRI-0621 for the treatment of severe fibrotic lung diseases such as idiopathic pulmonary fibrosis (IPF), a life-threatening progressive fibrotic disease of the lung that affects approximately 140,000 people in the United States, with up to 40,000 new cases per year in the United States. Some estimate that IPF affects 3 million globally. While there are currently two approved therapies for the treatment of lung fibrosis, neither has been associated with improvements in overall survival, and both therapies have been associated with significant side effects leading to poor therapeutic adherence. In preliminary and topline data from our trials to date with GRI-0621, and earlier trials with oral tazarotene, we have observed GRI-0621 to be well-tolerated and to inhibit iNKT cell activity in subjects. We and others have shown that activated iNKT are upregulated in IPF, primary sclerosing cholangitis (PSC), metabolic dysfunction-associated steatohepatitis (MASH), alcoholic liver disease (ALD), systemic lupus erythematosus (SLE), multiple sclerosis (MS), ulcerative colitis (UC) patients as well as other indications. In these patients activated iNKT cells are correlated with more severe disease.

We most recently evaluated GRI-0621 in a randomized, double-blind, multi-center, 2-arm Phase 2a clinical trial for the treatment of patients diagnosed with IPF. The primary endpoint for this Phase 2a trial was safety and tolerability of oral GRI-0621 as assessed by clinical labs, vital signs and adverse events after 12 weeks of treatment. Secondary endpoints were baseline changes in serum biomarkers, differentially expressed genes measured by ribonucleic acid sequencing (RNAseq), T cell receptor sequencing (TCRseq), and flow cytometry in PBMC samples collected at week six and week 12; an assessment of the pharmacokinetics (PK) of GRI-0621 at the week 12 visit of treatment (steady state); and a determination of the pharmacodynamic activity of oral GRI-0621 as measured by inhibition of immune cell activation in peripheral blood mononuclear cells (PBMCs) after six weeks and 12 weeks, and from bronchoalveolar lavage fluid (BAL) fluid after 12 weeks of treatment. Concurrently, a sub-study examined the number and activity of immune cells in BAL fluid in eight subjects (across various centers). Additional exploratory endpoints for the trial included assessment of the effect of GRI-0621 on pulmonary function at baseline and after six weeks and 12 weeks of treatment. 35 patients were enrolled in the trial and randomly assigned to a placebo arm and a GRI-0621 treatment arm, of which 19 patients completed treatment in the treatment arm and nine patients completed treatment in the placebo arm. Based on topline results available to date, the clinical trial met its primary endpoint and the secondary endpoints measured to date (as described below). Secondary and exploratory endpoints relating to additional flow cytometry data, TCRseq, and the pharmacodynamic activity of GRI-0621 are being evaluated as analyses become available.

No treatment related serious adverse events were reported for GRI-0621-treated subjects and adverse events were grade 2 (17%) or grade 3 (4%), with dry skin, dry lips, muscle and joint pain as the most common adverse events reported. There were no increases in cough (0% in the GRI-0621-treated arm compared to 25% in the placebo arm) or gastrointestinal disorders reported in the GRI-0621-treated arm compared to the placebo arm (diarrhea reported in 13% versus 33%, respectively). 80% of the subjects enrolled were taking background pirfenidone or nintedanib. No changes in liver enzymes, triglycerides or cholesterol were observed over 12 weeks in patients treated with GRI-0621 and standard of care.

Changes from baseline of serum biomarkers of type I, III and VI collagen in GRI-0621-treated subjects were suggestive of an anti-fibrotic effect, with decreases in biomarkers of fibrosis formation and increases in biomarkers of fibrosis resolution, including crosslinked type III collagen, observed after 12 weeks of treatment with GRI-0621. Changes from baseline in type IV collagen were suggestive of initiation of an alveolar basement membrane repair mechanism, an important step in repair of injured lung tissue. Reductions in neutrophil and macrophage activity (immune cell biomarkers upregulated in IPF and associated with disease progression) and downregulation of genes associated with fibrosis, disease progression and mortality were also observed in patients treated with GRI-0621 and standard of care.

Placebo-adjusted changes from baseline in Forced Vital Capacity (FVC) were observed to increase by 99 ml in the GRI-0621-treated arm and by 139 ml in the subset taking both GRI-0621 and standard of care compared to placebo plus standard of care. Breathing tests used to measure FVC are subject to large visit-to-visit variability and are dependent on the patient's effort, often

resulting in data outliers. To minimize the impact of outliers in this FVC dataset, a *post hoc* data analysis was performed excluding the data points with the largest gain or loss in FVC over 12 weeks from both arms. The results of this analysis demonstrated an increase in placebo-adjusted change from baseline in FVC of 54 ml in the GRI-0621-treated arm and an increase of 81 ml in the subset taking both GRI-0621 and standard of care. Overall, 39% of GRI-0621 treated subjects experienced an increase in FVC at 12 weeks compared to 80% of subjects who experienced a decline in FVC at 12 weeks in the placebo-treated arm. GRI-0621-treated subjects also demonstrated increased TCR expression after 12 weeks of treatment compared with baseline or placebo-treated subjects receiving standard of care, suggestive of iNKT inactivation following GRI-0621 treatment. T cell subsets demonstrated increased type 1-associated cytokines (IFN-γ) and reduced type 2 (IL-4 and IL-13) and type 3-associated cytokines (IL-17A and IL-22) in both BAL and PBMC samples. Similarly, TGF-β was observed to be reduced after 12 weeks of GRI-0621 treatment in T cell subsets (e.g. Treg and Treg-like), B cells, monocytes, macrophages and neutrophils in BAL and PBMC samples compared to baseline or placebo-treated subjects receiving standard of care. GRI-0621 treatment also improved expression of genes associated with lung injury, fibroblast differentiation, extracellular matrix deposition, basement membrane repair, and type II alveolar epithelial cell-to-type I alveolar epithelial cell transition. The RNAseq data is supportive of and consistent with earlier reported serum biomarker and flow cytometry data.

Final results from this trial will be used to determine dose, safety sample size, clinically relevant endpoints and clinical trial duration in communication with the FDA in designing future trials. Based on these results and subject to FDA clearance and obtaining the requisite additional funding or resources, we plan to initiate (either ourselves or with a strategic partner) a Phase 2b trial that could support an application for conditional approval of GRI-0621 in the European Union and could have the potential to be regarded as a registrational trial in the United States.

Our product candidate portfolio also includes GRI-0803 and a proprietary library of 500+ compounds. GRI-0803, the lead molecule selected from the library, is a novel oral agonist of type 2 diverse Natural Killer T (dNKT) cells and would be developed for the treatment of autoimmune disorders, with much of our preclinical work in SLE or lupus and MS. In lupus, the immune system mistakenly attacks its own healthy tissues, especially joints and skin, but can affect almost every organ and tissue of the body. The condition can be fatal and often causes debilitating bouts of fatigue and pain that prevent nearly half of adult patients from working. Lupus affects between 160,000 - 200,000 patients in the United States, with around 80,000 – 100,000 patients in the United States suffering from kidney nephritis, one of the most serious manifestations of SLE, typically within five years of diagnosis. There is no cure for lupus, but medical interventions and lifestyle changes can help control it. SLE treatment consists primarily of immunosuppressive drugs that inhibit the activity of the immune system. Only two drugs have been approved for lupus in the past 50 years, and new treatment options are sorely needed. In order to focus our resources on our GRI-0621 program, we previously limited our development of GRI-0803 pending additional funding. We intend to complete IND-enabling studies and file an IND application to evaluate GRI-0803 in a Phase 1a and 1b trial in healthy volunteers in 2026. We expect to continue to evaluate indications to select the best fit for further development of the program, but our initial focus would be on lupus.

Our Pipeline

We have retained global development and commercialization rights to all of the product candidates in our pipeline. The chart below summarizes key information about our programs. We are also progressing several preclinical and clinical assets that have shown promise in preclinical models associated with disease

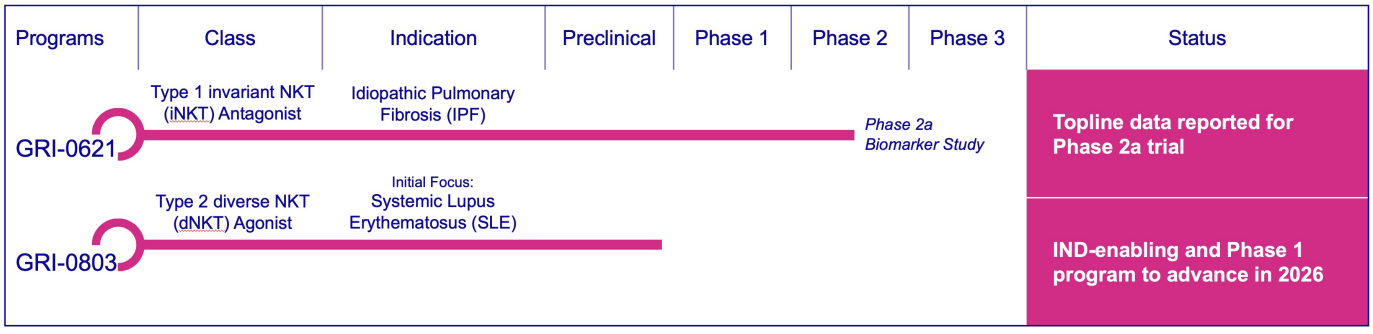


Figure 1. GRI's pipeline - GRI-0621 and GRI-0803

GRI-0621 is an oral formulation of tazarotene, a synthetic retinoid acid receptor (RAR)-beta and gamma selective agonist. While no oral formulations are approved, tazarotene is approved in the United States for topical treatment of psoriasis and acne. GRI-0621 inhibits the activity of iNKT cells that have been shown to accumulate in IPF patients and other interstitial lung disease patients. We, and others, have shown that activated iNKT cells are overexpressed in IPF, hepatic and other fibrotic

conditions and are significantly correlated with advanced disease. We believe GRI-0621 has the potential to treat multiple fibrotic and related diseases, including other pulmonary fibrotic diseases, MASH, ALD, renal fibrosis, acute-on-chronic liver failure, drug-induced liver injury (DILI) and other acute indications. In numerous preclinical studies, inhibiting the activity of iNKT cells significantly reduced inflammation, activation of macrophage populations, transforming growth factor (TGF)-beta and fibrosis. There are currently no therapeutics approved that specifically target iNKT cells.

We most recently evaluated GRI-0621 in a randomized, double-blind, multi-center Phase 2a clinical trial for the treatment of patients diagnosed with IPF. The primary endpoint for this Phase 2a trial was safety and tolerability of oral GRI-0621 as assessed by clinical labs, vital signs and adverse events after 12 weeks of treatment. Secondary endpoints were baseline changes in serum biomarkers, differentially expressed genes measured by RNAseq, TCRseq, and flow cytometry in PBMC samples collected at week six and week 12; an assessment of the PK of GRI-0621 at the week 12 visit of treatment (steady state); and a determination of the pharmacodynamic activity of oral GRI-0621 as measured by inhibition of immune cell activation in PBMCs after six weeks and 12 weeks, and from BAL fluid after 12 weeks of treatment. Concurrently, a sub-study examined the number and activity of immune cells in BAL fluid in eight patients (across various centers). Additional exploratory endpoints for the trial included assessment of the effect of GRI-0621 on pulmonary function at baseline and after six weeks and 12 weeks of treatment. 35 patients were enrolled in the trial and randomly assigned to a placebo cohort and a GRI-0621 treatment cohort, of which 19 patients completed treatment in the treatment cohort and nine patients completed treatment in the placebo cohort. Based on the topline results available to date, the clinical trial met its primary endpoint and secondary endpoints that have been evaluated to date as more fully described below.

Prior to our most recently completed, Phase 2a trial, we also evaluated GRI-0621 in a pilot Phase 2a trial in 14 hepatically impaired chronic liver disease patients. The study was originally intended to evaluate 60 patients, but we made the administrative decision to halt the study after enrolling 14 patients due to recruitment challenges and updated FDA guidance regarding the design of MASH clinical studies. In this limited number of patients, GRI-0621 was observed to be well-tolerated, however, the study was underpowered to meet its endpoints with statistical significance.

We are also developing GRI-0803, a novel orally administered activator of diverse Natural Killer T (dNKT) cells, from which we observed potential therapeutic benefits in multiple models of autoimmunity in preclinical studies. We believe GRI-0803 has the potential to treat SLE and related kidney nephritis, MS, autoimmune hepatitis and other autoimmune disorders.

In addition, we have a library of over 500 novel compounds acquired from JADO Technologies GmbH. The library was designed to mimic the structure and function of GRI-0124 (miltefosine), a potent activator of dNKT cells. GRI-0803 is the lead product candidate selected from the library.

We are built upon decades of experience studying the activity of NKT cells and their role in health and disease. Our company was founded by three immunologists, including an internationally recognized leader in NKT cell research who contributed to the initial characterization of NKT subsets, characterized the T cell receptor binding of iNKT and dNKT cells with their respective ligands and identified and characterized the role of iNKT and dNKT cells in inflammatory, fibrotic and autoimmune disorders.

We believe that our founders' and management's experience provide unique insights into the activity of NKT cells and their role in chronic inflammatory, fibrotic, and autoimmune disorders. We are led by W. Marc Hertz, Ph.D., our President and Chief Executive Officer, a biotechnology executive who previously served as Chief Executive Officer of Pharmexa, Inc. and Multimeric Biotherapeutics, Inc. and as part of the senior management of Pharmexa A/S. Albert Agro, Ph.D., our Chief Medical Officer, has extensive experience in the biotechnology and pharmaceutical industries and previously held senior positions in global clinical development Boehringer Ingelheim International GmbH and Bayer Inc., as well as executive positions at Cynapsus Therapeutics Inc. (Chief Medical Officer), vTv Therapeutics Inc. (Sr. Vice President Development) and Sublimity Therapeutics Limited (Chief Executive Officer). Dr. Agro maintains a faculty appointment at McMaster University in the Department of Pathology and Molecular Medicine. Vipin Kumar Chaturvedi, Ph.D. (Dr. Kumar), our Chief Scientific Officer, is an internationally recognized leader in NKT cell research. GRI's technologies are based on his work identifying NKT cell subsets and their differential roles in inflammatory, fibrotic and autoimmune disease. Dr. Kumar is an Adjunct Professor at the University of California, San Diego, and former Professor of Medicine where he headed the Laboratory of Immune Regulation. We are supported by our Board of Directors (the Board) and clinical advisory boards with extensive life science expertise.

Our Strategy

Our goal is to become a leader in developing and commercializing therapeutics that target diseases with significant unmet needs. Our initial focus is on developing product candidates that target the activity of NKT cells and their role in driving dysregulated immune responses. Our strategy is focused on the following key components:

- **Efficiently advance the clinical development of GRI-0621 in IPF**. We conducted a randomized double-blind placebo-controlled Phase 2a trial in 35 patients with IPF in which, based on topline data, GRI-0621 met its primary and secondary endpoints evaluated to date. This orphan disease is therapeutically underserved, and we believe that GRI-0621 may have the ability to become the first true disease-modifying therapy for these patients. Based on the results of the Phase 2a trial, and subject to obtaining the requisite additional funding or resources, we plan to initiate (either ourselves or in partnership with a strategic partner) a Phase 2b trial that could support an application for conditional approval of GRI-0621 in the European Union and could have the potential to be regarded as a registrational trial in the United States.
- **Advance GRI-0803 through Phase 1a/1b studies initially targeting SLE**. Subject to IND clearance, we intend to evaluate GRI-0803 in a Phase 1a and 1b trial in healthy volunteers. We expect to file an IND with respect to this trial in 2026.
- **Leverage our understanding of iNKT and dNKT cells in disease and continue evaluating GRI-0621, GRI-0803, and additional product candidates in subsequent indications**. We intend to expand our leadership as a company dedicated to developing therapies that directly target the biological processes driving dysregulated immune responses. We also intend to selectively pursue business development opportunities to expand our product portfolio and supporting technologies.
- **Continue to build a patient-focused company across a broad range of inflammatory, fibrotic and autoimmune diseases**. In building a patient-focused company to address the needs of patients, we will work with clinicians, patient advocacy groups, medical centers of excellence and medical key opinion leaders to better understand the symptoms and consequences of these diseases, to expeditiously develop and provide better treatments to patients and to increase awareness of these diseases.
- **Maximize the commercial value of our product candidates**. We have retained worldwide development and commercial rights for all our product candidates. We intend to commercialize, either ourselves or with a strategic partner, any products in our portfolio for which we receive regulatory approvals in certain rare indications in the United States and the European Union with a limited and targeted commercial team. We also intend to retain the flexibility to evaluate strategic collaborations and to seek partners to commercialize our products in other geographies and for our products in highly prevalent indications which require significant investment to build a commercial infrastructure.

NKT Cells and the Immune System

Our approach is founded on the discovery that NKT cells are a functional link between the innate and adaptive immune systems and that dysregulated immune responses can be reset by regulating the activity of NKT cells to potentially treat a broad array of acute and chronic conditions.

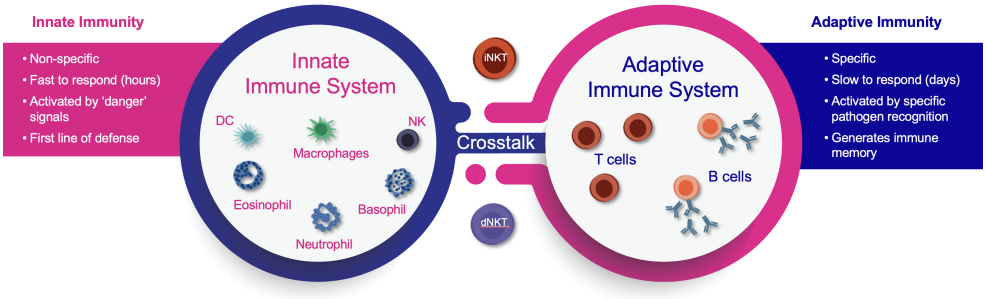


Figure 2. NKT cells are innate-like T cells that bridge the adaptive and innate immune systems.

NKT cells are innate-like T cells that bridge the adaptive and innate immune systems (see Figure 2). They share properties of both NK and T cells, control the expression of key cytokines/chemokines and are critical regulators of immune responses. iNKT cells are effector T cells that can play a pathogenic role in lung, liver and autoimmune indications; while dNKT cells are regulatory T cells that inhibit the activity of iNKT cells, as well as other cell types, and support an anti-inflammatory response.

dNKT cells can shift the response from a destructive pro-inflammatory and cytotoxic environment towards an anti-inflammatory and protective environment (see Figure 3) and are critical for minimizing the damage caused by inflammatory responses in certain fibrotic and autoimmune diseases.

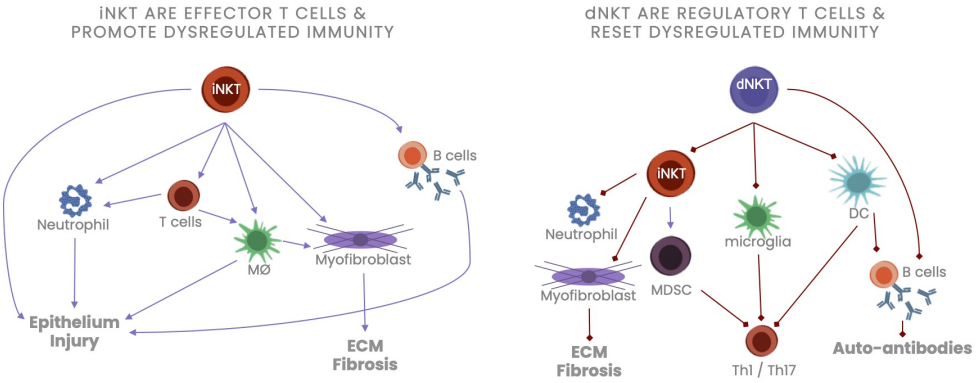


Figure 3. iNKT and dNKT cells have opposing roles in controlling inflammation (arrows in the left panel indicate activation and arrows in the right panel indicate inhibition).

Repeated activation of iNKT cells can lead to chronic pulmonary diseases and are elevated in patients. Regulating iNKT cell activity has been observed to be therapeutic in animal models of IPF and activated iNKT cells accumulate in the lungs of IPF, MASH and SLE patients, as well as other chronic inflammatory, fibrotic and autoimmune disease populations.



Figure 4. Activated iNKT cells are increased in PBMC samples from IPF, MASH and SLE patients compared to healthy subjects.

Current IPF therapies slow the decline in lung function but do not improve overall survival. Regulating iNKT cell activity and their ability to promote macrophage polarization, TGF-beta production and activation of myofibroblasts suggests they may reduce fibrosis progression and lead to improved survival outcomes in IPF. Activated iNKT cells are significantly upregulated in IPF patients and have the potential to be an important pharmacodynamic biomarker for these patients. We have observed that

activated iNKT cells increase in patients with MASH as the disease progresses from healthy individuals to mild non-alcoholic fatty liver disease and advanced MASH and believe iNKT may be a similar biomarker for IPF patients (see Figure 5).

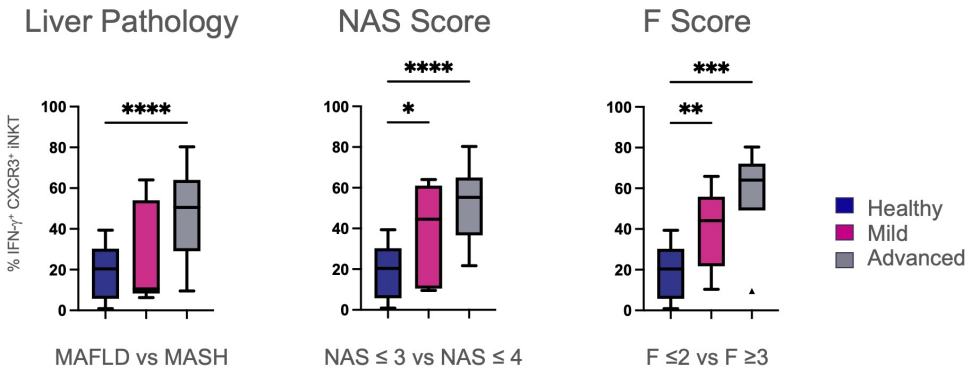


Figure 5. CXCR3+ IFN-gamma+ activated iNKT cells increase in MASH patients as disease progresses from healthy, mild to advanced disease.

In models of pulmonary, renal, and hepatic fibrosis - including IPF, SLE, MASH, ALD, DILI, and autoimmune hepatitis - iNKT cells play an important pathogenic role in mediating tissue damage by rapidly accumulating, becoming activated and secreting cytokines and chemokines for induction of a pro-inflammatory cascade that includes activation of the IL-1beta inflammasome and neutrophil recruitment, differentiation and activation of pro-fibrotic myofibroblasts / hepatic stellate cells, collagen deposition and fibrosis.

GRI has also identified several modulators of dNKT cell activity, including cis-tetracosenoyl sulfatide (sulfatide), certain phospholipids and GRI-0124. GRI-0803, as well as GRI's library of over 500 compounds, are structurally related to GRI-0124. In vivo administration of GRI-0803 and GRI-0124 activates dNKT cells and inhibits the expansion of activated iNKT cells. Together, we believe these data support a model of iNKT inhibitors, such as GRI-0621, and dNKT modulators, such GRI-0803, as well as GRI-0124 and GRI-0729, working together to balance inflammatory immune responses.

Pulmonary Disease

IPF is a rare life-threatening disease characterized by progressive fibrosis and abnormal scarring that destroys the structure and function of the lungs over time by blocking the movement of oxygen into the bloodstream, leading to their deterioration and destruction. The most common symptoms of IPF are shortness of breath and a dry persistent cough.

Our Product Candidate Portfolio

GRI-0621 for the treatment of IPF

GRI-0621 is an oral gel capsule formulation of an FDA-approved topical dermatology product, tazarotene (ethyl 6-[2-(4,4-dimethylthiochroman-6-yl)ethynyl]nicotinate), a synthetic RAR-beta and gamma-selective agonist and potent inhibitor of iNKT cells. While there are no approved oral formualtions of tazarotene, tazarotene is approved in topical formulations for psoriasis and acne and has been evaluated in over 1,700 patients as an oral product dosed in subjects for up to 52-weeks. The Company is developing GRI-0621 for the treatment of IPF.

IPF background and market opportunity

IPF is the most common and severe form of progressive pulmonary fibrosis, affecting approximately 140,000 patients in the United States. Up to 40,000 new cases are diagnosed in the United States each year, primarily affecting individuals between the ages of 65 and 70, and prevalence in the United States is expected to rise with an aging population. The median survival is between two to three years after diagnosis, and the average life expectancy for patients with confirmed IPF is between three and five years.

Current treatments for IPF and their limitations

Some IPF patients with mild or moderate symptoms are treated with either nintedanib, marketed as OFEV by Boehringer Ingelheim Pharmaceuticals, Inc., pirfenidone, marketed as Esbriet by Genentech USA, Inc, or nerandomilst, recently approved in 2025, marketed as Jascayd by Boehringer Ingelheim Pharmaceuticals, Inc.. These drugs have been shown to slow progression of decrease in lung function associated with IPF and deterioration of pulmonary function, but none of these drugs have been associated with improvements in overall survival, and all three have been associated with significant side effects. It is

estimated that over 60% of patients dosed with nintedanib have diarrhea and approximately 14% experience elevated levels of liver enzymes. Approximately 30% of patients treated with pirfenidone have skin rash, and approximately 9% experience photosensitivity, both of which can lead to dose reductions or discontinuations. Both nintedanib and pirfenidone have some efficacy in patients with more advanced disease, but high rates of discontinuations due to adverse events in these frailer patients limit their use. A survey of 290 physicians published by a third-party in 2017 found that over half of IPF patients are not being treated with either agent for multiple reasons, including physicians not having sufficient confidence in clinical benefit and concerns about safety. A retrospective cohort analysis of prescription records conducted by researchers at the Mayo Clinic and presented in 2019 found that the adoption of pirfenidone and nintedanib by IPF patients was approximately 10% for each therapy, supporting the earlier observation that the majority of IPF patients are not actively being treated with either agent. Despite this, total worldwide sales of pirfenidone and nintedanib in 2022 were $4.3 billion combined.

Our Solution - GRI-0621

We are developing GRI-0621 as an oral gel capsule formulation to treat IPF patients. GRI-0621 is differentiated from current IPF therapies because it is designed to reset the dysfunctional immune response driving disease by inhibiting the activity of iNKT cells, as opposed to targeting a symptom of the disease that is downstream of the dysregulated immune response. GRI-0621 has been evaluated as an oral formulation in approximately 1,700 psoriasis, acne, and liver disease patients and in those patient populations and studies, the molecule was well-tolerated with typical reported adverse events associated with hypervitaminosis A (headache, back pain, foot pain, cheilitis, hyperglycemia, arthralgia, myalgia, joint disorder, nasal dryness, dry skin, rash and dermatitis).

In preclinical studies, animals lacking iNKT cells were observed to be protected from fibrosis in models of IPF, MASH, ALD, autoimmune liver disease and DILI. Similarly, inhibiting the activity of iNKT cells can protect and/or treat animals from developing fibrosis. Fibrosis is a complex dynamic process involving several signaling molecules, differentiation pathways and multiple cell types in different tissues. Thus, when the wound repair mechanism goes awry due to chronic inflammation/injury, this results in tissue scarring, stiffness and eventually malfunction. Despite its complexity, scientific literature suggests that there are common biological mechanisms that drive fibrosis in different tissues such as lung, liver and kidney.

In our preclinical studies, GRI-0621 administration in animal models of hepatic fibrosis was observed to inhibit secretion of pro-inflammatory cytokine secretion by iNKT cells (see Figure 6) and maturation and activation of pro-inflammatory Kupffer cells and pro-fibrogenic myofibroblasts/hepatic stellate cells (see Figures 7 and 10).

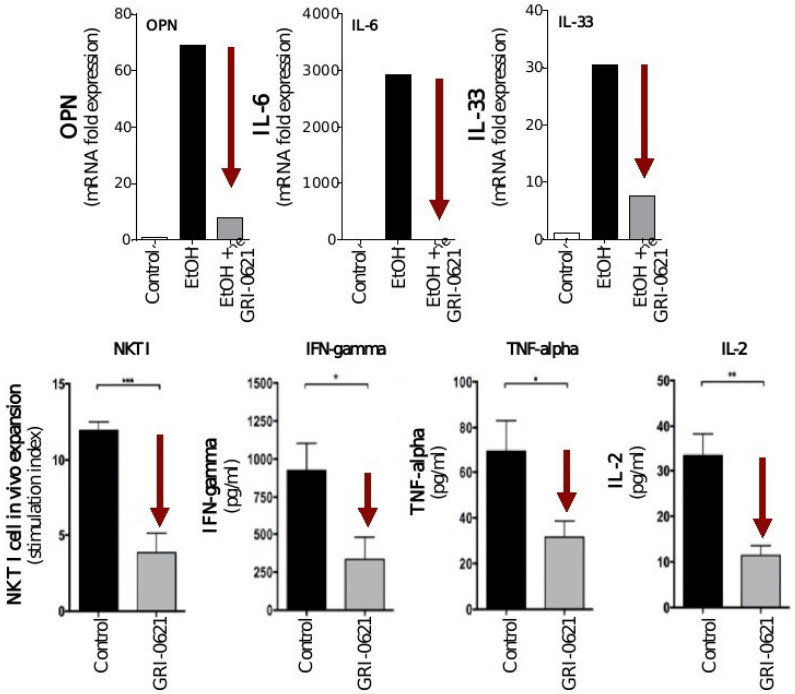


Figure 6. GRI-0621 observed to inhibit in vivo expansion and activation of iNKT cells and inhibits pro-inflammatory cytokines in animal models of fibrosis.

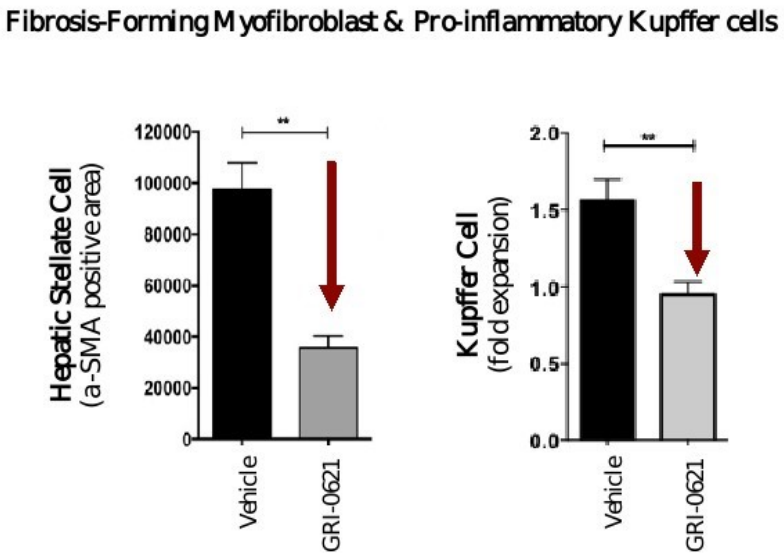


Figure 7. GRI-0621 observed to inhibit Kupffer cells and the activation and maturation of myofibroblasts / hepatic stellate cells.

Consistently, iNKT knock-out (KO) animals that lack iNKT cells were observed to fail to upregulate pro-fibrogenic genes relative to wild type (WT) animals in models of fibrosis (see Figure 8).

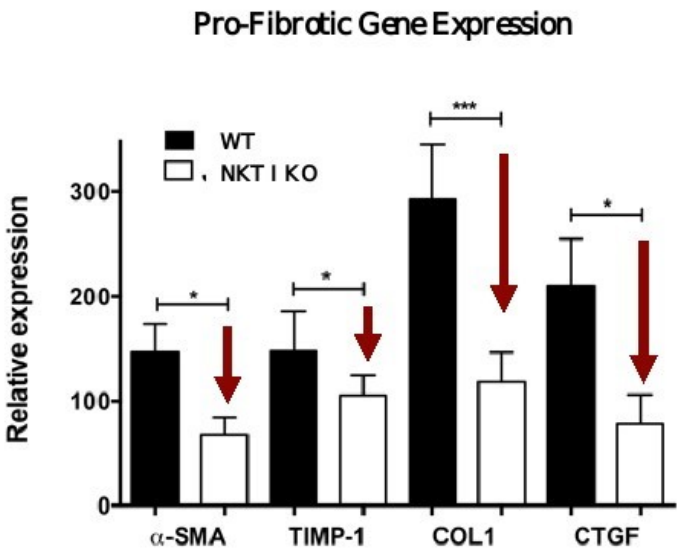


Figure 8. Inhibition of the key fibrogenic genes, including CTGF, observed in the iNKT-deficient animal model of fibrosis.

One of the most important signaling molecules driving fibrogenesis is TGF-beta. In our models of pulmonary and hepatic, and renal fibrosis, functional inactivation of iNKT cells with iNKT inhibitors or dNKT cell activators led to a significant inhibition of this key mediator of fibrosis (see Figure 9).

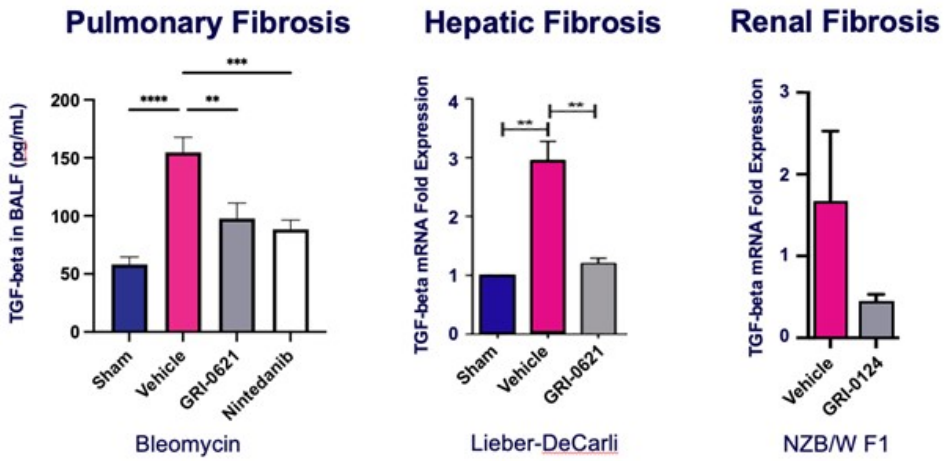


Figure 9. Inhibition of iNKT cells significantly reduced TGF-beta in models of pulmonary and hepatic fibrosis.

In our preclinical studies, a reduction in pro-inflammatory cytokines, Kupffer cells, activated myofibroblasts, pro-fibrogenic gene expression and the critical soluble mediator of fibrosis, TGF-beta, resulted in reduced collagen deposition and fibrosis in liver and lung models of fibrosis (see Figures 10, 11, and 12).

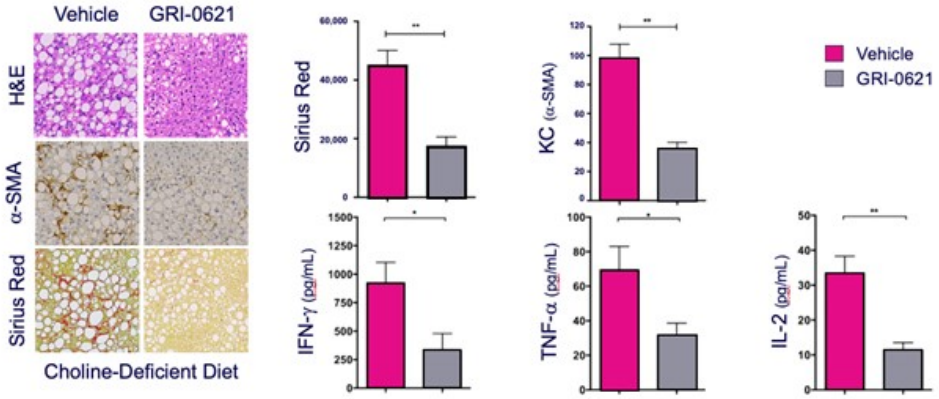


Figure 10. Hepatic inflammation & steatosis (H&E), myofibroblast activation (anti-SMA) and fibrosis (Sirius Red) were inhibited (left histology panels and upper bar graphs) as well as IFN-gamma, TNF-alpha, and IL-2 (lower bar graphs) following GRI-0621 administration in the choline-deficient L-amino-defined model of MASH.

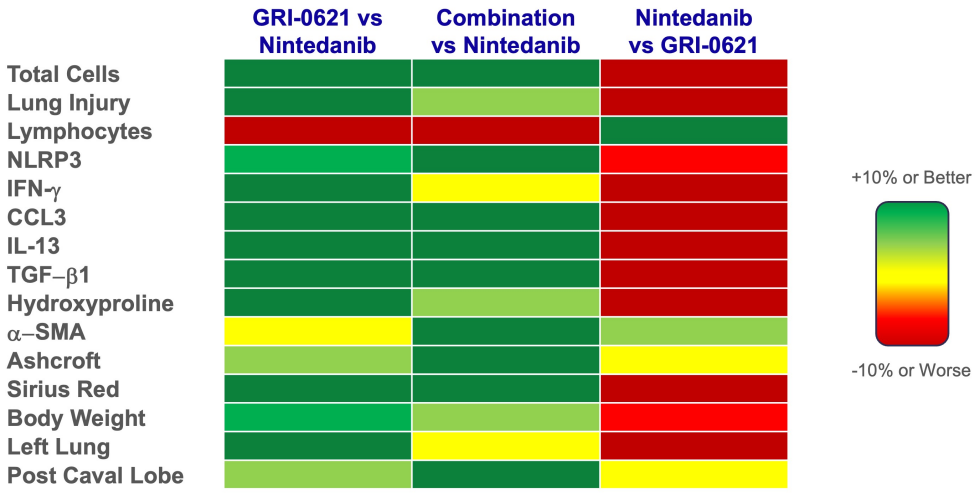


Figure 11. GRI-0621 alone, and in combination with nintedanib, observed to prevent inflammation, inflammatory cytokines,TGF-beta and collagen deposition in a bleomycin treatment model of pulmonary fibrosis.

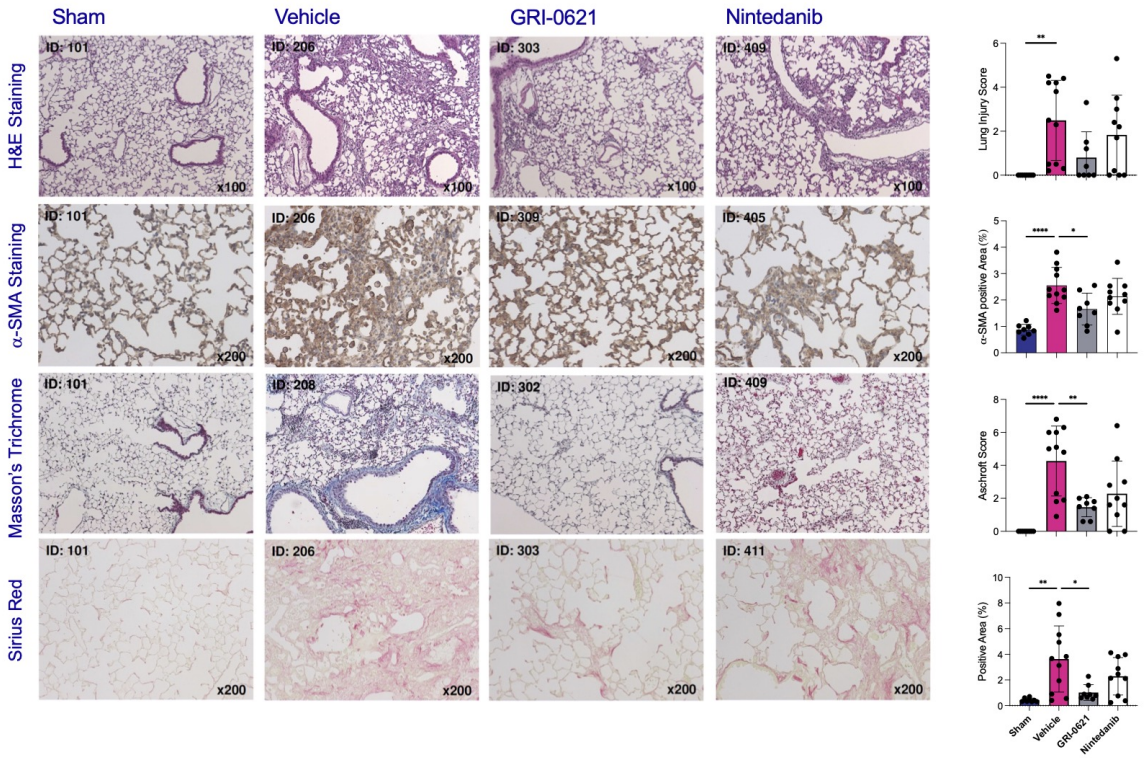


Figure 12. GRI-0621 observed to improve lung injury (H&E), myofibroblast activation (a-SMA) and fibrosis (Mason's Trichrome and Sirius Red) in a bleomycin treatment model of pulmonary fibrosis.

GRI-0621 Pilot Phase 2a Trial in Hepatically Impaired Subjects

We evaluated GRI-0621 in a pilot Phase 2a trial in hepatically impaired chronic liver disease patients. The trial was originally intended to evaluate 60 patients, but we made the administrative decision to halt the trial after enrolling 14 patients due to recruitment challenges and updated guidance from the FDA regarding the design of NASH clinical studies. In this limited number of patients, GRI-0621 was observed to be well-tolerated and showed improvements in liver function tests, serum

CK-18, and in iNKT cell activity, however, the trial was underpowered to meet its endpoints with statistical significance. Adverse events were generally mild and consistent with RAR-beta and gamma agonism (see table below).

ALL-CAUSE	PLACEBO (n=4)	GRI-0621 4.5mg (n=4)	GRI-0621 6.0mg (n=5)
SERIOUS TEAEs	0	0	0
GRADE 1 TEAEs	0	0	0
GRADE 2 TEAEs	0	0	0
GRADE 3/4/5 TEAEs	0	0	0
TREATMENT RELATED			
CHELITIS	0	0	0
NASEAU	0	0	0
DRY SKIN	0	0	0
PURITIS	0	0	0
HEADACHE	0	0	0
MYLAGIA	0	0	0
HYPERTENSION	0	0	1*
GASTROENTERITIS	0	0	0
TONSILITIS	0	0	1*
CREATINE PHOSPHOKINASE	0	0	0
LACTATE DEHYDROGENASE	0	0	0
POTASSIUM	0	0	0

* Grade 2 treatment emergent adverse events (TEAE)

GRI-0621 Manufacturing

We rely on third-party contract manufacturers to manufacture GRI-0621 for preclinical studies and clinical trials, and do not own manufacturing facilities for producing any preclinical study or clinical trial product supplies. We rely on a limited number of suppliers for drug product and engage a single manufacturer to produce our formulated GRI-0621 drug product for clinical studies, as is standard industry practice in early to mid-stage clinical development. If these suppliers are unable to supply to us in the quantities we require, or at all, or otherwise default on their supply obligations to us, we may not be able to obtain alternative supplies from other suppliers on acceptable terms, in a timely manner, or at all. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturer or manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

GRI-0621 Phase 2a Trial in Patients with IPF

We recently completed a Phase 2a clinical trial investigating GRI-0621 in patients diagnosed with IPF. This trial was a 12-week, multicenter, multinational, randomized, placebo-controlled trial. A 4.5 mg dose was compared to placebo over 12 weeks of treatment in subjects with a confirmed diagnosis of IPF on background therapy. Subjects completed a screening visit to evaluate their medical history, present condition, laboratory assessments, comorbidities and concomitant medications. Based on these findings, subjects were randomly assigned to one of two treatment arms: 4.5 mg of GRI-0621 or placebo in a 2:1 randomization. Weekly visits out to 12 weeks evaluated safety, pharmacokinetics and efficacy/mechanism of action of GRI-0621 as assessed by the activation of iNKT cells from both PBMCs at weeks 6 and 12 and BAL fluid at week 12. Subjects were followed for at least two weeks after completion of dosing. Concurrently, a sub-study examined the number and activity of immune cells in BAL fluid in subjects across various sites. The primary endpoint for this trial was safety and tolerability of oral GRI-0621 as assessed by clinical labs, vital signs and adverse events after 12 weeks of treatment. Secondary endpoints were baseline changes in serum biomarkers, differentially expressed genes measured by RNAseq, TCRseq, and flow cytometry in samples collected at week six and week 12; an assessment of the PK of GRI-0621 at the week 12 visit of treatment (steady state); and a determination of the pharmacodynamic activity of oral GRI-0621 as measured by inhibition of immune cell activation in PBMCs after six weeks and 12 weeks, and from BAL fluid after 12 weeks of treatment. Additional exploratory

endpoints for the trial included assessment of the effect of GRI-0621 on pulmonary function at baseline and after 6 weeks and 12 weeks of treatment. 35 patients were enrolled in this trial of which 19 patients completed treatment in the treatment arm and nine patients completed treatment in the placebo arm. Based on topline results available to date, the trial met its primary endpoint and secondary endpoints measured to date as more fully described below. Secondary and exploratory endpoints relating to additional flow cytometry data, TCRseq, and the pharmacodynamic activity of GRI-0621 are being evaluated as analyses become available.

No treatment related serious adverse events were reported for subjects taking GRI-0621 and adverse events were grade 2 (17%) or grade 3 (4%), with dry skin, dry lips, muscle and joint pain as the most common adverse events reported. There were no increases in cough (0% in the GRI-0621-treated arm compared to 25% in the placebo arm) or gastrointestinal disorders reported in the GRI-0621-treated arm compared to the placebo arm (diarrhea reported in 13% versus 33%, respectively). 80% of the subjects enrolled were taking background pirfenidone or nintedanib. No changes in liver enzymes, triglycerides or cholesterol were observed over 12 weeks in patients treated with GRI-0621 and standard of care.

Changes from baseline of serum biomarkers of type I, III and VI collagen in GRI-0621-treated subjects were suggestive of an anti-fibrotic effect, with decreases in biomarkers of fibrosis formation and increases in biomarkers of fibrosis resolution, including crosslinked type III collagen, observed after 12 weeks of treatment with GRI-0621. Changes from baseline in type IV collagen were suggestive of initiation of an alveolar basement membrane repair mechanism, an important step in repair of injured lung tissue. Reductions in neutrophil and macrophage activity (immune cell biomarkers upregulated in IPF and associated with disease progression) and downregulation of genes associated with fibrosis, disease progression and mortality were also observed in patients treated with GRI-0621 and standard of care.

Placebo-adjusted changes from baseline in FVC were observed to increase by 99 ml in the GRI-0621-treated arm and by 139 ml in the subset taking both GRI-0621 and standard of care compared to placebo plus standard of care. Breathing tests used to measure FVC are subject to large visit-to-visit variability and are dependent on the patient's effort, often resulting in data outliers. To minimize the impact of outliers in this FVC dataset, a *post hoc* data analysis was performed excluding the data points with the largest gain or loss in FVC over 12 weeks from both arms. The results of this analysis demonstrated an increase in placebo-adjusted change from baseline in FVC of 54 ml in the GRI-0621-treated arm and an increase of 81 ml in the subset taking both GRI-0621 and standard of care. Overall, 39% of GRI-0621 treated subjects experienced an increase in FVC at 12 weeks compared to 80% of subjects who experienced a decline in FVC at 12 weeks in the placebo-treated arm. GRI-0621-treated subjects also demonstrated increased TCR expression after 12 weeks of treatment compared with baseline or placebo-treated subjects receiving standard of care, suggestive of iNKT inactivation following GRI-0621 treatment. T cell subsets demonstrated increased type 1-associated cytokines (IFN-γ) and reduced type 2 (IL-4 and IL-13) and type 3-associated cytokines (IL-17A and IL-22) in both BAL and PBMC samples. Similarly, TGF-β was observed to be reduced after 12 weeks of GRI-0621 treatment in T cell subsets (e.g. Treg and Treg-like), B cells, monocytes, macrophages and neutrophils in BAL and PBMC samples compared to baseline or placebo-treated subjects receiving standard of care. GRI-0621 treatment also improved expression of genes associated with lung injury, fibroblast differentiation, extracellular matrix deposition, basement membrane repair, and type II alveolar epithelial cell-to-type I alveolar epithelial cell transition. The RNAseq data is supportive of and consistent with earlier reported serum biomarker and flow cytometry data.

Final results from this trial will be used to determine dose, safety sample size, clinically relevant endpoints and clinical trial duration in communication with the FDA in designing future trials. Based on these results and subject to FDA clearance and obtaining the requisite additional funding or resources, we plan to initiate (either ourselves or with a strategic partner) a Phase 2b trial that could support an application for conditional approval of GRI-0621 in the European Union and could have the potential to be regarded as a registrational trial in the United States.

GRI-0803 for the Treatment of Lupus Nephritis Related to Systemic Lupus Erythematosus

Systemic Lupus Erythematosus Disease Background

SLE is the most common type of lupus, affecting between 160,000-200,000 patients in the United States, and as many as 24,000 people in the United States are diagnosed with the disease each year. SLE predominantly affects women and often starts between the ages of 15 and 44. SLE is an autoimmune disease in which the immune system attacks its own tissues, causing widespread inflammation and tissue damage in the affected organs. It can affect the joints, skin, brain, lungs, kidneys and blood vessels. There is no cure for lupus, but medical interventions and lifestyle changes can help control it. While people of all races can have the disease, African American women have a three-times higher number of new cases than white, non-Hispanic women. African American women tend to develop the disease at a younger age than white, non-Hispanic women and develop more serious and life-threatening complications. It is also more common in women of Hispanic, Asian and Native American descent. Adherence to treatment regimens is often a problem, especially among young women of childbearing age. Because SLE treatment may require the use of strong immunosuppressive medications that can have serious side effects, female patients must stop taking the medication before and during pregnancy to protect unborn children from harm.

Current Treatments for SLE, their Limitations and Lupus Nephritis

The treatment and management of SLE depends on disease severity and disease manifestations. Hydroxychloroquine plays a central role in the long-term treatment of SLE and is the cornerstone of SLE therapy. Corticosteroids, nonsteroidal anti-inflammatory drugs and immunosuppressive agents (e.g., azathioprine, cyclophosphamide, cyclosporine, methotrexate and mycophenolate mofetil) have also been used in the treatment and management of SLE. These treatments are only modestly effective and present safety and/or immune suppression concerns with prolonged use. The B cell-depleting antibody rituximab, while not approved for treatment of SLE, appears to be beneficial in certain subsets of patients.

Two targeted therapies for SLE have been approved by the FDA in the past 50 years, belimumab and anifrolumab. In 2011, the FDA approved belimumab (Benlysta®), an antibody that targets B lymphocyte stimulator, for the treatment of mild to moderate SLE in combination with standard therapy, providing additional clinical validation of the therapeutic benefit of B cell-targeted therapy for autoimmune diseases. However, the modest therapeutic benefit of Benlysta® and delayed onset of disease intervention indicate the need for additional therapeutic strategies to inhibit overactive B cells. In 2021, the first-in-class type 1 interferon receptor antibody, anifrolumab, the first new drug for the disease in a decade, was approved for adults with moderate to severe disease who are receiving standard therapy.

Lupus nephritis is a common manifestation of SLE and can lead to irreversible renal impairment. This disease is complex, heterogeneous and involves multiple cell types as well as immune and non-immune mechanisms. Disease progression is characterized by glomerular injury, inflammation, cellular infiltration and fibrosis. The deposition of immune complexes leads to inflammasome and type I interferon mediated pathways contributing to endothelial dysfunction in conjunction with complement-mediated injury owing to pathogenic antibodies.

Our Solution - GRI-0803

Scientific studies have suggested that iNKT plays an important pathogenic role in kidney diseases, including acute kidney injury, ischemic reperfusion injury and lupus nephritis. Accordingly, iNKT cells were activated in peripheral blood of lupus patients (see Figure 4, above) and in spontaneous models of lupus. Notably, activation of dNKT leads to a dendritic cell-mediated inhibition of iNKT cells. In our preclinical studies, a dNKT activating molecule, GRI-0803, was observed to inhibit both murine and human iNKT cells. Oral administration of GRI-0803, was observed to inhibit lupus nephritis and to significantly improve overall survival in mice.

Following a weekly oral administration of GRI-0803 in preclinical studies using a mouse model of spontaneous lupus nephritis significant inhibition of pro-inflammatory cytokines, including IL-17 and IL-6 (see Figure 13) was observed. Other fibrogenic molecules, including TGF-beta, were also observed to be inhibited leading to blocking of collagen deposition and renal fibrosis (see Figure 14). This was observed to be accompanied by inhibition of cellular infiltration (including B cells and T cells) into the kidney and glomerular pathology. Furthermore, following GRI-0803 administration, significant inhibition of pathogenic anti-dsDNA antibodies and proteinuria as measured in urine (see Figures 15 and 16) was observed. Additionally, GRI-0803 was observed in such preclinical studies to block activation of plasmacytoid dendritic cells and type I interferon signaling pathway genes involved in renal injury. Inhibition of renal disease was reflected in the improvement of overall survival of proteinuria-free animals.

Lipocalin 2 (LCN2) is a glycoprotein secreted by several immune cells and promotes pro-inflammatory immune responses in autoimmune diseases and suggested to be an indicator of the severity of lupus nephritis. Interestingly, among other

inflammatory genes, significant inhibition of LCN2 expression in the kidney was observed in animals orally treated with GRI-0803 in comparison to that in the control group (see Figure 13).

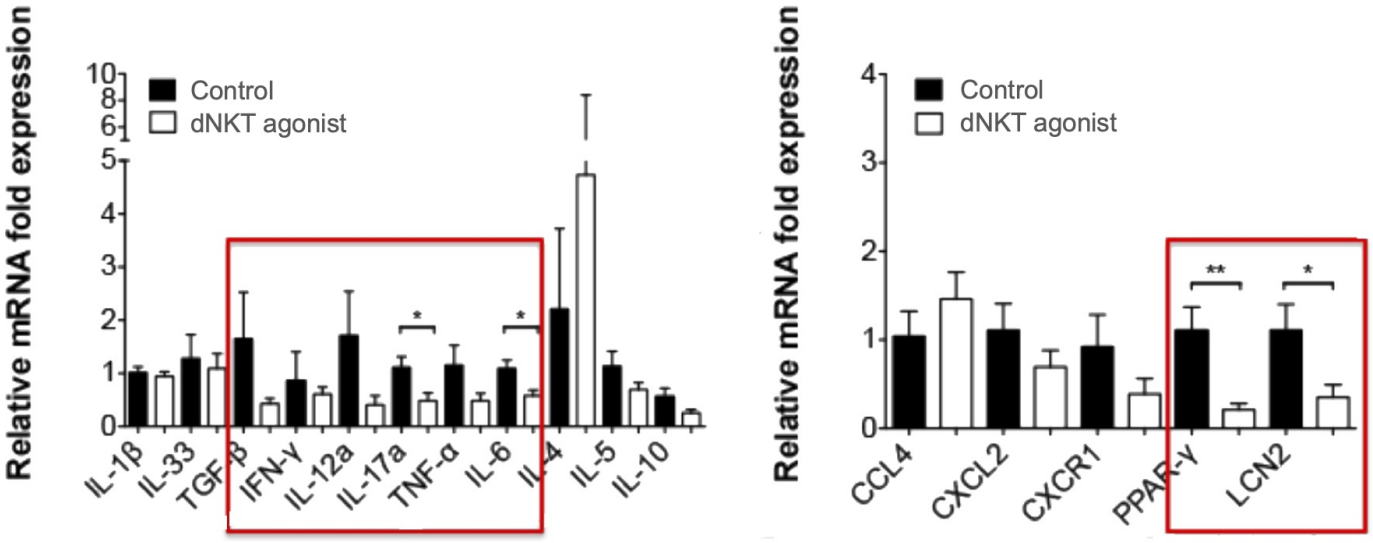


Figure 13. Inhibition of several key pro-inflammatory, fibrotic and kidney disease promoting genes in a spontaneous lupus model observed following oral administration of GRI-0803.

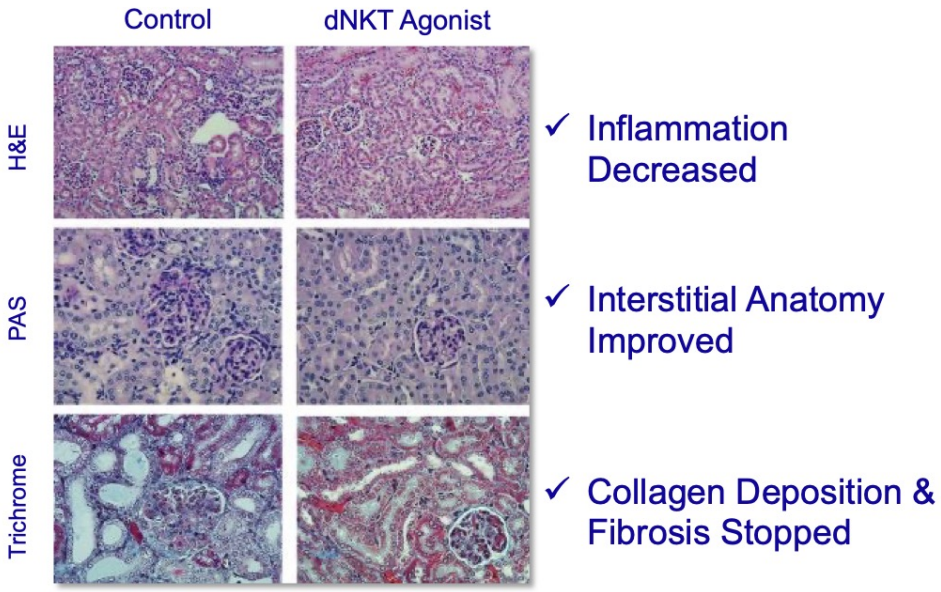


Figure 14. GRI-0803 administration observed to inhibit inflammatory cellular infiltration (H&E), glomerular pathology (PAS), and kidney fibrosis (Trichrome) in a spontaneous lupus model.

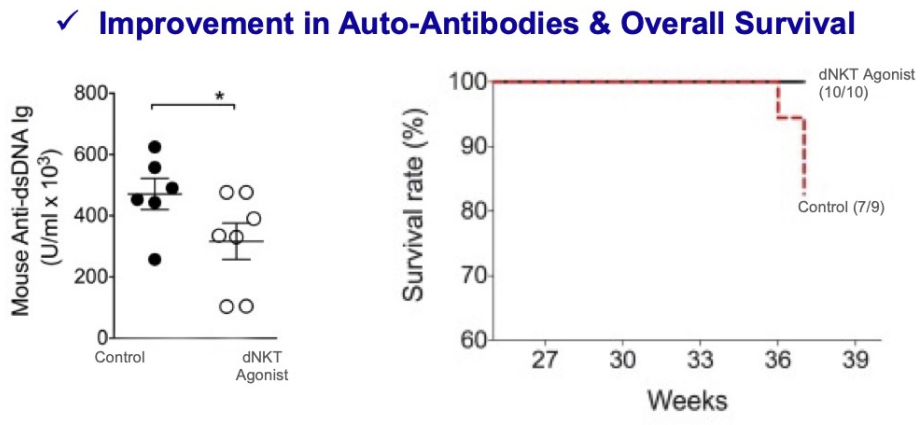


Figure 15. Observed inhibition anti-dsDNA antibodies in serum and increased overall survival in a lupus model following treatment with GRI-0803.

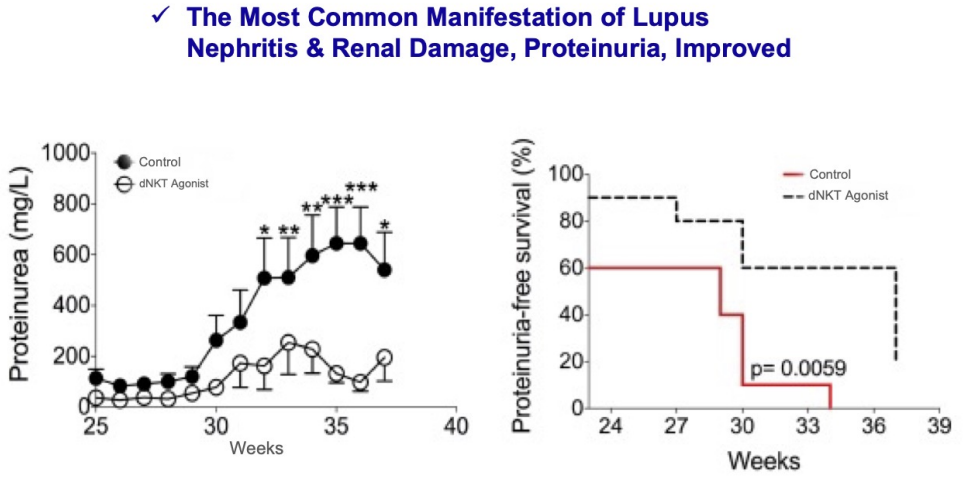


Figure 16. Significant inhibition of proteinuria in urine and spontaneously occurring lupus nephritis observed in animals orally treated with GRI-0803.

GRI-0803 Manufacturing

We rely on third-party contract manufacturers to manufacture GRI-0803 for preclinical studies and do not own manufacturing facilities for producing any preclinical study product supplies. We rely on a single or limited number of suppliers for drug product and engage a single manufacturer to produce our formulated GRI-0803 drug product for clinical studies, as is standard industry practice in early to mid-stage clinical development. If these suppliers are unable to supply to us in the quantities we require, or at all, or otherwise default on their supply obligations to us, we may not be able to obtain alternative supplies from other suppliers on acceptable terms, in a timely manner, or at all. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturer or manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

GRI-0803 Phase 1 Trial

We plan to complete IND-enabling studies and file an IND for a Phase 1 trial for GRI-0803 in 2026. This planned Single Ascending Dose (SAD) trial will be run in healthy volunteers. According to the current trial design, up to six doses will be evaluated in cohorts of 12 subjects with ten receiving a dose of GRI-0803 and two receiving placebo. The safety in each cohort will be evaluated with an Independent Safety Review Board (ISRB) along with the GRI clinical management. After completion of the first cohort, subsequent cohorts will begin within two weeks of dosing the previous cohort. Pharmacokinetics and safety

will be the primary endpoint of the SAD trial. We expect this planned trial will be completed approximately three months after the first cohort is dosed.

A planned Multiple Ascending Dose (MAD) trial will begin upon the completion of Dose 3 in the SAD trial based on the recommendation of the ISRB. The MAD trial will examine four doses of GRI-0803 with doses dependent on the results of the SAD. Under the current trial design, a total of ten subjects will be assigned among the cohorts: eight on GRI-0803 and two on placebo. Cohorts will be dosed for four weeks with two weeks of safety follow up post dosing with the first two cohorts being in healthy subjects and the two highest doses may be completed in patients with SLE. Safety and multi-dose pharmacokinetics will be the primary endpoint of the MAD trial. Exploratory outcomes will be examined in the third and fourth cohorts and will include several biomarkers (e.g., cytokines) as well as NKT cell activation markers.

Competitive Landscape

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, the expertise of our management team, clinical capabilities, research and development experience and scientific knowledge provide us with competitive advantages, we face increasing competition from many different sources, including biotechnology and biopharmaceutical companies, academic institutions, governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

There are several large biotechnology and biopharmaceutical companies that are currently pursuing the development of products for the treatment of conditions we are also targeting, or may target in the future, including IPF, SLE, MS, UC, PSC and MASH. While we know of no other companies currently in clinical development targeting NKT cells as a method of treating any of the above conditions, companies that we are aware of that are targeting the treatment of these diseases include large companies with significant financial resources such as:

IPF - AbbVie Inc., AstraZeneca PLC, Avalyn Pharma Inc., Boehringer Ingelheim International GmbH, Bristol-Myers Squibb Co., Contineum Therapeutics, Inc. , Daewoong Pharmaceutical Co. LTD., Eli Lilly and Company, Endeavor Biomedicines, Inc., Genentech, Inc., GlaxoSmithKline plc, Guangzhou JOYO Pharma Co., Ltd., InSilico Medicine Hong Kong Ltd., Mediar Therapeutics, Inc., PureTech Health plc, Redx Pharma Ltd., Rein Therapeutics, Inc., Sunshine Lake Pharma Co., Ltd., Suzhou Zelgen Biopharmaceuticals Co. Ltd., United Therapeutics Corp. and Vicore Pharma Holding AB.

SLE - Amgen Inc. Astellas Pharma Inc., AstraZeneca PLC, Aurinia Pharmaceuticals Inc., Biogen Inc., Bristol-Myers Squibb Co., Gilead Sciences, Inc., GlaxoSmithKline plc, Guangdong Hengrui Pharmaceutical Co., Ltd, Johnson & Johnson, Nektar Therapeutics, Novartis AG, Pfizer Inc., Roche Holding AG, Sanofi S.A., and UCB S.A.

The key competitive factors affecting the success of our product candidates are likely to be efficacy, safety, cost and convenience. Many of our competitors, either alone or with their collaborators, have significantly greater resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific, sales, marketing and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Additional mergers and acquisitions may result in even more resources being concentrated in our competitors.

Intellectual Property

We strive to protect the proprietary technology and information commercially or strategically important to our business. We seek to obtain and maintain, patent rights intended to cover the technologies incorporated into, or used to produce, our product candidates, the compositions of matter of our product candidates and their methods of use and manufacture, as well as other inventions that are important to our business. We also seek to obtain strategic or commercially valuable patent rights in the United States and other jurisdictions.

To cover our proprietary technologies and our current pipeline of proprietary products and related methods, such as methods of use, we have filed patent applications and obtained several issued patents in the United States and foreign jurisdictions.

Specifically, we own one patent family with claims directed to GRI-0621, and related methods of using the same to treat diseases, e.g., inflammatory conditions. As of January 26, 2026, three United States patents were granted and 20 foreign patents were granted in this family in Australia, Brazil, Canada, China, Europe (validated in nine countries), Hong Kong, Japan, South Korea, Mexico and Russia. Patent applications in this family are pending in multiple jurisdictions, including, for example, the

European Patent Organization, China and Japan. Patents in this patent family are expected to expire in 2032, absent any patent term adjustment, extension or disclaimer.

We also own one patent family with claims directed to GRI-0803 and related methods of using the same to treat diseases. Three United States patents were granted and 17 foreign patents were granted in Canada, Europe (validated in nine countries) and Hong Kong. As of January 26, 2026, a patent application in this family is pending in the United States. Patents in this patent family are expected to expire in 2032, absent any patent term adjustment, extension or disclaimer.

We own one patent family directed to GRI-0729 and related methods of using the same to treat diseases. As of January 26, 2026, four U.S. patents were granted and 13 total foreign patents were granted in this family in Canada, Europe (validated in 11 countries) and Hong Kong. Patents in this patent family are expected to expire in 2032, absent any patent term adjustment, extension or disclaimer.

Additionally, we also own one patent family with claims directed to GRI-0124 and related methods of using the same to treat diseases. As of January 26, 2026, 16 total foreign patents have been granted in this family in Taiwan, Australia, China, Europe (validated in seven countries), Hong Kong, Mexico and Russia. Patent applications in this family are pending, for example, in the United States, United Arab Emirates, China and Hong Kong. Patents in this patent family are expected to expire in 2035, absent any patent term adjustment, extension or disclaimer.

We continually assess and refine our intellectual property strategy as we develop new technologies and product candidates. As our business evolves, we may, among other activities, file additional patent applications in pursuit of our intellectual property strategy, to adapt to competition or to seize potential opportunities.

The term of individual patents depends upon the laws of the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing of a non-provisional patent application. However, the term of U.S. patents may be extended for delays incurred due to compliance with FDA requirements or by delays encountered during prosecution that are caused by the USPTO. For example, the Hatch-Waxman Act permits a patent term extension for FDA-approved drugs of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those product candidates. We intend to seek patent term extensions in any jurisdiction where these are available and where we also have a patent that may be eligible; however there is no guarantee that the applicable authorities, including the USPTO and FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

Further, we expect to rely on data exclusivity, market exclusivity, patent term adjustment and patent term extensions when available.

Government Regulation and Product Approval

Government authorities in the United States at the federal, state and local level, and in other countries, extensively regulate, among other things, the research, development, clinical trials, testing, manufacture (including any manufacturing changes), authorization, pharmacovigilance, adverse event reporting, recalls, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products and product candidates such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

United States Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions brought by the FDA and the Department of Justice (DOJ), or other governmental entities, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil and/or criminal penalties.

The process required by the FDA before a new drug may be marketed in the United States generally involves the following:

- completion of nonclinical and preclinical studies, such as laboratory tests, potentially animal studies and formulation studies, in compliance with FDA regulations for Good Laboratory Practices (GLPs) and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an IRB covering each clinical site before a trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices (GCPs) to establish the safety and efficacy of the proposed drug product for each indication;
- submission to the FDA of an NDA with payment of application user fees, if applicable, and FDA acceptance of that NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practices (cGMPs) and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of audits of clinical trial sites conducted by FDA to assure compliance with GCPs and the integrity of clinical data; and
- FDA review and approval of the NDA.

Preclinical Studies

Preclinical or nonclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as potential animal studies to assess potential safety and efficacy. The Consolidated Appropriations Act for 2023, signed into law on December 29, 2022, (P.L. 117-328) amended the FDCA to specify that nonclinical testing for drugs may, but is not required to, include in vivo animal testing. According to the amended language, a sponsor may fulfill nonclinical testing requirements by completing various in vitro assays (e.g., cell-based assays, organ chips, or microphysiological systems), in silico studies (i.e., computer modeling), other human or non-human biology-based tests (e.g., bioprinting), or in vivo animal tests.

Preclinical tests intended for submission to the FDA to support the safety of a product candidate must be conducted in compliance with GLP regulations and the U.S. Department of Agriculture's Animal Welfare Act. A drug sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available ex-U.S. clinical data or relevant literature, among other things, to the FDA as part of an IND. Some nonclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. A clinical hold may occur at any time during the life of an IND and may affect one or more specific studies or all studies conducted under the IND.

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 subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial 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.

Clinical Trials

Clinical trials involve the administration of the IND to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial (unless the consent requirement has been waived by an IRB) along with the requirement to ensure that the data and results reported from the clinical trials are credible and accurate. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the criteria for determining subject eligibility, the dosing plan, the parameters to be used in monitoring safety, the procedure for timely reporting of adverse events, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB must review and approve the plan for any clinical trial before it commences.

Information about certain clinical trials and clinical trial results must be submitted within specific timeframes to the National Institutes of Health for public dissemination on the Clinicaltrials.gov registry. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant

party from receiving future grant funds from the federal government. The government has brought enforcement actions against clinical trial sponsors that fail to comply with such requirements.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

Phase 1: The product candidate is initially introduced into healthy human subjects or 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. During Phase 1 clinical trials, sufficient information about the investigational drug's pharmacokinetics and pharmacological effects may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials.

Phase 2: The product candidate is administered to a larger, but still limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted indications and to determine dosage tolerance and optimal dosage. Phase 2 clinical trials are typically well-controlled and closely monitored.

Phase 3: The product candidate 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. Phase 3 clinical trials usually involve a larger number of participants than a Phase 2 clinical trial. Post-approval trials, sometimes referred to as "Phase 4" clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may mandate the performance of "Phase 4" clinical trials.

Human clinical trials are inherently uncertain, and Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Moreover, a given clinical trial may combine the elements of more than one phase and a company's designation of a clinical trial as being of a particular phase is not necessarily indicative that the study will be sufficient to satisfy the FDA requirements of that phase because this determination cannot be made until the protocol and data have been submitted and reviewed.

A pivotal trial is a clinical trial that is believed to satisfy FDA requirements for the evaluation of a product candidate's safety and efficacy such that it can be used, alone or with other pivotal or non-pivotal trials, to support regulatory approval. Generally, pivotal trials are Phase 3 trials, but they may be Phase 2 trials if the design provides a well-controlled and reliable assessment of clinical benefit, particularly in an area of unmet medical need. In recent years, the FDA has been increasingly willing to exercise regulatory flexibility when determining the types, amount, and timing of data submissions to support the demonstration of a "substantial evidence of effectiveness," which is the legal standard applicable to new drug approvals and is discussed further below.

Congress also recently amended the FDCA in order to require sponsors of a Phase 3 clinical trial, or other "pivotal study" of a new drug to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must include the sponsor's diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Sponsors must submit a diversity action plan to the FDA by the time the sponsor submits the relevant clinical trial protocol to the agency for review. The FDA may grant a waiver for some or all of the requirements for a diversity action plan. If the FDA objects to a sponsor's diversity action plan or otherwise requires significant changes to be made, it could potentially delay initiation of the relevant clinical trial.

Interactions with FDA During the Clinical Development Program

Following the clearance of an IND and the commencement of clinical trials, the sponsor will continue to have interactions with the FDA. Progress reports detailing the results of clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. 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 product; and any clinically important increase in the occurrence of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

In addition, sponsors are given opportunities to meet with the FDA at certain points in the clinical development program. Specifically, sponsors may meet with the FDA prior to the submission of an IND (pre-IND meeting), at the end of Phase 2 clinical trial (EOP2 meeting) and before an NDA is submitted (pre-NDA meeting). Meetings at other times may also be requested. These meetings provide an opportunity for the sponsor to share information about the data gathered to date with the FDA and for the FDA to provide advice on the next phase of development. For example, at an EOP2, a sponsor may discuss its Phase 2 clinical results and present its plans for the pivotal Phase 3 clinical trial(s) that it believes will support the approval of the new product. Such meetings may be conducted in person, via teleconference/videoconference or written response only with minutes reflecting the questions that the sponsor posed to the FDA and the agency's responses. The FDA has indicated that its

responses, as conveyed in meeting minutes and advice letters, only constitute recommendations and/or advice made to a sponsor and, as such, sponsors are not bound by such recommendations and/or advice. Nonetheless, from a practical perspective, a sponsor's failure to follow the FDA's recommendations for design of a clinical program may put the program at significant risk of failure.

Acceptance of NDAs

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, along with information relating to the product's chemistry, manufacturing, controls, safety updates, patent information, abuse information and proposed labeling, are submitted to the FDA as part of an application requesting approval to market the product candidate for one or more indications. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of a drug product. The fee required for the submission and review of an application under the Prescription Drug User Fee Act (PDUFA) is substantial, and the sponsor of an approved application is also subject to an annual program fee assessed based on eligible prescription drug products. These fees are typically adjusted annually, and exemptions and waivers may be available under certain circumstances, such as where a waiver is necessary to protect the public health, where the fee would present a significant barrier to innovation, or where the applicant is a small business submitting its first human therapeutic application for review. Congress is required to re-authorize the agency's user fee programs every five years, and current legislative provisions supporting the PDUFA program are set to expire on September 30, 2027.

The FDA conducts a preliminary review of all applications within 60 days of receipt and must inform the sponsor at that time or before whether an application is sufficiently complete to permit substantive review. In pertinent part, the FDA's regulations state that an application "shall not be considered as filed until all pertinent information and data have been received" by the FDA. In the event that the FDA determines that an application does not satisfy this standard, it will issue a Refuse to File (RTF) determination to the applicant. Typically, an RTF will be based on administrative incompleteness, such as clear omission of information or sections of required information; scientific incompleteness, such as omission of critical data, information or analyses needed to evaluate safety and efficacy or provide adequate directions for use; or inadequate content, presentation, or organization of information such that substantive and meaningful review is precluded. The FDA may request additional information rather than accept an application for filing. 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.

Review of NDAs

After the submission is accepted for filing, the FDA begins an in-depth substantive review of the application.

Under the current PDUFA goals and policies agreed to by the FDA, the agency has ten months from the filing date in which to complete its initial review of a standard application that is a new molecular entity, and six months from the filing date for an application with "priority review." The review process may be extended by the FDA for three additional months to consider new information or in the case of a clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission. Despite these review goals, the NDA review process can be very lengthy and it is not uncommon for FDA review of an application to extend beyond the PDUFA target action date. Most innovative drug products (other than biological products) obtain FDA marketing approval pursuant to an NDA submitted under Section 505(b)(1) of the FDCA, commonly referred to as a traditional or "full NDA." In 1984, with passage of the Hatch-Waxman Act that established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs based on an innovator or "reference" product, Congress also enacted Section 505(b)(2) of the FDCA, which provides a hybrid pathway combining features of a traditional NDA and a generic drug application. Section 505(b)(2) enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy data for an existing product, or published literature, in support of its application. Section 505(b)(2) NDAs may provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products that would require new clinical data to demonstrate safety or effectiveness. Section 505(b)(2) permits the filing of an NDA in which the applicant relies, at least in part, on information from studies made to show whether a drug is safe or effective that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use. A Section 505(b)(2) applicant may eliminate or reduce the need to conduct certain preclinical or clinical studies, if it can establish that reliance on studies conducted for a previously-approved product is scientifically appropriate. The FDA may also require companies to perform additional studies or measurements, including nonclinical and clinical studies, to support the change from the approved product. The types of studies and extent of data necessary to establish the safety and/or effectiveness of the new product, such as the effects of changing the drug's route of administration from topical to oral, are scientifically driven and determined on a case-by-case basis. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication for which the Section 505(b)(2) NDA applicant has submitted data.

In connection with its review of an application, the FDA will typically submit information requests to the applicant and set deadlines for responses thereto. The FDA will also conduct a pre-approval inspection of the manufacturing facilities for the new

product to determine whether the manufacturing processes and facilities comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMPs and are adequate to assure consistent production of the product within required specifications.

The FDA also may inspect the sponsor and one or more clinical trial sites to assure compliance with IND and GCP requirements and the integrity of the clinical data submitted to the FDA. To ensure compliance with cGMPs and GCPs by its employees and third-party contractors, an applicant may incur significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control. The FDA generally accepts data from foreign clinical trials in support of an NDA if the trials were conducted under an IND. If a foreign clinical trial is not conducted under an IND, the FDA nevertheless may accept the data in support of an NDA if the study was conducted in accordance with GCPs and the FDA is able to validate the data through an on-site inspection, if deemed necessary. Although the FDA generally requests that marketing applications be supported by some data from domestic clinical trials, the FDA may accept foreign data as the sole basis for marketing approval if (1) the foreign data are applicable to the United States population and United States medical practice, (2) the studies were performed by clinical investigators with recognized competence, and (3) the data may be considered valid without the need for an on-site inspection or, if the FDA considers the inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

Additionally, the FDA may refer an application, including applications for novel product candidates which present difficult questions of safety or efficacy, to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. 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 recommendation of an advisory committee, but it considers such recommendations when making final decisions on approval.

Data from clinical trials are not always conclusive, and the FDA or its advisory committee may interpret data differently than the sponsor interprets the same data. The FDA may also re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process or delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all.

The FDA also may require submission of a risk evaluation and mitigation strategy (REMS) if it determines that a REMS is necessary to ensure that the benefits of the drug product outweigh its risks and to assure the safe use of the product. The REMS could include medication guides, physician communication plans, assessment plans and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS is needed, the sponsor of the application must submit a proposed REMS and the FDA will not approve the application without a REMS.

In addition, under the Pediatric Research Equity Act of 2003, as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug 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. 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. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Decisions on NDAs

The FDA reviews an application to determine, among other things, whether the product is safe and whether it is effective for its intended use(s), with the latter determination being made on the basis of substantial evidence. The term “substantial evidence” is defined under the FDCA as “evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the product involved, on the basis of which it could fairly and responsibly be concluded by such experts that the product will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.”

The FDA has interpreted this evidentiary standard to require at least two adequate and well-controlled clinical investigations to establish effectiveness of a new product. Under certain circumstances, however, the FDA has indicated that a single trial with certain characteristics and additional information may satisfy this standard. This approach was subsequently endorsed by Congress in 1998 with legislation providing, in pertinent part, that “If [the FDA] determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the FDA may consider such data and evidence to constitute substantial evidence.” This modification to the law recognized the potential for the FDA to find that one adequate and well controlled

clinical investigation with confirmatory evidence, including supportive data outside of a controlled trial, is sufficient to establish effectiveness. In December 2019, the FDA issued draft guidance further explaining the studies that are needed to establish substantial evidence of effectiveness. In September 2023, the agency supplemented and expanded the recommendations in the 2019 "substantial evidence of effectiveness" draft guidance with a second draft guidance entitled "Demonstrating Substantial Evidence of Effectiveness Based on One Adequate and Well-Controlled Clinical Investigation and Confirmatory Evidence." The second document complements the first by providing further detail on the use of data drawn from one or more sources (e.g., clinical data, mechanistic data, animal data) in order to support the results of one adequate and well-controlled clinical investigation and provides examples of types of data that could be considered confirmatory evidence. Due to the case-by-case nature of such determinations, the FDA continues to emphasize the need for sponsors to engage early with the agency if they intend to establish substantial evidence of effectiveness with one adequate and well-controlled clinical investigation plus confirmatory evidence.

After evaluating the application and all related information, including the advisory committee recommendations, if any, and inspection reports of manufacturing facilities and clinical trial sites, the FDA will issue either a Complete Response Letter (CRL) or an approval letter. To reach this determination, the FDA must determine that the drug is effective and that its expected benefits outweigh its potential risks to patients. This "benefit-risk" assessment is informed by the extensive body of evidence about the product's safety and efficacy in the NDA. This assessment is also informed by other factors, including: the severity of the underlying condition and how well patients' medical needs are addressed by currently available therapies; uncertainty about how the premarket clinical trial evidence will extrapolate to real-world use of the product in the post-market setting; and whether risk management tools are necessary to manage specific risks. In connection with this assessment, the FDA review team will assemble all individual reviews and other documents into an "action package," which becomes the record for FDA review. The review team then issues a recommendation, and a senior FDA official makes a decision.

A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. The CRL may require additional clinical or other data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time- consuming requirements related to clinical trials, preclinical studies or manufacturing. If a CRL is issued, the applicant will have one year to respond to the deficiencies identified by the FDA, at which time the FDA can deem the application withdrawn or, in its discretion, grant the applicant an additional six-month extension to respond. The FDA has committed to reviewing resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even with the submission of this additional information, however, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

An approval letter, on the other hand, authorizes commercial marketing of the product with specific prescribing information for specific indications. That is, the approval will be limited to the conditions of use (e.g., patient population, indication) described in the FDA-approved labeling. Further, depending on the specific risk(s) to be addressed, the FDA may require that contraindications, warnings or precautions be included in the product labeling, require that post-approval trials, including Phase 4 clinical trials, be conducted to further assess a product's safety after approval, require testing and surveillance programs to monitor the product after commercialization or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a 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-marketing trials or surveillance programs. After approval, some 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.

Special FDA Expedited Review Programs

The FDA is authorized to designate certain products for expedited development or 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 include fast track designation, breakthrough therapy designation, and priority review designation. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides additional opportunities for interaction with the FDA's review team and may allow for a rolling review of NDA components before the completed application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. In addition, fast track designation may be withdrawn by the sponsor or rescinded by the FDA if the designation is no longer supported by data emerging in the clinical trial process.

In addition, with the enactment of the FDA Safety and Innovation Act (FDASIA) in 2012, Congress created a new regulatory program for product candidates designated by the FDA as "breakthrough therapies" upon a request made by the IND sponsors. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug 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 must take certain actions with respect to breakthrough therapies, such as holding timely meetings with and providing advice to the product sponsor, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Finally, the FDA may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines at the time that the marketing application is submitted, on a case-by-case basis, whether the proposed drug represents a significant improvement in treatment, prevention or diagnosis of disease 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 drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review 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 ten months to six months for an NDA for a new molecular entity from the date of filing.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, breakthrough therapy designation and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

Accelerated Approval Pathway

In addition, a product studied for its safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, meaning that it may be approved on (i) the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or (ii) on an intermediate clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM) and that is reasonably likely to predict an effect on IMM or other clinical benefits, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on IMM or other clinical endpoints, and the drug may be subject to expedited withdrawal procedures. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval. All promotional materials for drug products being considered and approved under the accelerated approval program are subject to prior review by the FDA.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints but has indicated that such endpoints generally may support accelerated approval when the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate long-term clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. For example, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large clinical trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. In addition, as part of the Consolidated Appropriations Act for 2023, Congress provided FDA additional statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these amendments to the FDCA, the agency may require a sponsor of a product granted accelerated approval to have a confirmatory trial underway prior to approval. The sponsor must

also submit progress reports on a confirmatory trial every six months until the trial is complete, and such reports will be published on FDA's website. Failure to conduct required post-approval studies, or to confirm the predicted clinical benefit of the product during post-marketing studies, would allow the FDA to withdraw approval of the drug. Congress also recently amended the law to give FDA the option of using expedited procedures to withdraw product approval if the sponsor's confirmatory trial fails to verify the claimed clinical benefits of the product. Prior to the recent statutory amendments enacted by Congress, several oncology sponsors voluntarily withdrew specific indications for their drug products that were being marketed pursuant to accelerated approval. More recently, in February 2024 the FDA announced its first use of the law's amended procedures to withdraw an accelerated approval following the drug's confirmatory study failing to verify clinical benefit. Scrutiny of the accelerated approval pathway is likely to continue in the coming years and may lead to further legislative and/or administrative changes in the future.

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, 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. Certain modifications to the product, including changes in indications or manufacturing processes or facilities, may require the applicant to develop additional data or conduct additional preclinical studies and clinical trials to support the submission to FDA. As previously noted, there also are continuing, annual user fee requirements for any marketed products, as well as new application fees for supplemental applications with clinical data.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMPs include requirements relating to the organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and some state agencies and are subject to periodic unannounced inspections by the FDA for compliance with cGMPs and other laws. Changes to the manufacturing process are strictly regulated and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers. Accordingly, manufacturers must continue to expend time, money, and effort in production and quality control to maintain compliance with cGMPs and other aspects of quality control and quality assurance.

The FDA strictly regulates the marketing, labeling, advertising and promotion of drug products that are placed on the market. A product cannot be commercially promoted before it is approved, and approved drugs may generally be promoted only for their approved indications and for use in patient populations described in the product's approved labeling. Promotional claims must also be consistent with the product's FDA-approved label, including claims related to safety and effectiveness. The government closely scrutinizes the promotion of prescription drugs in specific contexts such as direct-to-consumer advertising, industry-sponsored scientific and educational activities, and promotional activities involving the Internet and social media. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA has recently published a draft guidance outlining modernized recommendations for how drug manufacturers can share truthful, scientifically sound, and clinically relevant information on unapproved uses with health care providers.

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 mandatory 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 of regulatory non-compliance include, among other things:

- restrictions on, or suspensions of, the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- interruption of production processes, including the shutdown of manufacturing facilities or production lines or the imposition of new manufacturing requirements;
- fines, warning letters or other enforcement letters or clinical holds on post-approval clinical trials;

- mandated modification of promotional materials and labeling and the issuance of corrective information;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; or
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act (PDMA) which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug 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. The Drug Supply Chain Security Act (the DSCSA) was enacted in 2013 with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States. The DSCSA mandated and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period that was designed to culminate in November 2023. However, the FDA announced a one-year "stabilization period" until November 2024, followed by trading partner-specific exemptions through specified dates in 2025, to accommodate additional time that trading partners in the pharmaceutical supply chain needed in order to fully implement DSCSA requirements for electronic drug tracing at the package level.

From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. For example, FDA released proposed regulations in February 2022 to amend the national standards for licensing of wholesale drug distributors by the states; establish new minimum standards for state licensing third-party logistics providers; and create a federal system for licensure for use in the absence of a State program, each of which is mandated by the DSCSA. It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Regulatory Exclusivity and Approval of Follow-on Products

Hatch-Waxman Exclusivity

In addition to enacting Section 505(b)(2) of the FDCA as part of the Hatch-Waxman Amendments to the FDCA, Congress also established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, drugs previously approved by the FDA pursuant to NDAs. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application (ANDA) to the agency. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, bioequivalence, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are "abbreviated" because they cannot include preclinical and clinical data to demonstrate safety and effectiveness. Instead, in support of such applications, a generic manufacturer must rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug (RLD).

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, the strength of the drug and the conditions of use of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to an RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug." Unlike the 505(b)(2) NDA pathway that permits a follow-on applicant to conduct and submit data from additional clinical trials or nonclinical studies in order to support the proposed change(s) to the reference product, the ANDA regulatory pathway does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data.

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." Physicians and pharmacists consider a therapeutically 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 physician or patient. Given the importance of such Orange Book designations to the practice of pharmacy, Congress recently directed FDA to perform therapeutic equivalence evaluations for certain 505(b)(2) drugs no later than six months after approval when the applicant requests such an evaluation.

As part of the NDA review and approval process, applicants are required to list with the FDA each patent that has claims that cover the applicant's product or method of therapeutic use. Upon approval of a new drug, each of the patents listed in the application for the drug is then published in the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential follow-on competitors in support of approval of an ANDA or 505(b)(2) NDA. FDA's role in this process is purely "ministerial" and it does not review or assess the claims within each patent to determine whether they cover the drug product or its approved method of use. Patents that may fall outside the scope of what the FDCA and FDA's implementing regulations define as needing to be listed by the NDA holder are periodically challenged by competitors and other stakeholders, either through FDA's administrative challenge process or in the court system as anticompetitive or unfair behavior. In particular, the Federal Trade Commission (FTC) issued a policy statement in September 2023 indicating that it would be scrutinizing the "improper" submission of patents for listing in the Orange Book on the basis that such listings may harm competition from cheaper generic alternatives and keep brand prices artificially high. The FTC followed that action in November 2023 by publicly calling out over 100 "improper" patent listings made by ten large pharmaceutical companies and initiating an FDA administrative process with respect to those patents. The controversy regarding the appropriateness of listing such patents has led to numerous lawsuits alleging anticompetitive conduct by biopharmaceutical companies. It is unclear whether the FTC, under the Trump Administration, will continue to prioritize the policy issue of "improper" patent listings or whether Congress may take any legislative actions related to this issue.

When an ANDA applicant submits its application to the FDA, it is required to certify to the FDA concerning any patents listed for the reference product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. Moreover, to the extent that the Section 505(b)(2) NDA applicant is relying on studies conducted for an already approved product, the applicant also is required to certify to the FDA concerning any patents listed for the NDA-approved product in the Orange Book to the same extent that an ANDA applicant would.

If the follow-on applicant does not challenge the innovator's listed patents, the FDA will not approve the ANDA or 505(b)(2) application until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the follow-on 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 of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) applicant.

An ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivities listed in the Orange Book for the referenced product have expired. The Hatch-Waxman Amendments to the FDCA provided a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity (NCE). For the purposes of this provision, an 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 or 505(b)(2) NDA 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 data exclusivity if an NDA or NDA supplement includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as new indications, dosage forms, route of administration or combination of ingredients. 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 or 505(b)(2) NDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product; rather, this three-year exclusivity covers only the conditions of use associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving follow-on applications for drugs containing the original active ingredient.

Five-year and three-year exclusivity also will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDCA; however, an applicant submitting a traditional NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects either (i) fewer than 200,000 individuals in the United States, or (ii) more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Legislative proposals to revise or revoke the second option available for a product candidate to receive an orphan designation, the so-called "cost recovery" pathway, are periodically considered by Congress.

Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use will be disclosed publicly by the FDA; the posting will also indicate whether a drug is no longer designated as an orphan drug. Recent court cases have challenged the FDA's approach to determining the scope of orphan drug exclusivity; however, at this time the agency continues to apply its long-standing interpretation of the governing regulations and has stated that it does not plan to change any orphan drug implementing regulations. Congress may also act to amend the law in this area at some point in the future.

More than one product candidate may receive an orphan drug designation for the same indication, and the same product candidate can be designated for more than one qualified orphan indication. The benefits of orphan drug designation include research and development tax credits and exemption from FDA prescription drug user fees. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process if or when an NDA for the product candidate is filed.

If a product that has orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan product exclusivity, which means that for seven years, the FDA may not approve any other marketing applications for the same drug for the same indication, except under limited circumstances described further below. Orphan exclusivity does not block the approval of a different drug for the same rare disease or condition, nor does it block the approval of the same drug for different conditions. As a result, the FDA can still approve different drugs for use in treating the same indication or disease. Additionally, if a drug designated as an orphan product receives marketing approval for an indication broader than what was designated, it may not be entitled to orphan drug exclusivity.

Orphan exclusivity will not bar approval of another product with the same drug for the same condition under certain circumstances, including if a subsequent product with the same drug for the same condition is shown to be clinically superior to the approved product on the basis of greater efficacy or safety or a major contribution to patient care, or if the company with orphan drug exclusivity cannot assure the availability of sufficient quantities of the drug to meet the needs of persons with the disease or condition for which the drug was designated. The FDA is now required to publish a summary of the clinical superiority findings when a drug is eligible for orphan product exclusivity on the basis of a demonstration of clinical superiority.

In addition, the FDA has finalized guidance indicating that it does not expect to grant any additional orphan drug designation to products for pediatric subpopulations of common diseases. Nevertheless, FDA intends to still grant orphan drug designation to a drug that otherwise meets all other criteria for designation when it prevents, diagnoses or treats either (i) a rare disease that includes a rare pediatric subpopulation, (ii) a pediatric subpopulation that constitutes a valid orphan subset, or (iii) a rare disease that is, in fact, a different disease in the pediatric population as compared to the adult population.

Patent Term Extension

A patent claiming a prescription drug for which FDA approval is granted may be eligible for a limited patent term extension under the FDCA, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review provided that certain statutory and regulatory requirements are met. The length of the patent term extension is related to the length of time the drug is under regulatory review while the patent is in force. The restoration period granted on a patent covering a new FDA-regulated medical product is typically one-half the time between the date a clinical investigation on human beings is begun and the submission date of an application for premarket approval of the product, plus the time between the submission date of an application for approval of the product 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 products for which approval is sought can only be extended in connection with one of the marketing approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity available in the United States and, if granted, it provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity or listed patents. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Under the Best Pharmaceuticals for Children Act (BPCA), certain product candidates may obtain an additional six months of exclusivity if the sponsor submits information requested in writing by the FDA, referred to as a "Written Request," relating to the use of the active moiety of the product candidate in children. The data do not need to show the product to be effective in the pediatric population studied; rather, the additional protection is granted if the pediatric clinical trial is deemed to have fairly responded to the FDA's Written Request. Although the FDA may issue a Written Request for studies on either approved or unapproved indications, it may only do so where it determines that information relating to that use of a product candidate in a pediatric population, or part of the pediatric population, may produce health benefits in that population. The issuance of a Written Request does not require the sponsor to undertake the described trials.

Congress periodically considers enacting new incentives or mandates applicable to pediatric drug development, and the regulatory requirements applicable to pediatric drug developers may change in the future. For example, bipartisan legislation introduced in the House of Representatives during the last congressional session (2023-2024) would have increased funding for pediatric trials; mandated that drugs for rare diseases be studied in children; and granted FDA authority to assess penalties against companies that do not complete required pediatric studies.

Other U.S. Healthcare Laws and Regulations

Manufacturing, sales, promotion and other activities following product approval may also be subject to regulation by other regulatory authorities in the United States in addition to the FDA. Depending on the nature of the product, those authorities may include the Centers for Medicare & Medicaid Services (CMS), other divisions of the Department of Health and Human Services (HHS), the DOJ, the FTC, the Drug Enforcement Administration, the Occupational Safety and Health Administration, and state and local governments.

For example, in the United States, sales and marketing for prescription biopharmaceutical products must comply with state and federal fraud and abuse laws. These laws include the federal Anti-Kickback Statute (AKS), which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by imprisonment, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, the Patient Protection and Affordable Care Act (ACA), among other things, amended the intent requirement of the federal AKS and two of the five criminal healthcare fraud statutes created by Health Insurance Portability and Accountability Act (HIPAA). A person or entity no longer needs to have actual knowledge of these two provisions in the statute or specific intent to violate them; specifically with respect to the prohibition on executing or attempting to execute a scheme or artifice to defraud or to fraudulently obtain money or property of any healthcare benefit program and the prohibition on disposing of assets to enable a person to become eligible for Medicaid. Moreover, the government may now assert that a claim including items or services resulting from a violation of the federal AKS constitutes a false or fraudulent claim for purposes of the False Claims Act.

Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. There also are federal transparency requirements under the Physician Payments Sunshine Act that require manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report, on an annual basis, to CMS information related to payments and other transfers of value to physicians, teaching hospitals, and certain advanced non-physician healthcare practitioners and physician ownership and investment interests. Prescription drug products also must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act.

Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, or the relevant compliance guidance promulgated by the federal government, in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures to the extent that those laws impose requirements that are more stringent than the Physician Payments Sunshine Act. State, federal, and foreign laws, including the Federal Trade Commission Act, also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts.

Government Regulation Outside the United States

In addition to regulations in the United States, we will be subject to a variety of foreign regulations that govern, among other things, clinical trials and any commercial sales and distribution of our products, if approved, either directly or through distribution partners. Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in foreign countries or economic areas, such as the EU, Canada, and the United Kingdom, among other foreign countries, before we may commence clinical trials or market products in those countries or areas. The foreign regulatory approval process includes all of the risks associated with the FDA approval described above, and the time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Some foreign jurisdictions have a drug product approval process similar to that in the United States, which requires the submission of a clinical trial application much like the IND prior to the commencement of clinical studies. In Europe, for example, a clinical trial application (CTA) must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed. To obtain regulatory approval of a medicinal product candidate under EU regulatory systems, we would be required to submit a Marketing Authorisation Application (MAA), which is similar to the NDA, except that, among other things, there are country-specific document requirements. For countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, and recently the United Kingdom, the requirements governing the conduct of clinical trials, product approval, pricing and reimbursement vary from country to country. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others. Moreover, some nations may not accept clinical studies performed for United States approval to support approval in their countries or require that additional studies be performed on natives of their countries. In addition, in certain foreign markets, the pricing of drug products is subject to government control and reimbursement may in some cases be unavailable or insufficient. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

As of January 31, 2020, the United Kingdom is no longer a member state of the EU, and therefore a separate marketing authorization application and approval will be required to market a medicinal product in the United Kingdom. The MHRA is the United Kingdom's standalone pharmaceutical regulator.

Clinical Trials and Regulation of Medicinal Products in Europe

As in the United States, medicinal products can be marketed in the EU only if a marketing authorization from the competent regulatory agencies has been obtained. Similar to the United States, the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls.

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the EU has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of a EU member state in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial after a competent ethics committee has issued a favorable opinion. Clinical trial applications must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents. In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014 (Clinical Trials Regulation), was adopted and became effective on January 31, 2022. The Clinical Trials Regulation is directly applicable in all the EU Member States, repealing the prior Clinical Trials Directive 2001/20/EC. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation will depend on the duration of the individual clinical trial; if a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable the Clinical Trials Regulation will at that time begin to apply to the clinical trial. In addition, use of the new EU-wide application procedure being implemented via the Clinical Trial Information System (CTIS) became mandatory for new clinical trial application submissions as of February 1, 2023.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the EU. The main characteristics of the regulation include: a streamlined application procedure via a single entry point; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials.

To obtain marketing approval of a drug in the EU, an applicant must submit a MAA either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all EU member states, Iceland, Lichtenstein and Norway. The centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products (such as gene-therapy, somatic cell-therapy or tissue-engineered medicines) and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of certain diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the European Medicines Agency (EMA) is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Products for Human Use (CHMP). Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is of 150 days, excluding stop-clocks.

The decentralized procedure is available to applicants who wish to market a product in specific EU member states where such product has not received marketing approval in any EU member states before. The decentralized procedure provides for an applicant to apply to one-member state to assess the application (the reference member state) and specifically list other member states in which it wishes to obtain approval (concerned member states).

In the EU, only products for which marketing authorizations have been granted may be promoted. A marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

Moreover, even if authorized to be marketed in the EU, prescription medicines may only be promoted to healthcare professionals, not the general public. All promotion should be in accordance with the particulars listed in the summary of product characteristics. Promotional materials must also comply with various laws, and codes of conduct developed by pharmaceutical industry bodies in the EU which govern (among other things) the training of sales staff, promotional claims and their justification, comparative advertising, misleading advertising, endorsements, and (where permitted) advertising to the general public. Failure to comply with these requirements could lead to the imposition of penalties by the competent authorities of the EU member states. The penalties could include warnings, orders to discontinue the promotion of the drug product, seizure of promotional materials, fines and possible imprisonment.

In April 2023, the European Commission issued a proposal that will revise and replace the existing general pharmaceutical legislation. If adopted and implemented as currently proposed, these revisions will significantly change several aspects of drug development and approval in the EU.

Regulation of New Drugs in the United Kingdom

The United Kingdom left the EU on January 31, 2020 (commonly referred to as “Brexit”), with a transitional period that expired on December 31, 2020. The United Kingdom and the EU entered into a trade agreement known as the Trade and Cooperation Agreement, which went into effect on January 1, 2021. We are currently evaluating the potential impacts on our business of the Trade and Cooperation Agreement and guidance issued to date by the United Kingdom’s Medicines and Healthcare Products Regulatory Agency (MHRA) regarding the requirements for licensing and marketing medicinal products in the United Kingdom.

Since the regulatory framework for pharmaceutical products in the United Kingdom covering the quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of medicinal products is derived from European Union’s Directives and Regulations, Brexit could materially impact the future regulatory regime which applies to such products and the approval of product candidates in the United Kingdom. Such outcomes could make it more difficult and expensive for us to do business in Europe, complicate our clinical, manufacturing and regulatory strategies and impair our ability to obtain and maintain regulatory approval for, and, if approved, commercialize, our products and product candidates in Europe.

More recently, in March 2023, the United Kingdom government and the European Commission reached agreement on a regulatory framework to replace the Northern Ireland Protocol, referred to as the Windsor Framework. Effective as of January 1, 2025, the Windsor Framework introduced new rules for the regulation of pharmaceutical products in the United Kingdom. The MHRA is now responsible for approving all medicines intended to be marketed in the United Kingdom as a whole (i.e., Great Britain and Northern Ireland). Thus, the EMA is no longer involved in approving medicines intended for sale in Northern Ireland.

Regulation of Medicinal Products in Canada

Health Canada is the Canadian federal authority that regulates, evaluates and monitors the safety, effectiveness, and quality of drugs and other therapeutic products available to Canadians. Health Canada's regulatory process for review, approval and regulatory oversight of products is similar to the regulatory process conducted by the FDA. To initiate clinical testing of a product candidate in human subjects in Canada, a CTA must be filed with and approved by Health Canada. In addition, all federally regulated trials must be approved and monitored by research ethics boards. The review boards study and approve study-related documents and monitor trial data.

Prior to being given market authorization for a drug product, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality as required by the Food and Drugs Act (Canada) and its associated regulations, including the Food and Drug Regulations. This information is usually submitted in the form of a New Drug Submission (NDS). Health Canada reviews the submitted information, sometimes using external consultants and advisory committees, to evaluate the potential benefits and risks of a drug. If after of the review, the conclusion is that the patient benefits outweigh the risks associated with the drug, the drug is issued a Drug Identification Number (DIN), followed by a Notice of Compliance (NOC), which permits the market authorization holder (i.e., the NOC and DIN holder) to market the drug in Canada. Drugs granted an NOC may be subject to additional post-market surveillance and reporting requirements.

All establishments engaged in the fabrication, packaging/labeling, importation, distribution, and wholesale of drugs and operation of a testing laboratory relating to drugs are required to hold a Drug Establishment License to conduct one or more of the licensed activities unless expressly exempted under the Food and Drug Regulations. The basis for the issuance of a Drug Establishment License is to ensure the facility complies with cGMPs as stipulated in the Food and Drug Regulations and as determined by cGMP inspection conducted by Health Canada. An importer of pharmaceutical products manufactured at foreign sites must also be able to demonstrate that the foreign sites comply with cGMPs, and such foreign sites are included on the importer's Drug Establishment License.

Regulatory obligations and oversight continue following the initial market approval of a pharmaceutical product. For example, every market authorization holder must report any new information received concerning adverse drug reactions, including timely reporting of serious adverse drug reactions that occur in Canada and any serious unexpected adverse drug reactions that occur outside of Canada. The market authorization holder must also notify Health Canada of any new safety and efficacy issues that it becomes aware of after the launch of a product.

Pharmaceutical Coverage, Pricing and Reimbursement & Healthcare Reform

Sales of our products, if approved for marketing, will depend, in part, on the availability and extent of coverage and reimbursement by third-party payors, such as government health programs, including Medicare and Medicaid, commercial insurance and managed healthcare organizations. These third-party payors are increasingly challenging the price and limiting the coverage and reimbursement amounts for medical products and services. There may be significant delays in obtaining coverage and reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. It is time-consuming and expensive to seek reimbursement from third-party payors. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by third-party payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but they also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Accordingly, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product.

In addition, the containment of healthcare costs has become a priority for federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant

interest in implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement, and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payor to not cover our product candidates could reduce physician usage of the product candidate and have a material adverse effect on our sales, results of operations and financial condition. Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which 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 drug products. Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmacy benefits managers (PBMs) and other members of the healthcare and pharmaceutical supply chain, an important decision that has led to further and more aggressive efforts by states in this area. The FTC in mid-2022 also launched sweeping investigations into the practices of the PBM industry, and published interim reports with its findings in mid-2024 and January 2025, that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements ,including in the current 2025-2026 congressional session. Indeed both the U.S. Congress and state legislatures are increasingly scrutinizing the industry and proposing novel regulatory approaches to address various perceived public policy concerns. For example, during the previous congressional session, numerous bipartisan PBM reforms were considered in both the Senate and the House of Representatives; they include diverse legislative proposals such as eliminating rebates; divorcing service fees from the price of a drug, discount, or rebate; prohibiting spread pricing; limiting administrative fees; requiring PBMs to report formulary placement rationale; promoting transparency. Significant efforts to change the PBM industry as it currently exists in the United States may affect the entire pharmaceutical supply chain and the business of other stakeholders, including biopharmaceutical product developers like us.

Further, in August 2022, President Biden signed into the law the Inflation Reduction Act of 2022 (the IRA). Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. A manufacturer of drugs covered by Medicare Parts B or D must now pay a rebate to the federal government if their drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting for payment year 2026, CMS is negotiating drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities entering into agreements to conduct price negotiations with pharmaceutical manufacturers in October 2023 and ultimately announcing the first round of negotiated prices for the first 10 drugs in August 2024; those negotiated "maximum fair prices" will be effective as of January 1, 2026 (payment year 2026). CMS is currently engaged in its second round of negotiations and published the next 15 drugs selected for negotiation in January 2025. However, the impact of this program on the biopharmaceutical industry in the United States remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints.The outcome of such ongoing lawsuits, as well as potential legislative changes enacted by Congress or programmatic changes implemented at CMS by the Trump Administration, may impact the IRA drug price negotiation program in the future.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, in the EU, the sole legal instrument at the EU level governing the pricing and reimbursement of medicinal products is Council Directive 89/105/EEC (the Price Transparency Directive). The aim of the Price Transparency Directive is to ensure that pricing and reimbursement mechanisms established in the EU Member States are transparent and objective, do not hinder the free movement of and trade in medicinal products in the EU, and do not hinder, prevent or distort competition on the market. The Price Transparency Directive does not provide any guidance concerning the specific criteria on the basis of which pricing and reimbursement decisions are to be made in the individual EU Member States, nor does it have any direct consequence for pricing or reimbursement levels in the individual EU Member States. The EU Member States are free to restrict the range of medicinal products for which their national health insurance systems provide reimbursement, and to control the prices and/or reimbursement levels of medicinal products for human use. A EU Member State may approve a specific price or level of reimbursement for the medicinal product, or alternatively adopt a system of direct or indirect controls on the profitability of the company responsible for placing the medicinal product on the market, including volume-based arrangements, caps and reference pricing mechanisms.

Health Technology Assessment (HTA) of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including France, Germany, Ireland, Italy and Sweden. The HTA process in the EU Member States is governed by the national laws of these countries. HTA is the procedure according to which the assessment of the public health impact, therapeutic impact, and the economic and societal impact of the use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products as well as their potential implications for the healthcare system. Those elements of medicinal products are compared with other treatment options available on the market. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product vary between the EU Member States. For example, EU Member States that have not yet developed HTA mechanisms could rely to some extent on the HTA performed in countries with a developed HTA framework when adopting decisions concerning the pricing and reimbursement of a specific medicinal product.

Separately from cost containment efforts, in the United States and some foreign jurisdictions, there also have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates or restrict or regulate post-approval activities. For example, in April 2023 the European Commission issued a proposal for anew Directive and a new Regulation, which will revise and replace the existing general pharmaceutical legislation. If adopted and implemented as currently proposed, these revisions will significantly change several aspects of drug development and approval in the EU. The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our current or future product candidates.

Data Privacy and the Protection of Personal Information

We are subject to laws and regulations governing data privacy and the protection of personal information including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which will continue to affect our business. In the United States, we may be subject to state security breach notification laws, state laws protecting the privacy of health and personal information and federal and state consumer protections laws that regulate the collection, use, disclosure and transmission of personal information. These laws overlap and often conflict, and each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues. If we fail to comply with applicable laws and regulations, we could be subject to penalties or sanctions, including criminal penalties. Our customers and research partners must comply with laws governing the privacy and security of health information, including HIPAA and state health information privacy laws. If we knowingly obtain health information that is protected under HIPAA, called "protected health information," our customers or research collaborators may be subject to enforcement, and we may have direct liability for the unlawful receipt of protected health information or for aiding and abetting a HIPAA violation.

In addition, the California Confidentiality of Medical Information Act imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information.

Other federal and state laws establish additional requirements for protecting the privacy and security of health information that is not protected by HIPAA. For instance, Washington state recently passed the "My Health My Data" Act, which will regulate "consumer health data," which is defined as "personal information that is linked or reasonably linkable to a consumer and that identifies a consumer's past, present, or future physical or mental health." The "My Health My Data" Act provides exemptions for personal data used or shared in connection with certain research activities, including data subject to 45 C.F.R. Parts 46, 50 and 56. Notably, the "My Health My Data" Act contains a private right of action. In addition, Nevada recently enacted a consumer health data privacy bill, SB 370, which also regulates "consumer health data" and shares many similarities with Washington's "My Health My Data" Act, and Connecticut recently amended its comprehensive privacy law to include heightened regulation of "consumer health data." Additional states may adopt health-specific privacy laws that could impact our business activities and our collection and handling of health-related data.

More broadly, various state laws regulate the processing of personal information. For example, California has enacted the California Consumer Privacy Act (CCPA), which went into effect in January of 2020. The CCPA gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that may increase data breach litigation. Although the CCPA includes exemptions for certain categories of health information, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. Additionally in 2020, California voters passed the

California Privacy Rights Act (CPRA), which went into full effect on January 1, 2023. The CPRA significantly amended the CCPA, potentially resulting in further uncertainty, additional costs and expenses in an effort to comply and additional potential for harm and liability for failure to comply. Among other things, the CPRA established a new regulatory authority, the California Privacy Protection Agency, which is tasked with enacting new regulations under the CPRA and has expanded enforcement authority. In addition to California, more U.S. states are enacting similar legislation, increasing compliance complexity and increasing risks of failures to comply. In 2023, comprehensive privacy laws in Virginia, Colorado, Connecticut, and Utah all took effect, and laws in Montana, Oregon, and Texas took effect during 2024. Laws in a number of other US states took effect, or are set to take effect, in 2025, in 2026, and beyond. Additional U.S. states have proposals under consideration, all of which are likely to increase our regulatory compliance costs and risks, exposure to regulatory enforcement action, and other liabilities.

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. For example, the European Parliament and the Council of the European Union adopted a comprehensive general data privacy framework called the General Data Protection Regulation (GDPR) which went into effect in May 2018, and implemented a broad data protection framework that expanded the scope of EU data protection law, and applies to entities located inside and outside of the EU that process, or control the processing of, personal data relating to individuals located in the EU, including clinical trial data. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification, and the use of third-party processors in connection with the processing of the personal data. In particular, medical or health data, and genetic and biometric data used to uniquely identify an individual are all classified as “special category” data under the GDPR and are subject to heightened restrictions and compliance obligations. Further, EU member states have a broad right to impose additional conditions – including restrictions – on these data categories. This is because the GDPR allows EU member states to derogate from the requirements of the GDPR mainly in regard to specific processing situations (including special category data and processing for scientific or statistical purposes). As EU member states continue to reframe their national legislation to harmonize with the GDPR, we will need to monitor compliance with all relevant EU member states’ laws and regulations, including where permitted derogations from the GDPR are introduced.

Relatedly, following Brexit and the expiry of the Brexit transition period, which ended on December 31, 2020, the EU GDPR has been implemented in the United Kingdom (as the UK GDPR). The UK GDPR sits alongside the United Kingdom Data Protection Act 2018 which implements certain derogations in the EU GDPR into United Kingdom law. Under the UK GDPR, companies not established in the United Kingdom but who process personal data in relation to the offering of goods or services to individuals in the United Kingdom , or to monitor their behavior will be subject to the UK GDPR – the requirements of which are (at this time) largely aligned with those under the GDPR and as such, may lead to similar compliance and operational costs with potential fines of up to £17.5 million or 4% of global turnover.

Transfers of personal data to certain countries outside of the EU and the UK are also highly regulated under the GDPR and UK GDPR. For example, the GDPR only permits exports of personal data outside of the EU to “non-adequate” countries where there is a suitable data transfer mechanism in place to safeguard personal data (e.g., the EU Commission approved Standard Contractual Clauses or certification under the newly-adopted Data Privacy Framework). On July 16, 2020, the Court of Justice of the EU (CJEU), issued a landmark opinion in the case Maximilian Schrems vs. Facebook (Case C-311/18) (Schrems II). This decision calls into question certain data transfer mechanisms as between the EU member states and the U.S. The CJEU is the highest court in Europe and the Schrems II decision heightened the burden to assess U.S. national security laws on their business, and future actions of EU data protection authorities are difficult to predict at this time. While the Data Privacy Framework was meant to address the concerns raised by the CJEU in Schrems II, it will likely be subject to future legal challenges. Consequently, there is some risk of any data transfers from the EU being halted. If we have to rely on third parties to carry out services for us, including processing personal data on our behalf, we are required under GDPR to enter into contractual arrangements to flow down or help ensure that these third parties only process such data according to our instructions and have sufficient security measures in place. Any security breach or non-compliance with our contractual terms or breach of applicable law by such third parties could result in enforcement actions, litigation, fines and penalties or adverse publicity and could cause customers to lose trust in us, which would have an adverse impact on our reputation and business. Any contractual arrangements requiring the processing of personal data from the EU to us in the U.S. will require greater scrutiny and assessments as required under Schrems II and may have an adverse impact on cross-border transfers of personal data or increase costs of compliance.

Applicable data privacy and data protection laws may conflict with each other, and by complying with the laws or regulations of one jurisdiction, we may find that we are violating the laws or regulations of another jurisdiction. Despite our efforts, we may not have fully complied in the past and may not in the future. That could require us to incur significant expenses, which could significantly affect our business. Failure to comply with data protection laws may expose us to risk of enforcement

actions taken by data protection authorities or other regulatory agencies, private rights of action in some jurisdictions, and potential significant penalties if we are found to be non-compliant. Furthermore, the number of government investigations related to data security incidents and privacy violations continue to increase and government investigations typically require significant resources and generate negative publicity, which could harm our business and reputation.

United States Foreign Corrupt Practices Act

In general, the Foreign Corrupt Practices Act of 1977, as amended (FCPA), prohibits offering to pay, paying, promising to pay, or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business for or with, or in order to direct business to, any person. The prohibitions apply not only to payments made to "any foreign official," but also those made to "any foreign political party or official thereof," to "any candidate for foreign political office" or to any person, while knowing that all or a portion of the payment will be offered, given, or promised to anyone in any of the foregoing categories. "Foreign officials" under the FCPA include officers or employees of a department, agency, or instrumentality of a foreign government. The term "instrumentality" is broad and can include state-owned or state-controlled entities. Importantly, United States authorities deem most healthcare professionals and other employees of foreign hospitals, clinics, research facilities and medical schools in countries with public healthcare and/or public education systems to be "foreign officials" under the FCPA. When we interact with foreign healthcare professionals and researchers in testing and marketing our products abroad, should any of our product candidates receive foreign regulatory approval in the future, we must have policies and procedures in place sufficient to prevent us and agents acting on our behalf from providing any bribe, gift or gratuity, including excessive or lavish meals, travel or entertainment in connection with marketing our products and services or securing required permits and approvals. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Environmental, Health and Safety Regulation

We are subject to numerous federal, state and local environmental, health and safety (EHS) laws and regulations relating to, among other matters, safe working conditions, product stewardship, environmental protection, and handling or disposition of products, including those governing the generation, storage, handling, use, transportation, release, and disposal of hazardous or potentially hazardous materials, medical waste, and infectious materials that may be handled by our partner research laboratories. Some of these laws and regulations also require us to obtain licenses or permits to conduct our operations. If we fail to comply with such laws or obtain and comply with the applicable permits, we could face substantial fines or possible revocation of our permits or limitations on our ability to conduct our operations. Certain of our development and manufacturing activities may involve, from time to time, use of hazardous materials, and we believe we are in compliance with the applicable environmental laws, regulations, permits, and licenses. However, we cannot ensure that EHS liabilities will not develop in the future. EHS laws and regulations are complex, change frequently and have tended to become more stringent over time. Although the costs to comply with applicable laws and regulations, have not been material, we cannot predict the impact on our business of new or amended laws or regulations or any changes in the way existing and future laws and regulations are interpreted or enforced, nor can we ensure we will be able to obtain or maintain any required licenses or permits.

Human Capital Resources

As of January 30, 2026 we had four employees, of which three were full-time employees and one was part-time. We believe the intellectual capital of our current and future employees and consultants is an impactful driver of our business and is key to our future prospects.

GRI's Corporate Information

Vallon was incorporated under the laws of the State of Delaware in January 2018 and completed its organization, formation and initial capitalization activities effective in June 2018. GRI Bio Operations, Inc. (GRI Operations), formerly known as GRI Bio, Inc., was incorporated under the laws of the State of Delaware in May 2009 under the name Glycoregimmune, Inc., and amended its certificate of incorporation to change its name to GRI Bio, Inc. on July 29, 2015.

On April 21, 2023, pursuant to the Merger Agreement, by and among Vallon, GRI Operations and Vallon Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of the Company (Merger Sub), Merger Sub was merged with and into GRI (the Merger), with GRI surviving the Merger as a wholly owned subsidiary of the Company. In connection with the closing of the Merger (the Closing), the Company amended its Charter to change its name from "Vallon Pharmaceuticals, Inc." to "GRI Bio, Inc."

Our principal executive offices are located at 2223 Avenida De La Playa #208, La Jolla, CA 92037.

Available Information

We are required to provide an annual report to our shareholders. We file our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, proxy and information statements, and other information with the SEC under the Securities Exchange Act of 1934, as amended (the Exchange Act). You can read our SEC filings at the SEC's website.

The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at *http://www.sec.gov.*

Our website address is *www.gribio.com*. Our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, proxy and information statements, and other information filed with the SEC under the Exchange Act are also available free-of-charge on our website as soon as reasonably practicable after these items are filed with or furnished to the SEC. The information contained in, and that can be accessed through, our website is not incorporated into and is not part of this Annual Report.

Emerging Growth Company Status

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act) and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not applicable to emerging growth companies. These exemptions include:

- reduced disclosure about our executive compensation arrangements;
- no non-binding stockholder advisory votes on executive compensation or golden parachute arrangements; and
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We have taken advantage of reduced reporting requirements in this report and may continue to do so until such time that we are no longer an emerging growth company. We will remain an "emerging growth company" until the earliest of (a) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more, (b) December 31, 2026, the last day of the fiscal year following the fifth anniversary of the completion of the IPO, (c) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years or (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period for complying with new or revised accounting standards.

Item 1A. RISK FACTORS

Careful consideration should be given to the following risk factors, in addition to the other information contained in this Annual Report and in our other public filings, in evaluating our company and business. Investing in our securities involves a high degree of risk. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected and the trading price of our securities could decline. Our actual results could differ materially from those anticipated in the forward looking statements as a result of factors that are described below and elsewhere in this Annual Report.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant net losses since inception, and we expect to continue to incur significant net losses for the foreseeable future. We have never been, and may never be, profitable.

We have incurred significant net losses since our inception and have financed our operations principally through equity and debt financing. We continue to incur significant research and development and other expenses related to our ongoing operations. Our net loss was $12.0 million and $8.2 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $51.7 million. We have devoted substantially all of our resources and efforts to research and development, and we expect that it will be several years, if ever, before we generate revenue from product sales. Even if we receive marketing approval for and commercialize one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to develop and, if approved, market additional potential product candidates.

We expect to continue to incur significant losses for the foreseeable future, and we anticipate that our expenses will increase substantially if, and as, we:

- advance our product candidates through clinical development, and, if successful, later-stage clinical trials (in particular and without a partner, we will incur substantial additional expense to complete a Phase 2b clinical trial of GRI-0621);
- discover and develop new product candidates;
- advance our preclinical development programs into clinical development;
- further develop manufacturing processes and manufacture our product candidates;
- experience delays or interruptions to preclinical studies, clinical trials, our receipt of services from our third-party service providers on whom we rely, or our supply chain due to pandemics, supply chain and labor shortages, international tariff policies or trade wars, labor strikes, work stoppages or boycotts, natural disasters and geopolitical conflicts, such as the conflicts in Ukraine and the Middle East;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- commercialize GRI-0621, our other product candidates and any future product candidates, if approved;
- increase the amount of research and development activities to identify and develop product candidates;
- hire additional clinical development, quality control, scientific and management personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development and manufacturing efforts and our operations as a public company;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties;
- maintain, expand and protect our intellectual property portfolio;
- invest in or in-license other technologies or product candidates; and
- continue to build out our organization to engage in such activities.

To become and remain profitable, we must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, marketing and selling products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never

succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs, future commercialization efforts or other operations or cease operations entirely. In particular, we will require substantial additional capital or resources to complete a Phase 2b clinical trial of GRI-0621.

Developing biotechnology and biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our clinical trials of GRI-0621, GRI-0803 and any other product candidates that we may develop or seek regulatory approvals for and, if approved, launch and commercialize. We also expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations. In particular, we expect to require substantial additional capital to complete a Phase 2b clinical trial of GRI-0621.

As of December 31, 2025, we had approximately $8.2 million in cash and cash equivalents and an accumulated deficit of approximately $51.7 million. We expect to devote substantial financial resources to our planned activities, particularly as we conduct our clinical trial of GRI-0621, GRI-0803, advance our discovery programs and, subject to obtaining the requisite additional capital or resources, complete a clinical trial of GRI-0621.

Based on our current operating plan, we believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements into the first quarter of 2027. We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. In particular, these estimates assume only the commencement of preliminary work towards the initiation of a Phase 2b trial of GRI-0621; we would require substantial additional capital or resources in order to complete a Phase 2b clinical trial of GRI-0621. Our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect. Our spending levels will vary based on new and ongoing development, corporate activities, and our ability to raise funds or resources for a Phase 2b clinical trial of GRI-0621. Because the length of time and activities associated with development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development, and assuming approval, marketing and commercialization activities.

We may also need to raise additional funds in the near term in order to maintain compliance with Nasdaq's continued listing requirements and continue operations. However, additional funding may not be available on acceptable terms, if at all. Until we can generate sufficient revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Further, to the extent that we raise additional capital through the sale of Common Stock or securities convertible or exchangeable into Common Stock, our stockholders' ownership interest will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also may be required to seek collaborators for any of our product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. Market volatility resulting from inflation, pandemics, geopolitical events or other financial markets factors could also adversely impact our ability to access capital as and when needed. If we are unable to secure adequate additional funding when needed or on acceptable terms, we will need to reevaluate our operating plans and may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, delay, scale back or eliminate some or all of our development programs, relinquish rights to our technology on less favorable terms than we would otherwise choose or cease operations entirely. These actions could materially impact our business, results of operations, our future prospects and

the value of shares of our Common Stock, and as a result, our stockholders may receive no value for their investment. In addition, attempting to secure additional financing diverts the time and attention of management from day-to-day activities and distract from our discovery and product development efforts, which could also detrimentally affect these efforts and our prospects.

Our management has expressed substantial doubt about our ability to continue as a going concern, and our auditors have included explanatory paragraphs in their audit reports about our ability to continue as a going concern. We may not be able to continue as a going concern if we do not obtain additional financing.

We have incurred losses since inception and, to date, have financed our operations by issuing equity and debt securities. We anticipate that we will continue to incur losses and generate negative operating cash flows in the foreseeable future as we continue to develop our product drug candidates and that we will require additional funding to support our planned operating activities. In particular, these estimates assume only the commencement of preliminary work towards the initiation of a Phase 2b trial of GRI-0621; we would require substantial additional capital or resources in order to complete a Phase 2b clinical trial of GRI-0621. The reports of our independent registered public accounting firms on our financial statements as of and for the years ended December 31, 2024 and December 31, 2025 include explanatory paragraphs indicating that there is substantial doubt about our ability to continue as a going concern. Until such time, if ever, when we can generate substantial product revenue, we expect we may continue to fund our operations and capital funding needs through equity offerings, debt financings or other capital sources, including strategic licensing, collaboration or other similar agreements. As stated above, if we are unable to secure adequate additional funding, we will need to reevaluate our operating plans and may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, delay, scale back or eliminate some or all of our development programs or relinquish rights to our technology on less favorable terms than it would otherwise choose. These actions could materially impact our business, results of operations, our future prospects and the value of shares of our Common Stock, and, as a result, our stockholders may receive no value for their investment.

Risks Related to Research and Development and the Pharmaceutical Industry

Our business is highly dependent on the success of our product candidates, GRI-0621 and GRI-0803, and any other product candidates that we may advance into clinical development. All of our product candidates will require significant additional development before we may be able to seek regulatory approval and launch a product commercially.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. If GRI-0621 or GRI-0803 encounter safety or efficacy problems, additional development delays, regulatory issues or other problems, our development plans and business would be significantly harmed. Before we can generate any revenue from sales of our product candidates, we must undergo additional clinical development, regulatory review and approval in one or more jurisdictions. These efforts will require substantial investment, and we may not have the financial resources to continue development of our product candidates.

We may experience setbacks that could delay or prevent regulatory approval of, or the extent of regulatory protection or our ability to commercialize, our product candidates, including:

- negative or inconclusive results from our preclinical studies or clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- product-related side effects experienced by subjects in our clinical trials or by individuals using drugs or therapeutics similar to our product candidates;
- further delays in submitting IND applications or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials, including any regulatory requirements for certain outcomes be measured during product development or to support market authorization;
- further delays in enrolling subjects in clinical trials, including due to pandemics, labor shortages or other geopolitical events;
- high drop-out rates of subjects from clinical trials;

- inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;
- challenges manufacturing our product candidates to regulatory requirements in a cost effective manner;
- greater than anticipated clinical trial costs;
- inability to compete with other therapies;
- failure to secure or maintain orphan designation in some jurisdictions;
- poor efficacy of our product candidates during clinical trials;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policies and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular; or
- varying interpretations of data by the FDA and similar foreign regulatory agencies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and our manufacturing, marketing, distribution and sales efforts or that of any future collaborator. Delays in regulatory approvals or our failure to obtain regulatory approvals would harm our business, prospects and results of operations.

Clinical development involves a lengthy, complex and expensive process, with an uncertain outcome. In addition, the results of preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials and interim or topline results of our clinical trials may not be representative of final results of our clinical trials.

To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive nonclinical studies and clinical trials that our product candidates are safe and effective in humans for their intended use(s). Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. In particular, the general approach for FDA approval of a new drug is dispositive data from two well-controlled, Phase 3 clinical trials of the relevant drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete.

A product candidate can fail at any stage of testing, even after observing promising signals of activity in earlier preclinical studies or clinical trials. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. In general, most product candidates that commence clinical trials are never approved as products, and there can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of GRI-0621, GRI-0803 or any of our other product candidates.

Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- preclinical studies or clinical trials may show the product candidates to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or to have unacceptable side effects or toxicities;
- failure to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- development of competing products in the same disease state;

- manufacturing costs, formulation issues, pricing or reimbursement issues or other factors that make a product candidate uneconomical; and
- the proprietary rights of others and their competing products and technologies that may prevent one of our product candidates from being commercialized.

In 2022, Congress amended the FDCA to require sponsors of a Phase 3 clinical trial, or other "pivotal study" of a new drug to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must describe appropriate diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Although none of our product candidates have reached Phase 3 of clinical development, we must submit a diversity action plan to the FDA by the time we submit a Phase 3 trial, or pivotal study, protocol to the agency for review, unless we are able to obtain a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect the planning and timing of any future Phase 3 trial for our product candidates. However, initiation of such trials may be delayed if the FDA objects to our proposed diversity action plans for any future Phase 3 trial for our product candidates, and we may experience difficulties recruiting a diverse population of patients in attempting to fulfill the requirements of any approved diversity action plan.

In addition, the standards that the FDA and comparable foreign regulatory authorities use when regulating our product candidates require judgment and can change, which makes it difficult to predict with certainty how they will be applied. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations. Examples of such regulations include future legislation or administrative action, or changes in FDA policy during the period of product development and FDA regulatory review. We cannot predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. For example, in April 2023, the European Commission issued a proposal for a new directive and a new regulation, which will revise and replace the existing general pharmaceutical legislation. If adopted and implemented as currently proposed, these revisions will significantly change several aspects of drug development and approval in the EU. As of the date of this Annual Report, these rules are still pending finalization.

The FDA may also require a panel of experts, referred to as an advisory committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the advisory committee, although not binding on the FDA, may have a significant impact on the agency's decision-making process and our ability to obtain approval of any product candidates that we develop.

If we seek to conduct clinical trials in foreign countries or pursue marketing approvals in foreign jurisdictions, we must comply with numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the United States and vice versa. Our competitors also may obtain FDA or regulatory approval from comparable foreign regulatory authorities for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated.

If we encounter additional difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of completion of our clinical studies depends in part on the speed at which we can recruit patients to participate in testing our product candidates, and we may again experience delays in our clinical trials if we encounter difficulties in enrollment. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility and exclusion criteria defined in the protocol;

- the size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- the willingness or availability of patients to participate in our trials;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- the availability of competing commercially available therapies and other competing product candidates' clinical trials;
- our ability to obtain and maintain patient informed consents;
- our ability to establish new sites in accordance with applicable regulatory requirements; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

For example, when we previously evaluated GRI-0621 in a pilot Phase 2a trial in hepatically impaired chronic liver disease patients, the study was originally intended to evaluate 60 patients but due to recruitment challenges and updated guidance from the FDA regarding the design of NASH clinical studies, we made the administrative decision to halt the study after enrolling 14 patients. This pilot Phase 2a trial was not resumed. In addition, the topline results of our recently completed Phase 2a clinical trial investigating GRI-0621 were delayed due in part to prior delays in enrollment for this trial.

Further, we are initially developing GRI-0621 for the treatment of IPF, which is an orphan indication. As a result, we have and may again encounter difficulties enrolling subjects in our clinical trials of GRI-0621 due, in part, to the small size of this patient population or the burden of safety labs included in the clinical protocol. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition may reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Further, timely enrollment in clinical trials is reliant on clinical trial sites which may be adversely affected by global health matters, including, among other things, pandemics, supply and labor shortages, international trade policy and geopolitical events. These delays and potential delays to development timelines may adversely affect our business, prospects and results of operations.

Interim, topline and preliminary data from our clinical trials (including topline data from our recently completed Phase 2a trial for GRI-0621) that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we publicly disclose interim, preliminary or topline data from our clinical studies (including recent disclosures of interim data and the topline data from our Phase 2a clinical trial for GRI-0621), which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analysis of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline or preliminary results of clinical trials we report, including for our Phase 2a clinical trial for GRI-0621, may differ from final results reported for those studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final, complete data are available.

Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. There can be no guarantee that a favorable interim analysis will result in a favorable final result at the completion of the clinical trial.

Likewise, in light of the fact that our previous evaluation of GRI-0621 in a pilot Phase 2a trial in hepatically impaired chronic liver disease patients was originally intended to evaluate 60 patients and that we made the administrative decision to halt the study after enrolling 14 patients due to recruitment challenges and updated guidance from the FDA regarding the design of NASH clinical studies, our disclosures that GRI-0621 was observed to be well-tolerated and showed improvements in liver function tests, serum CK-18, and in iNKT cell activity in this limited number of patients is qualified by the fact that the study was underpowered to meet its endpoints with statistical significance. Our observations from this terminated pilot Phase 2a trial and our recent interim or topline results for GRI-0621 may not be indicative of results from any potential future preclinical studies or clinical trials.

Changes in regulatory requirements, FDA guidance or unanticipated events during our preclinical studies and clinical studies of our product candidates may occur, which may result in changes to preclinical or clinical study protocols or additional preclinical or clinical study requirements, which could result in increased costs to us and could delay our development timeline.

Changes in regulatory requirements, FDA guidance or unanticipated events during our preclinical studies and clinical studies may force us to amend preclinical studies and clinical study protocols. The FDA or comparable foreign regulatory authorities may also impose additional preclinical studies and clinical study requirements. Amendments or changes to our clinical study protocols, including changes to endpoints, would require resubmission to the FDA or comparable foreign regulatory authorities and Institutional Review Boards for review and approval, which may increase the cost or delay the timing or successful completion of clinical studies. Similarly, amendments to our preclinical studies may increase the cost or delay the timing or successful completion of those preclinical studies. If we experience delays completing, or if we terminate, any of our preclinical or clinical studies, or if we are required to conduct additional preclinical or clinical studies, the commercial prospects for our product candidates may be harmed and our ability to recognize product revenue will be delayed.

If product liability lawsuits are brought against us, we may incur substantial financial or other liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of testing GRI-0621, GRI-0803 and any of our other product candidates in clinical trials and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. As an oral formulation of an active ingredient that has previously been approved by the FDA only for topical administration, in particular, GRI-0621 may be subject to the identification of new serious adverse events as it is administered to larger numbers of research subjects in order to evaluate its safety/ effectiveness in chronic use indications and in new patient populations. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even a successful defense of these claims would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- inability to bring a product candidate to the market;
- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- fines, injunctions or criminal penalties;
- costs to defend the related litigation;
- diversion of management’s time and our resources;

- substantial monetary awards to trial participants;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate, if approved; and
- decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We may be unable to obtain, or may obtain on unfavorable terms, clinical trial insurance in amounts adequate to cover any liabilities from any of our clinical trials. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

We expect to utilize the FDA's Section 505(b)(2) pathway for our product candidate, GRI-0621, and if that pathway is not available, the development of this product candidate will likely take significantly longer, cost significantly more and entail significantly greater complexity and risk than currently anticipated, and, in any case, may not be successful.

We intend to develop and seek approval for GRI-0621, and potentially other candidates that we may develop, pursuant to the FDA's 505(b)(2) pathway. If the FDA determines that we may not use this regulatory pathway, then we would need to seek regulatory approval via a "full" or "stand-alone" New Drug Application (NDA) under Section 505(b)(1) of the FDCA. This would require us to conduct additional clinical trials, provide additional safety and efficacy data and other information and meet additional standards for regulatory approval including possibly nonclinical data. If this were to occur, the time and financial resources required to obtain FDA approval, as well as the development complexity and risk associated with these programs, would likely substantially increase, which could have a material adverse effect on our business and financial condition.

The Drug Price Competition and Patent Term Restoration Act of 1984, informally known as the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies and information that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to certain of our product candidates under the FDCA, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds. Such an approach could expedite the development programs for GRI-0621. In addition, although 505(b)(2) applicants have significant flexibility in the types of studies, data and information they may submit in a 505(b)(2) NDA to support the requirements for NDA approval, establish a favorable benefit-risk profile for the new drug product and demonstrate the new drug's substantial evidence of effectiveness for its proposed intended use(s), the applicant bears the burden of establishing a scientific bridge between its drug product and each listed drug that the applicant seeks to rely upon and that the studies it is proposing to conduct are scientifically justified. If the FDA disagrees with an applicant's proposed development plan for the follow-on drug product, it may require the sponsor to perform additional studies or measurements, including nonclinical and clinical studies, to support the change from the approved product. The FDA also may request or require studies to incorporate additional clinical endpoints than what the sponsor proposes. The extent of data necessary to establish the safety and/or effectiveness of the new product, such as the effects of changing the drug's route of administration from topical to oral, are therefore scientifically driven and determined on a case-by-case basis. There can be no assurance that the studies and clinical trials we propose to the FDA to establish the safety and effectiveness of GRI-0621 for the treatment of IPF, or any future candidates we may develop using the 505(b)(2) NDA pathway, will be deemed sufficient to support all of the differences between our product candidate and the relevant listed drug. For example, we may be required to collect more safety data than we anticipate in order to gain approval of an oral formulation of an active ingredient that has previously been approved by the FDA only for topical administration.

If the FDA's interpretation of Section 505(b)(2) is successfully challenged, or if Congress were to amend the statute to alter the currently available regulatory pathway, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed

to protect the patent rights of sponsors of previously approved drugs referenced in a Section 505(b)(2) NDA. Even if we are able to utilize the Section 505(b)(2) regulatory pathway for one or more of our candidates, there is no guarantee this would ultimately lead to faster product development or earlier approval.

Moreover, any delay resulting from our inability to pursue the FDA's 505(b)(2) pathway could result in new competitive products reaching the market more quickly than our GRI-0621 product candidate, which may have a material adverse impact our competitive position and prospects. Even if we are allowed to pursue the FDA's 505(b)(2) pathway, we cannot assure you that GRI-0621 or any of our future product candidates will receive the requisite approvals for commercialization.

We may seek Fast Track designation for one or more of our product candidates, but we might not receive such designation, and even if we do, such designation may not actually lead to a faster development or regulatory review or approval process.

If a product candidate is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, a product sponsor may apply for FDA Fast Track designation. If we seek Fast Track designation for a product candidate, we may not receive it from the FDA. However, even if we receive Fast Track designation, it would not ensure that we will receive marketing approval or that approval will be granted within any particular time frame. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

Risks Related to Regulatory Approval of Our Product Candidates

Even if we receive regulatory approval of any product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review. Maintaining compliance with ongoing regulatory requirements may result in significant additional expense to us, and any failure to maintain such compliance could subject us to penalties and cause our business to suffer.

If any of our product candidates are approved, we will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval.

Manufacturers and their facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs and applicable electronic package-level tracing requirements. We and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMPs and adherence to commitments made in any marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any future regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS program as a condition of approval of one or more of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves any of our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration. If our original marketing approval for a product candidate was obtained through an accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial in order to confirm the clinical benefit for that product. An unsuccessful post-marketing clinical trial or failure to complete such a trial could result in the withdrawal of marketing approval.

We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we hope to obtain marketing approval. The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is

not inconsistent with the labeling, and the FDA has published draft guidance with recommendations for how drug manufacturers can share scientifically sound and clinically relevant information on unapproved uses with health care providers so long as such presentations are not promotional. 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.

The FDA may impose consent decrees or withdraw 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 our product candidates (or with drugs that contain the same active ingredients as our product candidates), including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or 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 restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- new requirements to conduct post-marketing studies or clinical trials;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us;
- suspension or revocation of drug product approvals;
- voluntary or mandatory product recalls and related publicity requirements;
- total or partial suspension of production;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions, consent decrees or the imposition of civil or criminal penalties.

In addition, adverse side effects caused by any drugs that contain the same active ingredients as or may otherwise be similar in nature to our product candidates could delay or prevent marketing approval of our product candidates or limit the commercial profile of an approved label for our product candidates.

Any government investigation of alleged violations of law would be expected to require us to expend significant time and resources in response and could generate adverse publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to develop and commercialize our products and our value and our operating results would be adversely affected. In addition, the policies of the FDA and of other regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Risks Related to Commercialization of Our Product Candidates

Even if a product candidate we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if GRI-0621, GRI-0803 or any other product candidate we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients and third-party payors, such as Medicare and Medicaid programs and managed care organizations and others in the medical community. In addition, the availability of coverage by third-party payors may be affected by existing and future health care reform measures designed to reduce the cost of health care. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable.

The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the recommendations with respect to our product candidates in guidelines published by various scientific organizations applicable to us and our product candidates;
- the strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement; and
- the prevalence and severity of any side effects, as well as the language and scope of any labeled warnings (including boxed warnings), precautions or contraindications.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our products are safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable. If government and other third-party payors do not provide coverage and adequate reimbursement levels for any products we commercialize, market acceptance and commercial success would be reduced.

Failure to obtain or maintain adequate reimbursement or insurance coverage for our approved product candidates, if any, could limit our ability to market those product candidates and decrease our ability to generate revenue.

The pricing, coverage and reimbursement of our approved products, if any, must be sufficient to support our commercial efforts and other development programs, and the availability and adequacy of coverage and reimbursement by third-party payors, including governmental and private insurers, are essential for most patients to be able to afford medical treatments. Sales of our approved products, if any, will depend substantially, both domestically and abroad, on the extent to which the costs of our approved products, if any, will be paid for or reimbursed by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations or government payors and private payors. If coverage and reimbursement are not available, or are available only in limited amounts, we may have to subsidize or provide products for free or we may not be able to successfully commercialize our products.

In addition, there is significant uncertainty related to the insurance coverage and reimbursement for newly approved products. In the United States, the principal decisions about coverage and reimbursement for new drugs are typically made by the CMS, an agency within the HHS, as CMS decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel product candidates such as ours and what reimbursement codes our product candidates may receive if approved.

Outside the United States, international operations are generally subject to extensive governmental price controls and other price-restrictive regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of prescription drugs. In many countries, the prices of drugs are subject to varying price control mechanisms as part of national health systems. Price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products, if any. Accordingly, in markets outside the United States, the potential revenue may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and private payors in the United States and abroad to limit or reduce healthcare costs may result in restrictions on coverage and the level of reimbursement for new drugs and, as a result, they may not cover or provide adequate payment for our products, if any. We expect to experience pricing pressures in

connection with drugs due to the increasing trend toward managed healthcare, including the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, and prescription drugs in particular, has and is expected to continue to increase in the future. As a result, profitability of our products, if any, may be more difficult to achieve even if any of them receive regulatory approval.

Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize these product candidates outside of the United States, which could limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience as a company in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

We currently have no marketing and sales organization and have no experience as a company in commercializing products. We would have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue from any of our product candidates that may be approved.

We have no internal sales, marketing or distribution capabilities. We have no prior experience as a company in the marketing, sale and distribution of pharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our sales, marketing and distribution capabilities would adversely impact the commercialization of any product candidates that may obtain approval. We may also choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over these third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing any approved product candidates that we may have, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

Our relationships with healthcare providers, physicians, prescribers, purchasers, third-party payors, charitable organizations and patients will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal AKS and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain

customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. See the section entitled, "*Business—Government Regulation and Product Approval—Other U.S. Healthcare Laws and Regulations*."

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from other aspects of its business.

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, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, reputational harm, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as 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. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Any action for violation of these laws, even if successfully defended, could cause significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, changes to our manufacturing arrangements; additions or modifications to product labeling; the recall or discontinuation of our products; or additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability. See the section entitled, "*Business—Government Regulation and Product Approval—Pharmaceutical Coverage, Pricing and Reimbursement & Healthcare Reform*."

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad, including in Canada and Europe, to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. In August 2022, former President Biden signed into the law the IRA, which among other things, contains multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States.

Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. A manufacturer of drugs or biological products covered by Medicare Parts B or D must now pay a rebate to the federal government if their drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting for payment year 2026, CMS is negotiating drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities and entered into the first set of agreements with pharmaceutical manufacturers to conduct price negotiations in October 2023 and ultimately announcing the first round of negotiated prices for the first ten drugs in August 2024; those negotiated "maximum fair prices" will be effective as of January 1, 2026 (payment year 2026). CMS is currently engaged in its second round of negotiations and published the next 15 drugs selected for negotiation in January 2025. However, the

IRA's impact on the biopharmaceutical industry in the United States remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. The outcome of such ongoing lawsuits, as well as potential legislative changes enacted by Congress or programmatic changes implemented at CMS by the Trump Administration, may impact the IRA drug price negotiation program. For example, the One Big Beautiful Bill Act (OBBBA), which President Trump signed into law in July 2025, modified the IRA's exclusion protecting orphan drugs designated for a single rare disease indication from required pricing negotiations by expanding it to apply to drugs designated for multiple rare diseases and by prohibiting Medicare price negotiations until seven years after an orphan drug, or 11 years after an orphan biologic, is approved for a non-orphan indication, which will significantly delay pricing negotiations for certain high-priced and widely used drugs.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, financial condition, results of operations and prospects. In addition, the U.S. Supreme Court held unanimously in December 2020 that federal law does not preempt the states' ability to regulate PBMs and other members of the health care and pharmaceutical supply chain, an important decision that has led to further and more aggressive efforts by states in this area.

In mid-2022, the FTC also launched sweeping investigations into the practices of the PBM industry, and published interim reports with its findings in mid-2024 and January 2025, that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks or financial arrangements, including in the current 2025-2026 congressional session. Both the U.S. Congress and state legislatures are increasingly scrutinizing the industry and proposing novel regulatory approaches to address various perceived public policy concerns. Significant efforts to change the PBM industry as it currently exists in the United States may affect the entire pharmaceutical supply chain and the business of other stakeholders, including biopharmaceutical product developers like us. Further, in September 2023, the FTC issued a policy statement articulating its view that certain "improper" patent listings by drug developers in FDA's Orange Book represent an unfair trade practice and indicated that industry should be prepared for potential enforcement actions based on its analysis. The FTC followed that action in November 2023 by publicly calling out over 100 "improper" patent listings made by ten large pharmaceutical companies and initiating an FDA administrative process with respect to those patents. The controversy regarding the appropriateness of listing such patents has led to numerous lawsuits alleging anticompetitive conduct by biopharmaceutical companies. It remains to be seen whether the FTC under the Trump Administration will continue to prioritize the policy issue of "improper" patent listings or whether Congress may take any legislative actions related to this issue. Accordingly, regulatory and government interest in biopharmaceutical industry business practices continues to expand and pose a risk of uncertainty.

These laws and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Additionally, we expect to experience pricing pressures in connection with the sale of any future approved product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

Inadequate funding for the FDA, the SEC and/or other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government shutdowns, government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. It is often unclear how long a shutdown will last and what impacts it may have on the federal agencies that have jurisdiction over our various operations. Additionally, regulatory agencies including the FDA have experienced significant disruptions which are expected to continue under the Trump Administration relating to funding restrictions, personnel reductions, deregulation policies and executive orders affecting policy decisions. Ongoing uncertainty or a prolonged government shutdown or slowdown could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future disruptions to the FDA and other agencies could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. It is also unclear if or how the FDA will choose to or be able to implement or enforce its regulations in the future, including those that have substantial impact on our business.

In addition, three decisions from the U.S. Supreme Court issued in July 2024 may lead to an increase in litigation against regulatory agencies that could create uncertainty and thus negatively impact our business. The first decision overturned established precedent that required courts to defer to regulatory agencies' interpretations of ambiguous statutory language. The second decision overturned regulatory agencies' ability to impose civil penalties in administrative proceedings. The third decision extended the statute of limitations within which entities may challenge agency actions. These cases may result in increased litigation by industry against regulatory agencies, including but not limited to the FDA and SEC, and may impact how such agencies choose to pursue enforcement and compliance actions. However, the specific, lasting effects of these decisions, which may vary within different judicial districts and circuits, is unknown. We also cannot predict the extent to which FDA and SEC regulations, policies and decisions may become subject to increasing legal challenges, delays and changes.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations (collectively, "Trade Laws") prohibit companies and their employees, agents, clinical research organizations (CROs), legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business, financial condition or results of operations.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations; environmental damage resulting in costly clean-up; and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of specified materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and

have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry hazardous waste insurance coverage.

Risks Related to Our Intellectual Property

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our business depends in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our product candidates, their respective components, synthetic intermediates, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities and whether a court would issue an injunctive remedy. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected.

The patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The patenting process is subject to numerous risks and there can be no assurance that we will be successful in obtaining patents for which we have applied. In addition, we may not pursue, obtain or maintain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees.

The strength of patents in the biotechnology and biopharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our technology, including our product candidates, or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

We cannot be certain that we were the first to file any patent application related to our technology, including our product candidates, and, if we were not, we may be precluded from obtaining patent protection for our technology, including our product candidates.

We cannot be certain that we were the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the United States Patent and Trademark Office (USPTO) to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. Similarly, for U.S. applications in which at least one claim is not entitled to a priority date before March 16, 2013, derivation proceedings can be instituted to determine whether the subject matter of a patent claim was derived from a prior inventor's disclosure.

We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent or patent application claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, would adequately protect our product candidates or would be found by a court to be infringed by a competitor's technology or product. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities and consider that we are free to operate in relation to our product candidates, but our competitors may obtain issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our

patents or other intellectual property rights or will design around the claims of patents that may issue that cover our products.

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 our competitive advantage.

We may enter into license or other collaboration agreements in the future that may impose certain obligations on us. If we fail to comply with our obligations under such future agreements with third parties, we could lose license rights that may be important to our future business.

In connection with our efforts to expand our pipeline of product candidates, or in an effort to realize value for our current product candidates in development (including GRI-0621), we may enter into certain licenses or other collaboration agreements pertaining to the in-license of rights to additional product candidates or of rights to our candidates. However, there can be no assurance that any efforts to enter into collaborations or partnership arrangements will be successful or on terms favorable to us. Such agreements may impose various diligence, milestone payment, royalty, insurance or other obligations on us. If we fail to comply with these obligations, our licensor or collaboration partners may have the right to terminate the relevant agreement, in which event we would not be able to develop or market the products covered by such licensed intellectual property.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners royalty obligations and calculation (both for royalties that may be due to us or owed to us); and
- the priority of invention of patented technology.

In addition, the agreements under which we currently, or may in the future, license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our 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. Moreover, if disputes over intellectual property that we have licensed from others or to others to prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

In addition, we may have limited control over the maintenance and prosecution of in-licensed patents and patent applications, 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 any licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which our licensors 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. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

Third-party claims of intellectual property infringement may be costly and time consuming to defend and could prevent or delay our product discovery, development and commercialization efforts.

Our commercial success depends in part on our, or a partner's, ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and biopharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post grant review and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by

third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and biopharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our Common Stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure.

Third parties may assert that we are employing their proprietary technology without authorization.

There may be third-party patents of which we are currently unaware with claims to compositions of matter, materials, formulations, methods of manufacture or methods for treatment that encompass the composition, use or manufacture of our product candidates. There may be currently pending patent applications of which we are currently unaware which may later result in issued patents that our product candidates or their use or manufacture may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patent were held by a court of competent jurisdiction to cover our product candidates, intermediates used in the manufacture of our product candidates or our materials generally, aspects of our formulations or methods of manufacture or use, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

As is common in the biotechnology and biopharmaceutical industries, we employ individuals who were previously employed at universities or other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or

independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. 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. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of such hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our Common Stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

Others may claim an ownership interest in our intellectual property, which could expose us to litigation and have a significant adverse effect on our prospects.

A third-party may claim an ownership interest in one or more of our or our licensors' patents or other proprietary or intellectual property rights. A third-party could bring legal actions against us and seek monetary damages and/or enjoin clinical testing, manufacturing and marketing of the affected product or products. Litigation, could consume a substantial portion of our resources and cause a significant diversion of effort by our technical and management personnel. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product, in which case we may be required to pay substantial royalties or grant cross-licenses to our patents. We cannot predict whether any such license will be available on commercially acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product candidate or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree.

We may not be successful in obtaining or maintaining necessary rights to develop any future product candidates on acceptable terms.

Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently, and these rights may be held by others. We may develop products containing our compounds and pre-existing biotechnology and biopharmaceutical compounds. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors or collaboration or strategic partners, or challenging the patent rights of others, which could be expensive, time-consuming and unsuccessful.

Competitors or other third parties such as chemical and reagent suppliers may infringe our patents or the patents of our current or future licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question or for other reasons. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

We may choose to challenge the patentability of claims in a third-party's U.S. patent by requesting that the USPTO review the patent claims in an ex-parte re-examination, inter partes review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third-party's patent in patent opposition proceedings in the European Patent Office (EPO) or other foreign patent offices. The costs of these opposition proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent offices, we may be exposed to litigation by a third-party alleging that the patent may be infringed by our product candidates or proprietary technologies.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent or first to file a patent application covering the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference or derivation proceeding declared by the USPTO to determine priority of invention in the United States. If we or one of our licensors is a party to an interference or derivation proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert management's time and expend other resources, even if we are successful.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

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. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our Common Stock.

Obtaining and maintaining our 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.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on our owned and in-licensed issued patents and patent applications are or will be due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and

following the issuance of a patent. While an inadvertent 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. Noncompliance 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. In certain circumstances, even inadvertent noncompliance events may permanently and irrevocably jeopardize patent rights. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Any patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO (or foreign patent offices). Our patents may expire before or, soon after, or products are approved or commercialized.

If we or one of our licensors initiate legal proceedings against a third-party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third-party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

Our earliest patents may expire before, or soon after, our first product achieves marketing approval in the United States or foreign jurisdictions, or is commercialized, particularly if we are unable to secure any patent term extensions. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, results of operations, financial condition and prospects. We own pending patent applications covering our proprietary technologies or our product candidates that if issued as patents are expected to expire from 2032 through 2035, without taking into account any possible patent term adjustments or extensions. However, we cannot be assured that the USPTO, EPO or other relevant foreign patent offices will grant any of these patent applications, or that we would receive any extension on these or any issued patents..

Changes in patent law in the United States and in foreign jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States or in foreign jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 16, 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. On March 16, 2013, under the Leahy-Smith America Invents Act (the America Invents Act), the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. A third-party that files a patent application in the USPTO on or after March 16, 2013, but before us, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third-party. This requires us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also included a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary

standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third-party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third-party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biotechnology and biopharmaceuticals are particularly uncertain. 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. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

We have limited foreign intellectual property rights and may not be able to protect and enforce our intellectual property rights throughout the world.

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. 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 where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of, and may require a compulsory license to, patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology and biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

If we do not obtain patent term extension and data exclusivity or similar non-U.S. legislation extending the term of protection covering any product candidates we may develop, our business may be materially harmed.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are approved or commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permit a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failure to exercise due diligence during the testing phase or regulatory review process, failure to apply within applicable deadlines,

failure to apply prior to expiration of relevant patents or otherwise failure to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, within the EU, regulatory protections afforded to medicinal products such as data exclusivity, marketing protection, market exclusivity for orphan indications and pediatric extensions are currently under review and could be curtailed in future years. If we are unable to obtain patent term extension or the term of any such extension is less than we request, if our terms of our patents expire before we are able to commercialize or complete development of our product candidates, or if data exclusivity or other regulatory protections are reduced, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our clinical trials, manufacture our product candidates and perform other services. If these third parties do not successfully carry out their contractual duties, meet expected timelines or otherwise conduct the trials as required or perform and comply with regulatory or contractual requirements, we may not be able to successfully complete clinical development, obtain regulatory approval or commercialize our product candidates when expected or at all, and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to conduct, monitor and manage our clinical programs. We rely on these parties for execution of clinical trials and we manage and control only some aspects of their activities. We remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards; our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with all applicable laws, regulations and guidelines, including those required by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. If we, or any of our CROs or vendors, fail to comply with applicable laws, regulations or guidelines, or as otherwise required, the results generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials or repeat clinical trials before approving our marketing applications. We cannot be assured that our CROs or other vendors will meet these requirements, or that upon inspection by any regulatory authority, such regulatory authority will determine that a CRO's development efforts, including any of our clinical trials, comply with applicable requirements. Our failure to comply with these laws, regulations or guidelines, and the repetition of or requirement for additional clinical trials would be costly and delay the regulatory approval process.

If any of our relationships with these third-party CROs terminates, or they otherwise are subject to quarantines, shelter-in-place orders, shutdowns, disruptions or other restrictions and must scale back their operations unexpectedly we may not be able to enter into arrangements with alternative CROs in a timely manner or do so on commercially reasonable terms. In addition, our CROs may not prioritize our clinical trials relative to those of other customers. Further, any turnover in CRO personnel or delays in the allocation of CRO employees by the CRO may negatively affect our clinical trials. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, our clinical trials may be delayed or terminated, and we may not be able to meet our current plans with respect to our product candidates. In addition, CROs may ultimately involve higher costs than anticipated, which could negatively affect our financial condition and operations.

In addition, we rely on third-party manufacturers to produce our clinical-stage product candidates, and their responsibilities often include purchasing from third-party suppliers the materials necessary to produce our product candidates for our clinical trials and regulatory approval. These purchases and this supply chain may be disrupted due to geopolitical conflicts, changes in international trade policies, boycotts, tariffs or embargoes. There are a limited number of suppliers for some of the raw materials that we expect to use to manufacture our product candidates, and we may not be able to identify alternative suppliers to prevent a possible disruption of the manufacture of our product candidates for our clinical trials, and, if approved, ultimately for commercial sale.

Although we generally do not expect to begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the trial, any significant delay or discontinuity in the supply of a product candidate, or the raw materials or other material components in the manufacture of the product candidate, could delay completion of our clinical trials and potential timing for regulatory approval of our product candidates, which would harm our business and results of operations. We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of our product candidates and our current costs to manufacture our product candidates may not be commercially feasible. As a result, we may never be able to develop a commercially viable product.

In addition, our reliance on third-party manufacturers exposes us to the following additional risks:

- we may be unable to identify manufacturers to manufacture our product candidates on acceptable terms, or at all, because the number of qualified potential manufacturers is limited. Following NDA approval, a change in the manufacturing site could require additional approval from the FDA. This approval would require new testing and compliance inspections;
- our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- our third-party manufacturers might be forced to scale back or terminate operations as a result of labor shortages, inflation, natural disasters, changes in trade policies (including tariffs) or geopolitical conflicts, which could harm our ability to conduct ongoing and future clinical trials of our product candidates;
- our future third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our product candidates;
- drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMPs and other government regulations and corresponding foreign standards, and we do not have control over third-party manufacturers' compliance with these regulations and standards;
- if any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own or be able to license, or we may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates; and
- our third-party manufacturers could breach or terminate their agreements with us.

Each of these risks could delay our clinical trials, the approval, if any, of our product candidates, or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. In addition, we rely on third parties to perform release testing on our product candidates prior to delivery to subjects in our clinical trials. If these tests are not appropriately conducted and test data are not reliable, subjects in our clinical trials, or patients treated with our product candidates, if any are approved in the future, could be put at risk of serious harm, which could result in product liability suits.

Our employees, independent contractors, principal investigators, CROs, consultants or vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants or vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA; manufacturing standards; federal and state healthcare fraud and abuse laws and regulations; or laws that require the true, complete and accurate reporting of financial information or data. 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 also involve the improper use or misrepresentation of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and serious harm to our reputation.

It is not always possible to identify and deter misconduct by our 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 be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person 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, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished potential profits and future earnings and curtailment of our operations, any of which could adversely affect our business, financial condition, results of operations or prospects.

Because we rely on third-party manufacturing and supply vendors, our supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.

We rely on third-party contract manufacturers to manufacture our product candidates for preclinical studies and clinical trials. We do not own manufacturing facilities for producing any clinical trial product supplies. There can be no assurance that our preclinical and clinical development product supplies will not be limited or interrupted, or that they will be of satisfactory quality or continue to be available at acceptable prices. The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. In the event that any of our manufacturers fails to comply with these requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third-party, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills or technology to a back-up or alternative supplier, or we may not be able to transfer such skills or technology at all. Furthermore, a manufacturer may possess technology related to the manufacture of our product candidate that such manufacturer owns independently. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our product candidates.

We have historically relied on a sole supplier for the manufacture of GRI-0621. If this supplier is unable to supply us the quantities we require, or at all, or otherwise defaults on their supply obligations to us, we may not be able to obtain alternative supplies from other suppliers on acceptable terms, in a timely manner, or at all. Moreover, in the event this supplier breaches its contracts with us, our legal remedies associated with such a breach may be insufficient to compensate us for any damages we may suffer. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturer or manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for GRI-0621, GRI-0803 or any other product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully.

We may enter, or attempt to enter, into collaborations with third parties for the development and commercialization of our product candidates, and our future collaborations will be important to our business. If we are unable to enter into collaborations that we deem beneficial, or if these collaborations are not successful, our business could be adversely affected.

A part of our strategy is to consider partnerships in indications and geographies where we believe partners can add significant commercial and/or development capabilities and, potentially, in an effort to further development of our product candidates or maximize value for our product candidates. As noted above, we do not yet have any capability for commercialization and will need to raise substantial additional capital or resources to complete a Phase 2b clinical trial of GRI-0621. Accordingly, we have and may in the future enter into collaborations with other companies to provide us with important technologies and funding for our programs and technology. Any future collaborations we enter into may pose a number of risks, including that (i) collaborators may have significant discretion in determining the efforts and resources that they will apply and may not perform their obligations as expected, (ii) collaborators may not provide us with timely and accurate information regarding development progress and activity under any future license agreement, which could adversely impact our ability to report progress to our investors and otherwise plan development of our product candidates, and (iii) we may have disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development. These circumstances might cause delays or terminations

of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive. In addition, collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates than we would otherwise expect.

We face significant competition in seeking appropriate collaborators for our product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully establish a collaboration for one or more of our product candidates, potential collaborators must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available products for licensing by other companies. Collaborations are complex and time-consuming to negotiate and document. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into future collaborations or do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates, bring them to market and generate revenue from sales of drugs or continue to develop our technology, and our business may be materially and adversely affected. Even if we are successful in our efforts to establish new strategic collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any delay in entering into new strategic collaboration agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

Risks Related to Managing Our Business and Operations

If we lose key management personnel, or if we fail to recruit and retain additional highly skilled personnel, our ability to develop current product candidates or identify and develop new product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.

Our ability to compete in the highly competitive biotechnology and biopharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including W. Marc Hertz, Ph.D., our President and Chief Executive Officer, Vipin Kumar, Ph.D., our Chief Scientific Officer and Albert Agro, our Chief Medical Officer. Our key employees are at-will employees, which means that any of our employees could leave our employment at any time, with or without notice. Further, we do not currently have “key person” insurance for our members or management. There is no guarantee that any “key person” insurance policy we would have or may enter into would adequately compensate us for the loss of any key employee. The further loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.

We have modified our employment arrangements with Dr. Agro. On June 16, 2024, our Board approved an amendment to Dr. Agro’s employment agreement, which reduced Dr. Agro's service for us to at least 70 hours per month. Dr. Agro may devote the balance of his time to other consulting or employment activities. The further loss or loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity awards that vest over time. The value to employees of equity awards that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice.

The biotechnology industry has also experienced a high rate of turnover in recent years. Our ability to compete in the highly competitive biopharmaceuticals industry depends upon our ability to attract, retain, and motivate highly skilled and experienced personnel with scientific, medical, regulatory, manufacturing and management skills and experience. We may not be able to attract or retain qualified personnel in the future due, in part, to the intense competition for a limited number of qualified personnel among biopharmaceutical companies. We conduct our operations at our facility in La Jolla, California. This region is headquarters to many other biotechnology companies, biopharmaceutical companies,

and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. Many of the other biopharmaceutical companies against which we compete or will compete have greater financial and other resources, different risk profiles and a longer history in the industry. Our competitors may provide higher compensation, more diverse opportunities and/or better opportunities for career advancement. Any or all of these competing factors may limit our ability to continue to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize our product candidates and to grow our business and operations as currently contemplated.

We may be unable to adequately protect our internal information systems, or those used by our CROs, clinical sites or other contractors or consultants upon which we rely, from cyberattacks, compromises, cybersecurity incidents or other disruptions, which could result in the compromise of confidential, sensitive or proprietary information, lead to operational or service interruption, harm our reputation and subject us to litigation, fines and other significant financial and legal exposure and other material and adverse consequences.

In the ordinary course of our business, we, and the third parties upon which we rely, process confidential, sensitive and proprietary information and, as a result, we and the third parties upon which we rely face a variety of evolving threats which could cause material cybersecurity incidents.

Despite our implementation of security measures, our internal computer systems and those of our CROs, clinical sites and other collaborators, contractors or consultants upon which we rely are vulnerable to cyberattacks, computer viruses, malware, bugs, worms or other malicious code, software or hardware failures, loss of data or other information technology assets, phishing or other unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, and other similar threats. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel, such as through theft or misuse, sophisticated nation states and nation-state-supported actors. In particular, ransomware attacks, including those from organized criminal threat actors, nation-states and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays or outages in our operations, loss of data, including significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the negative impact of a ransomware attack, it may be preferable to make payments to the threat actor(s), but we may be unwilling or unable to do so, including, for example, if applicable laws or regulations prohibit such payments.

Some threat actors also now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors, for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties upon which we rely, and our customers may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks that could materially disrupt our systems and operations. In addition to experiencing a cybersecurity incident, third parties may gather, collect or infer sensitive information about us from public sources, data brokers or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or research and development activities.

Additionally, remote work increases risks to our information technology systems and data, as our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

While we take steps to detect and remediate vulnerabilities, we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit such vulnerabilities change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a cybersecurity incident has occurred, if at all. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

We rely on third-party service providers and critical business information technology systems that we or our third-party service providers operate to process, transmit and store confidential, sensitive, and proprietary information in our day-to-day operations. We also rely on third-party service providers to assist with our clinical trials, provide other products or services, or otherwise to operate our research and development activities. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a cybersecurity incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition and in general, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have

not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems, including our services, or the third-party information technology systems that support us and our services.

Any of the previously identified or similar threats could cause a cybersecurity incident or other interruption that could result in unauthorized, unlawful or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of or access to our confidential, proprietary or sensitive data or to our information technology systems, or those of the third parties upon whom we rely. A cybersecurity incident or other interruption could materially and adversely disrupt our ability, and that of third parties upon whom we rely, to conduct clinical trials and our research and development activities.

The costs related to significant cybersecurity breaches or disruptions could be material and cause us to incur significant expenses. If the information technology systems of our CROs, clinical sites and other contractors and consultants become subject to disruptions or cybersecurity incidents, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

Any such incident could also result in a disruption of our development programs and our operations, financial loss, a loss of our trade secrets or other proprietary information and damage to our reputation and otherwise negatively impact us. For example, the loss of clinical trial data from ongoing or future clinical trials 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 cybersecurity incident were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential, sensitive or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. Applicable data privacy and security obligations may require us to notify relevant stakeholders, regulatory authorities and other individuals of cybersecurity incidents, and take other remedial measures. Such disclosures and measures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. Any such event could also result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant regulatory penalties and damage to our reputation and a loss of confidence in us and our ability to conduct clinical trials, which could delay the clinical development of our product candidates.

Our current operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster, including earthquakes, outbreak of disease or other natural disasters.

Our current operations are located in our facilities in La Jolla, California. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemic, power shortage, telecommunication failure or other natural or manmade accident or incident that results in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Some of these natural events may be exacerbated by climate change. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption or disruption of our business operations, all of which could have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented or interrupted us from using all or a significant portion of our headquarters, damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or 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 and procedures 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 any failure or inadequacy of our disaster recovery and business continuity plans and procedures, which, could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at reasonable levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of our insurance coverage will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed or delayed.

Our business could be adversely affected by the effects of health pandemics or epidemics in regions where it or third parties on which it relies have significant manufacturing facilities, concentrations of clinical trial sites, or other business operations.

Our business could be adversely affected by the effects of health pandemics or epidemics in regions where it has concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of third-party manufacturers and CROs upon whom it relies. Such pandemics or epidemics may negatively impact productivity, disrupt business and delay clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of any restrictions and other limitations placed on our ability to conduct business in the ordinary course as a result of any such pandemic or epidemic. These and similar disruptions in operations could negatively impact our business, operating results and financial condition.

Quarantines, stay at home and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, may impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which could disrupt our supply chain. While many of these materials may be obtained by more than one supplier, restrictions resulting from any pandemic may disrupt our supply chain or limit our ability to obtain sufficient materials for our product candidates.

Our insurance may not provide adequate levels of coverage against claims which may adversely affect our financial condition.

We maintain insurance that we believe is adequate for businesses of our size and type. However, there are types of losses that we believe are not economically reasonable to insure or that cannot be insured against.

It is possible that we may be subject to securities litigation in the future, including potential class action or stockholder derivative actions. Our indemnification agreements with our directors and certain officers, as well as the General Corporation Law of the State of Delaware (DGCL), may require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. If such liabilities are not adequately covered by director and officer liability insurance, the amounts we would pay to defend any such litigation or indemnify our officers and directors should they be subject to legal action based on their service to us could have a material adverse effect on our financial condition, results of operations and liquidity.

Risks Related to Our Common Stock, Financing and Capital Requirements

We expect the stock price of our Common Stock to be highly volatile.

The market price of shares of our Common Stock has been and is likely to continue to be subject to significant fluctuations. Market prices for securities of biotechnology and other life sciences companies historically have been particularly volatile subject even to large daily price swings. Some of the factors that may cause the market price of shares of our Common Stock to fluctuate include, but are not limited to:

- our ability to obtain timely regulatory approvals for future product candidates, and delays or failures to obtain such approvals;
- our ability to comply with the listing requirements of The Nasdaq Capital Market and any delisting or potential delisting of shares of our Common Stock;
- failure of product candidates, if approved, to achieve commercial success;
- issues in manufacturing future product candidates;
- the results of current and any future clinical trials;
- the entry into, or termination of, or breach by partners of collaboration or strategic agreements;
- the initiation of, material developments in, or conclusion of any litigation to enforce or defend any intellectual property rights or defend against the intellectual property rights of others;
- announcements of any dilutive equity financings and significant issuances of equity securities;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- failure to elicit meaningful stock analyst coverage and downgrades of our stock by analysts;

- short selling by investors or third parties and related market activity; and
- the loss of key employees.

Moreover, the stock markets in general have experienced substantial volatility in the biotechnology industry that has often been unrelated to the operating performance of individual companies or a certain industry segment. These broad market fluctuations may also adversely affect the trading price of our Common Stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation. Such litigation, if brought, could negatively impact our business.

Future sales and issuances of our securities could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations, including research and development, increased marketing, hiring new personnel, commercializing our products and continuing activities as an operating public company. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell shares of our 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. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

As of December 31, 2025, there were a total of (i) 19 shares of Common Stock directly or indirectly underlying Series B-1 common warrants (the Series B-1 Common Warrants) and Series B-2 common warrants (the Series B-2 Common Warrants, and together with the Series B-1 Common Warrants, the Series B Common Warrants), (ii) 9,186 shares of Common Stock directly or indirectly underlying Series C-1 common warrants (the Series C-1 Common Warrants) and Series C-2 common warrants (the Series C-2 Common Warrants, and together with the Series C-1 Common Warrants, the Series C Common Warrants), (iii) 3,208 shares of Common Stock directly or indirectly underlying Series D-1 common warrants (the Series D-1 Common Warrants) and Series D-2 common warrants (the Series D-2 Common Warrants, and together with the Series D-1 Common Warrants, the Series D Common Warrants), (iv) 148,815 shares of Common Stock directly or indirectly underlying the Series E Common Warrants, (v) 380,962 shares of Common Stock directly or indirectly underlying the Series F Common Warrants, (vi) 30,593 shares of Common Stock directly or indirectly underlying other outstanding warrants to purchase Common Stock, (vii) 11,127 shares of Common Stock issuable upon the exercise of vested outstanding options under the Company's Amended and Restated 2018 Equity Incentive Plan, as amended (A&R 2018 Plan), (viii) an additional 3,905 shares of Common Stock issuable upon the exercise of options that remain subject to vesting as of that date and (ix) 12 share of Common Stock available for future issuance under the A&R 2018 Plan.

We will not receive any proceeds from the exercise of warrants to the extent exercised on a cashless basis. The holders of these securities or their affiliates have and may sell large amounts of our Common Stock in the open market or in privately negotiated transactions, which, we believe has in the past and again, may result in a lower trading price of our Common Stock and substantial dilution to our stockholders. Additionally, the registration and availability of such a significant number of shares of Common Stock for trading in the public market, whether through the exercise of warrants or though our equity incentive plan, may increase the volatility in our stock price or put significant downward pressure on the price of our Common Stock.

We do not anticipate paying any dividends in the foreseeable future.

Our current expectation is that we will retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of the shares of our Common Stock will be our stockholders' sole source of gain, if any, for the foreseeable future.

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

As a public company, we incur significant legal, accounting and other expenses under the Exchange Act, the Sarbanes-Oxley Act of 2002, as amended (SOX) and other applicable securities rules and regulations. In addition, we are subject to the rules of Nasdaq and The Nasdaq Capital Market.

These rules impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs in recent years and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. In addition, the listing requirements of The Nasdaq Capital Market require that we satisfy certain corporate governance requirements relating to director independence, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel need to devote a substantial amount of time and resources in an effort to ensure that we comply with all of these requirements.

Management has determined that our internal controls were not effective as of December 31, 2024, March 31, 2025, June 30, 2025, September 30, 2025, and December 31, 2025 due to material weaknesses. We have remediated one material weakness and, resources permitting, plan to implement a plan to remediate the remaining material weakness. However, our efforts at remediation may be unsuccessful and the implementation of additional remediation is dependent upon additional resources and funding being available to us. If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

SOX requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. As a result, we are required to periodically perform an evaluation of our internal controls over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404 of SOX (Section 404). Additionally, and depending on our filing status, our independent auditors may be required to perform a similar evaluation and report on the effectiveness of our internal controls over financial reporting. These efforts to comply with Section 404 and related regulations have required, and continue to require, the commitment of significant financial and managerial resources. Based on management's processes and assessment, management has concluded that, as of December 31, 2024, March 31, 2025, June 30, 2025, September 30, 2025 and December 31, 2025 our internal control over financial reporting was not effective as a result of material weaknesses. In its evaluation, our principal financial officer used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013). These criteria are in the areas of control environment, risk assessment, control activities, information and communication and monitoring. Management's assessment included documenting, evaluating and testing the design and operating effectiveness of our internal controls over financial reporting. A material weakness in an internal control is defined as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

For the periods ending December 31, 2024 through September 30, 2025, the material weakness related to the inaccurate computation of the non-cash deemed dividend associated with the repricing of the Series B Common Warrants in accordance with applicable accounting principles generally accepted in the United States (GAAP) guidance. The amounts presented in our balance sheets, statements of changes in stockholders' equity (deficit) and statements of cash flows were not affected. This adjustment was corrected prior to the finalization of our Annual Report on Form 10-K for the year ended December 31, 2024 filed with the SEC on March 14, 2025. This inaccurate computation, if it had remained undetected, would have resulted in a single-digit percentage error in the amount of the net loss attributable to holders of our Common Stock used to compute basic and diluted net loss per share of Common Stock. To remediate this material weakness, we implemented a plan which included the (i) continued engagement of third-party professionals with appropriate expertise in accounting and reporting under GAAP and SEC regulations who have adequate experience related to non-recurring debt and equity transactions and (ii) the enhancement of our documentation procedures related to the accounting treatment for such transactions. These third-party professionals now assist in reviewing the attendant calculations/additional controls regarding the evaluation of non-recurring debt and equity transactions, and assist in reviewing the documentation and related documentation procedures for such transactions. Our management also refined our processes for communicating with our auditor as to when our financial statements and related materials have passed through the Company's internal control processes. As a result, our management has determined that this material weakness has been remediated.

However, during its evaluation of our internal controls for the period ending December 31, 2025, management determined there was an additional material weakness in our internal controls over financial reporting. This material weakness is related to the inherent limitations of the accounting software used to prepare our financial statements and the limited number of accounting personnel we employ. As a result of these software limitations and the limited number of accounting personnel, we determined that we have insufficient segregation of duties over the initiation, approval and recording of certain financial transactions. While we have implemented multiple compensating controls to mitigate these

limitations, management has concluded that these compensating controls are not sufficient to preclude a material weakness as a result of this insufficiency of segregation of duties. Thus, management determined that our internal controls over financial reporting were not effective as of December 31, 2025. Management has evaluated, and continues to evaluate, avenues for mitigating this material weakness, such as the retention of additional accounting personnel and/or the procurement of alternative accounting software, but these avenues have been deemed to be impractical and prohibitively costly, due to the size of our organization and resources available at the current time. Management expects to continue to utilize the compensating controls in place to mitigate the segregation of duty weakness and will seek to improve on such controls as reasonably possible, until such time as our resources allow for further remediation.

However, we cannot be certain that we will ever have sufficient resources to remediate this material weakness or that the compensating controls we have implemented will operate as expected or prevent future misstatements or errors in our financial reporting. Further, we cannot be certain that additional new material weaknesses will not be identified when we again test the effectiveness of our control systems in the future or that our remediation efforts will be or remain successful. If additional material weaknesses are identified or if we are unable to remediate our current material weakness, we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal controls, which could have an adverse effect on the market price of our stock.

We currently take advantage of reduced disclosure and governance requirements applicable to smaller reporting companies, which could result in our Common Stock being less attractive to investors.

We have a public float of less than $250.0 million and therefore qualify as a smaller reporting company under SEC rules. As a smaller reporting company, we are able to take advantage of reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements in our SEC filings. We are also not currently required to retain our independent auditors to attest to our internal controls. Decreased 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 if we rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile. We may take advantage of the reporting exemptions applicable to a smaller reporting company until we are no longer a smaller reporting company, which status would end once we have a public float greater than $250.0 million. In that event, we could still be a smaller reporting company if our prior fiscal year's annual revenues were below $100.0 million and we had a public float of less than $700.0 million.

We also take advantage of reduced disclosure and governance requirements applicable to emerging growth companies, which could result in our Common Stock being less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. Emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. As an emerging growth company, we are not being required to comply with the auditor attestation requirements of Section 404, we have reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and we are exempt from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Additionally, as an emerging growth company, we have elected to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As such, our financial statements may not be comparable to companies that comply with public company effective dates. We cannot predict if investors will find our stock less attractive because we may rely on these provisions. If some investors find our stock less attractive as a result, there may be a less active trading market for our shares and our stock price may be more volatile.

We will remain an emerging growth company until the earliest of (i) the end of the fiscal year in which the market value of our Common Stock that is held by non-affiliates exceeds $700 million as of the end of the second fiscal quarter, (ii) the end of the fiscal year in which we have total annual gross revenues of $1.235 billion or more during such fiscal year, (iii) the date on which we issue more than $1 billion in non-convertible debt in a three-year period or (iv) the end of the fiscal year following the fifth anniversary of the date of the first sale of our Common Stock pursuant to an effective registration statement filed under the Securities Act (December 31, 2026).

A delisting of our Common Stock from Nasdaq could adversely affect our ability to raise additional capital through the public or private sale of equity securities and our investors' ability to dispose of, or obtain accurate quotations as to the market value of, our Common Stock.

The rules of The Nasdaq Capital Market require that we maintain a closing price for shares of our Common Stock of at least $1.00 per share under the "Minimum Bid Price Rule" and that we meet other requirements for continued listing which include, among other things, requirements that we maintain a market value of listed securities of at least $35 million or, alternatively, stockholders' equity of at least $2.5 million, or, alternatively, annual net income from continuing operations of at least $500 thousand, as described in applicable listing requirements. As of the date of this Annual Report, the market value of our listed securities was less than $35 million, and we had not earned net income in excess of $500 thousand.

On November 26, 2025, we received a letter from the Staff of Nasdaq notifying us that we were not in compliance with the Stockholders' Equity Requirement for continued listing on The Nasdaq Capital Market (the Notice) based on the information provided in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2025. In accordance with Nasdaq rules, we were provided 45 calendar days, or until January 10, 2026, to submit a plan to regain compliance with the Stockholders' Equity Requirement (the Compliance Plan). Based on a subsequent notification from the Staff received on January 15, 2026, the Staff has deemed that we now conditionally comply with the Stockholders' Equity Requirement, but if we fail to demonstrate the requisite $2.5 million in future Exchange Act reports, shares of our Common Stock may be subject to delisting.

In order to remain listed on the Nasdaq Capital Market, shares of our Common Stock must also satisfy the Minimum Bid Price Rule set forth in Nasdaq Listing Rule 5550(a)(2) which requires that the closing bid price for our Common Stock remain above $1.00 per share. From early December and until January 26, 2026, the closing bid price of our Common Stock was less than $1.00 per share.

On January 21, 2026, we filed an amendment to our Charter to implement a reverse stock split of our Common Stock at a ratio of one-for-28 (the January 2026 Reverse Stock Split) in an attempt to maintain compliance with the Minimum Bid Price Rule. However, we may ultimately fail to maintain long-term compliance with the Minimum Bid Price Rule. We previously effected two reverse stock splits in 2024 prior to receiving a letter from Nasdaq in September 2024 and another in February 2025. As of the date of this Annual Report, we have exceeded the limits imposed by Nasdaq on reverse stock splits should we again fail to comply with the Minimum Bid Price Rule. Generally, listed companies may not complete more than one reverse split in a year or reverse splits with a cumulative ratio in excess of 250 in a two-year period and still be eligible for a compliance period or additional time to comply with deficiencies in connection with the Minimum Bid Price Rule. If the closing price of shares of our Common Stock is less than $1.00 for 30 consecutive trading days, the shares of our Common Stock will be subject to delisting.

If our Common Stock is delisted by Nasdaq, our Common Stock may be eligible to trade on the OTC Markets or another over-the-counter market, but a delisting, threatened delisting or trading on these markets would likely result in it being more difficult for us to raise additional capital through the public or private sale of equity securities and for investors to dispose of, or obtain accurate quotations as to the market value of, our Common Stock. In addition, there can be no assurance that our Common Stock would be eligible for trading on any such alternative exchange or markets.

Unless our Common Stock is listed on a national securities exchange, such as The Nasdaq Capital Market, our Common Stock may also be subject to the regulations and restrictions regarding trading in "penny stocks," which are those securities trading for less than $5.00 per share, and that are not otherwise exempted from the definition of a penny stock under other exemptions provided for in the applicable regulations. These requirements and regulations could severely limit the liquidity of securities in the secondary market because fewer brokers or dealers would likely to be willing to undertake related compliance activities. If our Common Stock is not listed on a national securities exchange, the rules and restrictions regarding penny stock transactions may limit an investor's ability to sell to a third-party and our trading activity in the secondary market may be reduced.

Any of these or the above circumstances could adversely affect our business, results of operation, prospects and the value of shares of our Common Stock. A delisting for any of the aforementioned reasons could materially affect our ability to raise capital, adversely affect our business and the price of our Common Stock.

The January 2026 Reverse Stock Split may have caused our stock price to decline relative to its value before the split and likely has reduced the liquidity of shares of our Common Stock.

We legally effected the January 2026 Reverse Stock Split on January 23, 2026 and, on January 26, 2026, our Common Stock began trading on a post-split basis. The January 2026 Reverse Stock Split may not result in a long-term sustained

proportionate increase in the market price of our Common Stock. Additionally, the trading volume of our shares following the reverse stock splits completed since 2023 has varied, and shares of our Common Stock have been less liquid as a result of these reverse stock splits. It is likely that the liquidity of the shares of our Common Stock will be affected adversely by the January 2026 Reverse Stock Split given the reduced number of shares outstanding following the January 2026 Reverse Stock Split. There can be no assurance that the liquidity of our Common Stock will increase now, following any future stock splits or otherwise.

Changes in tax law could adversely affect our business.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by the Internal Revenue Service (IRS), the U.S. Treasury Department and other governmental bodies. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our Common Stock. In recent years, many such changes have been made, including, most recently, under OBBBA, which President Trump signed into law on July 4, 2025, and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations.

An active trading market for our Common Stock may not develop, and our stockholders may not be able to resell their shares of Common Stock for a profit, if at all.

An active trading market for our shares of Common Stock may never develop or be sustained. If an active market for our Common Stock does not develop or is not sustained, it may be difficult for our stockholders to sell their shares at an attractive price or at all.

If equity research analysts do not publish research or reports, continue to publish reports or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our Common Stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may not elect to provide research coverage of our Common Stock or may elect to discontinue coverage of our Common Stock, and such lack of research coverage may adversely affect the market price of our Common Stock. We do not have any control over the analysts, or the content and opinions included in their reports. The price of our Common Stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research or discontinue coverage of our Common Stock. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our Common Stock could decrease, which in turn could cause our stock price or trading volume to decline.

We may become a defendant in one or more stockholder derivative or class-action litigations, and any such future lawsuit may adversely affect our business, financial condition, results of operations and cash flows.

We and certain of our officers and directors may become defendants in one or more future stockholder derivative actions or other class-action lawsuits. These lawsuits would divert our management's attention and resources from our ordinary business operations, and we would likely incur significant expenses associated with their defense (including, without limitation, substantial attorneys' fees and other fees of professional advisors and potential obligations to indemnify current and former officers and directors who are or may become parties to such actions). If these lawsuits do arise, we may be required to pay material damages, consent to injunctions on future conduct and/or suffer other penalties, remedies or sanctions. In addition, any such future stockholder lawsuits could adversely impact our reputation, our ability to continue to develop our product candidates, thereby harming our ability to generate revenue. Accordingly, the ultimate resolution of these matters could have a material adverse effect on our business, financial condition, results of operation and cash flow and, consequently, could negatively impact the trading price of our Common Stock.

Our Charter documents and Delaware law may inhibit a takeover that stockholders consider favorable.

Certain provisions of our Charter and our amended and restated bylaws (Bylaws) and applicable provisions of Delaware law may delay or discourage transactions involving an actual or potential change in control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. The provisions in our Charter and Bylaws:

- limit who may call stockholder meetings;
- do not provide for cumulative voting rights;
- provide that all vacancies may be filled only by the affirmative vote of a majority of directors then in office, even if less than a quorum;

- provide that the Court of Chancery of the State of Delaware will be the exclusive forum for certain legal claims; and
- provide that the federal district courts of the United States of America will be the exclusive forum for legal claims under the Securities Act.

In addition, Section 203 of the DGCL may limit our ability to engage in any business combination with a person who beneficially owns 15% or more of our outstanding voting stock unless certain conditions are satisfied. This restriction lasts for a period of three years following the share acquisition. These provisions may have the effect of entrenching our management team and may deprive stockholders' of the opportunity to sell their shares to potential acquirers at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our Common Stock.

Furthermore, our Charter specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claim for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers, and employees to our or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our Charter or our Bylaws or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. We believe these provisions provide increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, these provisions may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our Charter to be inapplicable or unenforceable in such action. This choice of forum provision does not preclude or contract the scope of exclusive federal jurisdiction for any actions brought under the Exchange Act. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction, and we do not intend for the exclusive forum provision to apply to Exchange Act claims. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Accordingly, there is uncertainty as to whether a court would enforce such a forum selection provision as written in connection with claims arising under the Securities Act. Additionally, this choice of forum provision will not apply to claims as to which the Court of Chancery of the State of Delaware does not have subject matter jurisdiction. The choice of forum provision in the Charter does not have the effect of causing our stockholders to have waived our obligation to comply with the federal securities laws and the rules and regulations thereunder.

Item 1B. UNRESOLVED STAFF COMMENTS.

None.

Item 1C. CYBERSECURITY.

Cybersecurity

We recognize the critical importance of maintaining the trust and confidence of patients, business partners and employees toward our business and are committed to protecting the confidentiality, integrity and availability of our business operations and systems. The Audit Committee of our Board (the Audit Committee) is actively involved in oversight of our risk management activities, and cybersecurity represents an important element of our overall approach to risk management. In general, we seek to address cybersecurity risks through a comprehensive approach that is focused on preserving the confidentiality, security and availability of the information that we collect and store by identifying, preventing and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

Cybersecurity Risk Management and Strategy; Effect of Risk

We face risks related to cybersecurity such as unauthorized access, cybersecurity attacks and other security incidents, including as perpetrated by hackers and unintentional damage or disruption to hardware and software systems, loss of data, and misappropriation of confidential information. To identify and assess material risks from cybersecurity threats, we maintain a cybersecurity program to ensure our systems are effective and prepared for information security risks, including regular oversight of our programs for security monitoring for internal and external threats to ensure the confidentiality and integrity of our information assets. We consider risks from cybersecurity threats alongside other company risks as part of our overall risk assessment process. As discussed in more detail under "Cybersecurity Governance; Management" below, the Audit Committee provides oversight of our cybersecurity risk management and strategy processes, which are led by our Chief Financial Officer.

To provide for the availability of critical data and systems, maintain regulatory compliance, manage our material risks from cybersecurity threats, and protect against and respond to cybersecurity incidents, we undertake the following activities:

- monitor emerging data protection laws and implement changes to our processes that are designed to comply with such laws;
- through our policies, practices and contracts (as applicable), require employees, as well as third parties that provide services on our behalf, to treat confidential information and data with care;
- employ technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality and access controls; and
- provide training for our employees regarding cybersecurity threats as a means to equip them with effective tools to address cybersecurity threats, and to communicate our evolving information security policies, standards, processes and practices.

Our incident response plan coordinates the activities we take to prepare for, detect, respond to and recover from cybersecurity incidents, which include processes to triage, assess severity for, escalate, contain, investigate and remediate the incident, as well as to comply with potentially applicable legal obligations and mitigate damage to our business and reputation.

Our processes also address cybersecurity threat risks associated with our use of third-party service providers who have access to employee data or our systems. In addition, cybersecurity considerations affect the selection and oversight of our third-party service providers.

We describe whether and how risks from identified cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, in Item 1A. under the heading "*We may be unable to adequately protect our internal information systems, or those used by our CROs, clinical sites, or other contractors or consultants upon which we rely, from cyberattacks, compromises, cybersecurity incidents, or other disruptions, which could result in the compromise of sensitive or proprietary information, lead to operational or service interruption, harm our reputation, and subject us to litigation, fines and other significant financial and legal exposure, and other adverse consequences,*" which disclosures are incorporated by reference herein.

In the last three fiscal years, we have not experienced any material cybersecurity incidents and the expenses we have incurred from cybersecurity incidents were immaterial. This includes penalties and settlements, of which there were none. The Company

does not believe that it has experienced any cybersecurity threats or incidents that have materially affected or that are reasonably likely to materially affect the Company or its operations.

Cybersecurity Governance; Management

Cybersecurity is an important part of our risk management processes and an area of focus for our Board and management. The Audit Committee is responsible for the oversight of risks from cybersecurity threats.

Our Audit Committee receives periodic updates from management about our cybersecurity threat risk management and strategy processes. Additionally, upon detection of a cybersecurity threat, our Audit Committee receives an update from management of our cybersecurity threat risk management and strategy processes, as well as the steps management has taken to respond to such identified cybersecurity threat. Our Board also receives prompt and timely information regarding any cybersecurity incident that meets establishing reporting thresholds, as well as ongoing updates regarding any such incident until it has been addressed

Our cybersecurity risk management and strategy processes, which are discussed in greater detail above, is managed by our Chief Financial Officer and supported by consultants with experience in managing information security, developing cybersecurity strategy, implementing effective information and cybersecurity programs as needed. As discussed above, the Chief Financial Officer reports to our Audit Committee about material cybersecurity threat risks.

Item 2. PROPERTIES.

Our executive offices are located at 2223 Avenida de La Playa #208, La Jolla, CA 92037, where we lease approximately 1,100 square feet of office space under a lease that expires in March 2027. We believe that our facilities are adequate to meet our current needs.

Item 3. LEGAL PROCEEDINGS.

We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results or financial condition. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have a material adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

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 is currently listed on The Nasdaq Capital Market under the symbol "GRI." As of January 29, 2026, there were 1,445,029 shares of Common Stock held by approximately 5 stockholders of record and no shares of preferred stock outstanding.

Securities Authorized for Issuance Under Equity Compensation Plans

See Part III, Item 12. "*Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*" for information relating to our equity compensation plans.

Recent Sales of Unregistered Securities

Not applicable.

Purchases of Equity Securities By the Issuer and Affiliated Purchasers

None.

Dividend Policy

We have not declared or paid any cash or other dividends on our Common Stock, and we do not expect to declare or pay any cash or other dividends in the foreseeable future.

Item 6. [RESERVED.]

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and related notes beginning on page F-1 of this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section entitled "Item 1A. Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" of this Annual Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained herein.

Overview

We are a clinical-stage biopharmaceutical company focused on discovering, developing, and commercializing innovative therapies that target serious diseases associated with dysregulated immune responses leading to inflammatory, fibrotic and autoimmune disorders. Our goal is to be an industry leader in developing therapies to treat these diseases and to improve the lives of patients suffering from such diseases.

Our product candidate, GRI-0621, is an oral inhibitor of type 1 iNKT cells. GRI-0621 is also an oral formulation of tazarotene, a synthetic retinoid acid receptor-beta and gamma selective agonist, that is approved in the United States for topical treatment of psoriasis and acne. While there are no approved oral formulations of tazarotene, as of December 31, 2025, it has been evaluated in over 1,700 patients as an oral product for up to 52-weeks. We are developing GRI-0621 for the treatment of severe fibrotic lung diseases such as IPF, a life-threatening progressive fibrotic disease of the lung that affects approximately 140,000 people in the United States, with up to 40,000 new cases per year in the United States. Some estimate that IPF affects 3 million globally. While there are currently two approved therapies for the treatment of lung fibrosis, neither has been associated with improvements in overall survival, and both therapies have been associated with significant side effects leading to poor therapeutic adherence. In preliminary and topline data from our trials to date with GRI-0621, and earlier trials with oral tazarotene, we have observed GRI-0621 to be well-tolerated and to inhibit iNKT cell activity in subjects. We and others have shown that activated iNKT are upregulated in IPF, primary sclerosing cholangitis, metabolic dysfunction-associated

steatohepatitis, alcoholic liver disease, SLE, MS, ulcerative colitis patients as well as other indications. In these patients activated iNKT cells are correlated with more severe disease.

We most recently evaluated GRI-0621 in a randomized, double-blind, multi-center, 2-arm Phase 2a clinical trial for the treatment of patients diagnosed with IPF. The primary endpoint for this Phase 2a trial was safety and tolerability of oral GRI-0621 as assessed by clinical labs, vital signs and adverse events after 12 weeks of treatment. Secondary endpoints were baseline changes in serum biomarkers, differentially expressed genes measured by ribonucleic acid sequencing (RNAseq), T cell receptor sequencing (TCRseq), and flow cytometry in PBMC samples collected at week six and week 12; an assessment of the PK of GRI-0621 at the week 12 visit of treatment (steady state); and a determination of the pharmacodynamic activity of oral GRI-0621 as measured by inhibition of immune cell activation in blood after six weeks and 12 weeks, and from BAL fluid after 12 weeks of treatment. Concurrently, a sub-study examined the number and activity of immune cells in BAL fluid in eight subjects (across various centers). Additional exploratory endpoints for the trial included assessment of the effect of GRI-0621 on pulmonary function at baseline and after six weeks and 12 weeks of treatment. 35 patients were enrolled in the trial and randomly assigned to a placebo arm and a GRI-0621 treatment arm, of which 19 patients completed treatment in the treatment arm and nine patients completed treatment in the placebo arm. Based on topline results available to date, the clinical trial met its primary endpoint and the secondary endpoints measured to date (as described below). Secondary and exploratory endpoints relating to additional flow cytometry data, TCRseq, and the pharmacodynamic activity of GRI-0621 are being evaluated as analyses become available.

No treatment related serious adverse events were reported for GRI-0621-treated subjects and adverse events were grade 2 (17%) or grade 3 (4%), with dry skin, dry lips, muscle and joint pain as the most common adverse events reported. There were no increases in cough (0% in the GRI-0621-treated arm compared to 25% in the placebo arm) or gastrointestinal disorders reported in the GRI-0621-treated arm compared to the placebo arm (diarrhea reported in 13% versus 33%, respectively). 80% of the subjects enrolled were taking background pirfenidone or nintedanib. No changes in liver enzymes, triglycerides or cholesterol were observed over 12 weeks in patients treated with GRI-0621 and standard of care.

Changes from baseline of serum biomarkers of type I, III and VI collagen in GRI-0621-treated subjects were suggestive of an anti-fibrotic effect, with decreases in biomarkers of fibrosis formation and increases in biomarkers of fibrosis resolution, including crosslinked type III collagen, observed after 12 weeks of treatment with GRI-0621. Changes from baseline in type IV collagen were suggestive of initiation of an alveolar basement membrane repair mechanism, an important step in repair of injured lung tissue. Reductions in neutrophil and macrophage activity (immune cell biomarkers upregulated in IPF and associated with disease progression) and downregulation of genes associated with fibrosis, disease progression and mortality were also observed in patients treated with GRI-0621 and standard of care.

Placebo-adjusted changes from baseline in FVC were observed to increase by 99 ml in the GRI-0621-treated arm and by 139 ml in the subset taking both GRI-0621 and standard of care compared to placebo plus standard of care. Breathing tests used to measure FVC are subject to large visit-to-visit variability and are dependent on the patient's effort, often resulting in data outliers. To minimize the impact of outliers in this FVC dataset, a *post hoc* data analysis was performed excluding the data points with the largest gain or loss in FVC over 12 weeks from both arms. The results of this analysis demonstrated an increase in placebo-adjusted change from baseline in FVC of 54 ml in the GRI-0621-treated arm and an increase of 81 ml in the subset taking both GRI-0621 and standard of care. Overall, 39% of GRI-0621 treated subjects experienced an increase in FVC at 12 weeks compared to 80% of subjects who experienced a decline in FVC at 12 weeks in the placebo-treated arm. GRI-0621-treated subjects also demonstrated increased TCR expression after 12 weeks of treatment compared with baseline or placebo-treated subjects receiving standard of care, suggestive of iNKT inactivation following GRI-0621 treatment. T cell subsets demonstrated increased type 1-associated cytokines (IFN-γ) and reduced type 2 (IL-4 and IL-13) and type 3-associated cytokines (IL-17A and IL-22) in both BAL and PBMC samples. Similarly, TGF-β was observed to be reduced after 12 weeks of GRI-0621 treatment in T cell subsets (e.g. Treg and Treg-like), B cells, monocytes, macrophages and neutrophils in BAL and PBMC samples compared to baseline or placebo-treated subjects receiving standard of care. GRI-0621 treatment also improved expression of genes associated with lung injury, fibroblast differentiation, extracellular matrix deposition, basement membrane repair, and type II alveolar epithelial cell-to-type I alveolar epithelial cell transition. The RNAseq data is supportive of and consistent with earlier reported serum biomarker and flow cytometry data.

Final results from this trial will be used to determine dose, safety sample size, clinically relevant endpoints and clinical trial duration in communication with the FDA in designing future trials. Based on these results and subject to FDA clearance and obtaining the requisite additional funding or resources we plan to initiate (either ourselves or with a strategic partner) a Phase 2b trial that could support an application for conditional approval of GRI-0621 in the European Union and could have the potential to be regarded as a registrational trial in the United States.

Our product candidate portfolio also includes GRI-0803 and a proprietary library of 500+ compounds. GRI-0803, the lead molecule selected from the library, is a novel oral agonist of type 2 diverse Natural Killer T cells and would be developed for the treatment of autoimmune disorders, with much of our preclinical work in SLE or lupus and MS. In lupus, the immune system mistakenly attacks its own healthy tissues, especially joints and skin, but can affect almost every organ and tissue of the body. The condition can be fatal and often causes debilitating bouts of fatigue and pain that prevent nearly half of adult patients from working. Lupus affects between 160,000 - 200,000 patients in the United States, with around 80,000 – 100,000 patients in the United States suffering from kidney nephritis, one of the most serious manifestations of SLE, typically within five years of diagnosis. There is no cure for lupus, but medical interventions and lifestyle changes can help control it. SLE treatment consists primarily of immunosuppressive drugs that inhibit the activity of the immune system. Only two drugs have been approved for lupus in the past 50 years, and new treatment options are sorely needed. In order to focus our resources on our GRI-0621 program, we previously limited our development of GRI-0803 pending additional funding. We intend to complete IND-enabling studies and file an IND application to evaluate GRI-0803 in a Phase 1a and 1b trial in healthy volunteers in 2026. We expect to continue to evaluate indications to select the best fit for further development of the program, but our initial focus would be on lupus.

Recent Developments

Reverse Stock Splits

On January 15, 2026, our stockholders approved the January 2026 Reverse Stock Split within a range of not less than one-for-two and not more than one-for-30, and our Board subsequently approved the January 2026 Reverse Stock Split at the ratio of one-for-28. Following these approvals, we filed an amendment to our Charter with the Secretary of State of the State of Delaware to effect the January 2026 Reverse Stock Split as of 4:01 p.m. Eastern Time on January 23, 2026. Shares of our Common Stock began trading on a post-split basis on January 26, 2026. The January 2026 Reverse Stock Split had the effect of reducing the aggregate number of outstanding shares of Common Stock from 15,960,229 outstanding shares on a pre-reverse split basis as of January 23, 2026 to a total of 570,002 shares outstanding on a post-reverse split basis as of January 23, 2026.

Previously, on January 29, 2024, we effected a reverse stock split of our Common Stock at a ratio of one-for-seven, on June 17, 2024, we effected a reverse stock split of our Common Stock at a ratio of one-for-13 and on February 21, 2025 we effected a reverse stock split of our Common stock at a ratio of on-for seventeen.

Unless otherwise noted, all financial information, share numbers, option numbers, warrant numbers, other derivative security numbers and exercise prices appearing in this Annual Report have been adjusted to give effect to the reverse stock splits described herein.

December 2025 Securities Purchase Agreement

On December 11, 2025, we entered into a securities purchase agreement (the December 2025 Purchase Agreement), pursuant to which we issued and sold, in a public offering (the December 2025 Offering), (i) 92,976 shares (the December 2025 Shares) of Common Stock, (ii) 287,977 pre-funded warrants (the December 2025 Pre-Funded Warrants) exercisable for an aggregate of 287,977 shares of Common Stock and (iii) 380,962 Series F common warrants (the Series F Common Warrants) exercisable for an aggregate of 380,962 shares of Common Stock. The securities were offered in combinations of (a) one December 2025 Share or one December 2025 Pre-Funded Warrant, together with (b) one Series F Common Warrant, for a combined purchase price of $21.00 (less $0.0028 for each December 2025 Pre-Funded Warrant).

The December 2025 Pre-Funded Warrants were exercisable for one share of Common Stock at a price of $0.0028 per share, were exercisable immediately and expired when exercised in full. The Series F Common Warrants are exercisable into one share of Common Stock at a price per share of $21.00 and are immediately exercisable. The Series F Common Warrants will expire on December 12, 2030. As of December 31, 2025, all of the December 2025 Pre-Funded Warrants have been exercised.

H.C. Wainwright & Co., LLC (Wainwright) acted as the exclusive placement agent in the December 2025 Offering. Pursuant to an engagement agreement, we issued to Wainwright, or its designees, warrants to purchase up to an aggregate of 26,667 shares of Common Stock (the December 2025 PA Warrants). The December 2025 PA Warrants have an exercise price of $26.25 per share, will expire on December 12, 2030 and are currently exercisable.

April 2025 Securities Purchase Agreement

On April 1, 2025, we entered into a securities purchase agreement (the April 2025 Purchase Agreement), pursuant to which we issued and sold, in a public offering (the April 2025 Offering), (i) 7,214 shares (the April 2025 Shares) of Common Stock, (ii) 42,389 pre-funded warrants (the April 2025 Pre-Funded Warrants) exercisable for an aggregate of 42,389 shares of Common Stock, (iii) 49,605 Series E-1 common warrants (the Series E-1 Common Warrants) exercisable for an aggregate of 49,605 shares of Common Stock, and (iv) 49,605 Series E-2 common warrants (the Series E-2 Common Warrants) exercisable for an aggregate of 49,605 shares of Common Stock, and (v) 49,605 Series E-3 common warrants (the Series E Common Warrants, and together with the Series E-1 Common Warrants and the Series E-2 Common Warrants, the Series E Warrants) exercisable for an aggregate of 49,605 shares of Common Stock. The securities were offered in combinations of (a) one April 2025 Share or one April 2025 Pre-Funded Warrant, together with (b) one Series E-1 Common Warrant, one Series E-2 Common Warrant and one Series E-3 Common Warrant, for a combined purchase price of $100.80 (less $0.0028 for each April 2025 Pre-Funded Warrant).

The April 2025 Pre-Funded Warrants were exercisable for one share of Common Stock at a price of $0.0028 per share, were exercisable immediately and expired when exercised in full. Each Series E Common Warrant is exercisable into one share of Common Stock at a price per share of $89.60 and is immediately exercisable. The Series E-1 Common Warrants will expire on April 2, 2030. The Series E-2 Common Warrants will expire on October 2, 2026. The Series E-3 Common Warrants expired on January 2, 2026. As of December 31, 2025, all of the April 2025 Pre-Funded Warrants have been exercised.

Wainwright acted as the exclusive placement agent in the April 2025 Offering. Pursuant to an engagement agreement, we issued to Wainwright, or its designees, warrants to purchase up to an aggregate of 3,474 shares of Common Stock (the April 2025 PA Warrants). The April 2025 PA Warrants have an exercise price of $126.00 per share, will expire on April 1, 2030 and are currently exercisable.

October 2024 Repricing Letter Agreements

On October 21, 2024, we entered into letter agreements (the Repricing Letter Agreements) with certain holders (the Holders) of our issued and outstanding Series B-1 Common Warrants and Series B-2 Common Warrants to purchase an aggregate of 1,602 shares of our Common Stock, offering these Holders the opportunity to exercise all of their Series B Common Warrants for cash at an exercise price equal to $476.00 per share. In addition, these Holders received new unregistered Series D-1 Common Warrants exercisable for up to an aggregate of 1,604 shares of Common Stock and new unregistered Series D-2 Common Warrants exercisable for up to an aggregate of 1,604 shares of Common Stock. The Series D Common Warrants are immediately exercisable and have an exercise price of $476.00 per share. The Series D-1 Common Warrants expire on October 22, 2029, and the Series D-2 Common Warrants expire on April 22, 2026. We refer to this transaction as the "Warrant Repricing Transaction."

Wainwright acted as the exclusive placement agent for the Warrant Repricing Transaction pursuant to an engagement agreement between us and Wainwright, dated as of October 21, 2024. In addition to a cash fee, management fee, and reimbursement of certain accountable and non-accountable expenses, we also issued to Wainwright or its designees warrants to purchase up to an aggregate of 114 shares of Common Stock (the October 2024 PA Warrants) as compensation for its placement agent services. The October 2024 PA Warrants are immediately exercisable, expire on October 22, 2029 and have an exercise price of $595.00 per share.

June 2024 Securities Purchase Agreement

On June 26, 2024, we entered into a securities purchase agreement (the June 2024 Purchase Agreement), pursuant to which we issued and sold, in a public offering (the June 2024 Offering), (i) 126 shares (the June 2024 Shares) of Common Stock, (ii) 4,466 pre-funded warrants (the June 2024 Pre-Funded Warrants) exercisable for an aggregate of 4,466 shares of Common Stock, (iii) 4,593 Series C-1 common warrants (the Series C-1 Common Warrants) exercisable for an aggregate of 4,593 shares of Common Stock, and (iv) 4,593 Series C-2 common warrants (the Series C-2 Common Warrants, and together with the Series C-1 Common Warrants, the Series C Common Warrants) exercisable for an aggregate of 4,593 shares of Common Stock. The securities were offered in combinations of (a) one June 2024 Share or one June 2024 Pre-Funded Warrant, together with (b) one Series C-1 Common Warrant and one Series C-2 Common Warrant, for a combined purchase price of $871.08 (less $0.0476 for each June 2024 Pre-Funded Warrant).

The June 2024 Pre-Funded Warrants have been exercised in full. Each Series C-1 Common Warrant is exercisable into one share of Common Stock at a price per share of $871.08 and expires on September 6, 2029. Each Series C-2 Common Warrant is exercisable into one share of Common Stock at a price per share of $871.08 and expires on March 6, 2026.

Wainwright acted as the exclusive placement agent in the June 2024 Offering. Pursuant to an engagement agreement, we issued to Wainwright, or its designees, warrants to purchase up to an aggregate of 324 shares of Common Stock (the June 2024 PA

Warrants). The June 2024 PA Warrants have an exercise price of $1,088.92 per share, will expire on June 26, 2029 and are currently exercisable.

May 2024 At The Market Offering

On May 20, 2024, we entered into an At The Market Offering Agreement (the Sales Agreement) with Wainwright, pursuant to which we may sell and issue, subject to the limitations in the Sales Agreement, shares up to $10.0 million of our Common Stock from time to time through Wainwright as our sales agent (the ATM Offering). Under the Sales Agreement, Wainwright is entitled to compensation of 3.0% of the gross offering proceeds of all shares of Common Stock sold through it pursuant to the Sales Agreement.

As of December 31, 2025, we have sold 60,003 shares of our Common Stock in the ATM Offering at a weighted-average price of $102.75 per share, raising $6.2 million of gross proceeds and net proceeds of $5.9 million, after deducting commissions to the sales agent and other ATM Offering related expenses. On January 9, 2026, we filed a prospectus supplement to our registration statement on Form S-3 (File No. 333-279348) to increase the amount of shares of Common Stock that we may offer and sell under the Sales Agreement and applicable registration statement to an aggregate offering price of up to $7.4 million, which amount does not include the shares of Common Stock having an aggregate gross sales price of approximately $6.2 million that were sold under the ATM Offering through January 8, 2026, in accordance with the limitations set forth in Instruction I.B.6 of Form S-3. Since December 31, 2025, the Company has sold 947,342 shares of Common Stock with an aggregate gross sales price of $6,474.

February 2024 Securities Purchase Agreement

On February 1, 2024, we entered into a securities purchase agreement (the February 2024 Purchase Agreement), pursuant to which we issued and sold, in a public offering, (i) 53 shares (the February 2024 Shares) of Common Stock, (ii) 755 pre-funded warrants (the February 2024 Pre-Funded Warrants) exercisable for an aggregate of 755 shares of Common Stock, (iii) 809 Series B-1 Common Warrants exercisable for an aggregate of 809 shares of Common Stock, and (iv) 809 Series B-2 Common Warrants exercisable for an aggregate of 809 shares of Common Stock. The Series B Common Warrants together with the February 2024 Pre-Funded Warrants are referred to in this Annual Report as the February 2024 Warrants. The securities were offered in combinations of (a) one February 2024 Share or one February 2024 Pre-Funded Warrant, together with (b) one Series B-1 Common Warrant and one Series B-2 Common Warrant, for a combined purchase price of $6,806.80 (less $0.6188 for each February 2024 Pre-Funded Warrant).

The February 2024 Pre-Funded Warrants have been exercised in full. Each Series B-1 Common Warrant is exercisable into one share of Common Stock at a price per share of $6,806.80 and expires on February 6, 2029. Each Series B-2 Common Warrant is exercisable into one share of Common Stock at a price per share of $6,806.80 and expires on August 6, 2026.

In connection with the issuance of the February 2024 Shares and the February 2024 Warrants pursuant to the February 2024 Purchase Agreement, the exercise price of the Series A-1 Warrants was reduced to par, or $0.0001 per share, pursuant to the terms of the Series A-1 Warrants. All of the Series A-1 Warrants have been exercised in full.

Critical Accounting Policies

Our consolidated financial statements are prepared in accordance with GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. 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 the notes to our financial statements, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued Research and Development

We have entered into various agreements with CROs and other service providers. Our research and development accruals are estimated based on the level of services performed, progress of the studies, and contracted costs. The estimated costs of research and development provided, but not yet invoiced, are included in accrued expenses on the balance sheet. If the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the accrual

accordingly. Payments made to third parties under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered.

Stock-Based Compensation

We recognize expense for employee and non-employee stock-based compensation in accordance with ASC Topic 718, *Compensation-Stock Compensation* (ASC Topic 718). ASC Topic 718 requires that such transactions be accounted for using a fair value-based method. The estimated fair value of the options is amortized over the vesting period, based on the fair value of the options on the date granted, and is calculated using the Black-Scholes option-pricing model. We account for forfeitures as incurred.

Estimating the fair value of option shares issued under the employee stock purchase plan requires the input of subjective assumptions, including the estimated fair value of our Common Stock, the expected life of the options, stock price volatility, the risk-free interest rate and expected dividends. The assumptions used in our Black-Scholes option-pricing model represent management's best estimates and involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective. If any assumptions change, our stock-based compensation expense could be materially different in the future.

These assumptions used in our Black-Scholes option-pricing model are estimated as follows:

- *Expected Term*. Due to the lack of sufficient company-specific historical data, the expected term of employee options 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. The expected term of nonemployee options is equal to the contractual term.
- *Expected Volatility*. The expected volatility is based on a weighted-average of our historical volatility and the historical volatilities of similar entities within our industry which were commensurate with the expected term assumption as described in SAB No. 107.
- *Risk-Free Interest Rat*e. 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 assumed expected term.
- *Expected Dividends*. The expected dividend yield is 0% because we have not historically paid, and do not expect for the foreseeable future to pay, a dividend on our Common Stock.

Leases

We account for leases in accordance with Accounting Standards Update (ASU) 2016-02, *Leases (Topic 842)* and ASU 2018-10, *Codification Improvements to Topic 842, Leases*, and ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, both of which clarify and enhance the certain amendments made in ASU 2016-02. The ASUs increase transparency and comparability among entities by recognizing lease assets and lease liabilities on the balance sheet for all leases and disclosing key information about lease arrangements. We entered into one lease for office space which we determined was an operating lease.

Financial Operations Overview

Research and Development Expenses

Research and development expenses include personnel costs associated with research and development activities, including third party contractors to perform research, conduct clinical trials and manufacture drug supplies and materials.

Our research and development expenses have consisted primarily of costs related to our development program for our product candidate, GRI-0621. These expenses include:

- employee-related expenses, such as salaries, bonuses and benefits, consultant-related expenses such as consultant fees and bonuses, stock-based compensation, overhead-related expenses and travel-related expenses for our research and development personnel; and
- expenses incurred under agreements with contract research organizations, contract manufacturing organizations and research laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities as well as consultants that support the implementation of our clinical and non-clinical studies.

Although our direct research and development expenses are tracked by product candidate, we do not allocate employee costs and costs associated with our discovery efforts, laboratory supplies and facilities, including other indirect costs, to specific product candidates as these costs are deployed across multiple programs. We expect our research and development expenses to increase over the next several years as we conduct our planned clinical and preclinical activities for our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation and consulting related expenses for executives and other administrative personnel, professional fees and other corporate expenses, including legal and accounting fees, travel expenses, facilities-related expenses, and consulting services relating to corporate matters.

We expect our general and administrative expenses will continue to increase as we incur costs associated with being a public company, including expenses related to services associated with maintaining compliance with The Nasdaq Capital Market and SEC requirements, directors' and officers' insurance, legal and accounting costs and investor relations costs, as well as an increase in personnel expenses as we hire additional personnel.

Warrant Liability

In May 2022, Vallon issued warrants (the May 2022 Warrants) in connection with a securities purchase agreement. Vallon evaluated the May 2022 Warrants in accordance with ASC 815-40, *Derivatives and Hedging — Contracts in Entity's Own Equity* (ASC 815-40), and concluded that a provision in the May 2022 Warrants related to the reduction of the exercise price in certain circumstances precludes the May 2022 Warrants from being accounted for as components of equity. As a result, the May 2022 Warrants were measured at fair value upon issuance using a Black-Scholes valuation model and are recorded as a liability on the consolidated balance sheet. The fair value of the May 2022 Warrants is measured at each reporting date and changes in fair value are recognized in the consolidated statements of operations in the period of change.

Interest Income

Interest income consists of interest earned on our cash and cash equivalents held with institutional banks.

Recently Adopted Accounting Pronouncements

In December 2023, FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures.* The amendments in ASU 2023-09 are intended to enhance the transparency and decision usefulness of income tax disclosures through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. ASU 2023-09 is effective for annual periods beginning after December 15, 2024 for public entities, with early adoption permitted. We have adopted the provisions of ASU 2023-09 and have included the required disclosures in this Annual Report.

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): *Improvements to Reportable Segment Disclosures* (ASU 2023-07). This amended guidance applies to all public entities and aims to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. This guidance is effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. We have adopted the provisions of ASU 2023-07 and have included the required disclosures in this Annual Report.

Recently Issued Accounting Pronouncements

We consider the applicability and impact of all ASUs. ASUs not discussed below were assessed and determined to be either not applicable or are expected to have minimal impact on the financial statements.

In November 2024, FASB issued ASU 2024-03, *Income Statement — Reporting Comprehensive Income — Expense Disaggregation Disclosures (Subtopic 220-40)* (ASU 2024-03). The amendments in ASU 2024-03 require disclosure, in the notes to financial statements, of specified information about certain costs and expenses. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, for all public entities. Early adoption is permitted. We are currently evaluating the impact of this update on our consolidated financial statements.

In October 2023, FASB issued ASU 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative.* The amendments in ASU 2023-06 represent changes to clarify or improve disclosure and presentation requirements of a variety of topics in the Codification and align those requirements with the SEC's regulation. For entities subject to the SEC's existing disclosure requirements, the effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. For all entities, if by June 30, 2027, the SEC has not removed the applicable requirement from

Regulation S-X or Regulation S-K, the pending content of the related amendment will be removed from the Codification and will not become effective for any entity. We are currently evaluating the impact of this update and its effective dates but do not expect the update to have a material effect on our consolidated financial statements.

Smaller Reporting Company Status

We are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of any fiscal year for so long as either (1) the market value of our shares of Common Stock held by non-affiliates does not equal or exceed $250.0 million as of the prior June 30th, or (2) our annual revenues did not equal or exceed $100.0 million during such completed prior fiscal year and the market value of our shares of Common Stock held by non-affiliates did not equal or exceed $700.0 million as of the prior June 30th. To the extent we take advantage of any reduced disclosure obligations, it may make comparison of our financial statements with other public companies difficult or impossible.

Emerging Growth Company Status

We are an "emerging growth company," as defined in the JOBS Act and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not applicable to emerging growth companies. These exemptions include:

- reduced disclosure about our executive compensation arrangements;
- no non-binding stockholder advisory votes on executive compensation or golden parachute arrangements; and
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We have taken advantage of reduced reporting requirements in this report and may continue to do so until such time that we are no longer an emerging growth company. We will remain an "emerging growth company" until the earliest of (a) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more, (b) December 31, 2026, the last day of the fiscal year following the fifth anniversary of the completion of Vallon's initial public offering, (c) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years or (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period for complying with new or revised accounting standards.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

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

	Year Ended December 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 6,819	$ 3,768
General and administrative	5,158	4,467
Total operating expenses	11,977	8,235
Loss from operations	(11,977)	(8,235)
Change in fair value of warrant liability	—	3
Interest income	21	25
Net loss	$ (11,956)	$ (8,207)

Research and Development Expenses

Research and development expenses were $6.8 million and $3.8 million for the years ended December 31, 2025 and 2024, respectively. The $3.0 million increase in research and development expenses was primarily due to increases of $2.9 million in expenses related to the registration development program of GRI-0621, $0.1 million in personnel expense, including stock-based compensation and a $0.1 million increase in consulting fees.

General and Administrative Expenses

General and administrative expenses were $5.2 million and $4.5 million for the years ended December 31, 2025 and 2024, respectively. The $0.7 million increase was primarily due to an increase of $0.7 million in personnel costs, including stock-based compensation expense.

Change in Fair Value of Warrant Liability

The change in fair value of $3,000 represents a decrease in the fair value of the warrants outstanding during the year ended December 31, 2025.

Interest Income

Interest income was $21,000 and $25,000 for the years ended December 31, 2025 and 2024, respectively.

Liquidity and Capital Resources

Since inception, we have incurred losses and expect to continue to incur losses for the foreseeable future. We incurred net losses of $12.0 million and $8.2 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $51.7 million.

We have financed our working capital requirements to date through the issuance of Common Stock, warrants, convertible notes and promissory notes. As of December 31, 2025, we had $8.2 million in cash and cash equivalents.

The following table summarizes our cash flows for the periods indicated (in thousands):

	Year Ended December 31,	
	2025	2024
Net cash provided by (used in):		
Operating activities	$ (10,186)	$ (8,611)
Investing activities	(3)	—
Financing activities	13,390	11,831
Net increase in cash and cash equivalents	$ 3,201	$ 3,220

Cash Flows from Operating Activities

For the years ended December 31, 2025 and 2024, $10.2 million and $8.6 million were used in operating activities, respectively. The $1.6 million decrease was primarily due to a $3.8 million increase in our net loss and decrease of $0.2 million in cash used for prepaid and other expenses and operating lease liabilities, offset by a $0.8 million increase in non-cash adjustments, including stock based compensation expense, and a $1.6 million decrease in cash used for the payment of accounts payable and accrued liabilities.

Cash Flows from Investing Activities

Net cash provided by investing activities was $3,000 for the year ended December 31, 2025, which was related to the purchase of computer equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities was $13.4 million during the year ended December 31, 2025 and was primarily related to $13.0 million of proceeds from the April 2025 Purchase Agreement and the December 2025 Purchase Agreement and $2.6 million of proceeds from the ATM Offering. These proceeds were offset by $2.2 million in stock issuance costs.

Net cash provided by financing activities was $11.8 million for the year ended December 31, 2024 and was primarily due to of $9.5 million from the February 2024 Purchase Agreement and the June 2024 Purchase Agreement, $3.6 million of proceeds from the ATM Offering and $0.8 million of proceeds from the exercise of certain Series B Common Warrants. These proceeds were offset by $2.0 million in stock issuance costs.

December 2025 Securities Purchase Agreement

For a description of the transactions contemplated by the December 2025 Securities Purchase Agreement, see "*Management's Discussion and Analysis of Financial Condition and Results of Operations — Overview — December 2025 Securities Purchase*

Agreement." The net proceeds from the offering were $6.3 million, after deducting placement agent fees and offering expenses of $1.7 million.

April 2025 Securities Purchase Agreement

For a description of the transactions contemplated by the April 2025 Securities Purchase Agreement, see "*Management's Discussion and Analysis of Financial Condition and Results of Operations — Overview — April 2025 Securities Purchase Agreement.*" The net proceeds from the offering were $4.0 million, after deducting placement agent fees and offering expenses of $1.0 million.

October 2024 Repricing Letter Agreements

For a description of the transactions contemplated by the October 2024 Repricing Letter Agreements, see "*Management's Discussion and Analysis of Financial Condition and Results of Operations — Overview — October 2024 Repricing Letter Agreements.*" The net proceeds from the exercise of certain Series B Common Warrants were $0.6 million after deducting placement agent fees and offering expenses of $0.2 million.

June 2024 Securities Purchase Agreement

For a description of the transactions contemplated by the June 2024 Securities Purchase Agreement, see "*Management's Discussion and Analysis of Financial Condition and Results of Operations — Overview — June 2024 Securities Purchase Agreement.*" The net proceeds from the offering were $3.2 million, after deducting placement agent fees and offering expenses of $1.1 million.

May 2024 At The Market Offering

For a description of the May 2024 At The Market Offering, see "*Management's Discussion and Analysis of Financial Condition and Results of Operations — Overview — May 2024 At The Market Offering.*" As of December 31, 2025, we have sold 60,003 shares of our Common Stock in the ATM Offering at a weighted-average price of $102.75 per share, raising $6.2 million of gross proceeds and net proceeds of $5.9 million, after deducting commissions to the sales agent and other ATM Offering related expenses.

February 2024 Securities Purchase Agreement

For a description of the transactions contemplated by the February 2024 Securities Purchase Agreement, see "*Management's Discussion and Analysis of Financial Condition and Results of Operations — Overview — February 2024 Securities Purchase Agreement.*" The net proceeds from the offering were $4.4 million, after deducting placement agent fees and offering expenses of $1.1 million.

Future Funding Requirements

Our net losses were $12.0 million and $8.2 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had $8.2 million in cash and an accumulated deficit of $51.7 million. We expect to devote substantial financial resources to our planned activities, particularly as we prepare for, initiate, and conduct our planned development of GRI-0803 (and, subject to obtaining additional capital and resources, GRI-0621), advance our discovery programs and continue our product development efforts. In addition, we expect to incur additional costs associated with operating as a public company.

Based on our current operating plan, we believe that our existing cash and cash equivalents will be sufficient to fund our currently planned operating expenses and capital expenditure requirements into the first quarter of 2027. In particular, these estimates assume only the commencement of preliminary work towards the initiation of a Phase 2b trial of GRI-0621; we would require substantial additional capital or resources in order to complete a Phase 2b clinical trial of GRI-0621.

We intend to raise capital through additional issuances of equity securities and/or short-term or long-term debt arrangements, and potentially through strategic partner and collaboration agreements, but there can be no assurances any such financing, collaborations or partnering opportunities will be available when needed on acceptable terms, or at all, even if our research and development efforts are successful. If we are unable to secure adequate additional funding when needed or on acceptable terms, we will need to reevaluate our operating plans and may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, delay, scale back or eliminate some or all of our development programs, or relinquish rights to our technology on less favorable terms than we would otherwise choose or cease operations entirely. These actions could materially impact our business, results of operations and future prospects and the value of shares of our Common Stock. In addition, attempting to secure additional financing may divert the time and attention of management from day-to-day activities and distract from our discovery and product development efforts. As a result, there is substantial doubt about our ability to continue as a going concern. We expect to continue to incur significant and increasing operating losses at least for the

foreseeable future. We do not expect to generate product revenue unless and until we successfully complete development, obtain regulatory approval for and successfully commercialize our current, or any future, product candidates.

See Item 1A. "*Risk Factors*" of this Annual Report for additional risks associated with our substantial capital requirements.

Contractual Obligations and Other Commitments

We enter into contracts in the normal course of business with third-party contract organizations for clinical trials, preclinical studies, manufacturing and other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice and therefore we believe that our non-cancelable obligations under these agreements are not material.

Off-Balance Sheet Arrangements

We are not party to any off-balance sheet transactions. We have no guarantees or obligations other than those which arise out of normal business operations.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The financial statements required pursuant to this item are incorporated by reference herein from the applicable information included in Item 15. "*Exhibits, Financial Statement Schedules*" of this Annual Report and are presented beginning on page F-1.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

On April 11, 2025, the audit committee dismissed Sadler Gibb & Associates LLC (Sadler) as our independent registered public accounting firm. The dismissal was not related to any disagreement with Sadler on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure.

The reports of Sadler on our financial statements as of and for the fiscal years ended December 31, 2024 and 2023 did not contain an adverse opinion or disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principles, except for the explanatory paragraph relating to our ability to continue as a going concern contained in such reports.

During the fiscal years ended December 31, 2024 and 2023 and during the interim period through April 11, 2025, there were (a) no disagreements within the meaning of Item 304(a)(1)(iv) of Regulation S-K between us and Sadler on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, any of which, if not resolved to the satisfaction of Sadler, would have caused Sadler to make reference thereto in their reports, and (b) no "reportable events" within the meaning of Item 304(a)(1)(v) of Regulation S-K, except for a material weakness in our internal control over financial reporting described above under the section "*Risk Factors—Risks Related to Our Common Stock, Financing and Capital Requirements—Management has determined that our internal controls were not effective as of December 31, 2024, March 31, 2025, June 30, 2025, September 30, 2025 and December 31, 2025 due to a material weakness. We have remediated one material weakness and, resources permitting, plan to implement a plan to remediate the remaining material weakness. However, our efforts at remediation may be unsuccessful and the implementation of additional remediation is dependent upon additional resources and funding being available to us. If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.*" No restatements of any prior periods were or have been required. The change in auditor was discussed among the audit committee and Sadler. We have authorized Sadler to respond fully and without limitation to all requests of WithumSmith+Brown, PC (Withum) concerning all matters related to periods audited by Sadler, including with respect to the subject matter of the material weakness described above.

Sadler furnished us with a letter addressed to the SEC stating whether it agrees with the statements made herein and, if not, stating the respects in which it does not agree. A copy of Sadler's letter dated April 15, 2025 is attached as Exhibit 16.1 of this Annual Report.

On April 11, 2025, the audit committee appointed Withum as our independent registered public accounting firm for the fiscal year ending December 31, 2025. During our two most recent fiscal years ended December 31, 2024 and 2023, and during the interim period through April 11, 2025, neither we, nor anyone on our behalf, has consulted with Withum regarding any of the matters described in Items 304(a)(2)(i) and (ii) of Regulation S-K.

Item 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to a company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Our Chief Executive Officer (our principal executive officer) and our Chief Financial Officer (our principal financial officer) evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a 15(e) and 15d 15(e) under the Exchange Act, as of the end of the period covered by this Annual Report. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of December 31, 2025 due to the material weakness described below.

Management’s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance of the reliability of financial reporting and of the preparation of financial statements for external reporting purposes, in accordance with GAAP.

The term “internal control over financial reporting” as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act is defined as a process designed by, or under the supervision of, a company’s principal executive and principal financial officers, or persons performing similar functions, and effected by the company’s board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and disposition of assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures are being made only in accordance with the authorization of its management and directors; and (3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on its financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of the effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures included in such controls may deteriorate.

Our Chief Executive Officer (our principal executive officer) and our Chief Financial Officer (our principal financial officer) have assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making this assessment, management used the criteria established by the COSO in Internal Control-Integrated Framework (2013). These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. Management’s assessment included documentation, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting. Based upon management’s processes and assessments, as described above, management has concluded that, as of December 31, 2025, our internal controls over financial reporting were not effective as the result of a material weakness. A material weakness in an internal control is defined as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

This material weakness is related to the inherent limitations of the accounting software used to prepare our financial statements and the limited number of accounting personnel we employ. As a result of these software limitations and the limited number of accounting personnel, we determined that we have insufficient segregation of duties over the initiation, approval and recording of certain financial transactions. While we have implemented multiple compensating controls to mitigate these limitations, management has concluded that these compensating controls are not sufficient to preclude a material weakness as a result of this insufficiency of segregation of duties. Thus, management determined that our internal controls over financial reporting were not effective as of December 31, 2025.

Management has evaluated, and continues to evaluate, avenues for mitigating this material weakness, such as the retention of additional accounting personnel and/or the procurement of alternative accounting software, but these avenues have been deemed to be impractical and prohibitively costly, due to the size of our organization and resources available at the current time. Management expects to continue to utilize the compensating controls in place to mitigate the segregation of duty weakness and will seek to improve on such controls as reasonably possible, until such time as our resources allow for further remediation.

Management does not believe that this control weaknesses has resulted in deficient financial reporting because each of our Chief Executive Officer and Chief Financial Officer is aware of his or her responsibilities under the SEC's reporting requirements and personally certifies our financial reports. Further, we have implemented a series of manual checks and balances to verify that the initiation, approval and recording of certain financial transactions in the current and prior reporting periods has been properly authorized and recorded. So, while management has identified certain material weaknesses in our system of internal control over financial reporting, management believes that it has taken reasonable and sufficient steps to ascertain that the financial information contained in this Annual Report is presented in accordance with GAAP.

Thus, notwithstanding this material weakness, we believe that our financial statements contained in this Annual Report on Form 10-K fairly present our financial position, results of operations and cash flows for the periods covered by this report in all material respects.

Remediation of Prior Material Weakness in Internal Control Over Financial Reporting

As previously disclosed in Item 9A of Part II of our Annual Report on Form 10-K for the year ended December 31, 2024, our management identified a material weakness in our internal control over financial reporting related to the inaccurate computation of the non-cash deemed dividend associated with the repricing of the Series B Common Warrants in accordance with applicable GAAP guidance. This inaccurate computation, if it had remained undetected, would have resulted in a single-digit percentage error in the amount of the net loss attributable to holders of our Common Stock used to compute basic and diluted net loss per share of Common Stock. The amounts presented in our balance sheets, statements of changes in stockholders' equity (deficit) and statements of cash flows were not affected. This adjustment was corrected prior to the finalization of our prior Annual Report on Form 10-K for the year ended December 31, 2024 and no restatements of any prior periods were required.

As of December 31, 2025, our management determined that this material weakness had been fully remediated. To remediate this material weakness, we implemented a plan which included the (i) continued engagement of third-party professionals with appropriate expertise in accounting and reporting under GAAP and SEC regulations who have adequate experience related to non-recurring debt and equity transactions and (ii) enhancement our documentation procedures related to the accounting treatment for such transactions. These third-party professionals now assist in reviewing the attendant calculations/ additional controls regarding the evaluation of non-recurring debt and equity transactions and assist in reviewing the documentation and related documentation procedures for such transactions. Our management also refined our processes for communicating with our auditor as to when our financial statements and related materials have passed through the Company's internal control processes. As a result, our management has now determined that this material weakness has been remediated.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our registered public accounting firm due to an exemption provided by the JOBS Act for "emerging growth companies."

Changes in Internal Control Over Financial Reporting

Except as disclosed above with respect to the remediation of the material weakness described above, there have been no changes in our internal control over financial reporting during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations of Effectiveness of Control

It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system are met. The design of any control system is based, in part, upon the benefits of the control system relative to its costs. Control systems can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. In addition, over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

Item 9B. OTHER INFORMATION.

Rule 10b5-1 Trading Arrangements

During the three months ended December 31, 2025, none of our directors or officers adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408 of Regulation S-K.

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The following table sets forth certain information about our directors and our executive officers as of January 26, 2026.

Name	Age	Position
Executive Officers		
W. Marc Hertz, Ph.D.	56	President, Chief Executive Officer and Director *(Principal Executive Officer)*
Leanne Kelly	49	Chief Financial Officer *(Principal Financial and Accounting Officer)*
Vipin Kumar, Ph.D.	66	Chief Scientific Officer
Albert Agro, Ph.D.	61	Chief Medical Officer
Non-Employee Directors		
David Szekeres[(1)(2)]	52	Director, Chair of the Board
David Baker	62	Director
Camilla V. Simpson, M.Sc.[(1)(2)(3)]	54	Director
Roelof Rongen[(1)(3)]	60	Director

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating and corporate governance committee.

Executive Officers

W. Marc Hertz, Ph.D., has served as our President and Chief Executive Officer and as a member of our Board since April 2023. He co-founded GRI Operations in 2009 and served as Chief Executive Officer and chairperson of its board of directors since its inception. In addition to his management positions, Dr. Hertz previously served on the boards of directors of GemVax AS from 2005 to 2009, Evozym Biologics Inc., from 2014 to 2018, and currently serves on the board of directors of Multimeric Biotherapeutics, a privately-held research and development biotechnology company, a position he has held since 2008. Dr. Hertz has also held several senior positions at companies in the biotechnology industry since 1998, including Pharmexa, Inc., Pharmexa A/S and Multimeric Biotherapeutics, Inc. Dr. Hertz received his undergraduate degree in biology from Bowdoin College and his Ph.D. in immunology and microbiology from the University of Colorado Medical School. We believe Dr. Hertz's service as GRI Operations' co-founder and Chief Executive Officer and his extensive experience in the biotechnology industry qualifies him to serve as a member of our Board.

Leanne Kelly has served as our Chief Financial Officer since the closing of the Merger in April 2023. She brings over 20 years of experience leading private and publicly-traded companies across life sciences, technology and e-commerce sectors with a foundation in public accounting. From May 2021 until the closing of the Merger, she served as the Chief Financial Officer of Vallon. From 2016 to 2021, she served as the Controller and Executive Director of Global Financial Reporting at OptiNose, Inc., a multi-million dollar revenue specialty pharmaceutical company. Over the course of her career, she has held Senior Vice President of Finance, Controller and Chief Financial Officer positions in private and public companies such as Flower Orthopedics, Iroko Pharmaceuticals, LLC, and Genaera Corporation. Ms. Kelly began her career as an auditor with KPMG LLP. While serving in those roles, Ms. Kelly's work included multi-million dollar financings, M&A diligence and support. She also has experience in financial oversight, internal and external financial reporting, forecasting, and financial analysis, as well as investor and public relations. Ms. Kelly received her Bachelor of Science degree in Business Economics with a concentration in Accounting from Lehigh University and is a licensed CPA (inactive status) in the state of Pennsylvania.

Vipin Kumar (Chaturvedi), Ph.D., has served as our Chief Scientific Officer since April 2023. He co-founded GRI Operations in 2009 and, since its inception and until the date of the Merger, served as a member of its board of directors and as chairperson of its scientific advisory board. Dr. Kumar served as GRI Operations' Chief Scientific Officer from 2009 to 2017 and from 2022 to April 2023. Dr. Kumar has served as a Professor of Medicine, Laboratory of Immune Regulation at the University of California, San Diego since April 2015. In 2015, Dr. Kumar co-founded Simomics, UK, a simulation software company and served as a non-executive director from 2015 to July 2022. Additionally, Dr. Kumar has served on the board of directors of Vidur Discoveries, LLC, a consulting company, since 2009. Dr. Kumar obtained his undergraduate degree in biology from the Kanpur University, India, his master's in biochemistry, molecular biology and immunology from the Institute of Medical Education & Research, India, and his Ph.D. in biochemistry from the Indian Institute of Science, India.

Albert Agro, Ph.D., has served as our Chief Medical Officer since April 2023. He co-founded GRI Operations in 2009 and served as a consultant to GRI Operations with the title Chief Medical Officer from August 2017 until April 2023. Dr. Agro has been serving as the Chief Executive Officer of Jocasta Neuroscience Inc. since June of 2024. He has also served as President and Chief Executive Officer of Columbia Therapeutics Inc. since April 2021 and has over 20 years of experience in the biotechnology and pharmaceutical industries having held several senior clinical and development positions, including Chief Executive Officer of Sublimity Therapeutics Inc. from March 2018 to April 2021 and Chief Medical Officer at Cynapsus from June 2012 to September 2016. Dr. Agro received his Ph.D. in immunology from the Department of Medicine at McMaster University.

Non-Employee Directors

David Szekeres has served as a member of our Board since April 2023. Mr. Szekeres currently serves as the President of Connect Biopharma Holdings Limited, a publicly-traded, U.S.-headquartered global clinical-stage biopharmaceutical company. He has more than two decades of experience in the global life sciences industry as a finance and business development executive, deal maker, legal counsel and board member. Mr. Szekeres joined Heron Therapeutics, Inc. in March 2016 and served as Chief Operating Officer and Head of Finance until August 2023. Prior to this, he served as Chief Business Officer, Principal Financial & Accounting Officer and General Counsel at Regulus Therapeutics Inc. from 2014 to 2016. Mr. Szekeres also served as head of Mergers and Acquisitions at Life Technologies Corporation from 2008 through its acquisition by Thermo Fisher Scientific in February 2014. Mr. Szekeres currently serves on the board of directors at Sanford Burnham Prebys, CureMatch, and Animantis, and as an executive advisory board member at Colossal Biosciences. He served on the board of directors of Edico Genome Inc. from March 2014 until its acquisition by Illumina in 2018 and Patara Pharma from October 2014 until its acquisition by Roivant Sciences in 2018. Mr. Szekeres received his undergraduate degree in criminology, law and society from the University of California, Irvine and his J.D. from Duke University School of Law. We believe that Mr. Szekeres's extensive experience as an executive and serving on other boards of directors in the biotechnology and biotherapeutics industry qualifies him to serve on our Board.

David Baker has served as a member of our Board from January 15, 2019 until August 23, 2019, and upon the consummation of the initial public offering of our Common Stock on February 12, 2021, he was again appointed as a director. He previously served as Vallon's President and Chief Executive Officer from January 15, 2019 until April 12, 2023. Mr. Baker has also been serving as the President and Consultant of DB Biopharma Consulting LLC, a life science consulting company, since April 2023. He previously served as the Interim Chief Executive Officer and Chief Commercial Officer of Alcobra Ltd. (now known as Arcturus), where he oversaw the development of ADAIR. Prior to joining Alcobra Ltd., he worked at Shire Pharmaceuticals for 10 years, including as Vice President of Commercial Strategy and New Business in the Neuroscience Business Unit. In that role, Mr. Baker led the commercial assessment of neuroscience licensing opportunities, managed commercial efforts on pipeline central nervous system (CNS) products, and led the long-term strategic planning process. Previously, he served as Global General Manager for Shire's Vyvanse® where he led the launch of Vyvanse and led global expansion efforts including successful establishment of a partnership in Japan and launches in Canada and Brazil. Prior to that, Mr. Baker served as Vice President of Marketing for all of Shire's ADHD products. From 1990 through 2004, Mr. Baker worked at Merck & Co., where he held positions of increasing responsibility in marketing, sales, market research, and business development. In addition to his knowledge and experience with CNS medications, Mr. Baker's expertise includes therapeutics for osteoporosis, migraine, and hyperlipidemia. He has been directly involved with the marketing of five medications with annual sales in excess of $1.0 billion each. Mr. Baker graduated Magna Cum Laude with a bachelor's degree in Economics and Computer Science from Duke University. He earned a Master of Business Administration in Marketing from Duke's Fuqua School of Business. Mr. Baker also serves on the board of directors of Benchworks, Inc., a private healthcare advertising agency. We believe that Mr. Baker' service as Vallon's President and Chief Executive Officer and his extensive expertise in the biotechnology industry qualifies him to serve as a member of our Board.

Roelof Rongen has served as a member of our Board since April 2023. He is a serial entrepreneur, company builder and Research and Development/Commercial Development leader with extensive experience across many therapeutic areas and functions. Mr. Rongen has served as Chief Executive Officer of Adolore BioTherapeutics, a gene-therapy company, since July 2022, Founder/Chief Executive Officer of Innovative Molecules since June 2019, and Managing Member of AsteRx Pharma Consulting since September 2018. In 2012, he founded and progressed Matinas BioPharma (omega-3 and lipid-crystal nano-particle drug delivery) into a public company (NYSE:MTNB) until his departure in March 2018. Mr. Rongen was integral to the development and commercialization of products such as Humira® and Lovaza®. Prior to founding Matinas BioPharma, Mr. Rongen served as Executive Vice President at Trygg Pharma from 2010 to 2012 where he facilitated Norway's Aker Group's entry into the prescription omega-3 business, and ultimate sale to FMC. Before Aker, Mr. Rongen was VP for IP and Portfolio Management at Reliant Pharmaceuticals (acquired by GlaxoSmithKline) where he in-licensed Lovaza® and led development and pre-launch activities. Earlier in his career, Mr. Rongen was Global Product Director for Humira® and other Immunology Programs at BASF Pharma (acquired by Abbott/Abbvie). Mr. Rongen started his professional career as a management

consultant at Arthur D. Little's Technology Innovation Management practice and as a biotechnology/pharmaceutical consultant at The Wilkerson Group (acquired by IBM). Mr. Rongen received a Master of Science in Engineering in Molecular Sciences (with Biotechnology/Bio-Process Technology focus) from Wageningen University in the Netherlands and a Master of Business Administration from the Kellogg Business School at Northwestern University. We believe that Mr. Rongen's experience in the biopharmaceutical industry qualifies him to serve on our Board.

Camilla V. Simpson, M.Sc., has served as a member of our Board since April 2023. She has served as a member of Spruce Biosciences board of directors since October 2017. Since April 2021, Ms. Simpson has been Chief Executive Officer of Zehna Therapeutics, an early stage biotechnology company and a spin-out from the Cleveland Clinic. Since April 2019, Ms. Simpson has been the Managing Member and President of Rare Strategic, LLC where she provides strategic advice and consulting services to biotechnology companies. Ms. Simpson joined the board of directors of Dyve Biosciences in December 2020. From April 2017 to April 2019, Ms. Simpson was SVP, Head of Product Portfolio Development at BioMarin where she was responsible for corporate and Research and Development governance, program leadership, project management, competitive intelligence, portfolio strategy, and business analytics. From October 2014 to April 2017, Ms. Simpson was Group Vice President Global Regulatory Affairs at BioMarin, and from March 2014 to October 2014, Ms. Simpson was Vice President Regulatory Affairs EU at BioMarin. She also spent 12 years at Shire, where after multiple roles of increasing responsibility, ultimately held the position of Vice President of Regulatory Affairs Early Development and Business Development. Ms. Simpson holds a Bachelor of Science from University College Galway, Ireland, a Bachelors of Science (Honors) from Kingston University, United Kingdom, and an Master of Science with distinction from University of London, UK. We believe that Ms. Simpson's extensive experience serving as an executive, director and consultant in the biotechnology industry qualifies her to serve as a member of our Board.

Family Relationships

There is no family relationship between any director, executive officer or person nominated to become a director or executive officer.

Board Composition

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the number of directors on our Board shall be determined from time to time by resolution of the Board or our stockholders, and the current size of our Board is five members.

Our amended and restated bylaws also provide that our directors may be removed from office with or without cause by vote of the holders of a majority of the shares of stock entitled to vote in the election of directors.

Our current and future executive officers and significant employees serve at the discretion of our Board.

Our Board is divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the directors whose terms then expire will be subject to re-election to serve until the third annual meeting following re-election. As a result, only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Our directors are divided among the three classes as follows:

- the Class I director is David Baker, and his term expires at the annual meeting of stockholders to be held in 2027;
- the Class II directors are Roelof Rongen and Camilla V. Simpson, M.Sc., and their term expires at the annual meeting of stockholders to be held in 2028; and
- the Class III directors are W. Marc Hertz, Ph.D., and David Szekeres, and their term expires at the annual meeting of stockholders to be held in 2026.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that only our Board can fill vacancies on the Board, including due to increases in the size of the Board. Any additional directorships resulting from an increase in the authorized number of directors would be placed among the three classes so that, as nearly as possible, each class consists of one-third of the authorized number of directors.

Director Independence

Under the listing requirements of The Nasdaq Capital Market, independent directors must comprise a majority of a listed company's board of directors within 12 months from the date of listing. In addition, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees must be independent within 12 months from the date of listing. Audit committee members must also satisfy additional independence criteria,

including those set forth in Rule 10A-3 under the Exchange Act and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. A director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3 under the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries, other than compensation for board service; or (2) be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board of directors must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director, and whether the director is affiliated with the company or any of its subsidiaries or affiliates.

Our Board has determined that all members of the Board, except W. Marc Hertz, Ph.D. and David Baker, are independent directors, including for purposes of the rules of The Nasdaq Capital Market and the SEC. In making such independence determination, our Board considered the relationships that each non-employee director has with us and all other facts and circumstances that our Board deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. The composition and functioning of our Board and each of our committees comply with all applicable requirements of The Nasdaq Capital Market and the rules and regulations of the SEC.

Committees of the Board of Directors

Our Board has the ability to establish committees and has established an audit committee, a compensation committee and a nominating and corporate governance committee and may establish other committees to facilitate the management of our business. Members serve on these committees until their resignation or until otherwise determined by our Board. Our Board and its committees set meeting schedules throughout the year and can also hold special meetings and act by written consent from time to time, as appropriate.

The committees regularly report on their activities and actions to the full Board. Each member of each committee of our Board qualifies as an independent director in accordance with the listing standards of The Nasdaq Capital Market. Each committee of our Board has a written charter that was approved by our Board.

Copies of each charter are posted on our website at www.gribio.com under the "*Investors*" section. Information contained on our website is not incorporated by reference into this Annual Report. We have included our website address in this Annual Report on Form 10-K solely as an inactive textual reference.

Audit Committee

The members of our audit committee are Roelof Rongen, Camilla V. Simpson, M.Sc., and David Szekeres, who is the chairperson of the audit committee.

Our audit committee assists our Board with its oversight of the integrity of our financial statements; our compliance with legal and regulatory requirements; the qualifications, independence and performance of the independent registered public accounting firm; the design and implementation of our financial risk assessment and risk management, including cybersecurity risk management. Among other things, our audit committee is responsible for reviewing and discussing with our management the adequacy and effectiveness of our disclosure controls and procedures. Our audit committee also discusses with our management and independent registered public accounting firm the annual audit plan and scope of audit activities, scope and timing of the annual audit of our financial statements, and the results of the audit, quarterly reviews of our financial statements and, as appropriate, initiates inquiries into certain aspects of our financial affairs.

Our audit committee is responsible for establishing and overseeing procedures for the receipt, retention and treatment of any complaints regarding accounting, internal accounting controls or auditing matters, as well as for the confidential and anonymous submissions by our employees of concerns regarding questionable accounting or auditing matters. In addition, our audit committee has direct responsibility for the appointment, compensation, retention and oversight of the work of our independent registered public accounting firm. Our audit committee has sole authority to approve the hiring and discharging of our independent registered public accounting firm, all audit engagement terms and fees and all permissible non-audit engagements with the independent auditor. Our audit committee reviews and oversees all related person transactions in accordance with our policies and procedures.

Each member of our audit committee is independent under the rules and regulations of the SEC and the listing standards of The Nasdaq Capital Market applicable to audit committee members. Our Board has determined that David Szekeres qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of The Nasdaq Capital Market listing standards. In making this determination, our Board has considered Mr. Szekeres' prior experience, business acumen and independence. Both our independent registered public accounting firm and management periodically meets privately with our audit committee.

We believe that the composition and functioning of our audit committee complies with all applicable requirements of Section 404 of SOX, and all applicable SEC and The Nasdaq Capital Market rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Compensation Committee

The members of our compensation committee are David Szekeres and Camilla V. Simpson, M.Sc., who is the chairperson of the compensation committee.

Each member of our compensation committee is independent under the rules and regulations of the SEC and the listing standards of The Nasdaq Capital Market applicable to compensation committee members. Our compensation committee assists our Board with its oversight of the forms and amount of compensation for our executive officers (including officers reporting under Section 16 of the Exchange Act), the administration of our equity and non-equity incentive plans for employees and other service providers and certain other matters related to our compensation programs. Our compensation committee, among other responsibilities, evaluates the performance of our Chief Executive Officer and, in consultation with him, evaluates the performance of our other executive officers (including officers reporting under Section 16 of the Exchange Act). Our compensation committee also administers our A&R 2018 Plan. The compensation committee is responsible for the determination of the compensation of our Chief Executive Officer, and will conduct its decision making process with respect to that issue without the Chief Executive Officer present.

The compensation committee has adopted the following processes and procedures for the consideration and determination of executive and director compensation:

- Evaluating, recommending, approving, and reviewing executive officer and director compensation arrangements, plans, policies, and programs;
- Administering our cash-based and equity-based compensation plans; and
- Making recommendations to our Board regarding any other Board responsibilities relating to executive compensation.

Nominating and Corporate Governance Committee

The members of our nominating and corporate governance committee are Camilla V. Simpson, M.Sc. and Roelof Rongen, who is the chairperson of the nominating and corporate governance committee.

Each member of our nominating and corporate governance committee is independent under the rules and regulations of the SEC and the listing standards of The Nasdaq Capital Market, applicable to nominating and corporate governance committee members. Our nominating and corporate governance committee's responsibilities include:

- evaluating and making recommendations to the full Board as to the composition, organization and governance of our Board and its committees;
- evaluating and making recommendations as to director candidates;
- evaluating current Board members' performance;
- developing continuing education programs for directors, as needed;
- overseeing the process for the dissemination of information to the Board and its committees;
- reviewing its own performance and the nominating and corporate governance committee charter annually;
- overseeing the process for chief executive officer and other executive officer succession planning; and
- developing and recommending governance guidelines for the Company.

Certain Corporate Governance Matters

Director Nominations

No material changes have been made to the procedures by which stockholders may recommend nominees to our Board.

Board Leadership Structure and Role of the Board in Risk Oversight

The Board is responsible for the control and direction of the Company. At present, the Board has elected to separate the positions of chairperson and Chief Executive Officer. Dr. Hertz will serve as Chief Executive Officer of the Company and as a member of the Board. Mr. Szekeres will serve as the chairperson of the Board. The Board believes that this structure will serve the Company well by maintaining a link between management, through Dr. Hertz's membership on the Board, and the non-executive directors led by Mr. Szekeres in his role as a non-executive chairperson.

One of the key functions of our Board is informed oversight of our risk management process. The Board does not have a standing risk management committee, but rather administers this oversight function directly through the Board as a whole, as well as through the various standing committees of our Board that address risks inherent in their respective areas of oversight. In particular, our Board is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures facing the Company and the steps management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices, including whether such practices are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

Compensation Committee Interlocks and Insider Participation

No member of our compensation committee has ever been an executive officer or employee of the Company. None of our officers currently serves, or has served during the last completed fiscal year, on any other entity's board of directors, compensation committee or other committee that serves an equivalent function as our compensation committee and that has one or more officers who serves as a member of our Board or compensation committee.

Code of Business Conduct and Ethics

We have adopted a written Code of Business Conduct and Ethics (the Code of Conduct) applicable to all of our employees, executive officers and directors. The Code of Conduct covers fundamental ethical and compliance-related principles and practices such as accurate accounting records and financial reporting, avoiding conflicts of interest, the protection and use of our property and information and compliance with legal and regulatory requirements. Our Code of Conduct is available on the "*Investors — Corporate Governance"* section of our website at www.gribio.com and will be made available to stockholders without charge, upon request, by writing to the Corporate Secretary at 2223 Avenida de la Playa, Suite 208, La Jolla, CA 92037.

Our nominating and corporate governance committee is responsible for overseeing our Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers or directors. We intend to disclose any future amendments to, or waivers from, our Code of Conduct in a Current Report on Form 8-K within four business days of the waiver or amendment, unless website posting or the issuance of a press release of such amendments or waivers is then permitted by Nasdaq rules.

Insider Trading Policy

We maintain an Insider Trading Policy that, among other things, generally prohibits all persons who are aware of material information about the Company that is not generally known or available to the public, including our officers, directors and employees, from engaging in transactions involving our shares (including transactions of our shares by or on behalf of the Company) without first obtaining pre-clearance of the transaction by following the procedures described in the Insider Trading Policy. This includes short sales, hedging of share ownership positions, and transactions involving derivative securities relating to our shares. This policy is included as Exhibit 19 to this Annual Report.

Item 11. EXECUTIVE COMPENSATION.

Summary Compensation Table

Our named executive officers for the year ended December 31, 2025 were W. Marc Hertz, Ph.D., our President and Chief Executive Officer; Leanne Kelly, our Chief Financial Officer; and Vipin Kumar, Ph.D., our Chief Scientific Officer. The

following table summarizes information concerning the compensation awarded to, earned by, or paid for services rendered in all capacities by our named executive officers during the years ended December 31, 2025 and 2024.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)[1]	Non-Equity Incentive Compensation ($)[2]	All Other Compensation ($)	Total ($)
W. Marc Hertz, Ph.D.	2025	575,900	—	274,738	158,373	18,209 [3]	1,027,219
President and Chief Executive Officer	2024	458,708	—	—	158,373	143	617,224
Leanne M. Kelly	2025	384,300	—	109,985	76,860	13,577 [4]	584,722
Chief Financial Officer	2024	342,417	50,000 [5]	—	76,860	143	469,420
Vipin Kumar, Ph.D.	2025	384,300	—	109,985	76,860	7,942 [6]	579,088
Chief Scientific Officer	2024	342,417	—	—	76,860	143	419,420

(1) Reflects the aggregate grant date fair value of stock options granted during the fiscal year calculated in accordance with FASB ASC Topic 718. These amounts do not necessarily correspond to the actual value that may be realized by the executive in connection with the option awards. The assumptions made in valuing the option awards reported in this column are described in the Company's audited consolidated financial statements (Note 3. *Summary of Significant Accounting Policies* and Note 8. *Stock Based Compensation*) included in this Annual Report.

(2) The amounts in this column represent performance bonuses earned by the named executive officers in the year shown based upon the achievement of pre-established performance objectives. See "Executive Compensation — Elements of Compensation — Bonuses and Non-Equity Incentive Plan Compensation" below.

(3) Consists of $18,083 in matching contributions to Dr. Hertz's account under the GRI Bio, Inc. 401K plan, and $126 in group term life insurance premiums paid on behalf of Dr. Hertz.

(4) Consists of $13,451 in matching contributions to Ms. Kelly's account under the GRI Bio, Inc. 401k plan, and $126 in group term life insurance premiums paid of behalf of Ms. Kelly.

(5) Pursuant to her employment agreement, Ms. Kelly was paid a retention bonus of $50,000 on April 21, 2024.

(6) Consists of $7,846 in matching contributions to Dr. Kumar's account under the GRI Bio, Inc. 401k plan and $96 group term life insurance premiums paid on behalf of Dr. Kumar.

Elements of Compensation

2025 Base Salaries

Effective August 1, 2024, the base salaries of Dr. Hertz, Ms. Kelly and Dr. Kumar were increased to $575,900, $384,300 and $384,300, respectively.

Bonuses and Non-Equity Incentive Plan Compensation

Dr. Hertz, Ms. Kelly and Dr. Kumar are each eligible to receive a discretionary annual performance bonus with a target bonus equal to 55%, 40% and 40% of their then current base salary, respectively. For the fiscal year ended December 31, 2025, based on the achievement level of performance objectives, the Board awarded an annual performance bonus of $158,373 to Dr. Hertz and $76,860 to each of Ms. Kelly and Dr. Kumar.

Option Awards Granted During 2025

On January 23, 2025, the Board granted 272 incentive stock options to purchase our Common Stock to Dr. Hertz and 91 incentive stock options to purchase our Common Stock to each of Ms. Kelly and Dr. Kumar with an exercise price of $326.48 per share which was equal to the closing price of our Common Stock on the date of grant. The shares underlying these options vested at the time of grant.

On August 26, 2025, the Board granted 953 incentive stock options to purchase our Common Stock to Dr. Hertz and 423 incentive stock options to purchase our Common Stock to each of Ms. Kelly and Dr. Kumar with an exercise price of $39.48 per share which was equal to the closing price of our Common Stock on the date of grant. An aggregate of 1,166 options vested at the time of grant. The unvested options will vest on a quarterly vesting schedule over three years from the date of grant, subject to the holder's continued service to the Company.

On September 18, 2025, the Board granted 3,680 incentive stock options to purchase our Common Stock to Dr. Hertz and 1,543 incentive stock options to purchase our Common Stock to each of Ms. Kelly and Dr. Kumar with an exercise price of $54.04 per share which was equal to the closing price of our Common Stock on the date of grant. An aggregate of 4,867 options vested at the time of grant. The unvested options will vest on a quarterly vesting schedule over three years from the date of grant, subject to the holder's continued service to the Company.

Pension Benefits

We do not have any qualified or non-qualified defined benefit plans or profit-sharing plans.

Non-qualified Deferred Compensation

We do not maintain any non-qualified defined contribution plans or other deferred compensation plans.

Employee Benefits

Our named executive officers participate in employee benefit programs available to our employees generally, including medical, vision and dental insurance and a tax-qualified 401(k) plan.

Employment Agreements

We have entered into an employment agreement with each of our named executive officers. The employment agreements provide that the executive will receive a base salary and be eligible to receive an annual cash bonus contingent upon the attainment of certain company milestones and/or individual objectives. Pursuant to the employment agreements, each executive's base salary and target bonus will be reviewed periodically by our compensation committee or Board. The employment agreements also provide for certain termination benefits, which are described below in the section entitled "*Potential Payments Upon a Termination or Change in Control*."

Our named executive officers are also entitled to participate in all of our retirement and group welfare plans, subject to the terms and conditions applicable to such plans. Further, each named executive officer's employment agreement contains restrictive covenants relating to non-disclosure of confidential information, mutual non-disparagement and assignment of inventions provisions. The employment agreement with Ms. Kelly also includes non-competition and non-solicitation provisions.

Potential Payments Upon a Termination or Change in Control

In addition to those potential payments described below, regardless of the manner in which a named executive officer's service terminates, that named executive officer is entitled to receive compensation amounts earned during his or her term of service, including unpaid salary and other accrued benefits, as applicable. In addition, each named executive officer is entitled to receive certain benefits upon the Company's termination of his or her employment without cause or his or her resignation for good reason.

W. Marc Hertz, Ph.D.

Pursuant to his employment agreement with us, if Dr. Hertz's employment were terminated by us without cause or terminated by Dr. Hertz for good reason, in either case not in connection with a change in control, then Dr. Hertz would be entitled to the following severance benefits:

- continued base salary for a period of 12 months, plus a pro-rated bonus for the year of termination, based on actual performance results for the entire year, and provided he was employed for at least six months during that year; and
- subsidized premiums for COBRA continuation coverage for a period of 12 months (or such earlier date that he obtains alternative coverage).

Pursuant to his employment agreement with us, if Dr. Hertz's employment were terminated by us without cause or terminated by Dr. Hertz for good reason, in either case within the one-year period following a change in control transaction, then Dr. Hertz would be entitled to the following severance benefits:

- a lump sum payment equal to 18 months of his annual base salary, plus a lump sum payment equal to 150% of his target bonus, without proration, for the fiscal year of termination;
- subsidized premiums for COBRA continuation coverage for a period of 18 months (or such earlier date that he obtains alternative coverage); and
- accelerated vesting of all outstanding stock-based awards held by the executive as of the date of termination, with any performance awards deemed satisfied at the "target" performance level, and any stock options remaining outstanding for their full term.

Leanne Kelly

Pursuant to her employment agreement with us, if Ms. Kelly's employment were terminated by us without cause or terminated by Ms. Kelly for good reason, in either case not in connection with a change in control, then Ms. Kelly would be entitled to the following severance benefits:

- continued base salary for a period of nine months, plus a pro-rated bonus for the year of termination, based on actual performance results for the entire year, and provided she was employed for at least six months during that year; and
- subsidized premiums for COBRA continuation coverage for a period of nine months (or such earlier date that she obtains alternative coverage).

Pursuant to her employment agreement with us, if Ms. Kelly's employment were terminated by us without cause or terminated by Ms. Kelly for good reason, in either case within the one-year period following a change in control transaction, then Ms. Kelly would be entitled to the following severance benefits:

- a lump sum payment equal to 12 months of her annual base salary, plus a lump sum payment equal to 100% of her target bonus, without proration, for the fiscal year of termination;
- subsidized premiums for COBRA continuation coverage for a period of 12 months (or such earlier date that she obtains alternative coverage); and
- accelerated vesting of all outstanding stock-based awards held by the executive as of the date of termination, with any performance awards deemed satisfied at the "target" performance level, and any stock options remaining outstanding for their full term.

Vipin Kumar, Ph.D.

Pursuant to his employment agreement with us, if Dr. Kumar's employment were terminated by us without cause or terminated by Dr. Kumar for good reason, in either case not in connection with a change in control, then Dr. Kumar would be entitled to the following severance benefits:

- continued base salary for a period of nine months, plus a pro-rated bonus for the year of termination, based on actual performance results for the entire year, and provided he was employed for at least six months during that year; and
- subsidized premiums for COBRA continuation coverage for a period of nine months (or such earlier date that he obtains alternative coverage).

Pursuant to his employment agreement with us, if Dr. Kumar's employment were terminated by us without cause or terminated by Dr. Kumar for good reason, in either case within the one-year period following a change in control transaction, then Dr. Kumar would be entitled to the following severance benefits:

- a lump sum payment equal to 12 months of his annual base salary, plus a lump sum payment equal to 100% of his target bonus, without proration, for the fiscal year of termination;
- subsidized premiums for COBRA continuation coverage for a period of 12 months (or such earlier date that he obtains alternative coverage); and
- accelerated vesting of all outstanding stock-based awards held by the executive as of the date of termination, with any performance awards deemed satisfied at the "target" performance level, and any stock options remaining outstanding for their full term.

Outstanding Equity Awards at Fiscal Year-End

Stock Option Awards

The following table sets forth the outstanding stock option awards as of December 31, 2025, held by our named executive officers, on an award-by-award basis, setting forth the total number of shares underlying each stock option award that are (i)

exercisable, but not yet exercised, (ii) unexercisable and not yet exercised, and (iii) total aggregate amount underlying each award.

	Option Awards				
Name	Number of Securities Underlying Unexercised, Options (#) Exercisable	Number of Securities Underlying Unexercised, Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
W. Marc Hertz, Ph.D.	272	—	—	326.48	1/23/2035
President and Chief Executive Officer	662	291 (1)	—	39.48	8/26/2035
	2,810	870 (2)	—	54.04	9/18/2035
Leanne M. Kelly	—	1 (3)	—	65,840.32	9/22/2033
Chief Financial Officer	91	—	—	326.48	1/23/2035
	278	145 (4)	—	39.48	8/26/2035
	1,107	436 (5)	—	54.04	9/18/2035
Vipin Kumar, Ph.D.	91	—	—	326.48	1/23/2035
Chief Scientific Officer	278	145 (4)	—	39.48	8/26/2035
	1,107	436 (5)	—	54.04	9/18/2035

(1) Represents option to purchase shares of our Common Stock granted on August 26, 2025, 662 shares underlying this option vested in full on the date of grant and the remaining 291 options, subject to continued service, vest in 12 substantially equal quarterly installments thereafter such that the stock option is fully vested on the third anniversary of the date of grant.

(2) Represents option to purchase shares of our Common Stock granted on September 18, 2025, 2,810 shares underlying this option vested in full on the date of grant (September 18, 2025) and the remaining 870 options, subject to continued service, vest in 12 substantially equal quarterly installments thereafter such that the stock option is fully vested on the third anniversary of the date of grant.

(3) Represents an option to purchase shares of our Common Stock granted on September 22, 2023.The shares underlying this stock option award vested 25% on the first anniversary of the date of grant and vests, subject to continued service, 2.083% (1/48th of such shares) on each subsequent month thereafter.

(4) Represents option to purchase shares of our Common Stock granted on August 26, 2025, 278 shares underlying this option vested in full on the date of grant and the remaining 145 options vest, subject to continued service, in 12 substantially equal quarterly installments thereafter such that the stock option is fully vested on the third anniversary of the date of grant.

(5) Represents option to purchase shares of our Common Stock granted on September 18, 2025, 1,107 shares underlying this option vested in full on the date of grant and the remaining 436 options vest, subject to continued service, in 12 substantially equal quarterly installments thereafter such that the stock option is fully vested on the third anniversary of the date of grant.

Director Compensation and Compensation Table

Our director compensation program is designed to enhance our ability to attract and retain highly qualified directors and to align their interests with the long-term interests of our stockholders. The program generally includes a cash component, which is designed to compensate non-employee directors for their service on our Board and an equity component, which is designed to align the interests of non-employee directors and stockholders. Directors who are employees of the Company receive no additional compensation for their service on our Board.

The compensation committee annually reviews compensation paid to our non-employee directors and makes recommendations for adjustments, as appropriate, to the full Board. As part of this annual review, the compensation committee considers the significant time commitment and skill level required by each non-employee director in serving on our Board and its various committees. The compensation committee seeks to maintain a market competitive director compensation program and benchmarks our director compensation program against those maintained by our peer group.

Our amended and restated non-employee director compensation program provides that each non-employee Board member will receive the following compensation:

- An annual cash retainer of $40,000 for service on the Board, an annual cash retainer of $7,500 for service on the audit committee, an annual cash retainer of $6,000 for service on the compensation committee and an annual cash retainer of

$5,000 for service on the nominating and corporate governance committee, which the non-employee director may instead elect to receive any of the annual retainers in an award of a stock option in lieu of cash, provided that the compensation committee determines in its discretion that a sufficient number of shares remain available for issuance pursuant to the A&R 2018 Plan or pursuant to any then-effective equity incentive plan.

- Non-employee directors who are first appointed or elected to the Board will receive an initial stock option grant to purchase a number of shares of our Common Stock equal to the quotient obtained by dividing $100,000 by the closing price of our Common Stock on the date of such director's initial election or appointment, provided, however, in no event will the number of shares underlying such grant exceed 0.36% of our issued and outstanding shares of Common Stock on such grant date, which generally will vest in quarterly installments over three years.
- A non-employee director who (i) is serving on the Board as of the date of any annual meeting of our stockholders after August 11, 2025 and has been serving as a non-employee director for at least six months as of the date of such meeting, and (ii) will continue to serve as a non-employee director immediately following such meeting, shall be automatically granted an option grant to purchase a number of shares of Common Stock equal to the quotient obtained by dividing $50,000 (or for the Chairperson or the Board, $83,333) by the closing price of the Common Stock on the date of such annual meeting rounded down to the nearest whole share; provided, however, in no event will the number of shares underlying such grant exceed 0.18% (or, for the Chairperson of the Board, 0.3%) of the issued and outstanding shares of Common Stock on such grant date. Such options generally will vest in quarterly installments over one year. Notwithstanding the foregoing, the directors did not receive stock options on the date of the 2024 annual meeting of our stockholders, and in lieu thereof, in January 2025, the directors, other than the chairman of the Board, received options to purchase an aggregate of 189 shares of Common Stock and the chairman of the Board received options to purchase 109 shares of Common Stock, all of which vested at the time of grant.

In addition to any other consideration received, our amended and restated non-employee director compensation program provides that non-employee Board members serving as a chairperson will receive the following additional consideration:

- The audit committee chairperson will receive an additional annual retainer of $15,000.
- The compensation committee chairperson will receive an additional annual retainer of $12,000.
- The nominating and corporate governance committee chairperson will receive an additional annual retainer of $10,000.
- The Board chairperson will receive an additional annual retainer of $30,000.

A non-employee director may instead elect to receive annual retainer for serving as a chairperson in an award of a stock option in lieu of cash.

Director Compensation

The following table provides information on compensation paid to our non-employee directors in 2025:

	Fees Earned or Paid in Cash ($)	Option Awards ($)[1][2]	Total ($)
David Baker	40,000	66,690	106,690
Roelof Rongen	57,500	66,690	124,190
Camilla V. Simpson, M.Sc.	64,500	66,690	131,190
David Szekeres	91,000	113,173	204,173

(1) Reflects the aggregate grant date fair value of stock options granted during the fiscal year calculated in accordance with FASB ASC Topic 718. These amounts do not necessarily correspond to the actual value that may be realized by the executive in connection with the option awards. The assumption made in valuing the option awards reported in this column are described in the Company's audited consolidated financial statements (Note 3. *Summary of Significant Accounting Policies* and Note 9. *Stock Based Compensation*) included in this Annual Report. Following the 2025 annual meeting of stockholders, Messrs. Baker and Rongen and Ms. Simpson were granted a stock option to purchase 161 shares, and Mr. Szekeres was granted a stock option to purchase 269 shares,

each with an exercise price equal to $36.40 The shares underlying the stock options vest subject to the director's continued service through the applicable vesting dates.
(2) The following table shows the aggregate number of outstanding shares of Common Stock underlying outstanding option awards held by our non-employee directors as of December 31, 2025.

Name	Outstanding Option Awards
David Baker	1,281
Roelof Rongen	1,281
Camilla V. Simpson, M. Sc.	1,281
David Szekeres	2,169

Policies and Procedures Related to the Grant of Certain Equity Awards

We do not purposefully time our grants to coincide or be near in time to the release of material non-public information (MNPI), and we do not time the release of material nonpublic information based on equity award grant dates. However, from time to time, we may grant options close in time to the release of MNPI to the extent those options are being granted upon the hiring of new executive officers and in connection with annual grants being made as part of our director compensation policy, upon appointment of a new director and on an annual basis at each annual meeting.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The following table sets forth certain information known to us regarding beneficial ownership of our capital stock as of January 17, 2026 for:

- each person or group of affiliated persons known by us to be the beneficial owner of more than five percent of our capital stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers, and directors as a group.

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under those rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power, and includes securities that the individual or entity has the right to acquire, such as through the exercise of stock options, within 60 days of January 17, 2026. Except as noted by footnote, and subject to community property laws where applicable, we believe, based on the information provided to us, that the persons and entities named in the table below have sole voting and investment power with respect to all Common Stock shown as beneficially owned by them.

The percentage of beneficial ownership in the table below is based on 536,747 shares of Common Stock deemed to be outstanding as of January 17, 2026.

Name and Address of Beneficial Owner	Common Stock Beneficially Owned: Number of Shares of Beneficial Ownership	Common Stock Beneficially Owned: Percentage of Total Common Stock
Greater Than 5% Stockholders		
Intracoastal Capital LLC[1]	58,344	9.99 %
Lincoln Alternative Strategies LLC[2]	42,776	7.97 %
Directors and Named Executive Officers[3]		
W. Marc Hertz, Ph.D.[4]	3,778	*
Leanne Kelly[5]	1,489	*
Vipin Kumar, Ph.D.[6]	1,492	*
David Baker[7]	1,004	*
Roelof Rongen[8]	1,004	*
Camilla V. Simpson, M.Sc.[8]	1,004	*
David Szekeres[9]	1,690	*
All directors and executive officers as a group (8 persons)[10]	11,464	2.09 %

* Represents beneficial ownership of less than one percent of our outstanding Common Stock.

(1) Pursuant to a Schedule 13G filed on December 17, 2025 by Intracoastal Capital LLC ("Intracoastal"), Mitchell P. Kopin and Daniel B. Asher, consists of (i) 11,356 shares of Common Stock held by Intracoastal and (ii) 46,988 shares of Common Stock issuable upon exercise of Series F Common Warrants held by Intracoastal. The shares of Common Stock issuable upon exercise of the Series F Common Warrants are subject to limitations on exercise if such exercise would result in the holder beneficially owning more than 9.99% of our issued and outstanding Common Stock. The address of Mr. Kopin and Intracoastal is 245 Palm Trail, Delray Beach, Florida 33483. The address of Mr. Asher is 1011 Lake Street, Suite 311, Oak Park, Illinois 60301.

(2) Pursuant to a Schedule 13G filed on December 29, 2025, consists of 42,776 shares of Common Stock held by Lincoln Alternative Strategies LLC ("Lincoln"). The address of Lincoln is 404 Washington Ave., Suite 650, Miami Beach, FL 33139.

(3) Except as otherwise noted below, the address of the beneficial owner is c/o GRI Bio, Inc. 2223 Avenida de la Playa, Suite 208, La Jolla, CA 92037.

(4) Consists of (i) 8 shares of Common Stock and (ii) 3,770 shares of Common Stock issuable pursuant to stock options exercisable within 60 days of January 17, 2026.

(5) Consists of 1,489 shares of Common Stock issuable pursuant to stock options exercisable within 60 days of January 17, 2026.

(6) Consists of (i) 3 shares of Common Stock and (ii) 1,489 shares of Common Stock issuable pursuant to stock options exercisable within 60 days of January 17, 2026.

(7) Consists of 1,004 shares of Common Stock issuable pursuant to stock options exercisable within 60 days of January 17, 2026.

(8) Consists of 1,004 shares of Common Stock issuable pursuant to stock options exercisable within 60 days of January 17, 2026.

(9) Consists of 1,690 shares of Common Stock issuable pursuant to stock options exercisable within 60 days of January 17, 2026.

(10) Consists of (i) the shares of Common Stock described in footnotes (2) through (6) above and (ii) 3 shares of Common Stock held by Albert Agro, Ph.D.

Equity Compensation Plan Information

The following table sets forth information regarding our equity compensation plans as of December 31, 2025:

Plan category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders[1]	15,032	$ 68.44	19,919 [2]
Equity compensation plans not approved by security holders	—	—	—
Total	15,032		19,919

(1) The number of shares of our Common Stock authorized under the A&R 2018 Plan automatically increases on January 1st of each year until the expiration of the A&R 2018 Plan, in an amount equal to four percent of the total number of shares of our Common Stock outstanding on December 31st of the preceding calendar year, subject to the discretion of our Board or compensation committee to determine a lesser number of shares shall be added for such year. This total does not reflect the automatic increase in the number of shares available for issuance under the A&R 2018 Plan that was effective on January 1, 2026 pursuant to the evergreen provisions.

(2) Includes shares of our Common Stock under the A&R 2018 Plan. For a description of this plan, refer below and to Note 8. "*Stock Based Compensation*" to the financial statements included in this Annual Report.

Description of Amended and Restated GRI Bio, Inc. 2018 Equity Incentive Plan, as Amended

On April 21, 2023, the stockholders of the Company approved the A&R 2018 Plan. On July 7, 2025, the Board approved an amendment to the A&R 2018 Plan to increase the amount of shares authorized for issuance thereunder by 14,285 shares, which was subsequently approved by the stockholders of the Company on August 13, 2025. The A&R 2018 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock, performance units, performance shares, restricted stock units and other stock-based awards to our employees, directors and consultants. The purpose of the A&R 2018 Plan is to attract and retain the best available personnel for positions of substantial responsibility, to provide additional incentive to our employees, directors and consultants and to promote the success of our business. The A&R 2018 Plan provides for an annual increase on the first day of each calendar year beginning January 1, 2025 and ending on and including January 1, 2033, equal to the less of (x) 4% of the aggregate number of shares outstanding on the final day of the immediately preceding calendar year and (y) such smaller number of shares as is determined by the Board. The A&R 2018 Plan further authorizes the administrator to amend the exercise price and terms of certain awards thereunder.

As currently in effect, 34,951 shares of our Common Stock are reserved for issuance pursuant to the A&R 2018 Plan, of which 15,032 are subject to issued and outstanding awards.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The following is a summary of each transaction or series of similar transactions since January 1, 2024, to which we have been a party that:

- The amount involved exceeded or exceeds $120,000 or is greater than 1% of the average of our total assets as of December 31, 2025 and 2024; and
- any of our directors or executive officers, any holder of 5% of our capital stock or any member of their immediate family had or will have a direct or indirect material interest.

Employment Agreements

We have entered into employment agreements with each of our executive officers. See Item 11. "*Executive Compensation.*"

Equity Grants

We have granted stock options to each of our executive officers and members of our Board. See Item 11. "*Executive Compensation.*"

Indemnification and Limitation on Liability

Section 145 of the DGCL (Section 145) authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

We have adopted provisions in our amended and restated certificate of incorporation and our amended and restated bylaws that limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our amended and restated bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our Board, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and
- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our Board, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We have entered into indemnification agreements with each of our directors and officers. These agreements provide that we will indemnify each of our directors, our executive officers and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director, executive officer or affiliate in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as a director or officer brought on behalf of us or in furtherance of our rights. Additionally, certain of our directors or officers may have certain rights to indemnification, advancement of expenses or insurance provided by their affiliates or other third parties, which indemnification relates to and might apply to the same proceedings arising out of such director's or officer's services as a director referenced herein. Nonetheless, we have agreed in the indemnification agreements that our obligations to those same directors or officers are primary and any obligation of such affiliates or other third parties to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

Policies and Procedures for Related Party Transactions

We have adopted a written policy that requires all future transactions between us and any director, executive officer, holder of 5% or more of any class of our capital stock or any member of the immediate family of, or entities affiliated with, any of them, or any other related persons, as defined in Item 404 of Regulation S-K, or their affiliates, in which the amount involved is equal to or greater than the threshold amount proscribed by Item 404 of Regulation S-K, be approved in advance by our Audit Committee. Any request for such a transaction must first be presented to our Audit Committee for review, consideration and approval. In approving or rejecting any such proposal, our Audit Committee is to consider the relevant facts and circumstances available and deemed relevant to the Audit Committee, including, but not limited to, the extent of the related party's interest in the transaction, and whether the transaction is on terms no less favorable to us than terms we could have generally obtained from an unaffiliated third party under the same or similar circumstances.

Director Independence

See Item 10. "*Directors, Executive Officers and Corporate Governance Management — Director Independence*."

Committees of our Board of Directors

Our Board has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which operates pursuant to a written charter adopted by our Board. See Item 10. "*Directors, Executive Officers and Corporate Governance Management — Committees of the Board of Directors*."

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

Our independent registered public accounting firm is WithumSmith+Brown, PC, San Francisco, California, Auditor Firm ID: 100.

On April 11, 2025, the audit committee of the Board dismissed Sadler as our independent registered public accounting firm and appointed Withum as our independent registered public accounting firm for the fiscal year ending December 31, 2025. The

dismissal was not related to any disagreement with Sadler on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure.

The following table represents aggregate fees incurred for Withum services during the year ended December 31, 2025 by us.

	December 31, 2025
Audit Fees [1]	$ 397,858
Audit Related Fees [2]	—
Tax Fees [3]	—
All Other Fees [4]	—
Total	$ 397,858

(1) *Audit Fees* represent the aggregate fees billed for professional services rendered by our independent registered public accounting firm for the audit of our annual financial statements, review of financial statements included in our quarterly reports or services that are normally provided in connection with statutory and regulatory filings or engagements for those fiscal years as well as the issuance of consents in connection with registration statement filings with the SEC and comfort letters in connection with securities offerings.

(2) *Audit Related Fees* represent the aggregate fees billed for assurance and related professional services rendered by our independent registered public accounting firm that are reasonably related to the performance of the audit or review of our financial statements and are not reported under "Audit Fees."

(3) *Tax Fees* represent the aggregate fees billed for professional services rendered by our independent registered public accounting firm for tax compliance, tax advice and tax planning services.

(4) *All Other Fees* represent the aggregate fees billed for all other products and services rendered by our independent registered public accounting firm other than the services reported in the other categories.

The following table represents aggregate fees incurred for Sadler services during the years ended December 31, 2025 and 2024 by us.

	December 31,	
	2025	2024
Audit Fees [1]	$ 82,500	$ 194,325
Audit Related Fees [2]	—	—
Tax Fees [3]	—	—
All Other Fees [4]	—	—
Total	$ 82,500	$ 194,325

(1) *Audit Fees* represent the aggregate fees billed for professional services rendered by our independent registered public accounting firm for the audit of our annual financial statements, review of financial statements included in our quarterly reports or services that are normally provided in connection with statutory and regulatory filings or engagements for those fiscal years as well as the issuance of consents in connection with registration statement filings with the SEC and comfort letters in connection with securities offerings.

(2) *Audit Related Fees* represent the aggregate fees billed for assurance and related professional services rendered by our independent registered public accounting firm that are reasonably related to the performance of the audit or review of our financial statements and are not reported under "Audit Fees."

(3) *Tax Fees* represent the aggregate fees billed for professional services rendered by our independent registered public accounting firm for tax compliance, tax advice and tax planning services.

(4) *All Other Fees* represent the aggregate fees billed for all other products and services rendered by our independent registered public accounting firm other than the services reported in the other categories.

The audit committee will approve in advance the engagement and fees of the independent registered public accounting firm for all audit services and non-audit services, based upon independence, qualifications and, if applicable, performance. The audit committee may form and delegate to subcommittees of one or more members of the audit committee the authority to grant pre-approvals for audit and permitted non-audit services, up to specific amounts. All audit services provided by Withum and Sadler for the periods presented were approved by our audit committee and ratified by our Board.

Pre-Approval of Audit and Non-Audit Services

Our audit committee has adopted policies and procedures relating to the approval of all audit and non-audit services that are to be performed by our independent registered public accounting firm. These policies and procedures generally provide that we will not engage our registered public accounting firm to render audit or non-audit services unless the service is specifically approved in advance by our audit committee or the engagement is entered into pursuant to one of the pre-approval procedures described below.

From time to time, our audit committee may pre-approve specified types of services that are expected to be provided to us by our independent registered public accounting firm during the next twelve months. Any such pre-approval is detailed as to the particular service or type of services to be provided and is also generally subject to a maximum dollar amount.

Consistent with requirements of the SEC and the Public Company Accounting Oversight Board regarding auditor independence, our audit committee is responsible for the appointment, compensation and oversight of the work of our independent registered public accounting firm. In recognition of this responsibility, our audit committee, or the chairperson if such approval is needed between meetings of the audit committee, pre-approves all audit and permissible non-audit services provided by the independent registered public accounting firm. These services may include audit services, audit-related services, tax services and other services.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

(a) The following documents are filed as part of this report:

(1) Financial Statements. The financial statements of the Company, together with the reports thereon of WithumSmith+Brown, PC and Sadler, Gibb & Associates LLC, independent registered public accounting firms, are included in this Annual Report beginning on page F-1.

(2) Financial Statement Schedules. All schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

(3) Exhibits. See (b) below.

(b) Exhibits

The exhibits listed in the Exhibit Index below are filed or incorporated by reference as part of this Annual Report.

		Incorporated by Reference			
Exhibit No.	**Description**	**Filed Herewith**	**Form**	**Date**	**File Number**
2.1△	Agreement and Plan of Merger, by and among the Company, Vallon, and Vallon Merger Sub, Inc., dated as of December 13, 2022.		8-K	12/13/22	001-40034
2.2	Amendment to Agreement and Plan of Merger, by and among the Company, Vallon, and Vallon Merger Sub, Inc., dated as of February 17, 2023.		S-4/A	02/24/23	333-268977
3.1	Amended and Restated Certificate of Incorporation, as amended.	X			
3.2	Amended and Restated Bylaws.		8-K/A	05/26/23	001-40034
4.1	Specimen Common Stock Certificate.		S-1	10/23/20	333-249636
4.2△	Registration Rights Agreement, by and between Vallon and the investor party thereto, dated December 13, 2022.		8-K	12/13/22	001-40034
4.3	Form of Common Stock Purchase Warrant.		8-K	5/13/22	001-40034
4.4	Form of Amendment No. 1 to Common Stock Purchase Warrant.		8-K	07/26/22	001-40034
4.5	Form of Equity Warrant.		8-K	12/13/22	001-40034
4.6	Form of Exchange Warrant.		8-K	12/13/22	001-40034
4.7	Form of Senior Secured Note of GRI Bio Operations, Inc.		S-4	12/23/22	333-268977
4.8	Warrant to Purchase Stock issued to TEP Biotech, LLC, dated as of November 2, 2018.		S-4	12/23/22	333-268977
4.9	Warrant to Purchase Stock issued to TEP Biotech, LLC, dated as of December 3, 2019.		S-4	12/23/22	333-268977
4.10	Warrant to Purchase Stock issued to TEP Biotech, LLC, dated as of July 7, 2022.		S-4	12/23/22	333-268977
4.11	Warrant to Purchase Stock issued to Oppel Greeff, dated as of July 7, 2022.		S-4	12/23/22	333-268977
4.12	Form of Amendment to 2022 Warrant to Purchase Stock.		S-4/A	01/30/23	333-268977
4.13	Form of Series B-1 Common Warrant.		S-1/A	01/31/24	333-276025
4.14	Form of Series B-2 Common Warrant.		S-1/A	01/31/24	333-276025
4.15	Form of Placement Agent Warrant.		S-1/A	06/26/24	333-280323
4.16	Form of Series C-1 Common Warrant.		S-1/A	06/26/24	333-280323
4.17	Form of Series C-2 Common Warrant.		S-1/A	06/26/24	333-280323
4.18	Form of Placement Agent Warrant.		8-K	10/22/24	001-40034
4.19	Form of Series D-1 Common Warrant.		8-K	10/22/24	001-40034
4.20	Form of Series D-2 Common Warrant.		8-K	10/22/24	001-40034
4.21	Form of Placement Agent Warrant.		S-1	03/24/25	333-286072
4.22	Form of Pre-Funded Warrant.		S-1	03/24/25	333-286072
4.23	Form of Series E Warrant.		S-1	03/24/25	333-286072
4.24	Form of Placement Agent Warrant.		S-1	12/08/25	333-291999
4.25	Form of Pre-Funded Warrant.		S-1	12/08/25	333-291999
4.26	Form of Series F Warrant.		S-1	12/08/25	333-291999
4.27	Description of Securities.		10-K	03/15/25	001-40034
10.1#	Company's A&R 2018 Equity Incentive Plan, as Amended.		8-K	08/13/25	001-40034
10.2#	Form of Nonqualified Stock Option Agreement under the Company's A&R 2018 Equity Incentive Plan.		S-1	10/23/20	333-249636
10.3#	Form of Incentive Stock Option Agreement under the Company's A&R 2018 Equity Incentive Plan.		S-1	10/23/20	333-249636

10.4#	Form of Restricted Stock Unit Agreement under the Registrant's Amended and Restated 2018 Equity Incentive Plan.		S-8	08/13/25	333-289593
10.5#	Amended and Restated Non-Employee Director Compensation Policy.		10-Q	08/14/25	8/14/2025
10.6	License Agreement, by and between the Company and MEDICE Arzneimittel Putter GmbH & Co. KG, dated as of January 6, 2020.		S-1	10/23/20	333-249636
10.7△	Form of Securities Purchase Agreement.		8-K	05/13/22	001-40034
10.8△	Amendment No. 1 to Securities Purchase Agreement, by and between Vallon and each purchaser identified on the signature pages thereto, dated as of July 25, 2022.		8-K	07/26/22	001-40034
10.9#	Consulting and Clinical Advisory Board Agreement, by and between the Company and Rohit Loomba, M.D., dated as of June 3, 2016.		S-4	12/23/22	333-268977
10.10#	Consulting and Scientific Advisory Board Agreement, by and between the Company and Vipin Kumar Chaturvedi, personally or through Vidur Discoveries LLC, dated as of October 31, 2018.		S-4	12/23/22	333-268977
10.11	Securities Purchase Agreement, by and between the Company and Altium Growth Fund, LP, dated as of December 13, 2022.		8-K	12/13/22	001-40034
10.12	Securities Purchase Agreement, by and among the Company, Vallon and Altium Growth Fund, LP, dated as of December 13, 2022.		8-K	12/13/22	001-40034
10.13	Omnibus Amendment to Securities Purchase Agreements, by and among the Company, GRI Bio Operations, Inc., and Altium Growth Fund, LP, dated as of February 17, 2023.		S-4	03/06/23	333-268977
10.14△	Lease Agreement, by and between La Jolla Shores Plaza, LLC and GRI Bio Operations, Inc., dated as of March 2, 2018, for that property located at 2223 Avenida de la Playa, Suite 208, La Jolla, California, 92037, as amended on February 16, 2021 and February 20, 2024.		10-K	03/28/24	001-40034
10.15#	Form of Indemnification Agreement.		8-K	04/21/23	001-40034
10.16#	Employment Agreement, by and between GRI Bio Operations, Inc. and Marc Hertz, Ph.D., dated as of February 20, 2023.		S-4/A	02/24/23	333-268977
10.17#	Employment Agreement, by and between GRI Bio Operations, Inc. and Leanne M. Kelly, dated as of February 20, 2023.		S-4/A	02/24/23	333-268977
10.18#	Employment Agreement, by and between GRI Bio Operations, Inc. and Vipin Kumar Chaturvedi, dated as of February 20, 2023.		S-4/A	02/24/23	333-268977
10.19#	Separation Agreement, by and between the Company and David Baker, dated as of April 21, 2023.		8-K	04/21/23	001-40034
10.20#	Employment Agreement, by and between the Company and Albert Agro, Ph.D., dated as of July 1, 2023.		10-Q	08/14/23	001-40034
10.21△	Asset Purchase Agreement, by and between the Company and Aardvark Therapeutics, Inc., dated as of August 22, 2023.		8-K	08/23/23	001-40034
10.22△	Form of Securities Purchase Agreement.		S-1/A	01/31/24	333-276025
10.23	Form of Placement Agent Agreement.		S-1/A	01/31/24	333-276025
10.24△	Form of Securities Purchase Agreement.		S-1/A	06/26/24	333-280323
10.25	Form of Repricing Letter Agreement.		8-K	10/22/24	001-40034
10.26	At The Market Offering Agreement, dated May 20, 2024, by and between GRI Bio, Inc.		8-K	5/20/24	001-40034
10.27△	Form of Securities Purchase Agreement.		S-1	03/24/25	333-286072
10.28△	Form of Securities Purchase Agreement.		S-1	12/08/25	333-291999
10.29	Engagement Letter, dated October 21, 2024, by and between GRI Bio, Inc. and H.C. Wainwright & Co., LLC, as amended on December 5, 2025.		S-1/A	12/9/25	333-291999
16.1	Letter from Sadler Gibb & Associates LLC, dated April 15, 2025.		8-K	04/15/25	001-40034
19.1	Insider Trading Policy.		10-K	03/15/25	001-40034
21.1	Subsidiaries.		S-1/A	12/04/23	333-274972
23.1	Consent of WithumSmith+Brown, PC.	X			
23.2	Consent of Sadler Gibb and Associates, LLC.	X			
24.1	Powers of Attorney for directors and certain executive officers (contained on the signature page).				
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.	X			
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.	X			
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.	X			
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.	X			
97.1	Clawback Policy.		10-Q	11/14/23	001-40034
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Linkbase Document				

101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

Unless otherwise indicated, exhibits are filed herewith.

△ Schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company undertakes to furnish supplemental copies of any of the omitted schedules upon request by the U.S. Securities and Exchange Commission.

Indicates a management contract or any compensatory plan, contract or arrangement.

+ The certification attached as Exhibit 32.1 that accompany this Annual Report on Form 10-K is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

GRI BIO, INC.

Date: January 30, 2026

By: /s/ W. Marc Hertz, Ph.D.
Name: W. Marc Hertz, Ph.D.
Title: President and Chief Executive Officer

SIGNATURES AND POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints W. Marc Hertz, Ph.D. and Leanne Kelly as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto and all documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that such attorneys-in-fact and agents or any of them, or his or her or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ W. Marc Hertz, Ph.D. W. Marc Hertz, Ph.D.	President, Chief Executive Officer and Director *(Principal Executive Officer)*	January 30, 2026
/s/ Leanne Kelly Leanne Kelly	Chief Financial Officer *(Principal Financial and Accounting Officer)*	January 30, 2026
/s/ David Szekeres David Szekeres	Director, Chair of the Board	January 30, 2026
/s/ David Baker David Baker	Director	January 30, 2026
/s/ Roelof Rongen Roelof Rongen	Director	January 30, 2026
/s/ Camilla V. Simpson, M.Sc. Camilla V. Simpson, M.Sc.	Director	January 30, 2026

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
GRI Bio, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of GRI Bio, Inc. (the "Company") as of December 31, 2025, the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as 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 the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has an accumulated deficit at December 31, 2025 and, since inception, has incurred operating losses and negative cash flows from operations. The Company's cash and cash equivalents as of December 31, 2025 are not sufficient to fund the Company's planned operations for a period of twelve months from the date the consolidated financial statements are issued. Accordingly, the Company has determined that its planned operations raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 audit. 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 audit 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 audit, 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ WithumSmith+Brown, PC

We have served as the Company's auditor since 2025.

San Francisco, California
January 29, 2026

PCAOB ID Number 100

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of GRI Bio, Inc.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of GRI Bio, Inc. ("the Company") as of December 31, 2024, the related consolidated statement of operations, changes in stockholders' equity (deficit), and cash flows for the year ended December 31, 2024 and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. 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 audit 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 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 audit, 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 audit included performing procedures to assess the risks of material misstatement of the 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 financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Sadler, Gibb & Associates, LLC

We served as the Company's auditor from 2022 to 2024.

Draper, UT

March 14, 2025, except for the effect of the reverse stock split effected January 15, 2026, described in Note 1, as to which the date is January 29, 2026

GRI Bio, 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	$ 8,229	$ 5,028
Prepaid expenses and other current assets	363	587
Total current assets	8,592	5,615
Property and equipment, net	3	4
Operating lease right-of-use assets	71	120
Total assets	$ 8,666	$ 5,739
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,837	$ 897
Accrued expenses	750	691
Operating lease liabilities, current	56	48
Total current liabilities	2,643	1,636
Operating lease liabilities, non-current	15	71
Total liabilities	2,658	1,707
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, $0.0001 par value; 250,000,000 shares authorized; 497,693 and 18,768 shares issued and outstanding as of December 31, 2025 and 2024, respectively	—	—
Additional paid-in-capital	57,704	43,772
Accumulated deficit	(51,696)	(39,740)
Total stockholders' equity	6,008	4,032
Total liabilities and stockholders' equity	$ 8,666	$ 5,739

See accompanying notes to consolidated financial statements.

GRI Bio, Inc.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 6,819	$ 3,768
General and administrative	5,158	4,467
Total operating expenses	11,977	8,235
Loss from operations	(11,977)	(8,235)
Change in fair value of warrant liability	—	3
Interest income	21	25
Net loss	$ (11,956)	$ (8,207)
Deemed dividend on Series B Warrants	—	(1,911)
Net loss available to common stockholders	$ (11,956)	$ (10,118)
Net loss per share attributable to common stockholders, basic and diluted	$ (121.80)	$ (1,545.55)
Weighted-average common shares outstanding, basic and diluted	98,162	6,547

See accompanying notes to consolidated financial statements.

GRI Bio, Inc.
Consolidated Statements of Changes in Stockholders' Equity
(in thousands, except shares)

	Common Stock		Additional	Accumulated	Stockholders'
	Shares	Amount	Paid-in Capital	Deficit	Equity
Balance, December 31, 2023	104	$ —	$ 31,792	$ (31,533)	$ 259
Stock-based compensation expense	—	—	148	—	148
Warrant exercise	6,855	—	666	—	666
Issuance of common stock	11,809	—	11,166	—	11,166
Net loss	—	—	—	(8,207)	(8,207)
Balance, December 31, 2024	18,768	$ —	$ 43,772	$ (39,740)	$ 4,032
Stock-based compensation expense	—	—	793	—	793
Fractional share adjustment	(5)	—	(1)	—	(1)
Issuance of common stock and prefunded warrants, net of issuance costs	430,555	—	10,750	—	10,750
Issuance of common stock	48,375	—	2,390	—	2,390
Net loss	—	—	—	(11,956)	(11,956)
Balance, December 31, 2025	497,693	$ —	$ 57,704	$ (51,696)	$ 6,008

See accompanying notes to consolidated financial statements.

GRI Bio, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (11,956)	$ (8,207)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation expense	4	4
Stock-based compensation expense	793	148
Change in fair value of warrant liability	—	(3)
Change in operating lease right of use assets	48	(105)
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	251	313
Accounts payable	663	(387)
Accrued expenses	59	(479)
Operating lease liabilities	(48)	105
Cash used in operating activities	(10,186)	(8,611)
Investing activities:		
Purchase of property and equipment	(3)	—
Cash used in investing activities	(3)	—
Financing activities:		
Proceeds from issuance of common stock in financing transactions	13,000	9,499
Proceeds from issuance of common stock under ATM facility	2,560	3,604
Proceeds from warrant exercise	—	762
Payment for fractional shares in connection with reverse stock split	(1)	(1)
Payment of deferred stock issuance costs	(2,169)	(2,033)
Cash provided by financing activities	13,390	11,831
Net increase in cash and cash equivalents	3,201	3,220
Cash and cash equivalents at beginning of year	5,028	1,808
Cash and cash equivalents at end of year	$ 8,229	$ 5,028
Supplemental disclosure or noncash activities:		
Stock issuance costs included in accounts payable	$ 278	$ —
Issuance of warrants for payment of stock issuance costs	$ 440	$ 287

See accompanying notes to consolidated financial statements

GRI Bio, Inc.
Notes to Consolidated Financial Statements
(in thousands, except share and per share data)

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

GRI Bio, Inc. (GRI or the Company), based in La Jolla, CA, was incorporated in Delaware in May 2009, which is the date of inception.

GRI is a clinical-stage biopharmaceutical company focused on discovering, developing, and commercializing innovative therapies that target serious diseases associated with dysregulated immune responses leading to inflammatory, fibrotic and autoimmune disorders. The Company's goal is to be an industry leader in developing therapies to treat these diseases and to improve the lives of patients suffering from such diseases. The Company's product candidate, GRI-0621, is an oral inhibitor of type 1 invariant Natural Killer T cells and is being developed for the treatment of severe fibrotic lung diseases such as idiopathic pulmonary fibrosis (IPF). The Company's product candidate portfolio also includes GRI-0803 and a proprietary library of 500+ compounds. GRI-0803, the lead molecule selected from the library, is a novel oral agonist of type 2 diverse Natural Killer T cells and is being developed for the treatment of autoimmune disorders, with much of its preclinical work in Systemic Lupus Erythematosus Disease or lupus and multiple sclerosis (MS).

Reverse Stock Splits

On January 29, 2024, the Company effected a reverse stock split of its common stock at a ratio of one-for-seven (the January 2024 Reverse Stock Split). On June 17, 2024, the Company effected a reverse stock split of its Common Stock at a ratio of one-for-thirteen (the June 2024 Reverse Stock Split). On February 21, 2025, the Company effected a reverse stock split of its Common Stock at a ratio of one-for-seventeen (the February 2025 Reverse Stock Split). On January 23, 2026, the Company effected a reverse stock split of its common stock at a ratio of one-for-twenty-eight (the January 2026 Reverse Stock Split, and together with the February 2025 Reverse Stock Split, the January 2024 Reverse Stock Split and the June 2024 Reverse Stock Split, the Reverse Stock Splits). Unless otherwise noted, all references to share and per share amounts in these consolidated financial statements reflect the Reverse Stock Splits.

2. LIQUIDITY

These consolidated financial statements have been prepared on the basis that the Company is a going concern, which contemplates, among other things, the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has not generated any significant revenues from operations since inception and does not expect to do so in the foreseeable future. The Company has incurred operating losses since its inception in 2009 and as a result has incurred $51,696 in accumulated deficit through December 31, 2025. The Company has financed its working capital requirements to date through the issuance of equity and debt securities. As of December 31, 2025, the Company had cash of approximately $8,229.

On February 1, 2024, the Company entered into a securities purchase agreement (the February 2024 Purchase Agreement), pursuant to which the Company issued and sold Common Stock, pre-funded warrants and common warrants in a public offering (the February 2024 Offering) for net proceeds of $4,389, after deducting offering expenses of $1,110.

On May 20, 2024, the Company entered into an At The Market Offering Agreement (the Sales Agreement) with H.C. Wainwright & Co., LLC (Wainwright), pursuant to which the Company may sell and issue, subject to the limitations in the Sales Agreement, up to $10.0 million shares of Common Stock from time to time through Wainwright as its sales agent (the ATM Offering). Under the Sales Agreement, Wainwright is entitled to compensation of 3.0% of the gross offering proceeds of all shares of Common Stock sold through it pursuant to the Sales Agreement. As of December 31, 2025, the Company has sold 60,003 shares of Common Stock in the ATM Offering at a weighted-average price of $102.75 per share, raising $6,165 of gross proceeds and net proceeds of $5,858, after deducting commissions to the sales agent and other ATM Offering related expenses.

On January 9, 2026, the Company filed a prospectus supplement to its registration statement on Form S-3 (File No. 333-279348) to increase the amount of shares of Common Stock that the Company may offer and sell under the Sales Agreement and applicable registration statement to an aggregate offering price of up to $7,380, which amount does not include the shares of Common Stock having an aggregate gross sales price of approximately $6,165 that were sold under the ATM Offering through January 8, 2026, in accordance with the limitations set forth in Instruction I.B.6 of Form S-3. Since December 31, 2025, the Company has sold 947,342 shares of Common Stock with an aggregate gross sales price of $6,474.

GRI Bio, Inc.
Notes to Consolidated Financial Statements
(in thousands, except share and per share data)

On June 26, 2024, the Company entered into a securities purchase agreement (the June 2024 Purchase Agreement), pursuant to which the Company issued and sold Common Stock, pre-funded warrants and common warrants, in a public offering (the June 2024 Offering), for net proceeds of $3,172, after deducting offering expenses of $1,057.

On October 21, 2024, the Company entered into letter agreements (the Repricing Letter Agreements) with certain holders (the Holders) of its issued and outstanding common warrants to purchase shares of its Common Stock, pursuant to which these Holders exercised their common warrants for cash at a reduced exercise price. In addition, these Holders received new unregistered common warrants. The net proceeds to the Company from the exercise of the common warrants were $608 after deducting placement agent fees and offering expenses of $154.

On April 1, 2025, the Company entered into a securities purchase agreement (the April 2025 Purchase Agreement), pursuant to which the Company issued and sold Common Stock, pre-funded warrants and common warrants, in a public offering (the April 2025 Offering), for net proceeds of $4,020, after deducting offering expenses of $979.

On December 12, 2025, the Company entered into a securities purchase agreement (the December 2025 Purchase Agreement), pursuant to which the Company issued and sold Common Stock, pre-funded warrants and common warrants, in a public offering (the December 2025 Offering), for net proceeds of $6,288 after deducting offering expenses of $1,711.

Based on the Company's current operating plan, the Company believes that its existing cash and cash equivalents will be sufficient to fund its currently planned operating expenses and capital expenditure requirements into the first quarter of 2027. However, this estimate assumes that the Company only commences preliminary work towards the initiation of a Phase 2b trial of GRI-0621; the Company would not be able to complete a clinical trial of GRI-0621, which will require substantial additional capital or resources.

The Company's ability to continue as a going concern is dependent on its ability to raise additional capital to fund its business activities, including its research and development program. The Company intends to raise capital through additional issuances of equity securities and/or short-term or long-term debt arrangements and potentially through strategic partner and collaboration agreements, but there can be no assurances any such financing will be available when needed, even if the Company's research and development efforts are successful. If the Company is not able to obtain additional financing on acceptable terms and in the amounts necessary to fully fund its future operating requirements, it may be forced to reduce or discontinue its operations entirely. Therefore, there is substantial doubt about the Company's ability to continue as a going concern for a period of one year from the issuance of these financial statements. These financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might result from this uncertainty.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

References in this Annual Report to "authoritative guidance" is meant to refer to accounting principles generally accepted in the United States of America (GAAP) as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) of the Financial Accounting Standards Board (FASB).

Principles of Consolidation

The consolidated financial statements include the accounts of GRI Bio, Inc. and its wholly-owned subsidiary, GRI Bio Operations, Inc. All intercompany balances and transactions have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Estimates and assumptions are primarily made in relation to the valuation of share options, warrant issuance and subsequent revaluations, valuation allowances relating to deferred tax assets, accrued expenses and estimation of the incremental borrowing rate for the operating lease. If actual results differ from the Company's estimates, or to the extent these estimates are adjusted in future periods, the Company's consolidated results of operations could either benefit from, or be adversely affected by, any such change in estimate.

GRI Bio, Inc.
Notes to Consolidated Financial Statements
(in thousands, except share and per share data)

Cash and Cash Equivalents

Cash equivalents are highly-liquid investments that are readily convertible into cash with original maturities of three months or less when purchased and as of December 31, 2025 and 2024 included investment in money market funds. The Company maintains its cash and cash equivalent balances at domestic financial institutions. Bank deposits with US banks are insured up to $250 by the Federal Deposits Insurance Corporation. The Company had an uninsured cash balances of $7,443 and $4,257 at December 31, 2025 and 2024, respectively.

Fair Value Measurements

Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. To increase consistency and comparability in fair value measurements and related disclosures, ASC 820, *Fair Value Measurement* (ASC 820), establishes a fair value hierarchy which prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The three levels of fair value hierarchy defined by ASC 820 are described below:

Level 1: Quoted market prices available in active markets for identical assets or liabilities as of the reporting date.

Level 2: Pricing inputs other than quoted prices in active markets included in Level 1, which are either directly or indirectly observable as of the reporting date.

Level 3: Pricing inputs that are generally unobservable inputs and not corroborated by market data.

As of December 31, 2025, the Company's financial instruments included cash, cash equivalents, prepaid expenses and other current assets, accounts payable, accrued expenses and certain liability classified warrants. The carrying amounts reported in the consolidated balance sheets for cash, cash equivalents, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair value based on the short-term maturity of these instruments. The Company recognizes transfers between levels of the fair value hierarchy on the date of the event or change in circumstances that caused the transfer. At December 31, 2025, there were no financial assets or liabilities measured at fair value on a recurring basis other than the liability classified warrants.

In May 2022, Vallon Pharmaceuticals, Inc. (Vallon) issued warrants (the May 2022 Warrants) in connection with a securities purchase agreement. Vallon evaluated the May 2022 Warrants in accordance with ASC 815-40, *Derivatives and Hedging — Contracts in Entity's Own Equity* (ASC 815-40), and concluded that a provision in the May 2022 Warrants related to the reduction of the exercise price in certain circumstances precluded the May 2022 Warrants from being accounted for as components of equity. As a result, the May 2022 Warrants were recorded as a liability on the consolidated balance sheet. Vallon recorded the fair value of the May 2022 Warrants upon issuance using a Black-Scholes valuation model.

The Company is required to revalue the May 2022 Warrants at each reporting date with any changes in fair value recorded in its statement of operations. The valuation of the May 2022 Warrants is considered under Level 3 of the fair value hierarchy due to the need to use assumptions in the valuation that are both significant to the fair value measurement and unobservable. The change in the fair value of the Level 3 warrant liability is reflected in the statement of operations for the year ended December 31, 2024. As of December 31, 2025 and 2024, the fair value of the warrant liability was immaterial.

Deferred Stock Issuance Costs

Deferred stock issuance costs represent incremental costs incurred that are directly attributable to proposed offerings of securities. The costs are charged against the gross proceeds of the respective offering upon closing.

Property and Equipment

Property and equipment are stated at cost. The Company commences depreciation when the asset is placed in service. Computers and peripheral equipment are depreciated on a straight-line method over useful lives of three years.

GRI Bio, Inc.
Notes to Consolidated Financial Statements
(in thousands, except share and per share data)

Leases

The Company determines whether an arrangement is a lease at contract inception by establishing if the contract conveys the right to use, or control the use of, identified property, plant, or equipment for a period of time in exchange for consideration. Lease right-of-use (ROU) assets and lease liabilities recognized in the accompanying balance sheet represent the right to use an underlying asset for the lease term and an obligation to make lease payments arising from the lease respectively.

At the lease commencement date, the Company recognizes an ROU asset and a lease liability for its operating leases, except its short-term operating leases with original lease terms of twelve months or less. The ROU asset is initially measured at cost, which primarily comprises the initial amount of the lease liability plus any lease prepayments. The lease liability is initially measured at the present value of the lease payments not yet paid, discounted using an estimate of the Company's incremental borrowing rate for a collateralized loan with a similar amount and terms as the underlying lease in a similar economic environment. That discount rate is used because the interest rate implicit in the Company's lease contracts is typically not readily determinable.

Lease modifications that grant the right to use an existing leased asset for an additional period of time are not accounted for as separate contracts; however, the lease term, classification, discount rate, and measurement of the remaining consideration due under the contract are reassessed upon execution of such modifications.

Lease expense for operating leases is recognized on a straight-line basis over the term of the lease and is included in operating expenses.

Research and Development

Research and development costs are expensed as incurred. Research and development expenses include personnel costs associated with research and development activities, including third-party contractors to perform research, conduct clinical trials and manufacture drug supplies and materials. The Company accrues for costs incurred by external service providers, including contract research organizations and clinical investigators, based on its estimates of service performed and costs incurred.

Stock-Based Compensation

The Company recognizes expense for employee and non-employee stock-based compensation in accordance with ASC Topic 718, *Stock-Based Compensation* (ASC 718). ASC 718 requires that such transactions be accounted for using a fair value-based method. The estimated fair value of the options is amortized over the vesting period, based on the fair value of the options on the date granted, and is calculated using the Black-Scholes option-pricing model. The Company accounts for forfeitures as incurred.

Estimating the fair value of options and shares issued under the employee stock purchase plan requires the input of subjective assumptions, including the estimated fair value of the Company's Common Stock, the expected life of the options, stock price volatility, the risk-free interest rate and expected dividends. The assumptions used in the Company's Black-Scholes option-pricing model represent management's best estimates and involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective.

Income Taxes

Income taxes are accounted for under the asset and liability method. The Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities and the expected benefits of net operating loss carryforwards. The impact of changes in tax rates and laws on deferred taxes, if any, applied during the period in which temporary differences are expected to be settled, is reflected in the Company's financial statements in the period of enactment. The measurement of deferred tax assets is reduced, if necessary, if, based on the weight of the evidence, it is more likely than not that some, or all, of the deferred tax assets will not be realized. As of December 31, 2025 and 2024, the Company concluded

GRI Bio, Inc.
Notes to Consolidated Financial Statements
(in thousands, except share and per share data)

that a full valuation allowance was necessary for all of its net deferred tax assets. The Company had no amounts recorded for uncertain tax positions, interest or penalties in the accompanying consolidated financial statements.

Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during each period. Diluted net loss per common share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during each period, plus the dilutive effect of common stock equivalents outstanding during each period, in accordance with ASC 260, *Earnings Per Share*. As the Company had a net loss in each of the years ended December 31, 2025 and 2024, diluted net loss per common share is the same as basic net loss per common share for the period because the effects of potentially dilutive securities are antidilutive.

Common stock equivalents excluded from the diluted net loss per common share calculations are as follows:

	December 31,	
	2025	2024
Stock options	15,032	1
Warrants	572,781	12,882
	587,813	12,883

Recently Adopted Accounting Pronouncements

In December 2023, FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* (ASU 2023-09). The amendments in ASU 2023-09 are intended to enhance the transparency and decision usefulness of income tax disclosures through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. ASU 2023-09 is effective for annual periods beginning after December 15, 2024 for public entities, with early adoption permitted. Management is currently evaluating the impact of this update on the Company's financial statements. The Company has adopted the provisions of ASU 2023-09 and has included the required disclosures in this Annual Report. See Note 11 for additional disclosures.

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): *Improvements to Reportable Segment Disclosures* (ASU 2023-07). This amended guidance applies to all public entities and aims to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. This guidance is effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. The Company has adopted the provisions of ASU 2023-07 and has included the required disclosures in this Annual Report. See Note 9 for additional disclosures.

Recently Issued Accounting Pronouncements

The Company considers the applicability and impact of all ASUs. ASUs not discussed below were assessed and determined to be either not applicable or are expected to have minimal impact on the financial statements.

In November 2024, FASB issued ASU 2024-03, *Income Statement — Reporting Comprehensive Income — Expense Disaggregation Disclosures (Subtopic 220-40)* (ASU 2024-03). The amendments in ASU 2024-03 require disclosure, in the notes to financial statements, of specified information about certain costs and expenses. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, for all public entities. Early adoption is permitted. Management is currently evaluating the impact of this update on the Company's financial statements.

In October 2023, FASB issued ASU 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative (*ASU 2023-06). The amendments in ASU 2023-06 represent changes to clarify or improve disclosure and presentation requirements of a variety of topics in the Codification and align those requirements with the SEC's regulation. For entities subject to the Security and Exchange Commission's (SEC) existing disclosure requirements, the effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. For all entities, if by June 30, 2027, the SEC has not removed the applicable requirement from Regulation S-X or Regulation S-K, the pending content of the related amendment will be removed from the Codification and will not become effective for any entity. Management is currently evaluating the impact of this update and its effective dates but does not expect the update to have a material effect on the Company's financial statements.

GRI Bio, Inc.
Notes to Consolidated Financial Statements
(in thousands, except share and per share data)

4. PROPERTY AND EQUIPMENT.

	December 31,	
	2025	2024
Computer equipment	$ 24	$ 21
Furniture and fixtures	13	13
	37	34
Accumulated depreciation	(34)	(30)
	$ 3	$ 4

Depreciation expense related to property and equipment was $4 in each of the years ended December 31, 2025 and 2024.

5. LEASES.

The Company leases office facilities under an operating lease agreement. The lease agreement requires fixed monthly rental payments as well as payments for variable monthly utilities and operating costs throughout the lease term. The Company evaluates renewal options at lease inception on an ongoing basis and includes renewal options that it is reasonably certain to exercise in its expected lease terms when classifying leases and measuring lease liabilities. Lease agreements generally do not require material variable lease payments, residual value guarantees or restrictive covenants.

The table below presents the operating lease assets and liabilities recognized on the Company's consolidated balance sheets:

		December 31,	
	Balance Sheet Line Item	2025	2024
Non-current operating lease assets	Operating lease right-of-use asset	$ 71	$ 120
Operating lease liabilities:			
Current operating lease liabilities	Operating lease liabilities, current	56	48
Non-current operating lease liabilities	Operating lease liabilities, non-current	15	71
Total operating lease liabilities		$ 71	$ 119

The Company’s lease generally does not provide an implicit rate, and therefore, the Company uses its incremental borrowing rate as the discount rate when measuring operating leases liabilities. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of a lease. The Company used a discount rate of 12% for its operating lease. The operating lease has a remaining term of 1.25 years.

Future minimum lease payments are due as follows:

	Year Ended December 31,
2026	$ 62
2027	15
Total	$ 77
Less: Imputed interest	6
Present value of operating lease liabilities	$ 71

Operating lease costs were $62 for each of the years ended December 31, 2025 and 2024, respectively. Operating lease costs are included within selling, general and administrative expenses on the consolidated statements of operations.

Cash paid for amounts included in the measurement of operating lease liabilities were $60 and $59 for the years ended December 31, 2025 and 2024, respectively. This amount is included in operating activities in the consolidated statements of cash flows.

The Company’s principal office is in La Jolla, CA, where it leases approximately 1,100 square feet of office space pursuant to a lease that expires in March 2027.

GRI Bio, Inc.
Notes to Consolidated Financial Statements
(in thousands, except share and per share data)

6. ACCRUED EXPENSES.

Accrued expenses consisted of:

	December 31,	
	2025	2024
Accrued expenses:		
Research and development	$ 383	$ 342
General and administrative	31	12
Payroll and related	336	337
Total accrued expenses	$ 750	$ 691

7. STOCKHOLDERS EQUITY.

February 2024 Securities Purchase Agreement

On February 1, 2024, the Company entered into the February 2024 Purchase Agreement, pursuant to which the Company sold, in the February 2024 Offering, (i) 53 shares (the February 2024 Shares) of Common Stock, (ii) 755 pre-funded warrants (the February 2024 Pre-Funded Warrants) exercisable for an aggregate of 755 shares of Common Stock, (iii) 809 Series B-1 common warrants (the Series B-1 Common Warrants) exercisable for an aggregate of 809 shares of Common Stock and (iv) 809 Series B-2 common warrants (the Series B-2 Common Warrants, and together with the Series B-1 Common Warrants, the Series B Common Warrants) exercisable for an aggregate of 809 shares of Common Stock for net proceeds of $4,389, after deducting offering expenses of $1,110. The Series B Common Warrants together with the February 2024 Pre-Funded Warrants are referred to in this Annual Report as the "February 2024 Warrants." The securities were offered in combinations of (a) one February 2024 Share or one February 2024 Pre-Funded Warrant, together with (b) one Series B-1 Common Warrant and one Series B-2 Common Warrant, for a combined purchase price of $6,806.80 (less $0.6188 for each February 2024 Pre-Funded Warrant).

Subject to certain ownership limitations, the February 2024 Warrants were exercisable upon issuance. Each February 2024 Pre-Funded Warrant was exercisable for one share of Common Stock at a price per share of $0.6188 and expired when exercised in full. Each Series B-1 Common Warrant is exercisable into one share of Common Stock at a price per share of $6,806.80 for a five-year period after February 6, 2024, the date of issuance. Each Series B-2 Common Warrant is exercisable into one share of Common Stock at a price per share of $6,806.80 for an 18-month period after February 6, 2024, the date of issuance. The February 2024 Warrants were classified as equity and the allocated fair value of $4,279 is included in additional paid-in capital. As of December 31, 2025, all of the February 2024 Pre-Funded Warrants have been exercised.

The Company determined that the amount paid for the February 2024 Pre-Funded Warrants approximates their fair value. The Black-Scholes option-pricing model was used to estimate the fair value of the Series B-1 Common and Series B-2 Common Warrants with the following weighted-average assumptions:

Volatility	156.3 %
Expected term in years	1.63
Dividend rate	0.0 %
Risk-free interest rate	4.65 %

In connection with the issuance of the securities pursuant to the February 2024 Purchase Agreement, the exercise price of the Company's previously outstanding Series A-1 common warrants (the Series A-1 Warrants) was reduced to par, or $0.0001, per share pursuant to the terms of the Series A-1 Warrants. As of December 31, 2025, all of the Series A-1 Warrants have been exercised.

May 2024 At The Market Offering

On May 20, 2024, the Company entered into the Sales Agreement with Wainwright, pursuant to which the Company may sell and issue, subject to the limitations in the Sales Agreement, shares up to $10.0 million of Common Stock from time to time in the ATM Offering. Under the Sales Agreement, Wainwright is entitled to compensation of 3.0% of the gross offering proceeds of all shares of Common Stock sold through it pursuant to the Sales Agreement.

GRI Bio, Inc.
Notes to Consolidated Financial Statements
(in thousands, except share and per share data)

As of December 31, 2025, the Company has sold 60,003 shares of Common Stock in the ATM Offering at a weighted-average price of $102.75 per share, for gross proceeds of $6,165 and net proceeds of $5,858. During the year ended December 31, 2025, the Company sold 48,374 shares of Common Stock in the ATM Offering with a weighted average price of $52.93 per share, for gross proceeds of $2,560 and net proceeds of $2,391. During the year ended December 31, 2024, the Company sold 11,629 shares of Common Stock in the ATM Offering with a weighted average price of $309.97 per share, for gross proceeds of $3,604 and net proceeds of $3,467.

On January 9, 2026, the Company filed a prospectus supplement to its registration statement on Form S-3 (File No. 333-279348) to increase the amount of shares of Common Stock that the Company may offer and sell under the Sales Agreement and applicable registration statement to an aggregate offering price of up to $7,380, which amount does not include the shares of Common Stock having an aggregate gross sales price of approximately $6,165 that were sold under the ATM Offering through January 8, 2026, in accordance with the limitations set forth in Instruction I.B.6 of Form S-3.

June 2024 Securities Purchase Agreement

On June 26, 2024, the Company entered into the June 2024 Purchase Agreement, pursuant to which the Company issued and sold, in the June 2024 Offering, (i) 126 shares (the June 2024 Shares) of Common Stock, (ii) 4,466 pre-funded warrants (the June 2024 Pre-Funded Warrants) exercisable for an aggregate of 4,466 shares of Common Stock, (iii) 4,593 Series C-1 common warrants (the Series C-1 Common Warrants) exercisable for an aggregate of 4,593 shares of Common Stock, and (iv) 4,593 Series C-2 common warrants (the Series C-2 Common Warrants, and together with the Series C-1 Common Warrants, the Series C Common Warrants), exercisable for an aggregate of 4,593 shares of Common Stock for net proceeds of $3,172, after deducting offering expenses of $1,057. The Series C Common Warrants together with the June 2024 Pre-Funded Warrants are referred to in this Annual Report as the "June 2024 Warrants." The securities were offered in combinations of (a) one June 2024 Share or one June 2024 Pre-Funded Warrant, together with (b) one Series C-1 Common Warrant and one Series C-2 Common Warrant, for a combined purchase price of $871.08 (less $0.0476 for each June 2024 Pre-Funded Warrant).

The June 2024 Pre-Funded Warrants were exercisable for one share of Common Stock at a price per share of $0.0476, were exercisable immediately and have been exercised in full as of December 31, 2025. Each Series C-1 Common Warrant is exercisable into one share of Common Stock at a price per share of $871.08 or a five-year period beginning after September 6, 2024. Each Series C-2 Common Warrant is exercisable into one share of Common Stock at a price per share of $871.08 for an 18-month period beginning after September 6, 2024. The June 2024 Pre-Funded Warrants and the Series C Common Warrants were classified as equity and the allocated fair value of $2,908 is included in additional paid in capital.

Pursuant to an engagement agreement with Wainwright, the Company, in connection with the June 2024 Offering, issued to Wainwright, or its designees, warrants to purchase up to an aggregate of 324 shares of Common Stock (the June 2024 PA Warrants). The June 2024 PA Warrants have an exercise price of $1,088.92 per share and will expire on June 26, 2029. The June 2024 PA Warrants were classified as equity and the fair value of $229 is included in additional paid-in capital.

The Company determined that the amount paid for the June 2024 Pre-Funded Warrants approximates their fair value. The Black-Scholes option-pricing model was used to estimate the fair value of the Series C-1 Common Warrants, the Series C-2 Common Warrants, and the Placement Agent Warrants with the following weighted-average assumptions:

Volatility	159.1 %
Expected term in years	1.65
Dividend rate	0.0 %
Risk-free interest rate	4.92 %

GRI Bio, Inc.
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October 2024 Repricing Letter Agreement

On October 21, 2024, the Company entered into the Repricing Letter Agreements with certain Holders of its issued and outstanding Series B Common Warrants to purchase an aggregate of 1,602 shares of its Common Stock, pursuant to which these Holders exercised Series B Common Warrants for cash at a reduced exercise price equal to $476.00 per share. In addition, these Holders received new unregistered Series D-1 common warrants (the Series D-1 Common Warrants) exercisable for up to an aggregate of 1,604 shares of Common Stock and new unregistered Series D-2 common warrants (the Series D-2 Common Warrants, and together with the Series D-1 Common Warrants, the Series D Common Warrants) exercisable for up to an aggregate of 1,604 shares of Common Stock. The Series D Common Warrants are immediately exercisable and have an exercise price of $476.00 per share. The Series D-1 Common Warrants expire on October 22, 2029, and the Series D-2 Common Warrants expire on April 22, 2026. This transaction is referred to as the "Warrant Repricing Transaction."

Wainwright acted as the exclusive placement agent for the Warrant Repricing Transaction pursuant to an engagement agreement between the Company and Wainwright dated as of October 21, 2024. As compensation for such placement agent services, the Company agreed to pay Wainwright an aggregate cash fee equal to 7.0% of the gross proceeds received by the Company from the Warrant Repricing Transaction, plus a management fee equal to 1.0% of the gross proceeds received by the Company from the Warrant Repricing Transaction, and reimbursement for accountable expenses of $25,000 and non-accountable expenses of $10,000. The Company has also issued to Wainwright or its designees the October 2024 PA Warrants to purchase up to an aggregate of 114 shares of Common Stock (the October 2024 PA Warrants). The October 2024 PA Warrants are immediately exercisable, expire on October 22, 2029, and have an exercise price of $595.00 per share.

The net proceeds to the Company from the exercise of the Series B Common Warrants were $608 after deducting placement agent fees and offering expenses of $154. The issuance under the Repricing Letter Agreements represented $1,911 in additional value provided to the investors, which was recorded as a deemed dividend to common stockholders.

The Black-Scholes option-pricing model was used to estimate the fair value of the Series D-1 Common Warrants, the Series D-2 Common Warrants, and the October 2024 PA Warrants with the following weighted-average assumptions:

Volatility	174.4 %
Expected term in years	1.65
Dividend rate	0.0 %
Risk-free interest rate	4.16 %

April 2025 Securities Purchase Agreement

On April 1, 2025, the Company entered into the April 2025 Purchase Agreement, pursuant to which the Company issued and sold, in the April 2025 Offering, (i) 7,214 shares (the April 2025 Shares) of Common Stock, (ii) 42,389 pre-funded warrants (the April 2025 Pre-Funded Warrants) exercisable for an aggregate of 42,389 shares of Common Stock, (iii) 49,605 Series E-1 common stock warrants (the Series E-1 Common Warrants) to purchase up to 49,605 shares of Common Stock, (iv) 49,605 Series E-2 common stock warrants (the Series E-2 Common Warrants) to purchase up to 49,605 shares of Common Stock, and (v) 49,605 Series E-3 common stock warrants (the Series E-3 Common Warrants, and collectively with the Series E-1 Common Warrants and the Series E-2 Common Warrants, the Series E Common Warrants) to purchase up to 49,605 shares of Common Stock, for net proceeds of $4,020, after deducting offering expenses of $979.

The securities were offered in combinations of (a) one April 2025 Share or one April 2025 Pre-Funded Warrant, together with (b) one Series E-1 Common Warrant, one Series E-2 Common Warrant and one Series E-3 Common Warrant, for a combined purchase price of $100.80 (less $0.0028 for each April 2025 Pre-Funded Warrant). The April 2025 Pre-Funded Warrants had an exercise price of $0.0028 per share, became exercisable immediately upon issuance and expired when exercised in full. Each Series E Common Warrant has an exercise price of $89.60 per share and became exercisable immediately upon issuance. The Series E-1 Common Warrants expire on April 2, 2030. The Series E-2 Common Warrants expire on October 2, 2026. The Series E-3 Common Warrants expired on January 2, 2026. As of December 31, 2025, the April 2025 Pre-Funded Warrants have been exercised in full.

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Wainwright acted as the exclusive placement agent for the April 2025 Offering pursuant to an engagement agreement between the Company and Wainwright dated as of March 7, 2025. As compensation for such placement agent services, the Company agreed to pay Wainwright an aggregate cash fee equal to 7.0% of the gross proceeds received by the Company from the offering, plus a management fee equal to 1.0% of the gross proceeds received by the Company from the offering, reimbursement for accountable expenses of $25,000, reimbursement of up to $100,000 for legal fees and expenses and other out-of-pocket expenses and up to $15,950 for the clearing expenses. The Company also issued to Wainwright, or its designees, warrants to purchase up to an aggregate of 3,474 shares of Common Stock (the April 2025 PA Warrants). The April 2025 PA Warrants became exercisable immediately upon issuance, expire on April 1, 2030, and have an exercise price of $126.00 per share. The April 2025 PA Warrants were classified as equity and the fair value of $123 is included in additional paid-in capital.

The Company determined that the amount paid for the April 2025 Pre-Funded Warrants approximates their fair value. The Black-Scholes option-pricing model was used to estimate the fair value of the Series E Common Warrants and the April 2025 PA Warrants with the following weighted-average assumptions:

Volatility	156.44 %
Expected term in years	2.48
Dividend rate	— %
Risk-free interest rate	4.02 %

December 2025 Securities Purchase Agreement

On December 12, 2025, the Company entered into the December 2025 Purchase Agreement, pursuant to which the Company issued and sold, in the December 2025 Offering, (i) 92,976 shares (the December 2025 Shares) of Common Stock (ii) 287,977 pre-funded warrants (the December 2025 Pre-Funded Warrants) exercisable for an aggregate of 287,977 shares of Common Stock and (iii) 380,962 Series F common stock warrants (the Series F Common Warrants) to purchase up to 380,962 shares of Common Stock for net proceeds of $6,288 after deducting offering expenses of $1,711.

The securities were offered in combinations of (a) one December 2025 Share or one December 2025 Pre-Funded Warrant, together with (b) one Series F Common Warrant for a combined purchase price of $21.00 (less $0.0028 for each December 2025 Pre-Funded Warrant). The December 2025 Pre-Funded Warrants had an exercise price of $0.0028 per share, became exercisable immediately upon issuance and expired when exercised in full. Each Series F Common Warrant has an exercise price of $21.00 per share, became exercisable immediately upon issuance and expire on December 12, 2030. As of December 31, 2025, the December 2025 Pre-Funded Warrants have been exercised in full.

Wainwright acted as the exclusive placement agent for the December 2025 Offering pursuant to an engagement agreement between the Company and Wainwright dated as of December 5, 2025. As compensation for such placement agent services, the Company agreed to pay Wainwright an aggregate cash fee equal to 7.0% of the gross proceeds received by the Company from the offering, plus a management fee equal to 1.0% of the gross proceeds received by the Company from the offering, reimbursement for accountable expenses of $25,000, reimbursement of up to $100,000 for legal fees and expenses and other out-of-pocket expenses and up to $15,950 for the clearing expenses. The Company also issued to Wainwright, or its designees, warrants to purchase up to an aggregate of 26,667 shares of Common Stock (the December 2025 PA Warrants). The December 2025 PA Warrants became exercisable immediately upon issuance, expire on December 12, 2030, and have an exercise price of $26.25 per share. The December 2025 PA Warrants were classified as equity and the fair value of $317 is included in additional paid-in capital.

The Company determined that the amount paid for the December 2025 Pre-Funded Warrants approximates their fair value. The Black-Scholes option-pricing model was used to estimate the fair value of the Series F Common Warrants and the December 2025 PA Warrants with the following weighted-average assumptions:

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Volatility	124.87 %
Expected term in years	5.0
Dividend rate	— %
Risk-free interest rate	3.75 %

Warrants

As of December 31, 2025, the Company had the following warrants outstanding to purchase common stock.

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Number of Shares	Exercise Price per Share	Expiration Date
49,605	$89.60	January 2026
9	$12,994,800.00	February 2026
4,593	$871.08	March 2026
1,604	$476.00	April 2026
49,605	$89.60	October 2026
1	$1,219,345.40	May 2027
1	$0.01	July 2027
3	$2,659,169.24	April 2028
19	$6,806.80	February 2029
324	$1,088.85	June 2029
4,593	$871.08	September 2029
1,604	$476.00	October 2029
114	$595.00	October 2029
49,605	$89.60	April 2030
3,474	$126.00	April 2030
380,962	$21.00	December 2030
26,667	$26.25	December 2030

8. STOCK BASED COMPENSATION.

Amended and Restated 2018 Equity Incentive Plan

On April 21, 2023, the stockholders of the Company approved the Amended and Restated GRI Bio, Inc. 2018 Equity Incentive Plan (the A&R 2018 Plan) and on August 13, 2025, the stockholders of the Company approved an amendment to the A&R 2018 Plan to increase the aggregate number of shares of the Company's Common Stock thereunder by 14,285. The A&R 2018 Plan provides the Company with the ability to grant stock options, restricted stock and other equity-based awards to employees, directors and consultants. Stock options granted by the Company under the A&R 2018 Plan generally have a contractual life of up to 10 years. As of December 31, 2025, awards granted under the A&R 2018 Plan representing the right to purchase or contingent right to receive up to an aggregate of 15,032 shares of the Company's Common Stock were outstanding and 15,044 shares of the Company's Common Stock were reserved for issuance under the A&R 2018 Plan. The number of shares reserved for issuance under the A&R 2018 Plan may be increased pursuant to the A&R 2018 Plan's "evergreen" provision on the first day of each calendar year beginning January 1, 2025 and ending on and including January 1, 2033, by a number of shares not to exceed 4% of the aggregate number of shares of the Company's Common Stock outstanding on the final day of the immediately preceding calendar year.

The Company recorded stock-based compensation related to equity-based awards issued under the A&R 2018 Plan in the following expense categories of its accompanying consolidated statements of operations for the years ended December 31, 2025 and 2024:

	For the Year Ended December 31,	
	2025	2024
Research and development	$ 86	$ —
General and administrative	707	148
Total	$ 793	$ 148

The Company measures equity-based awards granted to employees and non-employees based on their fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period or performance-based period, which is generally the vesting period of the respective award. The measurement date for service-based equity awards is the date of grant, and

equity-based compensation costs are recognized as expense over the requisite service period. The Company records expense for performance-based awards if the Company concludes that it is probable that the performance condition will be achieved.

The table below represents the activity of stock options granted to employees and non-employees for the year ended December 31, 2025:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at December 31, 2024	1	$ 65,840.32	7.75
Granted	15,031	$ 64.07	
Exercised	—		
Forfeited	—		
Outstanding at December 31, 2025	15,032	$ 68.44	9.67
Exercisable at December 31, 2025	11,127	$ 69.57	9.66
Vested and expected to vest at December 31, 2025	15,032	$ 68.44	9.67

As of December 31, 2025, all of the outstanding and exercisable stock options were out of the money and therefore had no intrinsic value. At December 31, 2025, the unrecognized compensation cost related to unvested stock options expected to vest was $249. This unrecognized compensation is expected to be recognized over a weighted-average amortization period of 0.92 years.

The Company granted 15,031 stock options to employees and non-employees during the year ended December 31, 2025. The Black-Scholes option-pricing model was used to estimate the grant date fair value of each stock option grant at the time of grant using the following weighted-average assumptions:

	For the Year Ended December 31, 2025
Volatility	120.89 %
Expected term in years	5.18
Dividend rate	0.00 %
Risk-free interest rate	3.75 %
Fair value of common stock on grant date	$ 64.07

No equity-based awards were granted during the year ended December 31, 2024.

Option valuation methods, including Black-Scholes, require the input of subjective assumptions, which are discussed below.

- The expected term of options is determined using the "simplified" method, as prescribed in SEC's SAB No. 107, Share Based Payment (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 volatility is based on a weighted average of the Company's historical volatility and the volatilities of similar 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 US Treasury securities in effect at the time of grant for a period that is commensurate with the assumed 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.

9. SEGMENT REPORTING.

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker (CODM), or decision-making group, in deciding how to allocate resources in assessing performance. The Company has one reportable segment: biotechnology research. The biotechnology research segment consists of the

research and development of products for the treatment of inflammatory disease. The Company's CODM is W. Marc Hertz, Ph.D., Chief Executive Officer and Director.

The accounting policies of the biotechnology research segment are the same as those described in the summary of significant accounting policies. The CODM assesses performance for the biotechnology research segment based on research and development expenses and general and administrative expenses as part of the overall review of the Company's consolidated net loss and consolidated cash flows as compared to prior quarters and the Company's operating budget.

The Company has incurred significant losses since its inception and anticipates incurring continued losses in the future. As such, the CODM uses cash forecast models in deciding how to allocate resources based on the Company's available cash resources, as well as its forecasted expenditures. This information, in conjunction with the assessment of the probability of the success of the Company's research and development activities, is used to plan the timing and size of future capital raises.

10. COMMITMENTS AND CONTINGENCIES.

Legal Proceedings

The Company is not currently a party to any material legal proceedings, and is not aware of any pending or threatened legal proceeding against the Company that it believes could have a material adverse effect on its business, operating results or financial condition. From time to time, the Company may become involved in legal proceedings arising in the ordinary course of its business. Regardless of outcome, litigation can have a material adverse impact on the Company due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Employment Agreements

The Company has entered into employment contracts with each of its officers that provide for severance and continuation of benefits in the event of termination of employment by the Company without cause or by the employee for good reason. In addition, in the event of termination of employment following a change in control, the vesting of certain equity awards may be accelerated.

Separation and Release Agreement

In connection with the resignation of David Baker, the Company's former Chief Executive Officer, pursuant to the Merger, the Company and Mr. Baker entered into a Separation and Release Agreement on April 21, 2023 (the Separation Agreement). Pursuant to the terms of the Separation Agreement and his employment agreement, Mr. Baker will receive continuation of his current salary and certain COBRA benefits for 18 months payable in accordance with the Company's payroll practices. Mr. Baker also received a lump sum payment equal to 150% of his target bonus and agreed to reduce amounts payable with respect to certain future milestone payments.

11. INCOME TAX.

A reconciliation of income tax expense (benefit) at the US federal statutory income tax rate and the income tax provision in the financial statements is as follows:

	December 31,			
	2025		2024	
	$	%	$	%
Expected income tax benefit at the U.S. federal statutory tax rate	(2,511)	21.0	(1,723)	21.0
State and local taxes, net of federal benefit[1]	2	—	1	—
Tax credits				
Research and development credits	—	—	136	(1.7)
Change in valuation allowance	2,195	(18.4)	1,842	(22.4)
Nontaxable or nondeductible items				
Equity compensation	316	(2.6)	6	(0.1)
Other nontaxable or nondeductible items	1	—	54	(0.6)
Deferred tax adjustment	—	—	(314)	3.8
Total	3	—	2	—

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(1) During the years ended December 31, 2025 and 2024, state taxes in California made up the majority (greater than 50%) of the tax effect in this category.

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

The principal components of the Company's deferred tax assets and liabilities are as follows:

	December 31,	
	2025	2024
Deferred tax assets:		
Federal and state net operating loss carryforwards	$ 16,784	$ 14,537
Share based compensation	—	200
Accruals and other	—	94
Lease liabilities	20	34
Capitalized research and development costs	3,161	1,846
Depreciation - Federal and state	2	2
Amortization - Federal and state	4	5
Gross deferred tax assets	$ 19,971	$ 16,718
Less: deferred tax liabilities	(20)	(34)
Less: valuation allowance	(19,951)	(16,684)
Net deferred tax assets	$ —	$ —

Based on the Company's history of losses, the Company recorded a full valuation allowance against its deferred tax assets as of December 31, 2025 and 2024. The Company increased its valuation allowance by approximately $3,267 for the year ended December 31, 2025. The Company intends to maintain a valuation allowance until sufficient positive evidence exists to support a reversal of the allowance.

As of December 31, 2025, the Company had federal, state and local net operating loss carryforwards of $59,173, $69,754, and $5,563, respectively; $53,048 of the federal net operating loss carryforwards do not expire and the remaining $6,124 begin to expire in 2029. The state losses also begin to expire in 2029. The local net operating losses began to expire in 2024. Under the provisions of Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (IRC), these net operating losses, credit carryforwards and other tax attributes may be subject to limitation based on previous significant changes in ownership and upon future significant changes in ownership of the Company, as defined by the IRC.

Under the provisions of Sections 382 and 383 of the IRC, certain substantial changes in the Company's ownership may have limited, or may limit in the future, the amount of net operating loss and credit carryforwards that can be used to reduce future income taxes if there has been a significant change in ownership of the Company, as defined by the IRC. Future owner or equity shifts could result in limitations on net operating loss and credit carryforwards. The Company has not conducted a Section 382 analysis to determine the potential limitations on the utilization of its net operating loss carryforwards and other tax attributes. Management does not believe that any such limitations, if applicable, would have a material impact on the Company's consolidated financial statements.

The Company files income tax returns in the US federal jurisdiction as well as California, Pennsylvania and Philadelphia. The tax years 2021 to 2024 remain open to examination by the major jurisdictions in which the Company is subject to tax. Fiscal years outside the normal statute of limitation remain open to audit by tax authorities due to tax attributes generated in those early years, which have been carried forward and may be audited in subsequent years when utilized.

The Company evaluates tax positions for recognition using a more-likely-than-not recognition threshold, and those tax positions eligible for recognition are measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon the effective settlement with a taxing authority that has full knowledge of all relevant information. As of December 31, 2025 and 2024, the Company had no unrecognized income tax benefits that would affect the Company's effective tax rate if recognized. The Company would recognize both accrued interest and penalties related to unrecognized benefits in income tax expense. The Company's uncertain tax positions yet to be determined would be related to years that remain subject to examination by relevant tax authorities. Since the Company is in a loss carryforward position, the Company is generally subject to examination by the U.S. federal, state and local income tax authorities for all tax years in which a loss carryforward is available.

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12. SUBSEQUENT EVENTS.

Recapitalization

On January 23, 2026, the Company effected the January 2026 Reverse Stock Split. Stockholders' equity and all references to share and per share amounts in the accompanying financial statements have been retroactively adjusted to reflect the one-for-twenty-eight reverse stock split for all periods presented.

May 2024 At The Market Offering

As discussed in Note 7, "Stockholders' Equity" to these audited consolidated financial statements, on January 9, 2026, the Company filed a prospectus supplement to its registration statement on Form S-3 (File No. 333-279348) to increase the amount of shares of Common Stock that the Company may offer and sell under the Sales Agreement and applicable registration statement to an aggregate offering price of up to $7,380, which amount does not include the shares of Common Stock having an aggregate gross sales price of approximately $6,165 that were sold under the ATM Offering through January 8, 2026, in accordance with the limitations set forth in Instruction I.B.6 of Form S-3. Since December 31, 2025, the Company has sold 947,342 shares of Common Stock with an aggregate gross sales price of $6,474.

Exhibit 3.1

Delaware
The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE RESTATED CERTIFICATE OF "VALLON PHARMACEUTICALS, INC.", FILED IN THIS OFFICE ON THE TENTH DAY OF FEBRUARY, A.D. 2021, AT 1:14 O'CLOCK P.M.



6705195 8100 Authentication: 202482772
SR# 20210402453 Date: 02-10-21
You may verify this certificate online at corp.delaware.gov/authver.shtml

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
VALLON PHARMACEUTICALS, INC.
(a Delaware corporation)

The present name of the corporation is Vallon Pharmaceuticals, Inc. (the "Corporation"). The Corporation was incorporated under its present name by the filing of its original certificate of incorporation (as heretofore amended, the "Original Certificate of Incorporation") with the Secretary of State of the State of Delaware on January 11, 2018. This Amended and Restated Certificate of Incorporation of the Corporation (as the same may be amended and/or restated from time to time, the "Certificate of Incorporation"), which amends, restates and integrates the provisions of the Original Certificate of Incorporation, was duly adopted in accordance with the provisions of Sections 242 and 245 of the General Corporation Law of die State of Delaware and by the written consent of the stockholders in accordance with Section 228 of the General Corporation Law of the State of Delaware. The Original Certificate of Incorporation of the Corporation is hereby amended and restated to read in its entirety as follows:

ARTICLE I
NAME

The name of the corporation is Vallon Pharmaceuticals, Inc. (the "Corporation").

ARTICLE II
AGENT

The address of the Corporation's registered office in the State of Delaware is c/o The Corporation Trust Company, 1209 Orange Street in the City of Wilmington, County of New Castle, 19801. The name of its registered agent at such address is The Corporation Trust Company.

ARTICLE III
PURPOSE

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware (the "DGCL").

ARTICLE IV
STOCK

4.1 Authorized Stock. The total number of shares which the Corporation shall have authority to issue is 260,000,000, of which 250,000,000 shall be designated as Common Stock, par value $0.0001 per share (the "Common Stock"), and 10,000,000 shall be designated as Preferred Stock, par value $0.0001 per share (the "Preferred Stock").

4.2 Common Stock.

(a) Each holder of Common Stock, as such, shall be entitled to one vote for each share of Common Stock held of record by such holder on all matters on which stockholders generally are entitled to vote; provided, however, that, except as otherwise required by law, holders of Common Stock, as such, shall not be entitled to vote on any amendment to this Certificate of Incorporation, including any certificate of designations relating to any series of Preferred Stock (each hereinafter referred to as a "Preferred Stock Designation" that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation (including any Preferred Stock Designation).

State of Delaware

Secretary of State

Division of Corporations

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(b) Dividends. Subject to the rights of the holders of any outstanding series of Preferred Stock, the holders of shares of Common Stock shall be entitled to receive dividends to the extent permitted by law when, as and if declared by the Board of Directors.

(c) Liquidation. Upon the dissolution, liquidation or winding up of the Corporation, subject to the rights of the holders of any outstanding series of Preferred Stock, the holders of shares of Common Stock shall be entitled to receive the assets of the Corporation available for distribution to its stockholders ratably in proportion to the number of shares held by them.

4.3 Preferred Stock. The Preferred Stock may be issued from time to time in one or more series. Subject to limitations prescribed by law and the provisions of this Article IV (including any Preferred Stock Designation), the Board of Directors is hereby authorized to provide by resolution and by causing the filing of a Preferred Stock Designation for the issuance of the shares of Preferred Stock in one or more series, and to establish from time to time the number of shares to be included in each such series, and to fix the designations, powers, preferences, and relative, participating, optional or other rights, if any, and the qualifications, limitations or restrictions, if any, of the shares of each such series.

4.4 No Class Vote on Changes in Authorized Number of Shares of Stock. Subject to the rights of the holders of any outstanding series of Preferred Stock, the number of authorized shares of Common Stock or Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of at least a majority of the voting power of the stock outstanding and entitled to vote thereon irrespective of the provisions of Section 242(b)(2) of the DGCL.

ARTICLE V
BOARD OF DIRECTORS

5.1 Number. Except as otherwise provided for or fixed pursuant to the provisions of Article IV hereof (including any Preferred Stock Designation), the Board of Directors shall consist of such number of directors as shall be determined from time to time solely by resolution adopted by the affirmative vote of a majority of the total number of directors then authorized.

5.2 Classification.

(a) Except as may be otherwise provided with respect to directors elected by the holders of any series of Preferred Stock provided for or fixed pursuant to the provisions of Article IV hereof (including any Preferred Stock Designation) (the "Preferred Stock Directors"), the Board of Directors shall be divided into three classes, designated Class I, Class II and Class III. Class I directors shall initially serve until the first annual meeting of stockholders following the initial effectiveness of this Section 5.2; Class II directors shall initially serve until the second annual meeting of stockholders following the initial effectiveness of this Section 5.2; and Class III directors shall initially serve until the third annual meeting of stockholders following the initial effectiveness of this Section 5.2. Commencing with the first annual meeting of stockholders following the initial effectiveness of this Section 5.2, directors of each class the term of which shall then expire shall be elected to hold office for a three-year term and until the election and qualification of their respective successors in office. The Board of Directors is authorized to assign members of the Board of Directors already in office to Class I, Class II or Class III, with such assignment becoming effective as of the initial effectiveness of this Section 5.2.

(b) Subject to the rights of the holders of any outstanding series of Preferred Stock, and unless otherwise required by law, newly created directorships resulting from any increase in the authorized number of directors and any vacancies in the Board of Directors resulting from death, resignation, retirement, disqualification, removal from office or other cause shall be filled solely by the affirmative vote of a majority of the remaining directors then in office (other than any director elected by a separate vote of the holders of one or more outstanding series of Preferred Stock), even though less than a quorum of the Board of Directors. Any director so chosen shall hold office until the next election of the class for which such director shall have been chosen and until his or her successor shall have been duly elected and qualified. No decrease in the authorized number of directors shall shorten the term of any incumbent director.

(c) Any director elected by the stockholders generally may be removed from office at any time, but only for cause and only by the affirmative vote of at least 66 2/3% of the voting power of the stock outstanding and entitled to vote thereon.

(d) During any period when the holders of any series of Preferred Stock have the right to elect additional directors as provided for or fixed pursuant to the provisions of Article IV hereof (including any Preferred Stock Designation), and upon commencement and for the duration of the period during which such right continues: (i) the then otherwise total authorized number of directors of the Corporation shall automatically be increased by such number of directors that the holders of any series of Preferred Stock have a right to elect, and the holders of such Preferred Stock shall be entitled to elect the additional directors so provided for or fixed pursuant to said provisions; and (ii) each Preferred Stock Director shall serve until such Preferred Stock Director's successor shall have been duly elected and qualified, or until such director's right to hold such office terminates pursuant to said provisions, whichever occurs earlier, subject to his or her earlier death, disqualification, resignation or removal. Except as otherwise provided for or fixed pursuant to the provisions of Article IV hereof (including any Preferred Stock Designation), whenever the holders of any series of Preferred Stock having such right to elect additional directors are divested of such right pursuant to said provisions, the terms of office of all Preferred Stock Directors elected by the holders of such Preferred Stock, or elected to fill any vacancies resulting from the death, resignation, disqualification or removal of such additional directors, shall forthwith terminate (in which case such Preferred Stock Director shall cease to be qualified as a director and shall cease to be a director) and the total authorized number of directors of the Corporation shall be automatically reduced accordingly.

5.3 Powers. Except as otherwise required by the DGCL or as provided in this Certificate of Incorporation (including any Preferred Stock Designation), the business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors.

5.4 Election: Annual Meeting of Stockholders.

(a) Ballot Not Required. The directors of the Corporation need not be elected by written ballot unless the Bylaws of the Corporation so provide.

(b) Notice. Advance notice of nominations for the election of directors, and of business other than nominations, to be proposed by stockholders for consideration at a meeting of stockholders of the Corporation shall be given in the manner and to the extent provided in or contemplated by the Bylaws of the Corporation.

(c) Annual Meeting. The annual meeting of stockholders, for the election of directors to succeed those whose terms expire and for the transaction of such other business as may properly come before the meeting, shall be held at such place, if any, either within or without the State of Delaware, on such date, and at such time as the Board of Directors shall fix.

ARTICLE VI
STOCKHOLDER ACTION

Except as otherwise provided for or fixed with respect to actions required or permitted to be taken solely by holders of Preferred Stock pursuant to the provisions of Article IV hereof (including any Preferred Stock Designation), no action that is required or permitted to be taken by the stockholders of the Corporation may be effected by consent of stockholders in lieu of a meeting of stockholders.

ARTICLE VII
SPECIAL MEETINGS OF STOCKHOLDERS

Except as otherwise required by law, and except as otherwise provided for or fixed pursuant to the provisions of Article IV hereof (including any Preferred Stock Designation), a special meeting of the stockholders of the Corporation may be called at any time only by the Board of Directors. Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting by or at the direction of the Board of Directors.

ARTICLE VIII
EXISTENCE

The Corporation shall have perpetual existence.

ARTICLE IX
AMENDMENT

9.1 Amendment of Certificate of Incorporation. The Corporation reserves the right at any time, and from time to time, to amend, alter, change or repeal any provision contained in this Certificate of Incorporation (including any Preferred Stock Designation), and other provisions authorized by the laws of the State of Delaware at the time in force may be added or inserted, in the manner now or hereafter prescribed by the laws of the State of Delaware, and all powers, preferences and rights of any nature conferred upon stockholders, directors or any other persons by and pursuant to this Certificate of Incorporation (including any Preferred Stock Designation) in its present form or as hereafter amended are granted subject to this reservation; provided, however, that except as otherwise provided in this Certificate of Incorporation (including any provision of a Preferred Stock Designation) that provides for a greater or lesser vote and in addition to any other vote required by law, the affirmative vote of at least 66 2/3% of the voting power of the stock outstanding and entitled to vote thereon, voting together as a single

class, shall be required to adopt, amend or repeal, or adopt any provision inconsistent with Section 5.2(c) of Article V of this Certificate of Incorporation.

9.2 Amendment of Bylaws. In furtherance and not in limitation of the powers conferred by the laws of the State of Delaware, but subject to the terms of any series of Preferred Stock then outstanding, the Board of Directors is expressly authorized to adopt, amend or repeal the Bylaws of the Corporation. Except as otherwise provided in this Certificate of Incorporation (including the terms of any Preferred Stock Designation that require an additional vote) or the Bylaws of the Corporation, and in addition to any requirements of law, the affirmative vote of at least 66 2/3% of the voting power of the stock outstanding and entitled to vote thereon, voting together as a single class, shall be required for the stockholders to adopt, amend or repeal, or adopt any provision inconsistent with, any provision of the Bylaws of the Corporation.

ARTICLE X
LIABILITY OF DIRECTORS

10.1 No Personal Liability. To the fullest extent permitted by the DGCL as the same exists or as may hereafter be amended, no director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director.

10.2 Amendment or Repeal. Any amendment, alteration or repeal of this Article X that adversely affects any right of a director shall be prospective only and shall not limit or eliminate any such right with respect to any proceeding involving any occurrence or alleged occurrence of any action or omission to act that took place prior to such amendment, alteration or repeal.

ARTICLE XI
FORUM FOR ADJUDICATION OF DISPUTES

11.1 Forum. Unless the Corporation consents in writing to the selection of an alternative forum, (A) (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer, other employee or stockholder of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, this Certificate of Incorporation or the Bylaws or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware or (iv) any action asserting a claim governed by the internal affairs doctrine of the law of the State of Delaware shall, to the fullest extent permitted by law, be exclusively brought in the Court of Chancery of the State of Delaware or, if such court does not have subject matter jurisdiction thereof, the federal district court of the State of Delaware; and (B) the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. To the fullest extent permitted by law, any person or entity purchasing or otherwise acquiring or holding any interest in shares of capital stock of the Corporation shall be deemed to have notice of and consented to the provisions of this Article XI.

11.2 Enforceability. If any provision of this Article XI shall be held to be invalid, illegal or unenforceable as applied to any person or entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law, the validity, legality and enforceability of such provision in any other circumstance and of the remaining provisions of this Article XI (including, without limitation, each portion of any sentence of this Article XI containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) and the application of such provision to other persons or entities or circumstances shall not in any way be affected or impaired thereby.

[The remainder of this page has been intentionally left blank.]

IN WITNESS WHEREOF, the Corporation has caused this Amended and Restated Certificate of Incorporation to be signed by the undersigned officer of the Corporation this 5th day of February, 2021.

VALLON PHARMACEUTICALS, INC.

By: /s/David Baker
Name: David Baker
Title: Chief Executive Officer

CERTIFICATE OF AMENDMENT
OF
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
VALLON PHARMACEUTICALS, INC.

(Pursuant to Section 242 of the General Corporation Law of the State of Delaware)

Vallon Pharmaceuticals, Inc., a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the "Corporation"), does hereby certify as follows:

1. That a resolution was duly adopted by the Board of Directors of the Corporation pursuant to Section 242 of the General Corporation Law of the State of Delaware setting forth an amendment to the Amended and Restated Certificate of Incorporation of the Corporation and declaring said amendment to be advisable and that such amendment be submitted to the stockholders of the Corporation for their consideration, as follows:

RESOLVED: That, effective at 10:00 a.m. Eastern time on April 21, 2023, Section 4.1 of Article IV of the Amended and Restated Certificate of Incorporation of the Corporation be and hereby is deleted in its entirety and the following is inserted in lieu thereof:

"Section 4.1 Authorized Stock. The total number of shares which the Corporation shall have authority to issue is 260,000,000, of which 250,000,000 shall be designated as Common Stock, par value $0.0001 per share (the "Common Stock," and 10,000,000 shall be designated as Preferred Stock, par value $0.0001 per share (the "Preferred Stock").

Effective at 10:00 a.m. Eastern time on April 21, 2023 (the "Reverse Stock Split Effective Time"), a one-for-30 reverse stock split of the Corporation's Common Stock shall become effective, pursuant to which each 30 shares of Common Stock outstanding and held of record by each stockholder of the Corporation (including treasury shares) immediately prior to the Reverse Stock Split Effective Time shall be reclassified and combined into one (1) validly issued, fully paid and nonassessable share of Common Stock automatically and without any action by the holder thereof upon the Reverse Stock Split Effective Time and shall represent one share of Common Stock from and after the Reverse Stock Split Effective Time (such reclassification and combination of shares, the "Reverse Stock Split"). No fractional shares of Common Stock shall be issued as a result of the Reverse Stock Split and, in lieu thereof, upon surrender after the Reverse Stock Split Effective Time of a certificate which formerly represented shares of Common Stock that were issued and outstanding immediately prior to the Reverse Stock Split Effective Time, any person who would otherwise be entitled to a fractional share of Common Stock as a result of the Reverse Stock Split, following the Reverse Stock Split Effective Time, shall be entitled to receive a cash payment equal to the fraction of a share of Common Stock to which such holder would otherwise be entitled multiplied by the fair value per share of the Common Stock immediately prior to the Reverse Stock Split Effective Time as determined by the Board of Directors of the Corporation.

Each stock certificate that, immediately prior to the Reverse Stock Split Effective Time, represented shares of Common Stock that were issued and outstanding immediately prior to the Reverse Stock Split Effective Time shall, from and after the Reverse Stock Split Effective Time, automatically and without the necessity of presenting the same for exchange, represent that number of whole shares of Common Stock after the Reverse Stock Split Effective Time into which the shares formerly represented by such certificate have been reclassified (as well as the right to receive cash in lieu of fractional shares of Common Stock after the Reverse Stock Split Effective Time); provided, however, that each person of record holding a certificate that represented shares of Common Stock that were issued and outstanding immediately prior to the Reverse Stock Split Effective Time shall receive, upon surrender of such certificate, a new certificate evidencing and representing the number of whole shares of Common Stock after the Reverse Stock Split

Effective Time into which the shares of Common Stock formerly represented by such certificate shall have been reclassified."

2. That, at a special meeting of stockholders of the Corporation, the aforesaid amendment was duly adopted by the stockholders of the Corporation.

3. That the aforesaid amendment was duly adopted in accordance with the applicable provisions of Section 242 of the General Corporation Law of the State of Delaware.

[Remainder of Page Intentionally Left Blank; Signature Page Follows]

IN WITNESS WHEREOF, this Certificate of Amendment has been executed by a duly authorized officer of the Corporation on this 21st day of April, 2023.

VALLON PHARMACEUTICALS, INC.

By: /s/ David Baker
Name: David Baker
Title: Chief Executive Officer

CERTIFICATE OF AMENDMENT
OF
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

Vallon Pharmaceuticals, Inc., a corporation duly organized and existing under the General Corporation Law of the State of Delaware (the "Corporation"), does hereby certify that:

FIRST: Effective at 10:02 a.m. Eastern time on April 21, 2023, Article I of the Amended and Restated Certificate of Incorporation be, and it hereby is, amended and restated in its entirety as follows:

"ARTICLE I
NAME

The name of the corporation is GRI Bio, Inc. (the "Corporation")."

SECOND: This Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Corporation was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware and shall be effective at 10:02 a.m. Eastern time on April 21, 2023.

IN WITNESS WHEREOF, the undersigned has caused this Certificate of Amendment to be duly executed this 21st day of April, 2023.

VALLON PHARMACEUTICALS, INC.

By: /s/ W. Marc Hertz
Name: W. Marc Hertz
Title: President and Chief Executive Officer

CERTIFICATE OF AMENDMENT
OF
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

The corporation organized and existing under the General Corporation Law of the State of Delaware, hereby certified that:

FIRST: The name of the corporation is **GRI Bio, Inc.** (the "Corporation").

SECOND: The Amended and Restated Certificate of Incorporation of the Corporation, as amended to date, is hereby further amended by striking Section 4.1 of Article IV in its entirety and by substituting in lieu of the following:

"Section 4.1 Authorized Stock. The total number of shares which the Corporation shall have authority to issue is 260,000,000 shares, of which (a) 250,000,000 shall be designated as Common Stock, $0.0001 par value per share (the "Common Stock") and (b) 10,000,000 shall be designated Preferred Stock, $0.0001 par value per share (the "Preferred Stock").

Effective at 4:01 p.m. Eastern Time on January 29, 2024 (the "Reverse Stock Split Effective Time"), a one-for-seven reverse stock split of the Corporation's Common Stock shall become effective, pursuant to which each seven (7) shares of Common Stock outstanding and held of record by each stockholder of the Corporation (including treasury shares) immediately prior to the Reverse Stock Split Effective Time shall be reclassified and combined into one (1) validly issued, fully paid and nonassessable share of Common Stock automatically and without any action by the holder thereof upon the Reverse Stock Split Effective Time and shall represent one share of Common Stock from and after the Reverse Stock Split Effective Time (such reclassification and combination of shares, the "Reverse Stock Split"). No fractional shares of Common Stock shall be issued as a result of the Reverse Stock Split and, in lieu thereof, upon surrender after the Reverse Stock Split Effective Time of a certificate which formerly represented shares of Common Stock that were issued and outstanding immediately prior to the Reverse Stock Split Effective Time, any person who would otherwise be entitled to a fractional share of Common Stock as a result of the Reverse Stock Split, following the Reverse Stock Split Effective Time, shall be entitled to receive a cash payment equal to the fraction of a share of Common Stock to which such holder would otherwise be entitled multiplied by the fair value per share of the Common Stock immediately prior to the Reverse Stock Split Effective Time as determined by the Board of Directors of the Corporation.

Each stock certificate that, immediately prior to the Reverse Stock Split Effective Time, represented shares of Common Stock that were issued and outstanding immediately prior to the Reverse Stock Split Effective Time shall, from and after the Reverse Stock Split Effective Time, automatically and without the necessity of presenting the same for exchange, represent that number of whole shares of Common Stock after the Reverse Stock Split Effective Time into which the shares formerly represented by such certificate have been reclassified (as well as the right to receive cash in lieu of fractional shares of Common Stock after the Reverse Stock Split Effective Time); provided, however, that each person of record holding a certificate that represented shares of Common Stock that were issued and outstanding immediately prior to the Reverse Stock Split Effective Time shall receive, upon surrender of such certificate, a new certificate evidencing and representing the number of whole shares of Common Stock after the Reverse Stock Split Effective Time into which the shares of Common Stock formerly represented by such certificate shall have been reclassified."

THIRD: The amendment of the Amended and Restated Certificate of Incorporation herein certified has been duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

GRI BIO, INC.

By: /s/ W. Marc Hertz
Name: W. Marc Hertz
Title: President and Chief Executive Officer

CERTIFICATE OF AMENDMENT
OF
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

The corporation organized and existing under the General Corporation Law of the State of Delaware, hereby certified that:

FIRST: The name of the corporation is **GRI Bio, Inc.** (the "Corporation").

SECOND: The Amended and Restated Certificate of Incorporation of the Corporation, as amended to date, is hereby further amended by striking Section 4.1 of Article IV in its entirety and by substituting in lieu of the following:

"Section 4.1 Authorized Stock. The total number of shares which the Corporation shall have authority to issue is 260,000,000 shares, of which (a) 250,000,000 shall be designated as Common Stock, $0.0001 par value per share (the "Common Stock") and (b) 10,000,000 shall be designated Preferred Stock, $0.0001 par value per share (the "Preferred Stock").

Effective at 4:01 p.m. Eastern Time on June 17, 2024 (the "Reverse Stock Split Effective Time"), a one-for-thirteen reverse stock split of the Corporation's Common Stock shall become effective, pursuant to which each thirteen (13) shares of Common Stock outstanding and held of record by each stockholder of the Corporation (including treasury shares) immediately prior to the Reverse Stock Split Effective Time shall be reclassified and combined into one (1) validly issued, fully paid and nonassessable share of Common Stock automatically and without any action by the holder thereof upon the Reverse Stock Split Effective Time and shall represent one share of Common Stock from and after the Reverse Stock Split Effective Time (such reclassification and combination of shares, the "Reverse Stock Split"). No fractional shares of Common Stock shall be issued as a result of the Reverse Stock Split and, in lieu thereof, upon surrender after the Reverse Stock Split Effective Time of a certificate which formerly represented shares of Common Stock that were issued and outstanding immediately prior to the Reverse Stock Split Effective Time, any person who would otherwise be entitled to a fractional share of Common Stock as a result of the Reverse Stock Split, following the Reverse Stock Split Effective Time, shall be entitled to receive a cash payment equal to the fraction of a share of Common Stock to which such holder would otherwise be entitled multiplied by the fair value per share of the Common Stock immediately prior to the Reverse Stock Split Effective Time as determined by the Board of Directors of the Corporation.

Each stock certificate that, immediately prior to the Reverse Stock Split Effective Time, represented shares of Common Stock that were issued and outstanding immediately prior to the Reverse Stock Split Effective Time shall, from and after the Reverse Stock Split Effective Time, automatically and without the necessity of presenting the same for exchange, represent that number of whole shares of Common Stock after the Reverse Stock Split Effective Time into which the shares formerly represented by such certificate have been reclassified (as well as the right to receive cash in lieu of fractional shares of Common Stock after the Reverse Stock Split Effective Time); provided, however, that each person of record holding a certificate that represented shares of Common Stock that were issued and outstanding immediately prior to the Reverse Stock Split Effective Time shall receive, upon surrender of such certificate, a new certificate evidencing and representing the number of whole shares of Common Stock after the Reverse Stock Split Effective Time into which the shares of Common Stock formerly represented by such certificate shall have been reclassified."

THIRD: The amendment of the Amended and Restated Certificate of Incorporation herein certified has been duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

GRI BIO, INC.

By: /s/ W. Marc Hertz

Name: W. Marc Hertz

Title: President and Chief Executive Officer

CERTIFICATE OF AMENDMENT
OF
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

The corporation organized and existing under the General Corporation Law of the State of Delaware, hereby certified that:

FIRST. The name of the corporation is GRI Bio, Inc. (the "Corporation").

SECOND. The Amended and Restated Certificate of Incorporation of the Corporation, as amended to date, is hereby further amended by striking Section 4.1 of Article IV in its entirety and by substituting in lieu of the following:

"Section 4.1 Authorized Stock. The total number of shares which the Corporation shall have authority to issue is 260,000,000 shares, of which (a) 250,000,000 shall be designated as Common Stock, $0.0001 par value per share (the "Common Stock") and (b) 10,000,000 shall be designated Preferred Stock, $0.0001 par value per share (the "Preferred Stock").

Effective at 4:01 p.m. Eastern Time on February 21, 2025 (the "Reverse Stock Split Effective Time"), a one-for-seventeen reverse stock split of the Corporation's Common Stock shall become effective, pursuant to which each seventeen (17) shares of Common Stock outstanding and held of record by each stockholder of the Corporation (including treasury shares) immediately prior to the Reverse Stock Split Effective Time shall be reclassified and combined into one (1) validly issued, fully paid and nonassessable share of Common Stock automatically and without any action by the holder thereof upon the Reverse Stock Split Effective Time and shall represent one share of Common Stock from and after the Reverse Stock Split Effective Time (such reclassification and combination of shares, the "Reverse Stock Split"). No fractional shares of Common Stock shall be issued as a result of the Reverse Stock Split and, in lieu thereof, upon surrender after the Reverse Stock Split Effective Time of a certificate which formerly represented shares of Common Stock that were issued and outstanding immediately prior to the Reverse Stock Split Effective Time, any person who would otherwise be entitled to a fractional share of Common Stock as a result of the Reverse Stock Split, following the Reverse Stock Split Effective Time, shall be entitled to receive a cash payment equal to the fraction of a share of Common Stock to which such holder would otherwise be entitled multiplied by the fair value per share of the Common Stock immediately prior to the Reverse Stock Split Effective Time as determined by the Board of Directors of the Corporation.

Each stock certificate that, immediately prior to the Reverse Stock Split Effective Time, represented shares of Common Stock that were issued and outstanding immediately prior to the Reverse Stock Split Effective Time shall, from and after the Reverse Stock Split Effective Time, automatically and without the necessity of presenting the same for exchange, represent that number of whole shares of Common Stock after the Reverse Stock Split Effective Time into which the shares formerly represented by such certificate have been reclassified (as well as the right to receive cash in lieu of fractional shares of Common Stock after the Reverse Stock Split Effective Time); provided, however, that each person of record holding a certificate that represented shares of Common Stock that were issued and outstanding immediately prior to the Reverse Stock Split Effective Time shall receive, upon surrender of such certificate, a new certificate evidencing and representing the number of whole shares of Common Stock after the Reverse Stock Split Effective Time into which the shares of Common Stock formerly represented by such certificate shall have been reclassified."

THIRD. The amendment of the Amended and Restated Certificate of Incorporation herein certified has been duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

GRI BIO, INC.

By: /s/ W. Marc Hertz, Ph.D.
Name. W. Marc Hertz, Ph.D.
Title. President and Chief Executive Officer

CERTIFICATE OF AMENDMENT
OF
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

The corporation organized and existing under the General Corporation Law of the State of Delaware, hereby certified that:

FIRST. The name of the corporation is GRI Bio, Inc. (the "Corporation").

SECOND. The Amended and Restated Certificate of Incorporation of the Corporation, as amended to date, is hereby further amended by striking Section 4.1 of Article IV in its entirety and by substituting in lieu of the following:

"Section 4.1 Authorized Stock. The total number of shares which the Corporation shall have authority to issue is 260,000,000 shares, of which (a) 250,000,000 shall be designated as Common Stock, $0.0001 par value per share (the "Common Stock") and (b) 10,000,000 shall be designated Preferred Stock, $0.0001 par value per share (the "Preferred Stock").

Effective at 4:01 p.m. Eastern Time on January 23, 2026 (the "Reverse Stock Split Effective Time"), a one-for-28 reverse stock split of the Corporation's Common Stock shall become effective, pursuant to which each twenty-eight (28) shares of Common Stock outstanding and held of record by each stockholder of the Corporation (including treasury shares) immediately prior to the Reverse Stock Split Effective Time shall be reclassified and combined into one (1) validly issued, fully paid and nonassessable share of Common Stock automatically and without any action by the holder thereof upon the Reverse Stock Split Effective Time and shall represent one share of Common Stock from and after the Reverse Stock Split Effective Time (such reclassification and combination of shares, the "Reverse Stock Split"). No fractional shares of Common Stock shall be issued as a result of the Reverse Stock Split and, in lieu thereof, upon surrender after the Reverse Stock Split Effective Time of a certificate which formerly represented shares of Common Stock that were issued and outstanding immediately prior to the Reverse Stock Split Effective Time, any person who would otherwise be entitled to a fractional share of Common Stock as a result of the Reverse Stock Split, following the Reverse Stock Split Effective Time, shall be entitled to receive a cash payment equal to the fraction of a share of Common Stock to which such holder would otherwise be entitled multiplied by the fair value per share of the Common Stock immediately prior to the Reverse Stock Split Effective Time as determined by the Board of Directors of the Corporation.

Each stock certificate that, immediately prior to the Reverse Stock Split Effective Time, represented shares of Common Stock that were issued and outstanding immediately prior to the Reverse Stock Split Effective Time shall, from and after the Reverse Stock Split Effective Time, automatically and without the necessity of presenting the same for exchange, represent that number of whole shares of Common Stock after the Reverse Stock Split Effective Time into which the shares formerly represented by such certificate have been reclassified (as well as the right to receive cash in lieu of fractional shares of Common Stock after the Reverse Stock Split Effective Time); provided, however, that each person of record holding a certificate that represented shares of Common Stock that were issued and outstanding immediately prior to the Reverse Stock Split Effective Time shall receive, upon surrender of such certificate, a new certificate evidencing and representing the number of whole shares of Common Stock after the Reverse Stock Split Effective Time into which the shares of Common Stock formerly represented by such certificate shall have been reclassified."

THIRD. The amendment of the Amended and Restated Certificate of Incorporation herein certified has been duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

GRI BIO, INC.

By: /s/ W. Marc Hertz, Ph.D.
Name: W. Marc Hertz, Ph.D.
Title: President and Chief Executive Officer

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

GRI Bio, Inc.
La Jolla, CA

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 (Nos. 333-274972, 333-276205, 333-280323, 333-286072 and 333-291999) Form S-3 (Nos. 333-279348, 333-283234, 333-274972, 333-272276 and 333-293065), and Form S-8 (Nos. 333-284149, 333-289593, 333-255972 and 333-293063) of GRI Bio, Inc. of our report dated January 29, 2026 (which includes an explanatory paragraph regarding GRI Bio, Inc.'s ability to continue as a going concern), relating to the consolidated financial statements of GRI Bio, Inc. as of and for the year ended December 31, 2025, which appears in this Form 10-K.

/s/ WithumSmith+Brown, PC

WithumSmith+Brown, PC
San Francisco, CA
January 29, 2026

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

GRI Bio, Inc.
La Jolla, CA

We consent to the inclusion in the Registration Statements on Form S-1 (Nos. 333-274972, 333-276205, 333-280323, 333-286072 and 333-291999), Form S-3 (Nos. 333-279348, 333-283234,333-272276, 333274972 and 333-293065), and Form S-8 (Nos. 333-284149, 333-289593, 333-255972 and 333-293063) of GRI Bio, Inc. ("the Company"), of our report dated March 14, 2025, on our audits of the consolidated financial statements of GRI Bio, Inc. as of December 31, 2024, for the year then ended, which report is included in this Annual Report on Form 10-K to be filed on or about January 29, 2026. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern.

/s/ Sadler, Gibb & Associates, LLC

Sadler, Gibb & Associates, LLC
Draper, UT
January 29, 2026

Exhibit 31.1

**CERTIFICATION 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**

I, W. Marc Hertz, Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2025 of GRI Bio, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: January 30, 2026

By: /s/ W. Marc Hertz, Ph.D.
W. Marc Hertz, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

**CERTIFICATION 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**

I, Leanne Kelly, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2025 of GRI Bio, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: January 30, 2026

By: /s/ Leanne Kelly
Leanne Kelly
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 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

I, W. Marc Hertz, Ph.D., President and Chief Executive Officer of GRI Bio, Inc. (the Company), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Annual Report on Form 10-K of the Company for the year ended December 31, 2025 (the Annual Report) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. the information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

January 30, 2026

By: /s/ W. Marc Hertz, Ph.D.
W.Marc Hertz, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 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

I, Leanne Kelly, Chief Financial Officer of GRI Bio, Inc. (the Company), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Annual Report on Form 10-K of the Company for the year ended December 31, 2025 (the Annual Report) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. the information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

January 30, 2026

By: /s/ Leanne Kelly
Leanne Kelly
Chief Financial Officer
(Principal Financial and Accounting Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.