As filed with the Securities and Exchange Commission on June 18, 2024.

Registration No. 333-

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

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

GRI BIO, INC.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**82-4369909**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

2223 Avenida de la Playa, #208
La Jolla, CA 92037
(619) 400-1170
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

W. Marc Hertz, Ph.D.
President and Chief Executive Officer
GRI Bio, Inc.
2223 Avenida de la Playa, #208
La Jolla, CA 92037
(619) 400-1170
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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3580 Carmel Mountain Road, Suite 300
San Diego, California 92130
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Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box.x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering. o

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	o	Accelerated filer	o
Non-accelerated filer	x	Smaller reporting company	x
		Emerging growth company	x

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 7(a)(2)(B) of the Securities Act. o

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion, dated June 18, 2024

PRELIMINARY PROSPECTUS

Up to Shares of Common Stock and accompanying Warrants to Purchase Up to Shares of Common Stock

or

Up to Pre-Funded Warrants to Purchase Up to Shares of Common Stock and accompanying Warrants to Purchase Up to Shares of Common Stock

Up to Placement Agent Warrants to Purchase Up to Shares of Common Stock

Up to Shares of Common Stock Issuable Upon Exercise of the Warrants, Pre-Funded Warrants and Placement Agent Warrants

We are offering up to shares of common stock, par value $0.0001 per share (the "Common Stock"), together with warrants to purchase up to shares of common stock (the "Warrants"), pursuant to this prospectus. The assumed combined public offering price for each share of Common Stock, together with an accompanying Warrant to purchase one share of Common Stock, is $, which is equal to the last reported sale price of our Common Stock on The Nasdaq Capital Market on 2024. The shares of Common Stock and Warrants will be separately issued, but the shares of Common Stock and Warrants will be issued to purchasers in the ratio of one to one. Each Warrant will have an exercise price of $ per share, will be exercisable beginning on the effective date of stockholder approval of the issuance of the shares upon exercise of the Warrants (the "Warrant Stockholder Approval"), provided however, if the Pricing Conditions (as defined below) are met, the Warrant Stockholder Approval will not be required and the Warrants will be exercisable upon issuance (the "Initial Exercise Date"). The Warrants will expire on the anniversary of the Initial Exercise Date. As used herein "Pricing Conditions" means that the combined public offering price per share and accompanying Warrant is such that the Warrant Stockholder Approval is not required under the rules of The Nasdaq Stock Market LLC ("Nasdaq") because either (i) the offering is an at-the-market offering under Nasdaq rules and such price equals or exceeds the sum of (a) the applicable "Minimum Price" per share under Nasdaq Rule 5635(d) plus (b) $0.125 per whole share of Common Stock underlying the Warrants or (ii) the offering is a discounted offering where the pricing and discount (including attributing a value of $0.125 per whole share underlying the Warrants) meet the pricing requirements under Nasdaq's rules.

We are also offering up to pre-funded warrants (the "Pre-Funded Warrants") to those purchasers whose purchase of shares of Common Stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding Common Stock following the consummation of this offering in lieu of the shares of our Common Stock that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%). Each Pre-Funded Warrant will be exercisable for one share of Common Stock at an exercise price of $0.0001 per share. Each Pre-Funded Warrant is being issued together with the same Warrants described above being issued with each share of Common Stock. The assumed combined public offering price for each such Pre-Funded Warrant, together with an accompanying Warrant to purchase one share of Common Stock, is $, which is equal to the last reported sale price of our Common Stock on The Nasdaq Capital Market on , 2024, minus $0.0001, the exercise price of the Pre-Funded Warrants. Each Pre-Funded Warrant will be exercisable upon issuance and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. The Pre-Funded Warrants and accompanying Warrants are immediately separable and will be issued separately in this offering, but the Pre-Funded Warrants and Warrants will be issued to purchasers in the ratio of one to one. This prospectus also relates to the offering of the shares of Common Stock issuable upon exercise of the Warrants, Pre-Funded Warrants and Placement Agent Warrants (as defined herein). For each Pre-Funded Warrant sold, the number of shares of Common Stock sold will be reduced on a one-for-one basis.

There is no established public trading market for the Warrants or the Pre-Funded Warrants, and we do not expect a market to develop. We do not intend to apply for listing of the Warrants or the Pre-Funded Warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Warrants and the Pre-Funded Warrants will be limited.

This offering will terminate on , 2024, unless we decide to terminate the offering (which we may do at any time in our discretion) prior to that date. We will have one closing for all the securities purchased in this offering. The combined public offering price per share of Common Stock (or Pre-Funded Warrant in lieu thereof) and accompanying Warrants will be fixed for the duration of this offering.

We have engaged (the "Placement Agent"), to act as our exclusive placement agent in connection with this offering. The Placement Agent has agreed to use its reasonable best efforts to arrange for the sale of the securities offered by this prospectus. The Placement Agent is not purchasing or selling any of the securities we are offering and the Placement Agent is not required to arrange the purchase or sale of any specific number of securities or dollar amount. We have agreed to pay to the Placement Agent the Placement Agent fees set forth in the table below, which assumes that we sell all of the securities offered by this prospectus. There is no minimum number of securities or amount of proceeds required as a condition to closing in this offering. In addition, because there is no escrow trust or similar arrangement and no minimum offering amount, investors could be in a position where they have invested in our company, but we are unable to fulfill all of our contemplated objectives due to a lack of interest in this offering. Investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to pursue our business goals described in this prospectus. Further, any proceeds from the sale of securities offered by us will be available for our immediate use, despite uncertainty about whether we would be able to use such funds to effectively implement our business plan. We will bear all costs associated with the offering. See "Plan of Distribution" on page 150 of this prospectus for more information regarding these arrangements.

Our Common Stock is listed on The Nasdaq Capital Market under the symbol "GRI". On June 17, 2024, the last reported sale price of our Common Stock on The Nasdaq Capital Market was $2.861 per share (as adjusted for the Reverse Stock Splits (as defined below)).

The assumed combined offering used throughout this prospectus has been included for illustration purposes only, and may not be indicative of the final offering price. The actual combined public offering price per share of Common Stock and accompanying Warrant and the combined public offering price per Pre-Funded Warrant and accompanying Warrant we are offering and the exercise price and other terms of the Warrants will be negotiated between us and the purchasers, in consultation with the Placement Agent based on the trading of our Common Stock prior to this offering, among other factors. Other factors considered in determining the offering price of the securities we are offering and the exercise price and other terms of the Warrants include the history and prospects of our company, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant. The combined public offering price per share of Common Stock and accompanying Warrant and the combined public offering price per Pre-Funded Warrant and accompanying Warrant may be at a discount to the current market price of our Common Stock. Therefore, the recent market price used throughout this prospectus may differ substantially from the combined public offering price.

You should read this prospectus, together with additional information described under the heading "Where You Can Find More Information" carefully before you invest in any of our securities.

On June 17, 2024, we effected a reverse stock split of our Common Stock at a ratio of one-for-thirteen (the "June 2024 Reverse Stock Split"). Unless otherwise indicated, all financial information, share numbers, option numbers, warrant numbers, other derivative security numbers and exercise prices appearing in this registration statement have been adjusted to give effect to the Reverse Stock Splits (as defined below).

We are an "emerging growth company" and a "smaller reporting company" under the federal securities laws and are subject to reduced public company disclosure standards. See "Prospectus Summary—Implications of Being an Emerging Growth Company" and "Prospectus Summary—Implications of Being a Smaller Reporting Company."

Investing in our securities involves risks. Prior to making an investment decision, you should carefully consider all of the information in this prospectus and, in particular, you should evaluate the risk factors set forth under the caption "Risk Factors" beginning on page 13 of this prospectus.

	Per Share and Accompanying Warrants	Per Pre-Funded Warrant and Accompanying Warrants	Total
Combined public offering price			
Placement Agent fees[1]			
Proceeds to us, before expenses[2]			

(1) Represents a cash fee equal to % of the aggregate purchase price paid by investors in this offering. In addition, we have also agreed to pay the Placement Agent a management fee equal to % of the gross proceeds raised in this offering and to reimburse the Placement Agent for its non-accountable expenses in the amount of $ and for its legal fees and expenses and other out-of-pocket expenses in an amount of $, and for its clearing expenses in the amount of $. In addition, we have agreed to issue to the Placement Agent, or its designees, warrants (the "Placement Agent Warrants") as compensation in connection with this offering to purchase a number of shares of our Common Stock equal to % of the aggregate number of shares of Common Stock and Pre-Funded Warrants being offered at an exercise price equal to % of the combined public offering price per share of Common Stock and accompanying Warrant. See the section entitled "Plan of Distribution" of this prospectus for a description of the compensation to be received by the Placement Agent.

(2) Because there is no minimum number of securities or amount of proceeds required as a condition to closing in this offering, the actual offering amount, Placement Agent fees, estimated expenses and net proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above. The amount of the proceeds to us presented in this table does not give effect to any exercise of the Warrants offered hereby.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Delivery of the securities to the purchasers is expected to be made on or about , 2024, subject to the satisfaction of customary closing conditions.

The date of this prospectus is , 2024

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You should rely only on the information contained in this prospectus. No one, including but not limited to the Placement Agent, has been authorized to provide you with information that is different from that contained in this prospectus. This prospectus is dated as of the date set forth on the cover hereof. You should not assume that the information contained in this prospectus is accurate as of any date other than that date.

ABOUT THIS PROSPECTUS

Unless the context otherwise requires or as otherwise noted, we use the terms "GRI," "Company," "we," "us" and "our" in this prospectus to refer to GRI Bio, Inc. (formerly Vallon Pharmaceuticals, Inc.) and its subsidiaries taken as a whole.

We have not, and the Placement Agent has not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the securities offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date.

The information provided in this prospectus contains statistical data and estimates, including those relating to market size and competitive position of the markets in which we participate, that we obtained from our own internal estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Industry publications, studies and surveys generally state that they have been obtained from sources believed to be reliable. While we believe our internal company research is reliable and the definitions of our market and industry are appropriate, neither this research nor these definitions have been verified by any independent source.

For investors outside the United States: We have not, and the Placement Agent has not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside the United States.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, incorporated by reference or that will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under "Where You Can Find More Information."

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our securities, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes thereto and the information set forth under the sections of this prospectus titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

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 lead product candidate, GRI-0621, is an oral inhibitor of type 1 Natural Killer T ("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. As of March 31, 2024, 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 and 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 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 ("MASH"), alcoholic liver disease, systemic lupus erythematosus ("SLE"), multiple sclerosis ("MS"), ulcerative colitis patients as well as other indications. In these patients activated iNKT cells are correlated with more severe disease. The U.S. Food and Drug Administration ("FDA") has cleared GRI's Investigational New Drug ("IND") application for GRI-0621 for the treatment of IPF and we plan to evaluate GRI-0621 in a randomized, double-blind, multi-center Phase 2a biomarker study, for which we commenced enrollment in December 2023. We expect interim data from this trial to be available in the third quarter of 2024 and topline results to be available in the fourth quarter of 2024. Additionally, on March 4, 2024, we received authorization of our clinical trial application ("CTA") from the United Kingdom Medicines and Healthcare Products Regulatory Agency ("MHRA") to initiate the Phase 2a biomarker study evaluating GRI-0621 for the treatment of IPF in the UK.

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 Natural Killer T ("type 2 NKT") cells. We are developing GRI-0803 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. Subject to IND clearance, we intend to evaluate GRI-0803 in a Phase 1a and 1b trial initially targeting SLE. Assuming positive data, we expect to file an IND with respect to this Phase 1a and 1b trial in the second half of 2024. We will continue to evaluate indications to select the best fit for further development of the program, but our initial focus is on lupus.

Recent Developments

January 2024 and June 2024 Reverse Stock Split

On January 19, 2024, our stockholders approved a reverse stock split of our Common Stock and our Board subsequently approved a reverse stock split of our Common Stock at a ratio of one-for-seven (the "January 2024 Reverse Stock Split"). Following this approval, we filed an amendment to our Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to effect the January 2024 Reverse Stock Split as of 4:01 p.m. Eastern Time on January 29, 2024. Shares of our Common Stock began trading on a post-split basis on January 30, 2024. As a result of the January 2024 Reverse Stock Split, every seven shares of our Common Stock, either issued or outstanding, immediately prior to the filing and effectiveness of our amendment to our Amended and Restated Certificate of Incorporation filed with the Secretary of State of the State of Delaware, was automatically combined and converted (without any further act) into one share of fully paid and nonassessable share of Common Stock. No fractional shares were issued in connection with the January 2024 Reverse Stock Split. Stockholders who otherwise would have received fractional shares of Common Stock received cash in lieu thereof at a price equal to the fraction to which the stockholder would have otherwise been entitled.

On June 7, 2024, our stockholders approved the June 2024 Reverse Stock Split. Our board of directors (the "Board") subsequently approved the June 2024 Reverse Stock Split ratio of one-for-thirteen. Following this approval, we filed an amendment to our Amended and Restated Certificate of Incorporation, as amended (the "Amended and Restated Certificate of Incorporation") with the Secretary of State of the State of Delaware to effect the June 2024 Reverse Stock Split as of 4:01 p.m. Eastern Time on June 17, 2024. Shares of our Common Stock began trading on a post-split basis on June 18, 2024. As a result of the June 2024 Reverse Stock Split, every thirteen shares of our Common Stock, either issued or outstanding, immediately prior to the filing and effectiveness of our amendment to our Amended and Restated Certificate of Incorporation filed with the Secretary of State of the State of Delaware, was automatically combined and converted (without any further act) into one share of fully paid and nonassessable share of Common Stock. No fractional shares were issued in connection with the June 2024 Reverse Stock Split. Stockholders who otherwise would have received fractional shares of Common Stock received cash in lieu thereof at a price equal to the fraction to which the stockholder would have otherwise been entitled. On its effective date, the June 2024 Reverse Stock Split had the effect of reducing the aggregate number of outstanding shares of Common Stock from 7,069,170 shares on a pre-reverse split basis to a total of 543,775 shares outstanding on a post-reverse split basis.

Unless otherwise noted, all financial information, share numbers, option numbers, warrant numbers, other derivative security numbers and exercise prices appearing in this prospectus have been adjusted to give effect to the January 2024 Reverse Stock Split and the June 2024 Reverse Stock Split.

May 2024 At The Market Offering

On May 20, 2024, we entered into an At The Market Offering Agreement (the "Sales Agreement") with H.C. Wainwright & Co., LLC ("Wainwright"), pursuant to which we may sell and issue 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.

The shares of Common Stock are being offered and sold in the ATM Offering pursuant to our effective shelf registration statement on Form S-3 (File No. 333-279348) and the accompanying base prospectus included therein as supplemented by the prospectus supplement, dated May 20, 2024, filed with the U.S. Securities and Exchange Commission (the "SEC").

As of June 17, 2024, we have sold 95,566 shares of our Common Stock in the ATM Offering at a weighted-average price of $3.9783 per share, raising $0.4 million of gross proceeds and net proceeds of $0.4 million, after deducting commissions to the sales agent and other ATM Offering related expenses. As of June 17, 2024, there remains approximately $0.6 million available for future sales of shares of Common Stock under the Sales Agreement.

February 2024 Offering

On February 1, 2024, we entered into a securities purchase agreement with each purchaser identified on the signature pages thereto (the "Purchase Agreement"), pursuant to which we agreed to issue and sell, in a public offering (the "Offering"), (i) 25,419 shares (the "Shares") of our Common Stock, (ii) 359,196 pre-funded warrants (the "February 2024 Pre-Funded Warrants") exercisable for an aggregate of 359,196 shares of Common Stock, (iii) 384,615 Series B-1 common warrants (the "Series B-1 Common Warrants") exercisable for an aggregate of 384,615 shares of Common Stock, and (iv) 384,615 Series B-2 common warrants (the "Series B-2 Common Warrants," and together with the Series B-1 Common Warrants, the "Series B Warrants") exercisable for an aggregate of 384,615 shares of Common Stock. The Series B Warrants together with the February 2024 Pre-Funded Warrants are referred to herein as the "February 2024 Warrants." The securities were offered in combinations of (a) one 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 $14.30 (less $0.0013 for each February 2024 Pre-Funded Warrant). The Offering closed on February 6, 2024. As of June 17, 2024, all of the February 2024 Pre-Funded Warrants have been exercised, and no Series B Warrants have been exercised.

Subject to certain beneficial 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 $0.0013. Each Series B-1 Common Warrant is exercisable into one share of Common Stock at a price per share of $14.30 (as adjusted from time to time in accordance with the terms thereof) 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 $14.30 (as may be adjusted from time to time in accordance with the terms thereof) for the 18-month period after February 6, 2024, the date of issuance.

In connection with the issuance of the securities pursuant to the Purchase Agreement, the exercise price of our previously issued 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. All of the Series A-1 Warrants have since been exercised.

Nasdaq Compliance - Stockholders' Equity Deficiency

On November 22, 2023, we received a letter (the "Notice") from the Listing Qualifications Department (the "Staff") of Nasdaq notifying us that we were not in compliance with the minimum stockholders' equity requirement for continued listing on The Nasdaq Capital Market based on the information provided in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2023. Nasdaq Listing Rule 5550(b)(1) requires that companies listed on The Nasdaq Capital Market with a market value of listed securities of less than $35.0 million and annual net income of less than $0.5 million maintain stockholders' equity of at least $2.5 million (the "Stockholders' Equity Requirement"). In accordance with Nasdaq rules, we were provided until January 8, 2024, to submit a plan to regain compliance with the Stockholders' Equity Requirement (the "Compliance Plan"). On January 22, 2024, the Staff granted us an extension until May 20, 2024 (the "May Compliance Date") to regain compliance with the Stockholders' Equity Requirement. Per the Staff's January 22, 2024 letter, we were required to complete an equity offering to raise gross proceeds of at least $6.0 million and furnish to the Staff and Nasdaq evidence of compliance with the Stockholders' Equity Requirement by filing a publicly available report prior to May 24, 2024. While we completed an equity offering with gross proceeds of $5.5 million and have met the minimum Stockholders' Equity Requirement as of the quarter ended March 31, 2024, on May 21, 2024, we received a staff determination letter (the "Determination Letter") from the Staff notifying us that we had not regained compliance with the Stockholders' Equity Requirement as of the May Compliance Date when taking into account our historical burn rate. We timely requested an appeal of the determination to a Hearings Panel (the "Panel"), and the hearing was scheduled for July 11, 2024. The appeal automatically stays any suspension or delisting action pending the hearing before the Panel, and our Common Stock will remain listed on The Nasdaq Capital Market pending the outcome of the hearing before the Panel. Pursuant to Nasdaq Listing Rules, the Panel has the authority to grant an additional extension not to exceed 180 days from the Staff's determination.

Notwithstanding the foregoing, there can be no assurance that the Panel will grant us an additional extension period or that we will ultimately regain compliance with all applicable requirements for continued listing on The Nasdaq Capital Market.

Nasdaq Compliance - Minimum Bid Price Deficiency

The rules of The Nasdaq Capital Market also require that we maintain a closing price for shares of our Common Stock of at least $1.00 per share (the "Minimum Bid Price Rule"). On January 5, 2024, we received a letter (the "Letter") from the Staff of Nasdaq indicating that we no longer meet the Minimum Bid Price Rule set forth in Nasdaq Listing Rule 5550(a)(2) because the closing bid price for our Common Stock was less than $1.00 for the previous 30 consecutive business days. The Letter is in addition to the Notice described above. The Letter has no immediate effect on our continued listing on The Nasdaq Capital Market. Under Nasdaq Listing Rule 5810(c)(3)(A), we have a 180-calendar day period, or until July 3, 2024 (the "July Compliance Date"), to regain compliance with the Minimum Bid Price Rule. The Minimum Bid Price Rule will be met if our Common Stock has a minimum closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days during the 180-calendar day period, unless Nasdaq exercises its discretion to extend such 10-day period. If we do not regain compliance by the July Compliance Date, we may be eligible for an additional 180-calendar day period, subject to satisfying the conditions in the applicable Nasdaq Listing Rules. If, before the Compliance Date, our Common Stock has a closing bid price of $0.10 per share or less for ten consecutive trading days, the Staff will issue a Staff Delisting Determination under Nasdaq Listing Rule 5810 with respect to our Common Stock. On January 29, 2024, we filed an amendment to our Amended and Restated Certificate of Incorporation to implement the January 2024 Reverse Stock Split to attempt to regain compliance with the Minimum Bid Price Rule, but were not able to regain compliance following the January 2024 Reverse Stock Split.

Our stockholders approved the June 2024 Reverse Stock Split on June 7, 2024, and our Board subsequently approved the June 2024 Reverse Stock Split ratio of one-for-thirteen. However, there can be no assurance that the stock price of our Common Stock will remain above the minimum $1.00 bid price required for any post-split Nasdaq monitoring period or otherwise.

Merger Transaction

On April 21, 2023, pursuant to the Agreement and Plan of Merger, dated as of December 13, 2022, as amended on February 17, 2023 (the "Merger Agreement"), by and among the Company, GRI Bio Operations, Inc., formerly known as GRI Bio, Inc. ("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 Operations (the "Merger"), with GRI Operations surviving the Merger as a wholly owned subsidiary of the Company. In connection with the Merger, and immediately prior to the effective time of the Merger (the "Effective Time"), the Company effected a reverse stock split of the Common Stock at a ratio of 1-for-30 (the "April 2023 Reverse Stock Split," and together with 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 this prospectus reflect the Reverse Stock Splits. Also, in connection with the closing of the Merger (the "Closing"), the Company changed its name from "Vallon Pharmaceuticals, Inc." to "GRI Bio, Inc."

At the Effective Time:

Each share of GRI Operations' common stock ("GRI Operations Common Stock") outstanding immediately prior to the Effective Time, including any shares of GRI Operations Common Stock issued pursuant to the Equity Financing (as defined below) automatically converted solely into the right to receive a number of shares of the Common Stock equal to 0.0374 (the "Exchange Ratio").

(a) Each option to purchase shares of GRI Operations Common Stock (each, a "GRI Operations Option") outstanding and unexercised immediately prior to the Effective Time under the GRI Bio, Inc. 2015 Equity Incentive Plan (the "GRI Operations Plan"), whether or not vested, converted into and became an option to purchase shares of Common Stock, and the Company assumed the GRI Operations Plan and each such GRI Operations Option in accordance with the terms of the GRI Operations Plan (the "Assumed Options"). The number of shares of Common Stock subject to each Assumed Option was determined by multiplying (i) the number of shares of GRI Operations Common Stock that were subject to such GRI Operations Option, as in effect immediately prior to the Effective Time, by (ii) the Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of Common Stock. The per share exercise price for the

Common Stock issuable upon exercise of each Assumed Option was determined by dividing (A) the per share exercise price of such Assumed Option, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio and rounding the resulting per share exercise price up to the nearest whole cent. Any restriction on the exercise of any Assumed Option continued in full force and effect and the term, exercisability, vesting schedule and any other provisions of such Assumed Option otherwise remained unchanged.

(b) Each warrant to purchase shares of GRI Operations Common Stock (the "GRI Operations Warrants") outstanding immediately prior to the Effective Time was assumed by the Company and converted into a warrant to purchase Common Stock (the "Assumed Warrants") and thereafter (i) each Assumed Warrant became exercisable solely for shares of Common Stock; (ii) the number of shares of Common Stock subject to each Assumed Warrant was determined by multiplying (A) the number of shares of GRI Operations Common Stock that were subject to such GRI Operations Warrant, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of Common Stock; (iii) the per share exercise price for the Common Stock issuable upon exercise of each Assumed Warrant was determined by dividing (A) the exercise price per share of the GRI Operations Common Stock subject to such GRI Operations Warrant, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio, and rounding the resulting exercise price up to the nearest whole cent.

(c) The Bridge Warrants (as defined below) were exchanged for warrants (the "Exchange Warrants") to purchase an aggregate of 4,632 shares of Common Stock. The Exchange Warrants contained substantively similar terms to the Bridge Warrants, and had an initial exercise price equal to $1,340.43 per share. The Exchange Warrants have since been fully exercised on a cashless basis.

(d) All rights with respect to GRI Operations restricted stock awards were assumed by us and converted into restricted stock awards with the number of shares subject to each restricted stock award multiplied by the Exchange Ratio and rounding the resulting number down to the nearest whole number of shares of Common Stock. The term, exercisability, vesting schedule and other provisions of the GRI Operations restricted stock awards otherwise remained unchanged.

Equity Financing

Securities Purchase Agreement (Bridge Financing)

In connection with signing the Merger Agreement, GRI Operations entered into a Securities Purchase Agreement, dated as of December 13, 2022 (the "Bridge SPA"), with the Altium Growth Fund, LP ("Altium"), pursuant to which, among other things, Altium purchased, and GRI Operations issued, senior secured notes in the aggregate principal amount of up to approximately $3.3 million, in exchange for an aggregate purchase price of up to approximately $2.5 million (the "Bridge Notes"). In addition, GRI Operations issued to Altium warrants to purchase an aggregate of 13,763 shares of GRI Operations Common Stock (the "Bridge Warrants"). As a result of the Merger, at the Effective Time, the Bridge Warrants were exchanged for the Exchange Warrants. The Exchange Warrants contain substantively similar terms to the Bridge Warrants, and, as noted above, had an initial exercise price equal to $1,340.43 per share and have been fully exercised on a cashless basis.

Securities Purchase Agreement (Equity Financing)

In addition to the Bridge SPA, in connection with signing the Merger Agreement, the Company, GRI Operations and Altium entered into a Securities Purchase Agreement, dated as of December 13, 2022 (the "Equity SPA"). Pursuant to the Equity SPA, immediately prior to the Closing, GRI Operations issued 74,584 shares of GRI Operations Common Stock (the "Initial Shares") to Altium and 298,339 shares of GRI Operations Common Stock (the "Additional Shares") into escrow with an escrow agent. At the Closing, pursuant to the Merger, the Initial Shares converted into an aggregate of 2,789 shares of Common Stock and the Additional Shares converted into an aggregate of 11,157 shares of Common Stock. On May 8, 2023, in accordance with the terms of the Equity SPA, we and Altium authorized the escrow agent to, subject to beneficial ownership limitations, disburse to Altium all of the shares of Common Stock issued in exchange for the Additional Shares (the "Escrow Shares").

Pursuant to the Equity SPA, we issued to Altium on May 8, 2023 (i) Series A-1 Warrants to purchase 13,947 shares of Common Stock with an initial exercise price of $1,229.41 per share (all of which have since been exercised, as described under the heading "Warrant Exercises" in Item 15 of Part II of this registration statement), (ii) Series A-2 Warrants to purchase 12,552 shares of Common Stock with an initial exercise price of $1,341.34 per share (all of which have since been exercised, as described under the heading "Warrant Exercises" in Item 15 of Part II of this registration statement), and (iii) Series T Warrants to purchase (x) 8,950 shares of Common Stock at an exercise price of $1,117.48 per share and (y) if the Series T Warrants are exercised in full by paying the Aggregate Exercise Price in cash, an additional amount of Series A-1 Warrants and Series A-2 Warrants, each to purchase 8,950 shares of Common Stock at their respective exercise price (collectively, the "Equity Warrants"). We may only force the exercise of Series T Warrants subject to the satisfaction of certain equity conditions. The Series T Warrants are not presently subject to forced exercise by us as the equity conditions for their forced exercise, which include, among other things, a requirement that shares of our Common Stock have a value weighted average price of at least $838.11 per share for the periods specified in the Series T Warrants, are not met. As of June 17, 2024, none of the Series T Warrants have been exercised.

Risk Factors

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this prospectus immediately following this prospectus summary. These risks include, among others, the following:

Risks Related to This Offering

- You will experience immediate dilution in the book value per share of the Common Stock purchased in the offering.
- If you purchase our securities in this offering you may experience future dilution as a result of future equity offerings or other equity issuances.
- A substantial number of shares of Common Stock may be sold in the market following this offering, which may depress the market price for our Common Stock.
- We have broad discretion to determine how to use the funds raised in this offering and may use them in ways that may not enhance our operating results or the price of our Common Stock.
- There is no public market for the Warrants and Pre-Funded Warrants being offered in this offering.
- The holders of Warrants and Pre-Funded Warrants purchased in this offering will have no rights as common stockholders until such holders exercise their Warrants and Pre-Funded Warrants and acquire shares of our Common Stock, except as set forth in the Warrants and Pre-Funded Warrants.
- The warrants are speculative in nature.
- The market price for our Common Stock has been volatile and may continue to fluctuate or may decline significantly in the future.
- This is a best efforts offering, no minimum amount of securities is required to be sold, and we may not raise the amount of capital we believe is required for our business plans, including our near-term business plans.

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 in addition to any proceeds from this offering to finance our operations and to potentially regain compliance with the Stockholders' Equity Requirement. 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 and/or maintain the listing of shares of our Common Stock.

- Our auditors have expressed substantial doubt about our ability to continue as a going concern, and we may not be able to continue as a going concern if we do not obtain additional financing.

Risks Related to Research and Development and the Pharmaceutical Industry

- Our business is highly dependent on the success of our lead product candidate, GRI-0621, 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.

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.
- 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.

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.
- 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.

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 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.
- 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.

Risks Related to Managing Our Business and Operations

- If we lose key management personnel, or if we fail to recruit 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 information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.

Risks Related to our Common Stock

- The listing of shares of our Common Stock does not currently comply with the rules of The Nasdaq Capital Market or any other Nasdaq Market tier. Pursuant to our agreements in connection with the Equity Financing, we are also subject to covenants that require us to maintain the listing of our Common Stock on Nasdaq. If we fail to comply with these obligations, we would be subject to substantial cash penalties and, as of the date of this prospectus, would likely not have the resources to make such payments and continue our operations. A delisting of our Common Stock from Nasdaq could also 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 June 2024 Reverse Stock Split could cause our stock price to decline relative to its value before the split and decrease the liquidity of shares of our Common Stock.

Corporate Information

Our principal offices are located at 2223 Avenida De La Playa #208, La Jolla, CA 92037, and our telephone number is (619) 400-1170. Our website address is *www.gribio.com*. Our website and the information contained on, or that can be accessed through, our website shall not be deemed to be incorporated by reference in, and are not considered part of, this prospectus. You should not rely on any such information in making your decision whether to purchase our Common Stock.

Implications of Being a Smaller Reporting Company

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 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.

Implications of Being an Emerging Growth Company

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 prospectus 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 our initial public offering ("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.

THE OFFERING

Securities we are offering:	Up to shares of Common Stock and accompanying Warrants to purchase up to shares of Common Stock, or Pre-Funded Warrants to purchase shares of Common Stock and accompanying Warrants to purchase shares up to shares of Common Stock. The shares of Common Stock, or Pre-Funded Warrants, and in each case the accompanying Warrants will be separately transferable immediately upon issuance, but the shares of Common Stock, or Pre-Funded Warrants, and in each case the accompanying Warrants will be issued to purchasers in the ratio of one to one. There is no established trading market for the Warrants or the Pre-Funded Warrants, and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the Warrants or the Pre-Funded Warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the Warrants and Pre-Funded Warrants will be limited.
Description of Warrants:	Each Warrant is exercisable for one share of Common Stock, will have an exercise price of $ per share, will be exercisable beginning on the effective date of the Warrant Stockholder Approval, provided however, if the Pricing Conditions are met, the Warrants will be exercisable upon the Initial Exercise Date. The Warrants will expire on the anniversary of the Initial Exercise Date. To better understand the terms of the Warrants, you should carefully read the "Description of Securities We Are Offering" section of this prospectus. You should also read the forms of Warrants, which will be filed as exhibits to the registration statement that includes this prospectus. This prospectus also relates to the offering of the shares of Common Stock issuable upon exercise of the Warrants.
Description of Pre-Funded Warrants:	If the issuance of shares of our Common Stock to a purchaser in this offering would result in such purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding Common Stock following the consummation of this offering, then such purchaser may purchase, if they so choose, in lieu of the shares of our Common Stock that would result in such excess ownership, a Pre-Funded Warrant to purchase shares of our Common Stock for a purchase price per share of Common Stock subject to such Pre-Funded Warrant equal to the per share combined public offering price for the Common Stock to be sold in this offering less $0.0001. Each Pre-Funded Warrant will have an exercise price of $0.0001 per share, will be exercisable upon issuance and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. Purchasers of Pre-Funded Warrants will also receive accompanying Warrants as if such purchasers were buying shares of our Common Stock in this offering. This prospectus also relates to the offering of the shares of Common Stock issuable upon exercise of these Pre-Funded Warrants. To better understand the terms of the Pre-Funded Warrants, you should carefully read the "Description of Securities We Are Offering" section of this prospectus. You should also read the form of Pre-Funded Warrant, which will be filed as an exhibit to the registration statement that includes this prospectus.

Description of Placement Agent Warrants	We have also agreed to issue to the Placement Agent or its designees as compensation in connection with this offering, the Placement Agent Warrants to purchase up to shares of Common Stock as compensation in connection with this offering. The Placement Agent Warrants will be exercisable beginning on the effective date of the Warrant Stockholder Approval, provided however, if the Pricing Conditions are met, such Placement Agent Warrants will be exercisable upon issuance and will have substantially the same terms as the Warrants, except that the Placement Agent Warrants will have an exercise price of $ per share (representing % of the combined public offering price per share of Common Stock and accompanying Warrants) and a termination date that will be five years from the commencement of the sales pursuant to this offering. See "Plan of Distribution" below. To better understand the terms of the Placement Agent Warrants, you should carefully read the descriptions of the Placement Agent Warrants in the "Description of Securities We Are Offering" and "Plan of Distribution" sections of this prospectus. You should also read the form of Placement Agent Warrant, which will be filed as an exhibit to the registration statement that includes this prospectus. This prospectus also relates to the offering of the shares of Common Stock issuable upon exercise of the Placement Agent Warrant.
Common Stock outstanding immediately prior to this offering	shares.
Common Stock to be outstanding after this offering	shares of Common Stock, assuming no sale of Pre-Funded Warrants in this offering and no exercise of the Warrants being issued in this offering and an assumed combined public offering price of $ per share and accompanying Warrant, which is equal to the last reported sale price per share of our common stock on the Nasdaq Capital Market on , 2024.
Use of proceeds	We estimate that the net proceeds of this offering based upon an assumed combined public offering price of $ per share of Common Stock and accompanying Warrants, which was the closing price of our Common Stock on Nasdaq on , 2024, after deducting Placement Agent fees and estimated offering expenses, will be approximately $ million, assuming no sale of the Pre-Funded Warrants offered hereby and no exercise of the Warrants and Placement Agent Warrants.We currently intend to use the net proceeds from this offering for working capital, product candidate development activities and general corporate purposes. See "Use of Proceeds."
Lock Up Agreements	The Company and our directors and officers have agreed with the Placement Agent, subject to certain exceptions, not to sell, transfer or dispose of, directly or indirectly, any of our Common Stock or securities convertible into or exercisable or exchangeable for our Common Stock for a period of ( ) days after the closing of this offering. See "Plan of Distribution" for more information.
Risk factors	An investment in our securities involves a high degree of risk and could result in a loss of your entire investment. Prior to making an investment decision, you should carefully consider all of the information in this prospectus and, in particular, you should evaluate the risk factors set forth under the caption "Risk Factors" in this prospectus.
Nasdaq Capital Market symbol	Our Common Stock is listed on The Nasdaq Capital Market under the symbol "GRI".

The number of shares of our Common Stock to be outstanding after this offering is based on 543,775 shares of our Common Stock outstanding as of June 17, 2024, and excludes, as of that date, the following:

- 778,503 shares of Common Stock issuable upon exercise of warrants outstanding with a weighted average exercise price of $29.27;
- 2,503 shares of Common Stock issuable upon the exercise of options outstanding, with a weighted average exercise price of $471.45 per share; and

- 1,864 shares of common stock reserved for future issuance under our A&R 2018 Plan.

Except as otherwise indicated, all information in this prospectus assumes or gives effect to:

- no exercise of the outstanding warrants described above;
- no exercise of the outstanding options described above; and
- no exercise of the Warrants, the Pre-Funded Warrants or the Placement Agent Warrants issued in this offering.

RISK FACTORS

Careful consideration should be given to the following risk factors, in addition to the other information set forth in this prospectus, including the section of this prospectus entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our consolidated financial statements and related notes, and in other documents that we file with the SEC, in evaluating our company and business. Investing in our securities involves a high degree of risk. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects could 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 prospectus.

Risks Related to This Offering

This offering is being made on a best efforts basis and we may sell fewer than all of the securities offered hereby and may receive significantly less in net proceeds from this offering, which will provide us only limited working capital.

This offering is being made on a best efforts basis and we may sell fewer than all of the securities offered hereby and may receive significantly less in net proceeds from this offering. Assuming that we receive net proceeds of approximately $ million from this offering (assuming an offering with gross proceeds of $ million), we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will meet our capital needs for the next months under our current business plan. Assuming that we receive net proceeds of approximately $ million from this offering (assuming an offering with gross proceeds of $ million), we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will satisfy our capital needs for the next months under our current business plan. Assuming that we receive net proceeds of approximately $ million from this offering (assuming an offering with gross proceeds of $ million), we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will satisfy our capital needs for the next months under our current business plan. Without giving effect to the receipt of any proceeds from this offering, we currently estimate that our existing cash and cash equivalents are sufficient to fund business operations into .

You will experience immediate dilution in the net tangible book value per share of the Common Stock purchased in the offering.

Since the effective public offering price of our Common Stock in this offering is substantially higher than the pro forma as adjusted net tangible book value per share of our outstanding Common Stock outstanding prior to this offering, you will suffer dilution in the book value of the Common Stock you purchase in this offering. After giving effect to the sale of our Common Stock in the aggregate offering amount of $ at an assumed effective offering price of $ per share of Common Stock (the last reported sale price of our Common Stock on The Nasdaq Capital Market on , 2024), assuming no sale of any Pre-Funded Warrants offered hereby, no exercise of the Warrants or the Placement Agent Warrants, and after deducting the Placement Agent's fees and estimated offering expenses payable by us, you would suffer immediate dilution of $ per share in the pro forma as adjusted net tangible book value of the Common Stock. See the section titled "Dilution" for a more detailed discussion of the dilution you will incur if you purchase securities in this offering.

If you purchase our securities in this offering you may experience future dilution as a result of future equity offerings or other equity issuances.

We will likely offer and issue additional shares of our Common Stock or other equity or convertible debt securities in order to raise additional capital. Future equity offerings or other equity issuances may be at a price per share that is equal to or greater than the price per share paid by investors in this offering. Future investors in such offerings may have rights superior to existing stockholders, and the price per share at which we sell additional shares of Common Stock or other equity or convertible debt securities in future transactions may be at a higher or lower price per share than the price per share in this offering.

A substantial number of shares of Common Stock may be sold in the market following this offering, which may depress the market price for our Common Stock.

The securities offered hereby will be freely tradable without restriction or further registration under the Securities Act of 1933, as amended (the "Securities Act"). Sales of a substantial number of shares of our Common Stock in the public market following this offering, or the perception that such sales could occur, could cause the market price of our Common Stock to decline.

We have broad discretion to determine how to use the funds raised in this offering and may use them in ways that may not enhance our operating results or the price of our Common Stock.

Our management will have broad discretion over the use of net proceeds from this offering, and we could spend the net proceeds from this offering in ways our stockholders may not agree with or that do not yield a favorable return, if at all. We currently expect to use the net proceeds from this offering for working capital, product candidate development activities and general corporate purposes, including costs and expenses associated with being a public company. However, our use of these net proceeds may differ substantially from our current plans. If we do not invest or apply the net proceeds of this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline. See "Use of Proceeds" for further information on the anticipated use of proceeds.

Financial Industry Regulatory Authority ("FINRA") sales practice requirements may limit a stockholder's ability to buy and sell our securities.

Effective June 30, 2020, the SEC implemented Regulation Best Interest requiring that "a broker, dealer, or a natural person who is an associated person of a broker or dealer, when making a recommendation of any securities transaction or investment strategy involving securities (including account recommendations) to a retail customer, shall act in the best interest of the retail customer at the time the recommendation is made, without placing the financial or other interest of the broker, dealer, or natural person who is an associated person of a broker or dealer making the recommendation ahead of the interest of the retail customer." This is a significantly higher standard for broker-dealers to recommend securities to retail customers than before under FINRA "suitability rules. FINRA suitability rules do still apply to institutional investors and require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending securities to their customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information, and for retail customers determine the investment is in the customer's "best interest" and meet other SEC requirements. Both SEC Regulation Best Interest and FINRA's suitability requirements may make it more difficult for broker-dealers to recommend that their customers buy speculative, low-priced securities. They may affect investing in our Common Stock, which may have the effect of reducing the level of trading activity in our securities. As a result, fewer broker-dealers may be willing to make a market in our Common Stock, reducing a stockholder's ability to resell our Common Stock.

Purchasers who purchase our securities in this offering pursuant to a securities purchase agreement may have rights not available to purchasers that purchase without the benefit of a securities purchase agreement.

In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers that enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. The ability to pursue a claim for breach of contract provides those investors with the means to enforce the covenants uniquely available to them under the securities purchase agreement including, but not limited to: (i) timely delivery of shares; (ii) agreement to not enter into variable rate financings for from closing, subject to certain exceptions; (iii) agreement to not enter into any financings for from closing, subject to certain exceptions; and (iv) indemnification for breach of contract.

There is no public market for the Warrants and Pre-Funded Warrants being offered in this offering.

There is no established public trading market for the Warrants and Pre-Funded Warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the Warrants or Pre-

Funded Warrants on any securities exchange or nationally recognized trading system, including The Nasdaq Capital Market. Without an active market, the liquidity of the Warrants or Pre-Funded Warrants will be limited.

The holders of Warrants and Pre-Funded Warrants purchased in this offering will have no rights as common stockholders until such holders exercise their Warrants or Pre-Funded Warrants and acquire shares of our Common Stock, except as set forth in the Warrants and Pre-Funded Warrants.

Until a holder of Warrants and Pre-Funded Warrants acquires the shares of Common Stock upon exercise of the Warrants and Pre-Funded Warrants, as the case may be, such holder will have no rights with respect to the shares of Common Stock underlying such Warrants and Pre-Funded Warrants, except as set forth in the Warrants and Pre-Funded Warrants. Upon exercise of the Warrants and Pre-Funded Warrants, holders will be entitled to exercise the rights of common stockholders only as to matters for which the record date occurs after the exercise date.

The Warrants and Pre-Funded Warrants are speculative in nature.

The Warrants and Pre-Funded Warrants do not confer any rights of Common Stock ownership on their holders, such as voting rights, but rather merely represent the right to acquire shares of Common Stock at a fixed price for a limited period of time. There can be no assurance that the market price of the Common Stock will ever equal or exceed the exercise price of the Warrants, and consequently, it may not ever be profitable for holders of the Warrants to exercise the Warrants.

The market price for our Common Stock has been volatile and may continue to fluctuate or may decline significantly in the future.

An active, liquid and orderly market for our Common Stock may not be sustained, which could depress the trading price of our Common Stock or cause it to continue to be highly volatile or subject to wide fluctuations. Some of the factors that could negatively affect our share price or result in fluctuations in the price or trading volume of our Common Stock include, among other things:

- the commencement, enrollment, or results of our current and future preclinical studies and clinical trials, and the results of trials of our competitors or those of other companies in our market sector;
- regulatory approval of our product candidates, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- manufacturing, supply or distribution delays or shortages;
- our ability to identify and successfully acquire or in-license new product candidates on acceptable terms;
- FDA, state or international regulatory actions, including actions on regulatory applications any of our product candidates;
- legislative or regulatory changes;
- judicial pronouncements interpreting laws and regulations;
- changes in government programs;
- announcements of new products, services or technologies, commercial relationships, acquisitions or other events by us or our competitors;
- market conditions in the pharmaceutical and biotechnology sectors;
- fluctuations in stock market prices and trading volumes of similar companies;
- changes in accounting principles;
- litigation or public concern about the safety of our product candidates or similar product candidates;

- sales of large blocks of our Common Stock, including sales by our executive officers, directors and significant shareholders; and
- our ability to obtain additional financing to advance our development operations;

These broad market and industry factors may decrease the market price of our Common Stock, regardless of our actual operating performance. The stock market in general has from time to time experienced extreme price and volume fluctuations. In addition, in the past, following periods of volatility in the overall market and decreases in the market price of a company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

This is a best efforts offering, no minimum amount of securities is required to be sold, and we may not raise the amount of capital we believe is required to continue our operations and to regain compliance with Nasdaq's Stockholders' Equity Requirement.

The Placement Agent has agreed to use its reasonable best efforts to solicit offers to purchase the securities in this offering. The Placement Agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, Placement Agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth herein. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to support our continued operations or to regain compliance with Nasdaq's Stockholders' Equity Requirement.

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 $1.9 million and $2.1 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, we had an accumulated deficit of $33.4 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 lead product candidate, GRI-0621, and our other product candidates through clinical development, and, if successful, later-stage clinical trials;
- 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, 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;
- we are, as described further below, unable to comply with the obligations of our registration rights agreements; 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. 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.

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 planned 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. In particular, we do not expect to be able to continue our clinical trials or development efforts without raising additional funds. We also expect 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. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce, or eliminate one or more of our research and drug development programs or future commercialization efforts.

As of March 31, 2024, we had approximately $4.1 million in cash and cash equivalents and an accumulated deficit of approximately $33.4 million. If we secure additional funds, we expect to devote substantial financial resources to our planned activities, particularly as we conduct our clinical trials of GRI-0621 and GRI-0803, advance our discovery programs and continue our product development efforts. We are also party to a registration rights agreement that requires us to, among other things, obtain effectiveness of a registration statement and to

maintain the effectiveness of the registration statements for resale of the shares underlying the Exchange Warrants and the Equity Warrants. If we fail to comply with these obligations, we would be subject to substantial cash penalties and would likely not have the resources to make such payments and continue our operations.

On October 13, 2023, we filed a registration statement on Form S-3 for the offer and resale of the shares underlying the Exchange Warrants and the Equity Warrants, as amended by a Pre-Effective Amendment No. 1 to Form S-3 on Form S-1, filed on December 4, 2023, which was declared effective on December 15, 2023. On February 1, 2024, we entered into the Purchase Agreement, pursuant to which we agreed to issue and sell, in a public offering, (i) the Shares, (ii) the February 2024 Pre-Funded Warrants, (iii) the Series B-1 Common Warrants and (iv) the Series B-2 Common Warrants.

In addition, we expect to continue 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 operating expenses and capital expenditure requirements only into the third quarter of 2024. The Series T Warrants issued pursuant to the Equity SPA currently can be force exercised. 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. Our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect, and we will require additional funding to recommence development of our product candidates. Our spending levels will vary based on new and ongoing development and corporate activities. 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 will need to raise substantial funds in the near term in addition to the funds raised in the offering completed in February 2024 in order to regain compliance with Nasdaq's currently applicable stockholders' equity requirement and continue operations, as discussed further below. We intend to raise additional funds in the near term. 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, 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.

Our auditors have expressed substantial doubt about our ability to continue as a going concern, and 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 drug candidates and that we will require additional funding to support our planned operating activities. The report of our independent registered public accounting firm on our financial statements as of and for the year ended December 31, 2023 includes an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. Until such time, if ever, in which 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 lead product candidate, GRI-0621, 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. Because GRI-0621 is our lead product candidate, if GRI-0621 encounters safety or efficacy problems, 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 lead product candidate, GRI-0621, GRI-0803 or any of our other 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;
- delays in submitting INDs 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;
- 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;
- further delays and changes in regulatory requirements, policy 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.

To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical 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 future 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.

Congress also recently amended the Federal Food, Drug, and Cosmetic Act (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 has 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 or what specific information FDA will expect in such plans. 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.

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 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 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; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

For example, when we 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 MASH clinical studies we made the administrative decision to halt the study after enrolling 14 patients.

Additionally, 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, among other things. 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 in such clinical trial site.

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 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 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, 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 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 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 MASH clinical studies, our disclosure 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 pilot Phase 2a trial may not be indicative of results from any potential future pre-clinical 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 IRBs 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 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 lead product candidate, and if that pathway is not available, the development of our 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" 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 us under the FDCA. This 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, which 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 the applicant's proposed development plan for the follow-on drug product, it may require companies to perform additional studies or measurements, including nonclinical and clinical studies, to support the change from the approved product. 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 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 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.

Risks Related to Regulatory Approval of Our Product Candidates

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, Fast Track designation does 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.

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 current good manufacturing practices ("cGMPs") and good clinical practices ("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 tracking and tracing requirements. As such, 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 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 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 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 our products. 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 recently published a 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, 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.

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 out 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 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 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 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, “Item 1. 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 is 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, “Item 1. 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. Most recently, in August 2022, 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 will negotiate 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. 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. Those lawsuits are currently ongoing.

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.

The Federal Trade Commission ("FTC") in mid-2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. 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. It remains to be seen whether the FTC, other governmental agencies, pharmaceutical manufacturers, or other stakeholders continue to prioritize the policy issue of "improper" patent listings and whether significant litigation will develop in this area. 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 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, including from December 22, 2018 through January 25, 2019, 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. If a prolonged government shutdown or slowdown occurs, it 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 government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. There have been U.S. government shutdowns historically, and recent government shutdowns have been threatened; 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.

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, United States. 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, 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 (the “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, we may enter into certain licenses or other collaboration agreements pertaining to the in-license of rights to additional product candidates. 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; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently 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 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 these 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 future 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 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 no claims against us are currently pending, and 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 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. While we are presently unaware of any claims or assertions by third parties with respect to our patents or other intellectual property, we cannot guarantee that a third party will not assert a claim or an interest in any of such patents or intellectual property. If we become involved in any litigation, it 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, which 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 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).

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. 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.

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 will require 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 includes 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 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 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, 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 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, and 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, 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 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 efforts, including any of our clinical trials, comply with applicable requirements. Our failure to comply with these laws, regulations or guidelines may require us to repeat clinical trials, which 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 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, and any turnover in 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. CROs also may 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. We expect there to be 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 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 rely on a sole supplier or, in some cases, a limited number of suppliers, for the manufacture of GRI-0621, GRI-0803 and our other product candidates. 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. Moreover, in the event any of these suppliers breach their 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 in the future seek 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, 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. Further, we do not yet have any capability for

commercialization. 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 collaborators have significant discretion in determining the efforts and resources that they will apply and may not perform their obligations as expected, 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, we may have disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, 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 and 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.

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 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, our President and Chief Executive Officer, Vipin Kumar Chaturvedi, our Chief Scientific Officer and Albert Agro, our Chief Medical Officer. The 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 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.

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. 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. There is no guarantee that any "key person" insurance policy we have or may enter into would adequately compensate us for the loss of any key employee. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior scientific and medical personnel.

If we fail to attract and retain management and other key personnel, we may be unable to successfully develop or commercialize our product candidates or otherwise implement our business plan.

The biotech industry has 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. Many of the other biopharmaceutical companies against which we 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. For example, on June 16, 2024, our board of directors approved an amendment to Dr. Agro's employment agreement, which provides that Dr. Agro is required to work at least 70 hours per month for the Company, and may devote the balance of his time to other consulting or employment activities. 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 information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.

Our internal computer systems and those of any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, phishing or other unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business 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 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 security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential 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.

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data, such as names, mailing addresses, email addresses, phone numbers and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial of service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect

our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of personal data, including study participant personal data could result in significant liability under state (e.g., state breach notification laws), federal (e.g., Section 5 of the FTC Act), and international (e.g., the GDPR) law and may cause a material adverse impact to our reputation, affect our ability to conduct our studies and potentially disrupt our business.

We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyberattacks, and any such attacks could result in the losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues, civil liability or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business. By way of example, the California Consumer Privacy Act (the "CCPA"), which went into effect on January 1, 2020, creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches increasing the potential for data breach litigation. The California Consumer Rights Act (the "CPRA") became effective on January 1, 2023 to strengthen elements of the CCPA. While there are exceptions for information that is subject to HIPAA and clinical trial regulations, the CCPA, as applicable, would still impact our business, and may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and actually implemented in other states. By way of example regarding foreign laws and regulations with respect to data privacy and security, the General Data Protection Regulation (the "GDPR") went into effect in the EU in May 2018 introducing strict requirements for processing the personal data of EU data subjects. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater.

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 epidemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result 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 of our business operations. Earthquakes or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. In addition, global climate change could result in certain types of natural disasters occurring more frequently or with more intense effects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time.

The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at 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 insurance 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.

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. Without D&O 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 key agreements, including key commercial partner 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;
- our ability to comply with our obligations pursuant to our registration rights agreements; and
- the loss of key employees.

Moreover, the stock markets in general have experienced substantial volatility in the biotech 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. In addition, such securities litigation often has ensued after a reverse merger or other merger and acquisition activity of the type engaged by us. Such litigation, if brought, could impact negatively 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 June 17, 2024, there were a total of (i) 26,850 shares of Common Stock directly or indirectly underlying the Equity Warrants (including (a) 8,950 shares of Common Stock underlying Series A-1 Warrants to purchase shares of Common Stock, which Series A-1 Warrants are issuable upon exercise of Series T Warrants, assuming that the Series T Warrants have been exercised in full by paying the aggregate exercise price in cash, (b) 8,950 shares of Common Stock underlying the Series T Warrants to purchase Common Stock and (c) 8,950 shares of Common Stock underlying Series A-2 Warrants to purchase shares of Common Stock, which Series A-2 Warrants are issuable upon exercise of Series T Warrants, assuming that the Series T Warrants have been exercised in full by paying the aggregate exercise price in cash), (ii) 769,210 shares of Common Stock underlying the Series B Warrants; (iii) 343 shares of Common Stock underlying other outstanding warrants to purchase Common Stock (iv) 456 shares of Common Stock issuable upon the exercise of vested outstanding options under the the A&R 2018 Plan, (v) an additional 2,047 shares of Common Stock issuable upon the exercise of options that remain subject to vesting as of

that date and no options available for future issuance under the GRI Operations Plan or the A&R 2018 Plan and (vi) approximately $0.6 million available for future sales of shares of Common Stock under the Sales Agreement. In connection with the issuance of the securities pursuant to the 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 since been exercised.

As of June 17, 2024, an aggregate of (i) 4,632 shares of our Common Stock have been issued upon the exercise of Exchange Warrants, (ii) 13,947 shares of our Common Stock have been issued upon the exercise of Series A-1 Warrants and (iii) 12,552 shares of our Common Stock have been issued upon the exercise of Series A-2 Warrants. The Exchange Warrants and the Series A-2 Warrants were exercised on a cashless basis for which the Company received no proceeds, and the Series A-1 Warrants were exercised on a cash basis. 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, 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 has and may increase the volatility in our stock price or put significant downward pressure on the price of our 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. In addition, if we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

As a public company, we incur significant legal, accounting and other expenses under the Exchange Ac), the Sarbanes-Oxley Act of 2022, 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 increase our legal and financial compliance costs 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 to ensure that we comply with all of these requirements. As a result, it may be difficult for us to attract and retain qualified persons to serve on our Board, our Board committees or as executive officers.

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, 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. While we anticipate maintaining the integrity of our internal controls over financial reporting and all other aspects of Section 404, we cannot be certain that a material weakness will not be identified when we test the effectiveness of our control systems in the future. If a material weakness is identified, 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 the rules of the SEC. 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. 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 annual revenues were below $100.0 million and we have 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.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such an election to opt out is irrevocable. We have elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, will not adopt the new or revised standard until the time private companies are required to adopt the new or revised standard. This may make comparison of our financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accountant standards used.

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).

The listing of shares of our Common Stock does not currently comply with the rules of The Nasdaq Capital Market or any other Nasdaq Market tier. Pursuant to our agreements in connection with the Equity Financing, we are also subject to covenants that require us to maintain the listing of our Common Stock on Nasdaq. If we fail to comply with these obligations, we would be subject to substantial cash penalties and, as of the date of this prospectus, would likely not have the resources to make such payments and continue our operations. A delisting of our Common Stock from Nasdaq could also 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 bid price of at least $1.00 per share for shares of our Common Stock 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 November 14, 2023, the date of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, the market value of our listed securities was less than $35 million, our reported stockholders' equity was less than the required $2.5 million and we had not earned net income in excess of $500 thousand in accordance with applicable listing requirements.

On November 22, 2023, we received a letter from the Staff of Nasdaq notifying GRI that it is not in compliance with the Stockholders' Equity Requirement for continued listing on The Nasdaq Capital Market based on the information provided in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2023. In accordance with Nasdaq rules, we were provided until January 8, 2024 to submit our Compliance Plan to regain compliance with the Stockholders' Equity Requirement, which we submitted on January 8, 2024. The Notice has no immediate effect on our continued listing on The Nasdaq Capital Market, subject to our compliance with other continued listing requirements. On January 22, 2024, the Staff granted us an extension until the May Compliance Date of May 20, 2024 to regain compliance with the Stockholders' Equity Requirement. Per the Staff's January 22, 2024 letter, we must complete the Equity Offering and furnish to the Staff and Nasdaq evidence of compliance with the Stockholders' Equity Requirement by filing a publicly available report prior to May 24, 2024. While we completed an equity offering with gross proceeds of $5.5 million and have met the Stockholders' Equity Requirement as of the quarter ended March 31, 2024, on May 21, 2024, we received the Staff's Determination Letter notifying us that we had not regained compliance with the Stockholders' Equity Requirement as of the May Compliance Date when taking into account our historical burn rate. We timely requested an appeal of the determination to the Panel, and the hearing was scheduled for July 11, 2024. The appeal automatically stays any suspension or delisting action pending the hearing before the Panel, and our Common Stock will remain listed on The Nasdaq Capital Market pending the outcome of the hearing before the Panel. Pursuant to Nasdaq Listing Rules, the Panel has the authority to grant an additional extension not to exceed 180 days from the Staff's determination. Notwithstanding the foregoing, there can be no assurance that the Panel will grant us an additional extension period or that we will ultimately regain compliance with all applicable requirements for continued listing on The Nasdaq Capital Market even assuming completion of this offering.

The rules of The Nasdaq Capital Market also require that we maintain a closing price for shares of our Common Stock of at least $1.00 per share. On January 5, 2024, we received a letter from the Staff of Nasdaq indicating that the Company no longer meets the Minimum Bid Price Rule set forth in Nasdaq Listing Rule 5550(a)(2) because the closing bid price of our Common Stock was less than $1.00 for the previous 30 consecutive business days. The letter is in addition to the letter described above and similarly has no immediate effect on our continued listing on The Nasdaq Capital Market. Under Nasdaq Listing Rule 5810(c)(3)(A), the Company has a 180-calendar day period, or until the Compliance Date, to regain compliance with the Minimum Bid Price Requirement. The Minimum Bid Price Requirement will be met if the Company's common stock has a minimum closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days during the 180-calendar day period, unless Nasdaq exercises its discretion to extend such 10-day period. If the Company does not regain compliance by the Compliance Date, the Company may be eligible for an additional 180-calendar day period, subject to satisfying the conditions in the applicable Nasdaq Listing Rules. If, before the Compliance Date, the Company's common stock has a closing bid price of $0.10 per share or less for ten consecutive trading days, the Staff will issue a Staff Delisting Determination under Nasdaq Listing Rule 5810 with respect to the Company's common stock. On January 29, 2024,

we implemented the January 2024 Reverse Stock Split to attempt to regain compliance with the Minimum Bid Price Rule. Nasdaq subsequently reported that our Common Stock had a closing bid price above $1.00 per share for 10 consecutive trading days during the 180-day period, but Nasdaq exercised its discretion to extend the 10-day period and did not deem that we regained compliance with the Minimum Bid Price Rule. On June 17, 2024, we implemented the June 2024 Reverse Stock Split, but there can be no assurance that we will be able to regain compliance or that the bid price of our Common Stock will remain above the minimum $1.00 bid price required for any post-split Nasdaq monitoring period or otherwise.

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.

Further, our failure to maintain compliance with applicable Nasdaq listing requirements will also cause us to fail to meet the equity conditions for us to require the exercise the Series T Warrants and would result in our being liable for penalties in the agreements related to the Equity Financing. Additionally, to the extent that we characterize this offering as a public offering, Nasdaq may not agree with our characterization, which could be grounds for delisting or cause to unwind the transaction. Nasdaq has in the past, and may again, request additional information to evaluate our whether our completed offerings are public offerings pursuant to Nasdaq rules. 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 this reason or any other reason could materially affect our ability to raise capital, adversely affect our business and the price of our Common Stock.

The June 2024 Reverse Stock Split could cause our stock price to decline relative to its value before the split and decrease the liquidity of shares of our Common Stock.

We legally effected the June 2024 Reverse Stock Split on June 17, 2024 and on June 18, 2024, our Common Stock began trading on a post-split basis. The primary intent for the June 2024 Reverse Stock Split is an anticipated increase in the price of our Common Stock immediately following and resulting from a reverse stock split due to a reduction in the number of issued and outstanding shares of our common stock to help us meet the Minimum Bid Price Rule. It cannot be assured that the June 2024 Reverse Stock Split will result in any sustained proportionate increase in the market price of our Common Stock, which is dependent upon many factors, including our business and financial performance, general market conditions, and prospects for future success, which are unrelated to the number of shares of our Common Stock outstanding. It is not uncommon for the market price of a company's common stock to decline in the period following a reverse stock split.

There is no assurance that the June 2024 Reverse Stock Split will not cause an actual decline in the value of our outstanding Common Stock. The trading volume of our shares following the April 2023 Reverse Stock Split and the January 2024 Reverse Stock Split has varied, and shares of our Common Stock may have been less liquid as a result of the April 2023 Reverse Stock Split and the January 2024 Reverse Stock Split. The liquidity of the shares of our Common Stock may be affected adversely by the June 2024 Reverse Stock Split given the reduced number of shares outstanding following the June 2024 Reverse Stock Split, especially if the market price of our Common Stock does

not increase as a result of the June 2024 Reverse Stock Split. In addition, the June 2024 Reverse Stock Split may increase the number of stockholders who own odd lots (less than 100 shares) of our Common Stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty effecting such sales.

Following a reverse stock split, the resulting market price of our Common Stock may not attract new investors, including institutional investors, and may not satisfy the investing requirements of those investors. Consequently, the trading liquidity of our Common Stock may not improve.

Although we believe that a higher market price of our Common Stock may help generate greater or broader investor interest, there can be no assurance that a reverse stock split, including the June 2024 Reverse Stock Split, will result in a share price that will attract new investors, including institutional investors. In addition, there can be no assurance that the market price of our Common Stock will satisfy the investing requirements of those investors. As a result, the trading liquidity of our Common Stock may not necessarily improve. The primary intent for the June 2024 Reverse Stock Split was to increase the price of our Common Stock in order to help us meet the Minimum Bid Price Requirement pursuant to Nasdaq listing requirements. It cannot be assured that a reverse stock split, including the June 2024 Reverse Stock Split, will result in any sustained proportionate increase in the market price of our Common Stock, which is dependent upon many factors, including our business and financial performance, general market conditions, and prospects for future success, which are unrelated to the number of shares of our Common Stock outstanding. It is not uncommon for the market price of a company's common stock to decline in the period following a reverse stock split or following an offering such as this offering.

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, 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 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, 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 have not currently elected and may not elect to provide research coverage of our Common Stock, and such lack of research coverage may adversely affect the market price of our Common Stock. In the event we have equity research analyst coverage, we will 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. 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 have in the past and may again 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 have in the past and may again 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 amended and restated certificate of incorporation (Charter) and our amended and restated bylaws (the "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 American 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 the 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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this prospectus are 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 our need to liquidate if we fail to obtain adequate funding, which could result in our stockholders receiving no value for their investment;
- our limited operating history and the difficulties encountered by a small developing company;
- expected restructuring-related cash outlays, including the timing and amount of those outlays;
- the timing of initiation of planned clinical trials;
- the timing of any planned INDs or new drug application;
- 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 the Company’s competitors and their industries;
- the impact of government laws and regulations;
- the Company’s ability to protect its intellectual property position;
- estimates regarding future revenue, expenses, capital requirements, and need for additional financing following the offering;
- any statements about the effect, or potential effect, of the June 2024 Reverse Stock Split on the price or trading of our Common Stock or our ability to regain compliance with and to maintain the listing of our Common Stock on The Nasdaq Capital Market;
- our ability to complete the best efforts offering; 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 “Risk Factors” and elsewhere in this prospectus. 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 prospectus 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 prospectus to conform these statements to new information, actual results or to changes in our expectations, except as required by law.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $ million, after deducting the Placement Agent's fees and estimated offering expenses payable by us, and assuming no sale of Pre-Funded Warrants in this offering and no exercise of the Warrants being issued in this offering. However, because this is a best efforts offering and there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, the Placement Agent's fees and net proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth on the cover page of this prospectus. The table below depicts how we plan to utilize the proceeds in the event that 25%, 50%, 75% and 100% of the securities in this offering are sold, after deducting estimated offering expenses payable by us:

Use of Proceeds	**100%**	**75%**	**50%**	**25%**
Product Candidate Development	$	$	$	$
General Corporate Purposes/Working Capital	$	$	$	$
Total:	$	$	$	$

These estimates exclude the proceeds, if any, from the exercise of the Warrants issued in this offering. If all of the Warrants issued in this offering were to be exercised in cash at an exercise price of $ per share of Common Stock, we would receive additional proceeds of approximately $ million. We cannot predict when or if these Warrants will be exercised. It is possible that these Warrants may expire and may never be exercised. Additionally, the Warrants contain a cashless exercise provision that permit exercise of Warrants on a cashless basis at any time where there is no effective registration statement under the Securities Act covering the issuance of the underlying shares.

We intend to use the net proceeds of this offering for product candidate development activities and general corporate purposes. General corporate purposes may include, and are not limited to, costs associated with, research and development costs, manufacturing costs, the acquisition or licensing of other businesses, products or product candidates, working capital and capital expenditures.

These expected uses represent our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of and results from clinical trials, as well as any new collaborations that we may enter into with third parties for our product candidates, the commercialization of our products or our product candidates, if approved, and any unforeseen cash needs. As a result, our management will have broad discretion in the application of the net proceeds from this offering, and the investors will be relying on the judgment of our management regarding the application of the net proceeds from this offering.

Pending application of the net proceeds as described above, we intend to invest the net proceeds of this offering in short-term, investment-grade, interest-bearing securities.

MARKET INFORMATION

Our Common Stock is currently listed on The Nasdaq Capital Market under the symbol “GRI.” As of June 17, 2024, there were 543,775 shares of Common Stock and no shares of preferred stock outstanding and held by 17 stockholders of record.

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, for use in the operation of our business and do not anticipate paying any cash dividends on our securities in the foreseeable future. Additionally, our ability to pay dividends on our capital stock could be limited by terms and covenants of any future indebtedness. Investors should not purchase our securities with the expectation of receiving cash dividends.

CAPITALIZATION

The following table sets forth our cash and capitalization as of March 31, 2024:

- on an actual basis;
- on a pro forma basis to give effect to (i) the issuance and sale by us of an aggregate of 95,566 shares of our Common Stock in the ATM Offering for net proceeds of $0.4 million, after deducting commissions to the sales agent and other ATM Offering related expenses and (ii) the issuance by us of an aggregate of 202,334 shares pursuant to the exercise of our outstanding warrants; and
- on a pro forma as adjusted basis to give further effect to the issuance and sale of shares of our Common Stock to purchase up to shares of our Common Stock in this offering at an assumed combined public offering price of $ per share of Common Stock and Warrants (the last reported sale price of our Common Stock on The Nasdaq Capital Market on , 2024), less Placement Agent fees and estimated offering expenses payable by us, for total net proceeds of approximately $, assuming no exercise of Warrants and no sale of any Pre-Funded Warrants.

You should read this table together with "Use of Proceeds" and our audited and unaudited financial statements and related notes thereto included elsewhere in this prospectus.

	As of March 31, 2024		
(In thousands, except share data)	**Actual (unaudited)**	**Pro Forma**	**Pro Forma, as adjusted**
Cash	$ 4,091		
Operating lease liability	43		
Shareholders' equity	4,587		
Common stock, $0.0001 par value, 250,000,000 shares authorized as of March 31, 2024; 245,875 shares issued and outstanding, actual; shares issued and outstanding, pro forma as adjusted	—		
Additional paid-in capital	36,218		
Accumulated deficit	(33,420)		
Total stockholders' equity	2,798		
Total capitalization	$ 4,587		

The table and discussion above is based on 245,875 shares of our Common Stock outstanding as of March 31, 2024 and excludes the following:

- 95,566 shares of Common Stock under the ATM Offering as of June 17, 2024;
- 778,503 shares of Common Stock issuable upon exercise of warrants outstanding as of March 31, 2024, with a weighted average exercise price of $29.27
- 202,334 shares of Common Stock issuable upon exercise of the Series A-1 Warrants and the February 2024 Pre-Funded Warrants outstanding as of March 31, 2024;
- 2,503 shares of Common Stock issuable upon the exercise of options outstanding, with a weighted average exercise price of $471.45 per share; and
- 1,864 shares of common stock reserved for future issuance under our A&R 2018 Plan.

The information discussed above is illustrative only and will adjust based on the actual public offering price, the actual number of shares and Warrants that we offer in this offering, and other terms of this offering determined at pricing. Except as indicated otherwise, the discussion and table above assume (i) no sale of the Pre-Funded

Warrants, which, if sold, would reduce the number of shares of Common Stock that we are offering on a one-for-one basis and (ii) no exercise of the Warrants accompanying the shares of Common Stock sold in this offering.

DILUTION

If you invest in our securities, your interest will be immediately diluted to the extent of the difference between the effective public offering price per share of Common Stock and the pro forma as adjusted net tangible book value per share of our Common Stock after this offering. Net tangible book value per share represents our total tangible assets less total liabilities, divided by the number of shares of our Common Stock outstanding.

As of March 31, 2024, our net tangible book value was $2.8 million, or $11.38 per share of Common Stock, based on 245,875 shares of Common Stock outstanding as of March 31, 2024.

After giving effect to the Pro Forma Adjustments, our net tangible book value as of March 31, 2024, would have been approximately $ million, or approximately $ per share.

After giving further effect to the sale of shares of our Common Stock and accompanying Warrants at an assumed public offering price per share of Common Stock of $, the last reported sale price of our Common Stock on The Nasdaq Capital Market on , 2024, assuming no sale of any Pre-Funded Warrants in this offering, and after deducting the estimated Placement Agent fees and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the Warrants issued in this offering, our pro forma as adjusted net tangible book value as of March 31, 2024 would have been approximately $ million, or approximately $ per share. This represents an immediate increase in the pro forma as adjusted net tangible book value to existing shareholders of $ per share and an immediate dilution in the pro forma as adjusted net tangible book value of $ per share of our Common Stock to the investors purchasing securities in this offering.

The following table illustrates this dilution to new investors purchasing shares of Common Stock in this offering:

Assumed combined public offering price per share of Common Stock and accompanying Warrant			$
Historical net tangible book value (deficit) per share as of March 31, 2024		$11.38	
Decrease in pro forma net tangible book value per share attributable to investors purchasing in this offering	$		
Pro forma net tangible book value per share as of March 31, 2024	$		
Decrease in net tangible book value per share attributable to investors purchasing in this offering	$		
Pro forma as adjusted net tangible book value per share as of March 31, 2024 after giving effect to this offering			$
Dilution per share to investors purchasing in this offering			$

Each $0.10 increase or decrease in the assumed combined public offering price per share of Common Stock and accompanying Warrants of $, the last reported sale price of our common stock on The Nasdaq Capital Market on , 2024, would increase or decrease the net proceeds to us from this offering by $ million, assuming that the number of share of Common Stock and accompanying Warrants offered by us, as set forth on the cover page of this prospectus, remains the same, assuming no sale of any Pre-Funded Warrants and accompanying Warrants, after deducting the estimated Placement Agent fees and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the Warrants issued pursuant to this offering. The as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering as determined between us and the Placement Agent at pricing.

The table and discussion above is based on 245,875 shares of our Common Stock outstanding as of March 31, 2024 and excludes the following:

- 95,566 shares of Common Stock under the ATM Offering as of June 17, 2024;
- 778,503 shares of Common Stock issuable upon exercise of warrants outstanding as of March 31, 2024, with a weighted average exercise price of $29.27;

- 202,334 shares of Common Stock issuable upon exercise of the Series A-1 Warrants and the February 2024 Pre-Funded Warrants outstanding as of March 31, 2024;
- 2,503 shares of Common Stock issuable upon the exercise of options outstanding, with a weighted average exercise price of $471.45 per share; and
- 1,864 shares of common stock reserved for future issuance under our A&R 2018 Plan.

Except as otherwise indicated, all information in this prospectus assumes or gives effect to:

- no exercise of the outstanding warrants described above;
- no exercise of the outstanding options described above; and
- no exercise of the Warrants or the Placement Agent Warrants issued to the Placement Agent or its designees as compensation in connection with this offering and no sale of the Pre-Funded Warrants.

Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and the related notes appearing elsewhere in this prospectus, the audited consolidated financial statements and notes thereto, as well as management's discussion and analysis of financial condition and results of operations, included in this prospectus. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for the business and related financing, include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 12E of the Exchange Act that involve risks and uncertainties. As a result of many factors, including those factors set out under the section entitled "Risk Factors" included in this registration statement, actual results could differ materially from the results described in or implied by these forward-looking statements. Unless otherwise defined in this section, the defined terms in this section have the meanings set forth in the audited consolidated financial statements and unaudited interim consolidated financial statements contained elsewhere in this prospectus.

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 lead product candidate, GRI-0621, is an oral inhibitor of type 1 Natural Killer T ("iNKT") cells. GRI-0621 is also an oral formulation of tazarotene, a synthetic retinoid acid receptor ("RAR")-beta and gamma selective agonist, that is approved in the United States for topical treatment of psoriasis and acne. As of March 31, 2024, 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 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. The U.S. Food and Drug Administration ("FDA") has cleared our Investigative New Drug ("IND") application for GRI-0621 for the treatment of IPF and we plan to evaluate GRI-0621 in a randomized, double-blind, multi-center Phase 2a biomarker study, for which we commenced enrollment in December 2023. We expect interim data from this trial to be available in the third quarter of 2024 and topline results to be available in the fourth quarter of 2024. Additionally, on March 4, 2024, we received authorization of our clinical trial application ("CTA") from the United Kingdom Medicines and Healthcare Products Regulatory Agency ("MHRA") to initiate the Phase 2a biomarker study evaluating GRI-0621 for the treatment of IPF in the United Kingdom (the "UK").

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 Natural Killer T cells. We are developing GRI-0803 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. Subject to IND clearance, we intend to evaluate GRI-0803 in a Phase 1a and 1b trial initially targeting SLE. We expect to file an IND with respect to this Phase 1a and 1b trial in the second half of 2024. We will continue to evaluate indications to select the best fit for further development of the program, but our initial focus is on lupus.

Recent Developments

January 2024 and June 2024 Reverse Stock Split

On January 19, 2024, our stockholders approved a reverse stock split of our Common Stock and our board of directors (the "Board") subsequently approved a reverse stock split of our Common Stock at a ratio of one-for-seven (the "January 2024 Reverse Stock Split"). Following this approval, we filed an amendment to our Amended and Restated Certificate of Incorporation, as amended (the "Amended and Restated Certificate of Incorporation") with the Secretary of State of the State of Delaware to effect the January 2024 Reverse Stock Split as of 4:01 p.m. Eastern Time on January 29, 2024. Shares of our Common Stock began trading on a post-split basis on January 30, 2024. As a result of the January 2024 Reverse Stock Split, every seven shares of our Common Stock, either issued or outstanding, immediately prior to the filing and effectiveness of our amendment to our Amended and Restated Certificate of Incorporation filed with the Secretary of State of the State of Delaware, was automatically combined and converted (without any further act) into one share of fully paid and nonassessable share of Common Stock. No fractional shares were issued in connection with the January 2024 Reverse Stock Split. Stockholders who otherwise would have received fractional shares of Common Stock received cash in lieu thereof at a price equal to the fraction to which the stockholder would have otherwise been entitled.

On June 7, 2024, our stockholders approved the June 2024 Reverse Stock Split. Our board of directors (the "Board") subsequently approved the June 2024 Reverse Stock Split ratio of one-for-thirteen. Following this approval, we filed an amendment to our Amended and Restated Certificate of Incorporation, as amended (the "Amended and Restated Certificate of Incorporation") with the Secretary of State of the State of Delaware to effect the June 2024 Reverse Stock Split as of 4:01 p.m. Eastern Time on June 17, 2024. Shares of our Common Stock began trading on a post-split basis on June 18, 2024. As a result of the June 2024 Reverse Stock Split, every thirteen shares of our Common Stock, either issued or outstanding, immediately prior to the filing and effectiveness of our amendment to our Amended and Restated Certificate of Incorporation filed with the Secretary of State of the State of Delaware, was automatically combined and converted (without any further act) into one share of fully paid and nonassessable share of Common Stock. No fractional shares were issued in connection with the June 2024 Reverse Stock Split. Stockholders who otherwise would have received fractional shares of Common Stock received cash in lieu thereof at a price equal to the fraction to which the stockholder would have otherwise been entitled. On its effective date, the June 2024 Reverse Stock Split had the effect of reducing the aggregate number of outstanding shares of Common Stock from 6,635,170 shares on a pre-reverse split basis to a total of 510,391 shares outstanding on a post-reverse split basis.

Unless otherwise noted, all financial information, share numbers, option numbers, warrant numbers, other derivative security numbers and exercise prices appearing in this prospectus have been adjusted to give effect to the January 2024 Reverse Stock Split and June 2024 Reverse Stock Split.

May 2024 At The Market Offering

On May 20, 2024, we entered into an At The Market Offering Agreement (the "Sales Agreement") with H.C. Wainwright & Co., LLC ("Wainwright"), pursuant to which we may sell and issue 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.

The shares of Common Stock are being offered and sold in the ATM Offering pursuant to our effective shelf registration statement on Form S-3 (File No. 333-279348) and the accompanying base prospectus included therein as supplemented by the prospectus supplement, dated May 20, 2024, filed with the U.S. Securities and Exchange Commission (the "SEC").

As June 17, 2024, we have sold 95,566 shares of our Common Stock in the ATM Offering at a weighted-average price of $3.9783 per share, raising $0.4 million of gross proceeds and net proceeds of $0.4 million, after deducting commissions to the sales agent and other ATM Offering related expenses. As of June 17, 2024, there remains approximately $0.6 million available for future sales of shares of Common Stock under the Sales Agreement.

Securities Purchase Agreement

On February 1, 2024, we entered into a securities purchase agreement (the "Purchase Agreement"), pursuant to which we agreed to issue and sell, in a public offering, (i) 25,419 shares (the "Shares") of the Company's common stock, par value $0.0001 per share (the "Common Stock"), (ii) 359,196 pre-funded warrants (the "Pre-Funded Warrants") exercisable for an aggregate of 359,196 shares of Common Stock, (iii) 384,615 Series B-1 common warrants (the "Series B-1 Common Warrants") exercisable for an aggregate of 384,615 shares of Common Stock, and (iv) 384,615 Series B-2 common warrants (the "Series B-2 Common Warrants," together with the Series B-1 Common Warrants, the "Common Warrants") exercisable for an aggregate of 384,615 shares of Common Stock for net proceeds of $4.4 million, after deducting offering costs of $1.1 million. The Common Warrants together with the Pre-Funded Warrants are referred to in this *Management's Discussion and Analysis of Financial Condition and Results of Operations* as the "Warrants." The securities were offered in combinations of (a) one Share or one 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 $14.30 (less $0.0013 for each Pre-Funded Warrant). As of June 17, 2024, no Series B Warrants have been exercised.

Subject to certain ownership limitations, the Warrants were exercisable upon issuance. Each Series B-1 Common Warrant is exercisable into one share of Common Stock at a price per share of $14.30 (as may be adjusted from time to time in accordance with the terms thereof) 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 $14.30 (as may be adjusted from time to time in accordance with the terms thereof) for the 18-month period after February 6, 2024, the date of issuance.

In connection with the issuance of the securities pursuant to the Purchase Agreement, the exercise price of our previously issued 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. All of the Series A-1 Warrants and Pre-Funded Warrants have since been exercised.

Nasdaq Compliance - Stockholders' Equity Deficiency

On November 22, 2023, we received a letter (the "Notice") from the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") notifying us that we were not in compliance with the minimum stockholders' equity requirement for continued listing on The Nasdaq Capital Market based on the information provided in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2023. Nasdaq Listing Rule 5550(b)(1) requires that companies listed on The Nasdaq Capital Market with a market value of listed securities of less than $35.0 million and annual net income of less than $0.5 million maintain stockholders' equity of at least $2.5 million (the "Stockholders' Equity Requirement"). In accordance with Nasdaq rules, we were provided until January 8, 2024, to submit a plan to regain compliance with the Stockholders' Equity Requirement (the "Compliance Plan"). On January 22, 2024, the Staff granted us an extension until May 20, 2024 to regain compliance with the Stockholders' Equity Requirement. Per the Staff's January 22, 2024 letter, we must complete an equity offering to raise gross proceeds of at least $6.0 million and furnish to the Staff and Nasdaq evidence of compliance with the Stockholders' Equity Requirement by filing a publicly available report prior to May 24, 2024. While we completed an equity offering with gross proceeds of $5.5 million and have met the minimum Stockholders' Equity Requirement as of the quarter ended March 31, 2024, the proceeds will likely be insufficient for us to maintain compliance with the Stockholders' Equity Requirement such that we will need to raise substantial additional funds in the near term. If we fail to evidence compliance with the Stockholders' Equity Requirement in our Quarterly Report on Form 10-Q for the quarter ending June 30, 2024 or as otherwise required by Nasdaq, we may be delisted.

Nasdaq Compliance - Minimum Bid Price Deficiency

The rules of The Nasdaq Capital Market also require that we maintain a closing price for shares of our Common Stock of at least $1.00 per share (the "Minimum Bid Price Rule"). On January 5, 2024, we received a letter (the "Letter") from the Staff of Nasdaq indicating that we no longer meet the Minimum Bid Price Rule set forth in Nasdaq Listing Rule 5550(a)(2) because the closing bid price for our Common Stock was less than $1.00 for the previous 30 consecutive business days. The Letter is in addition to the Notice described above. The Letter has no immediate effect on our continued listing on The Nasdaq Capital Market. Under Nasdaq Listing Rule 5810(c)(3)(A), we have a 180-calendar day period, or until July 3, 2024 (the "Compliance Date"), to regain compliance with the Minimum Bid Price Rule. The Minimum Bid Price Rule will be met if our Common Stock has a minimum closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days during the 180-calendar day period, unless Nasdaq exercises its discretion to extend such 10-day period. If we do not regain compliance by the Compliance Date, we may be eligible for an additional 180-calendar day period, subject to satisfying the conditions in the applicable Nasdaq Listing Rules. If, before the Compliance Date, our Common Stock has a closing bid price of $0.10 per share or less for ten consecutive trading days, the Staff will issue a Staff Delisting Determination under Nasdaq Listing Rule 5810 with respect to our Common Stock. On January 29, 2024, we filed an amendment to our Charter to implement the January 2024 Reverse Stock Split to attempt to regain compliance with the Minimum Bid Price Rule, but were not able to regain compliance following the January 2024 Reverse Stock Split. On June 7, 2024, our stockholders approved the June 2024 Reverse Stock Split and our Board subsequently approved the June 2024 Reverse Stock Split at a ratio of one-to-thirteen. Following this approval, we filed an amendment to our Amended and Restated Certificate of Incorporation to effect the June 2024 Reverse Stock Split to attempt to regain compliance with the Minimum Bid Price Rule. There can be no assurance that the stock price of our Common Stock will remain above the minimum $1.00 bid price required for any post-split Nasdaq monitoring period or otherwise.

Merger with Vallon Pharmaceuticals, Inc.

On April 21, 2023, the Company (formerly Vallon Pharmaceuticals, Inc.) consummated a merger with GRI Bio Operations, Inc. (formerly GRI Bio, Inc.) ("GRI Operations") pursuant to an Agreement and Plan of Merger, as amended (the "Merger Agreement"), by and among the Company, GRI Operations and Vallon Merger Sub, Inc. ("Merger Sub"), a Delaware corporation and wholly-owned subsidiary of the Company. The Merger Agreement provided for the merger of Merger Sub with and into GRI Operations, with GRI Operations continuing as a wholly-owned subsidiary of the Company and the surviving corporation of the merger (the "Merger"). In connection with the closing of the Merger (the "Closing"), the Company amended its certificate of incorporation and bylaws to change its name from "Vallon Pharmaceuticals, Inc." to "GRI Bio, Inc."

In connection with signing the Merger Agreement, GRI Operations entered into a Securities Purchase Agreement, dated as of December 13, 2022 (the "Bridge SPA"), with Altium Growth Fund, LP ("Altium"), pursuant to which GRI Operations issued senior secured promissory notes (the "Bridge Notes") in the aggregate principal amount of $3.3 million, in exchange for an aggregate purchase price of $2.5 million. The Bridge Notes were issued in two closings: (i) the first closing for $1.67 million in aggregate principal amount (in exchange for an aggregate purchase price of $1.25 million) closed on December 14, 2022; and (ii) the second closing for $1.67 million in aggregate principal amount (in exchange for an aggregate purchase price of $1.25 million) closed on March 9, 2023. In addition, upon the funding of each tranche, Altium received warrants to purchase an aggregate of 13,763 shares of GRI Operations' common stock (the "Bridge Warrants").

In addition to the Bridge SPA, and also in connection with signing the Merger Agreement, the Company, GRI Operations and Altium entered into a Securities Purchase Agreement on December 13, 2022 (the "Equity SPA") pursuant to which the Investor agreed to invest $12.25 million in cash and cancel any outstanding principal and accrued interest on the Bridge Notes in return for the issuance of shares of GRI Operations' common stock (the "GRI Operations Common Stock") immediately prior to the consummation of the Merger. Pursuant to the Equity SPA, immediately prior to the Closing, GRI Operations issued 74,584 shares of GRI Operations Common Stock (the "Initial Shares") to Altium and 298,339 shares of GRI Operations Common Stock (the "Additional Shares") into escrow with an escrow agent. At the Closing, pursuant to the Merger, the Initial Shares converted into an aggregate of 2,789 shares of the Company's Common Stock and the Additional Shares converted into an aggregate of 11,157 shares of the Company's Common Stock. On May 8, 2023, in accordance with the terms of the Equity SPA, the

Company and Altium authorized the escrow agent to, subject to beneficial ownership limitations, disburse to Altium all of the shares of the Company's Common Stock issued in exchange for the Additional Shares.

Pursuant to the Equity SPA, on May 8, 2023, the Company issued to Altium (i) Series A-1 Warrants to purchase 13,947 shares of the Company's Common Stock with an initial exercise price of $1,229.41 per share (all of which have since been exercised, as described under the heading "Warrant Exercises" in Item 15 of Part II of this registration statement), (ii) Series A-2 Warrants to purchase 12,552 shares of the Company's Common Stock with an initial exercise price of $1,341.34 per share (all of which have since been exercised, as described under the heading "Warrant Exercises" in Item 15 of Part II of this registration statement) and (iii) Series T Warrants to purchase at an exercise price of $1,117.48 per share (x) 8,950 shares of the Company's Common Stock and (y) upon exercise of the Series T Warrants, an additional amount of Series A-1 Warrants and Series A-2 Warrants, each to purchase 8,950 shares of the Company's Common Stock (collectively, the "Equity Warrants").

Upon the completion of the Merger, the outstanding principal and accrued interest on the Bridge Notes was cancelled and the Bridge Warrants were exchanged for warrants (the "Exchange Warrants") to purchase an aggregate of 4,632 shares of the Company's Common Stock.

As of June 17, 2024, all of the Series A-1 Warrants, the Series A-2 Warrants and the Exchange Warrants have been exercised and all of the T Warrants were outstanding.

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 lead 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 ("CROs"), contract manufacturing organizations ("CMOs") 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 increase substantially 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 the fair value upon issuance using a Black-Scholes valuation model and are recorded as a liability on the 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.

Other Income

On August 22, 2023, we entered into Asset Purchase Agreement (the "Aardvark Agreement") with Aardvark Therapeutics, Inc. ("Aardvark"), pursuant to which Aardvark agreed to purchase (i) our license agreement with Medice Arzneimittel Pűtter GmbH & Co. KG, dated January 6, 2020, (ii) certain patents related to our ADAIR product candidate, and (iii) files (of contract manufacturing and FDA correspondence) for a formulation described in IND No. 133072, ADAIR for the Treatment of Attention Deficit/Hyperactivity Disorder ("ADHD") and Narcolepsy, filed with the United States FDA. Under the terms of the Agreement, we received an upfront cash payment of $0.3 million, which was recognized as other income. We are also eligible to receive potential additional milestone payments contingent upon Aardvark achieving certain future ADAIR regulatory and sales milestones. Other than the upfront payment, we do not anticipate the receipt of any milestone payments from Aardvark in the near term, which potential milestone payments may or may not be achieved, paid or received in the future.

Extinguishment of Debt

Extinguishment of debt consists of expense recognized as a result of the amendment of certain tranches of convertible promissory notes (the "TEP Notes") held by TEP Biotech, LLC ("TEP"). The amendment was accounted for as extinguishment to which the excess fair value of the amended debt over the carrying value of the original debt resulted in a loss on extinguishment.

Interest Income (Expense)

Interest expense consists of amortization of debt discounts, debt issuance costs and interest expense related to the Bridge Notes. Interest income consists of interest earned on our cash and cash equivalents held with institutional banks.

Results of Operations

Comparison of the Three Months Ended March 31, 2024 and 2023

The following table summarizes the results of our operations for the periods indicated (in thousands):

	Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	$ 933	$ 116
General and administrative	962	872
Total operating expenses	1,895	988
Loss from operations	(1,895)	(988)
Change in fair value of warrant liability	2	—
Interest income (expense)	6	(1,162)
Net loss	$ (1,887)	$ (2,150)

Research and Development Expenses

Research and development expenses were $0.9 million and $0.1 million for the three months ended March 31, 2024 and 2023, respectively. The $0.8 million increase in research and development expenses was primarily due to increases of $0.5 million in expenses related to the development program of GRI-0621, $0.1 million in consulting fees and $0.2 million in personnel expenses.

General and Administrative Expenses

General and administrative expenses were $1.0 million and $0.9 million for the three months ended March 31, 2024 and 2023, respectively. The $0.1 million increase was primarily related to increased personnel expenses of $0.3 million as a result of increased headcount, increases in administrative and insurance expenses of $0.2 million, offset by a $0.4 million decrease in consulting and professional fees, including legal, accounting and investor relations fees.

Change in Fair Value of Warrant Liability

The change in fair value of $2,000 represents a decrease in the fair value of the May 2022 Warrants outstanding during the three months ended March 31, 2024.

Interest Income (Expense)

Interest income was $6,000 for the three months ended March 31, 2024. Interest expense was $1.2 million for the three months ended March 31, 2023 and related to the outstanding Bridge Notes.

Comparison of the Years Ended December 31, 2023 and 2022

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

	Year Ended December 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 3,232	$ 242
General and administrative	8,155	1,997
Total operating expenses	11,387	2,239
Loss from operations	(11,387)	(2,239)
Other income	250	—
Change in fair value of warrant liability	182	—
Loss on extinguishment of debt	—	(325)
Interest expense, net	(2,082)	(653)
Net loss	$ (13,037)	$ (3,217)

Research and Development Expenses

Research and development expenses were $3.2 million and $0.2 million for the years ended December 31, 2023 and 2022, respectively. The $3.0 million increase in research and development expenses was primarily due to increases of $1.9 million in expenses related to the registration development program of GRI-0621, $0.4 million in personnel expense, $0.6 million in consulting fees, and $0.1 million in intellectual property expenses.

General and Administrative Expenses

General and administrative expenses were $8.2 million and $2.0 million for the years ended December 31, 2023 and 2022, respectively. The $6.1 million increase was primarily due to an increase of $4.2 million in accounting, legal, investment banking and other fees as a result of the Merger and the cost of being a public company, an

increase of $1.5 million in personnel costs, an increase of $0.3 million in insurance expense, and an increase of $0.2 million in consulting and other general and administrative expenses.

Other Income

Other income was $0.3 million for the three months ended December 31, 2023 as a result of payments received under the terms of the Aardvark Agreement entered into in August 2023.

Change in Fair Value of Warrant Liability

The change in fair value of $0.2 million represents a decrease in the fair value of the warrants outstanding during the year ended December 31, 2023.

Extinguishment of Debt

Extinguishment of debt was $0.3 million for the year ended December 31, 2022, as a result of the amendment of certain tranches of the TEP Notes. The amendment was accounted for as extinguishment to which the excess fair value of the amended debt over the carrying value of the original debt resulted in a loss on extinguishment.

Interest Expense, net

Interest expense, net, was $2.1 million and $0.7 million for the years ended December 31, 2023 and 2022, respectively, and related to the outstanding promissory notes. The increase in interest expense, net, was due to interest related to the Bridge Notes.

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 $1.9 million and $2.2 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, we had an accumulated deficit of $33.4 million.

We have financed our working capital requirements to date through the issuance of Common Stock, warrants, convertible notes and promissory notes. As of March 31, 2024, we had $4.1 million in cash.

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

	Three Months Ended March 31,		Year Ended December 31,	
	2024	2023	2023	2022
Net cash provided by (used in):				
Operating activities	$ (2,202)	$ (579)	$ (8,990)	$ (1,085)
Investing activities	—	—	(8)	(3)
Financing activities	4,485	1,030	10,797	1,007
Net increase in cash and cash equivalents	$ 2,283	$ 451	$ 1,799	$ (81)

Cash Flows from Operating Activities

For the three months ended March 31, 2024 and 2023, $2.2 million and $0.6 million were used in operating activities, respectively. The $1.6 million increase was primarily due to a $1.3 million increase in cash used for accounts payable and accrued expenses and a $1.1 million decrease in non-cash adjustments primarily related to the amortization of debt discounts and debt issuance costs, offset by a $0.3 million decrease in net loss and a $0.5 million increase in prepaid and other assets.

For the years ended December 31, 2023 and 2022, $9.0 million and $1.1 million were used in operating activities, respectively. The $7.9 million increase was primarily due to a $9.8 million increase in our net loss and an increase of $1.1 million in cash used for prepaid and other expenses and accrued expenses, offset by a $1.8 million net increase in non-cash adjustments, including stock based compensation expense, the amortization of debt

discounts and debt issuance costs, and the loss on extinguishment of debt, and a $1.3 million decrease in cash used for the payment of accounts payable.

Cash Flows from Investing Activities

Net cash provided by investing activities was $8,000 and $3,000 for the years ended December 31, 2023 and 2022, which was related to the purchase of computer equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities was $4.5 million for the three months ended March 31, 2024 as a result of $5.5 million of proceeds from the Purchase Agreement, offset by $1.0 million of stock issuance costs. Net cash provided by financing activities was $1.0 million for the three months ended March 31, 2023 and was primarily related to $1.3 million proceeds from the funding of the second tranche of the Bridge Notes, offset by the payment of $0.2 million of debt and stock issuance costs.

Net cash provided by financing activities was $10.8 million during the year ended December 31, 2023 as a result of $12.3 million of proceeds from the Equity SPA (as defined below) and $1.3 million of proceeds from the funding of the second tranche of the Bridge Notes and $0.9 million of cash acquired in the connection with the Merger. These proceeds were offset by $3.0 million in costs associated with the Merger, the payment of $0.5 million of debt issuance costs related to the Bridge Notes and $0.2 million of stock issuance costs related the Equity SPA. Net cash provided by financing activities was $1.0 million for the year ended December 31, 2022, which primarily consisted of proceeds from promissory notes.

Securities Purchase Agreement

On February 1, 2024, we entered into the Purchase Agreement, pursuant to which we agreed to issue and sell, in a public offering (i) 25,419 Shares of Common Stock, (ii) 359,196 Pre-Funded Warrants exercisable for an aggregate of 359,196 shares of Common Stock, (iii) 384,615 Series B-1 Common Warrants exercisable for an aggregate of 384,615 shares of Common Stock, and (iv) 384,615 Series B-2 Common Warrants exercisable for an aggregate of 384,615 shares of Common Stock for net proceeds of $4.4 million after deducting offering costs of $1.1 million. The securities were offered in combinations of (a) one Share or one 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 $14.30 (less $0.0013 for each Pre-Funded Warrant).

Subject to certain ownership limitations, the Warrants are exercisable upon issuance. Each Pre-Funded Warrant is exercisable for one share of Common Stock at a price per share of $0.0013 and does not expire. Each Series B-1 Common Warrant is exercisable into one share of Common Stock at a price per share of$14.30 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 $14.30 for an 18-month period after February 6, 2024, the date of issuance. In connection with the issuance of the securities pursuant to the Purchase Agreement, the exercise price of the Series A-1 Warrants issued in connection with the Merger 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 and Pre-Funded Warrants have since been exercised.

Equity Securities Purchase Agreement

In connection with signing the Merger Agreement, Vallon, GRI Operations and the selling stockholder entered the Equity SPA pursuant to which the selling stockholder agreed to invest $12,250 in cash and cancel any outstanding principal and accrued interest on the Bridge Notes in return for the issuance of shares of GRI Operations' common stock immediately prior to the consummation of the Merger. Pursuant to the Equity SPA, immediately prior to the Closing, GRI Operations issued the Initial Shares to the selling stockholder and placed the Additional Shares into escrow with an escrow agent for net proceeds of $11,704, after deducting offering expenses of $546.

At Closing, pursuant to the Merger, the Initial Shares converted into an aggregate of 2,789 shares of our Common Stock and the Additional Shares converted into an aggregate of 11,157 shares of our Common Stock. On

May 8, 2023, in accordance with the terms of the Equity SPA, we, along with the selling stockholder, authorized the escrow agent to, subject to beneficial ownership limitations, disburse to the selling stockholder all of the shares of our Common Stock issued in exchange for the Additional Shares.

Merger with Vallon Pharmaceuticals, Inc.

In connection with signing the Merger Agreement, the Company, GRI Operations and Altium entered the Equity SPA pursuant to which Altium agreed to invest $12,250 in cash and cancel any outstanding principal and accrued interest on the Bridge Notes in return for the issuance of shares of GRI Operations' Common Stock immediately prior to the consummation of the Merger. Pursuant to the Equity SPA, immediately prior to the Closing, GRI Operations issued the Initial Shares to Altium and placed the Additional Shares into escrow with an escrow agent for net proceeds of $11,704, after deducting offering expenses of $546.

At Closing, pursuant to the Merger, the Initial Shares converted into an aggregate of 2,789 shares of our Common Stock and the Additional Shares converted into an aggregate of 11,157 shares of our Common Stock. On May 8, 2023, in accordance with the terms of the Equity SPA, we, along with Altium, authorized the escrow agent to, subject to beneficial ownership limitations, disburse to Altium all of the shares of our Common Stock issued in exchange for the Additional Shares.

Future Funding Requirements

Our net losses were $1.9 million and $2.2 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, we had $4.1 million in cash and an accumulated deficit of $33.4 million. We expect to devote substantial financial resources to our planned activities, particularly as we prepare for, initiate, and conduct our planned clinical trials of GRI-0621 and GRI-0803, 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 operating expenses and capital expenditure requirements into the third quarter of 2024.

Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. The Series T Warrants issued in connection with the Merger are not presently subject to forced exercise by the Company as the equity conditions for their forced exercise, which include, among other things, a requirement that shares of our Common Stock have a value weighted average price of at least $838.11 per share for the periods specified in the Series T Warrants, are not met. We intend to raise capital through additional issuances of equity securities and/or short-term or long-term debt arrangements, but there can be no assurances any such financing will be available when needed, even if our research and development efforts are successful. 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 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.

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.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of its financial condition and results of operations is based on its unaudited interim consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of these unaudited interim condensed consolidated financial statements requires us to make estimates and assumptions that affect the amounts reported in the unaudited interim consolidated financial statements and accompanying notes. Management evaluates these estimates and judgments on an ongoing basis. Management bases its estimates on historical experience and on various other factors that it believes are reasonable under the circumstances. Actual results could differ from those estimates.

Our significant accounting policies are described in more detail in Note 3, "Summary of Significant Accounting Policies", in the notes to the financial statements included in this prospectus.

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 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 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 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.

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 lead product candidate, GRI-0621, is an oral inhibitor of iNKT cells. GRI-0621 is also an oral formulation of tazarotene, a synthetic RAR-beta and gamma selective agonist, that is approved in the United States for topical treatment of psoriasis and acne. As of December 31, 2023, 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 people 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 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, PSC, MASH, ALD, SLE, MS, UC patients, as well as other indications. In these patients activated iNKT cells are correlated with more severe disease. The FDA has cleared our IND application for GRI-0621 for the treatment of IPF and we plan to evaluate GRI-0621 in a randomized, double-blind, multi-center Phase 2a biomarker study, for which we commenced enrollment in December 2023. We expect interim data from this trial to be available in the third quarter of 2024 and topline results to be available in the fourth quarter of 2024. Additionally, on March 4, 2024, we received authorization of our CTA from the MHRA to initiate the Phase 2a biomarker study evaluating GRI-0621 for the treatment of IPF in the UK.

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 NKT cells. We are developing GRI-0803 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. Subject to IND clearance, we intend to evaluate GRI-0803 in a Phase 1a and 1b trial initially targeting SLE. Assuming positive data, we expect to file an IND with respect to this Phase 1a and 1b trial in the second half of 2024. We will continue to evaluate indications to select the best fit for further development of the program, but our initial focus is 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 pre-clinical models associated with disease.

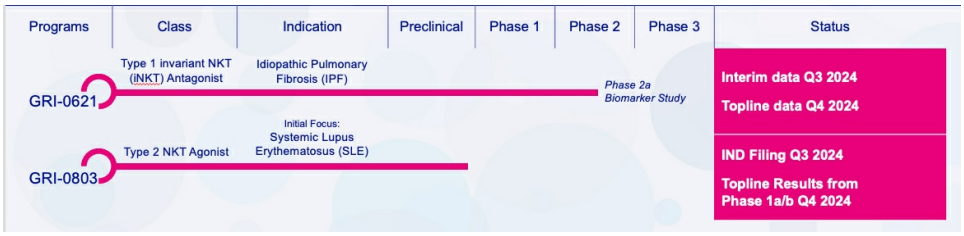

Figure 1. GRI's pipeline - GRI-0621 and GRI-0803

Our initial focus is developing GRI-0621 for the treatment of IPF. GRI-0621 is an oral formulation of tazarotene, a synthetic RAR-beta and gamma selective agonist that 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,TGF-beta and fibrosis. There are currently no therapeutics approved that specifically target iNKT cells.

We 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 guidance from the FDA 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. In December 2023, we commenced enrollment in our Phase 2a trial and we expect topline results from this trial to be available in the second half of 2024.

We are also developing GRI-0803, a novel orally administered activator of type 2 NKT cells, from which we observed therapeutic benefit in multiple models of autoimmunity. 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 type 2 NKT 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 type 1 and type 2 NKT cells with their respective ligands and identified and characterized the role of type 1 and type 2 NKT 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 biotech 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., 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 a Professor of Medicine and heads the Laboratory of Immune Regulation at the University of California, San Diego. We are supported by our Board and clinical advisory boards and have been funded to date by family offices and leading life sciences investors including TEP, Acquipharma Holdings Ltd and Altium Healthcare Inc.

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 intend to conduct a randomized double-blind placebo-controlled Phase 2a trial in approximately 36 patients with IPF with topline data expected in the second half of 2024. 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. Assuming a positive result in this trial, we plan to initiate a Phase 2b trial that could support an application for conditional approval of GRI-0621 in the European Union (the "EU") 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 initially targeting SLE. We expect to file an IND with respect to this trial in the second half of 2024.
- **Leverage our understanding of iNKT and type 2 NKT 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 any products in our portfolio for which we receive regulatory approvals in certain rare indications in the United States and the EU 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.

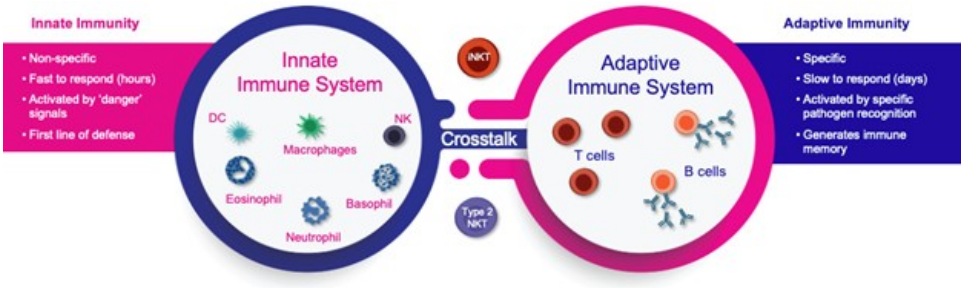

Figure 2. NKT cells are innate-like T cells that bridge the adaptive and innate immune systems.

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 type 2 NKT cells are regulatory T cells that inhibit the activity of iNKT cells, as well as other cell types, and support an anti-inflammatory response. Type 2 NKT 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.

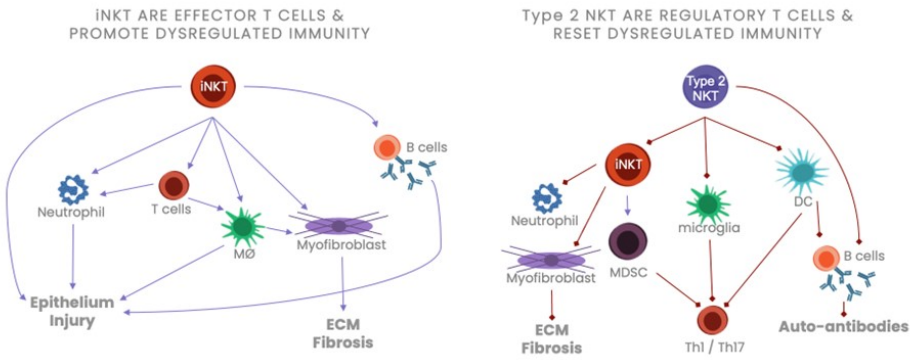

Figure 3. iNKT and type 2 NKT cells have opposing roles in controlling inflammation (arrows in the left panel indicate activation and arrows in the right panel indicate inhibition).

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 MASH patients as the disease progresses from healthy individuals to mild metabolic dysfunction-associated fatty liver disease and advanced MASH and believe iNKT may be a similar biomarker for IPF patients (see Figure 5).

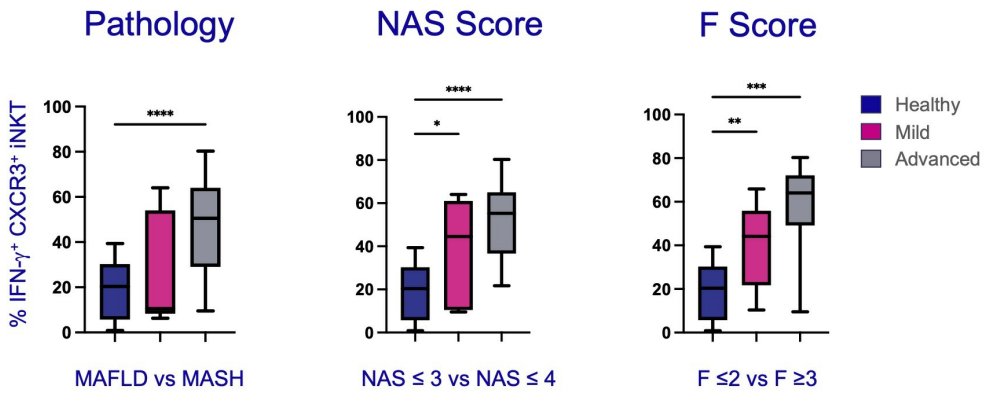

Figure 5. CXCR3+ IFN-gamma+ activated iNKT cells increase in MASH patients as disease progresses from healthy, mild to advanced disease.

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 type 2 NKT 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 type 2 NKT 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 type 2 NKT 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. 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., or pirfenidone, marketed as Esbriet by Genentech USA, Inc. These drugs have been shown to slow progression of decrease in lung function associated with IPF and deterioration of pulmonary function, but neither drug has been associated with improvements in overall survival, and both 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 agents 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. Despite this, total worldwide sales of pirfenidone and nintedanib in 2019 were over $1.2 billion and $1.6 billion, respectively.

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).

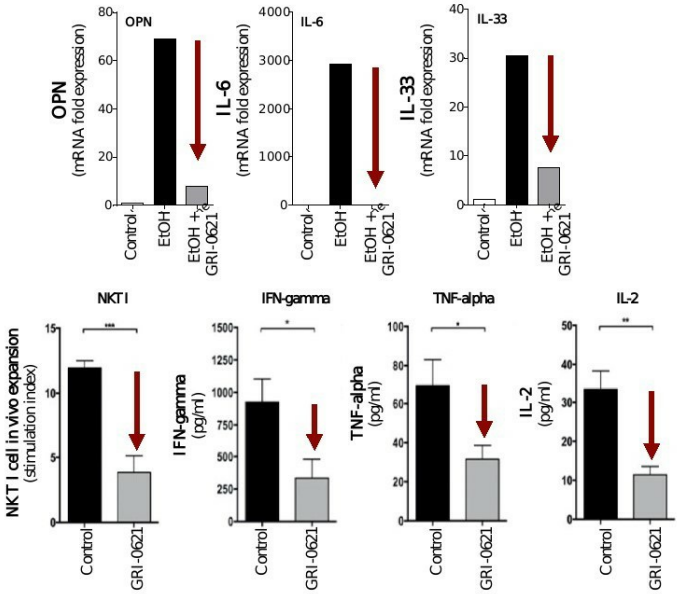

Figure 6. GRI-0621 observed to inhibit in vivo expansion and activation of iNKT cells and inhibits pro-inflammatory cytokines in animal models of fibrosis.

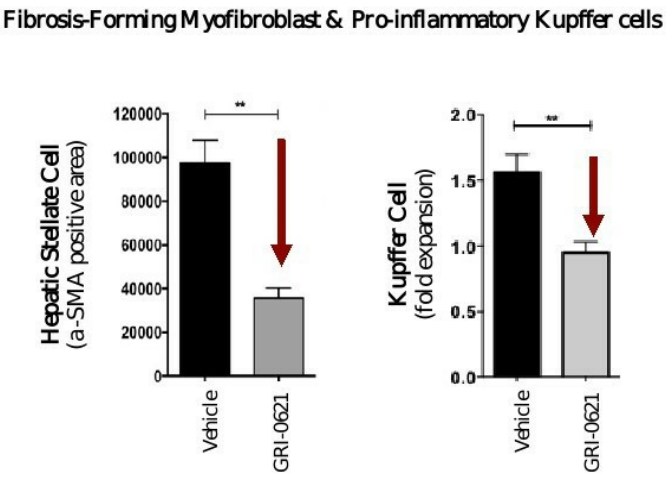

Figure 7. GRI-0621 observed to inhibit Kupffer cells and the activation and maturation of myofibroblasts / hepatic stellate cells.

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

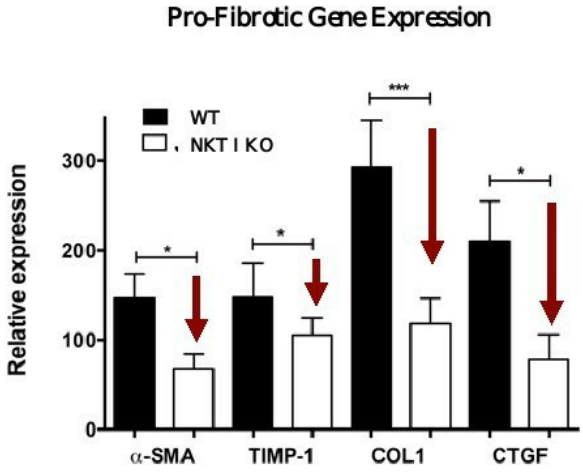

Figure 8. Inhibition of the key fibrogenic genes, including CTGF, observed in the iNKT-deficient animal model of fibrosis.

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 type 2 NKT cell activators led to a significant inhibition of this key mediator of fibrosis (see Figure 9).

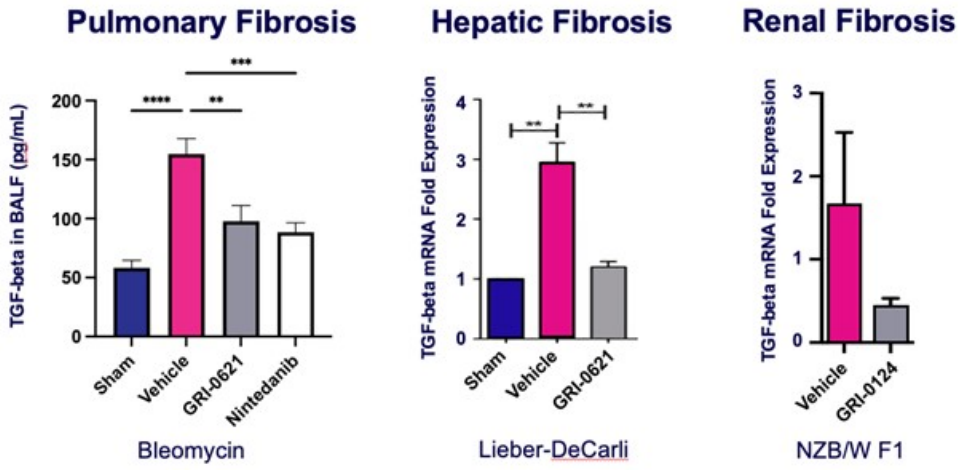

Figure 9. Inhibition of iNKT cells significantly reduced TGF-beta in models of pulmonary and hepatic fibrosis.

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).

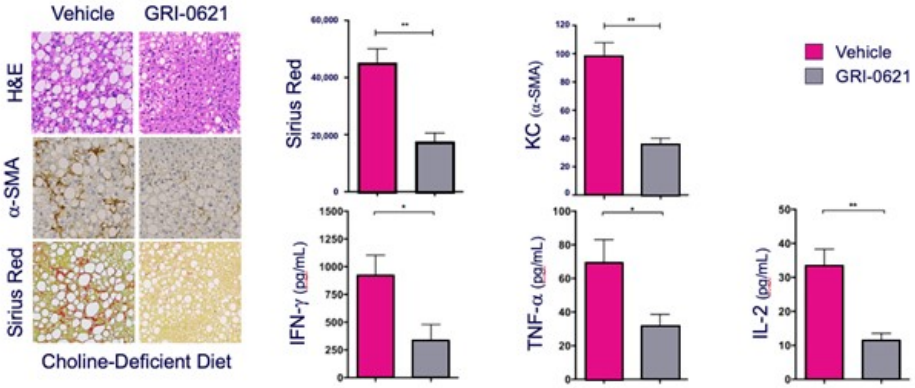

Figure 10. Hepatic inflammation & steatosis (H&E), myofibroblast activation ("anti-SMA") and fibrosis ("Sirius Red") were inhibited (left histology panels and upper bar graphs) as well as IFN-gamma, TNF-alpha, and IL-2 (lower bar graphs) following GRI-0621 administration in the choline-deficient L-amino-defined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

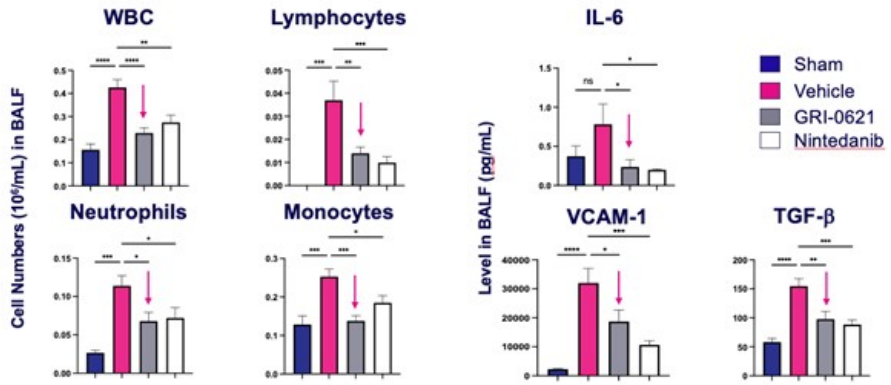

Figure 11. iNKT inhibitors observed to prevent inflammation, inflammatory cytokines, and TGF-beta in a bleomycin model of pulmonary fibrosis.

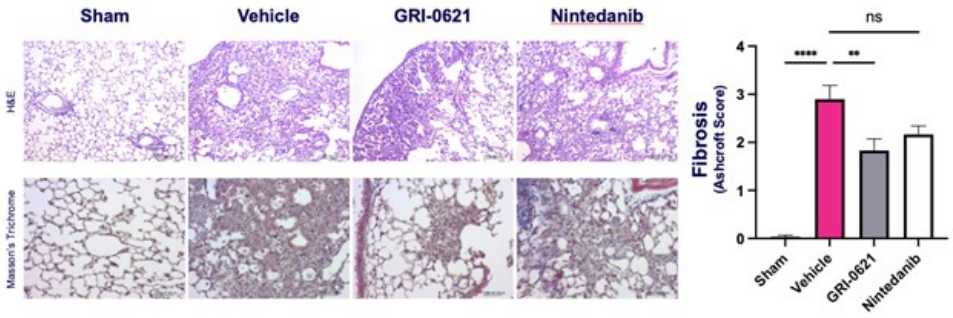

Figure 12. GRI-0621 observed to inhibit lung inflammation (H&E) and fibrosis (Mason's Trichrome) in a bleomycin model of pulmonary fibrosis.

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 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 guidance from the FDA regarding the design of MASH 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 study was underpowered

to meet its endpoints with statistical significance. Adverse events were generally mild and consistent with RAR-beta 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

In December 2023 we commenced enrollment for our Phase 2a trial. This trial will be a twelve-week, multicenter, multinational, randomized, placebo-controlled trial in approximately 36 patients with IPF. A 4.5 mg dose will be compared to placebo over twelve weeks of treatment in subjects with a confirmed diagnosis of IPF on background therapy. Subjects will complete a screening visit to evaluate their medical history, present condition, laboratory assessments, comorbidities, and concomitant medications. Based on these findings, subjects will be 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 twelve weeks will evaluate safety, pharmacokinetics, and efficacy/mechanism of action of GRI-0621 as assessed by the activation of iNKT cells from both blood at weeks 6 and 12 and bronchi-alveolar lavage fluid at

week 12. As a secondary endpoint, various biomarkers will also be evaluated to support the mechanism of action of GRI-0621. Subjects will be followed for at least two weeks after completion of dosing. This trial should take approximately six months to recruit the required number of subjects and be completed within approximately ten months of first subject's first visit.We expect interim data from this trial to be available in the third quarter of 2024 and topline results to be available in the fourth quarter of 2024. Final results from this trial will be used to determine dose, safety sample size, clinically relevant endpoints, and duration in communication with the FDA in designing the registration program moving forward.

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 type 2 NKT leads to a dendritic cell-mediated inhibition of iNKT cells. In our preclinical studies, a type 2 NKT

activating molecule, GRI-0803, was observed to inhibit both murine and human iNKT cells. Oral administration of GRI-0803, a type 2 NKT activating molecule, was observed to inhibit lupus nephritis and to significantly improve overall survival.

Following a weekly oral administration of GRI-0803 in a spontaneous model of lupus nephritis significant inhibition of pro-inflammatory cytokines, including IL-17 and IL-6 (see Figure 12) 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 13). 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 13 and 14) was observed. Additionally, GRI-0803 was observed 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 12).

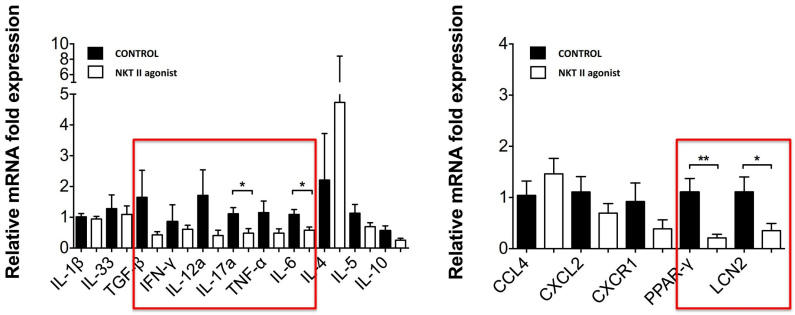

Figure 12. Inhibition of several key pro-inflammatory, fibrotic and kidney disease promoting genes in a spontaneous lupus model observed following oral administration of GRI-0803.

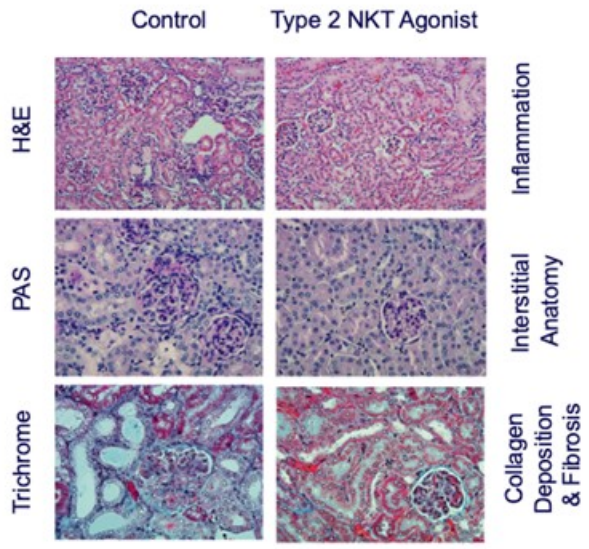

Figure 13. GRI-0803 administration observed to inhibit inflammatory cellular infiltration (H&E), glomerular pathology ("PAS"), and kidney fibrosis ("Trichrome") in a spontaneous lupus model.

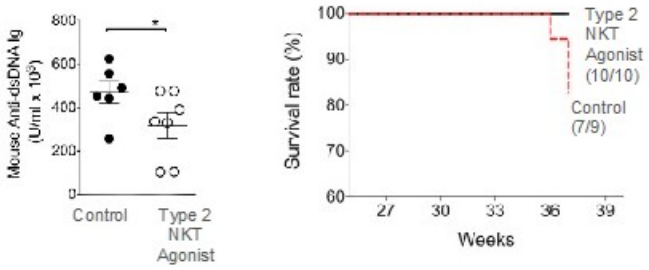

Figure 14. Observed inhibition anti-dsDNA antibodies in serum and increased overall survival in a lupus model following treatment with GRI-0803.

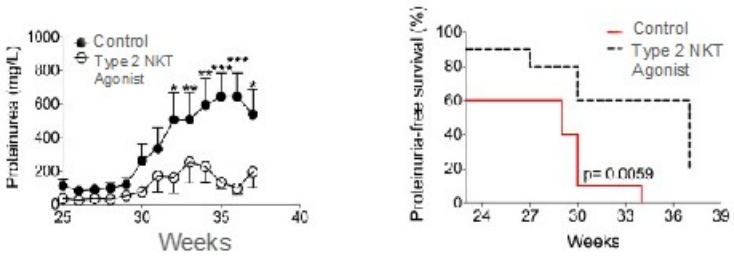

Figure 15. Significant inhibition of proteinuria in urine and spontaneously occurring lupus nephritis observed in animals orally treated with GRI-0803.

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 initiate a Phase 1 trial upon completion of the toxicology program for GRI-0803. Assuming positive results, we anticipate filing an IND in the second half of 2024. The Single Ascending Dose (“SAD”) trial will be run in healthy volunteers. Up to six doses will be evaluated in cohorts of 12 subjects with 10 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. The completion of this trial should take approximately three months from when the first cohort is dosed.

The 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. A total of 10 subjects will be in each cohort: 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 will 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. The MAD trial should take approximately five months to complete with topline results available late in the fourth quarter of 2024.

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 GRI is 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 - AstraZeneca PLC, Boehringer Ingelheim International GmbH, Bristol-Myers Squibb Co., and Novartis AG. Additional smaller companies with significant resources include Avalyn Pharma Inc., Bellerophon Therapeutics, Inc., Endeavor Biomedicines, Inc., Horizon Therapeutics Public Limited Company, Pliant Therapeutics, Inc., Suzhou Zelgen Biopharmaceuticals Co. Ltd., United Therapeutics Corp and Vicore Pharma Holding AB.

SLE - Astellas Pharma Inc., AstraZeneca PLC, Aurinia Pharmaceuticals Inc., Biogen Inc., GlaxoSmithKline PLC, Johnson & Johnson, Nektar Therapeutics, Roche Holding AG, Sanofi SA, and UCB S.A. Additional smaller companies with significant resources include Anthera Pharmaceuticals, Inc., Aurinia Pharmaceuticals Inc., ImmuPharma PLC, Kezar Life Sciences, Inc., Vera Therapeutics, Inc. and Viela Bio, Inc.

PSC - Albireo Pharma, Inc., Avolynt Inc., Calliditas Therapeutics AB, Cascade Pharmaceuticals, Inc., Chemomab Therapeutics Ltd., CymaBay Therapeutics, Inc., Dr. Falk Pharma GmbH, Galmed Pharmaceuticals Ltd., Gannex Pharma Co. Ltd., Genfit Corp., Gilead Sciences, Inc., HighTide Therapeutics Inc., Immunic, Inc., Invea Therapeutics, Inc., LISCure Biosciences Inc., Mirum Pharmaceuticals, Inc., Morphic Holding, Inc., Pliant Therapeutics, Inc., Selecta Biosciences Inc., Sirnaomics, Inc. and Qing Bile Therapeutics.

MASH - AstraZeneca PLC, Boehringer Ingelheim International GmbH, Eli Lilly and Company, Gilead Sciences, Inc., Madrigal Pharmaceuticals, Inc., Merck & Co. Inc., Novo Nordisk A/S, Novartis AG, Pfizer Inc. and Roche Holding AG. Additional smaller companies with significant resources include: Akero Therapeutics, Inc., Enanta Pharmaceuticals Inc., Ionis Pharmceuticals Inc., NGM Biopharmaceuticals Inc., Pliant Therapeutics, Inc., Terns Pharmaceuticals, Inc., Viking Therapeutics, Inc. and 89bio, Inc.

MS - Biogen Inc., Bristol-Myers Squibb Co., EMD Serono, Inc., Johnson & Johnson, Merck & Co. Inc., Novartis AG, Sanofi, Teva Pharmaceuticals Industries LTD and Roche Holding AG.

UC - AbbVie Inc., AstraZeneca PLC, Bristol -Myers Squibb Co., Eli Lilly and Company, Gilead Sciences, Inc., Janssen Biotech, Inc., Johnson & Johnson, Pfizer Inc., Merck & Co. Inc., Millennium Pharmaceuticals, Inc., Protagonist Therapeutics, Inc., Roche Holding AG, and Takeda Pharmaceutical Co Ltd.

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 therapeutic candidates, the compositions of matter of our therapeutic 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 representing six patent families. As of June 17, 2024, our patent estate included 12 issued United States patents, 2 United States pending non-provisional patent applications, 65 issued foreign patents and 13 foreign patent applications currently pending in various 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. Three United States and 20 foreign patents (Australia, Brazil, Canada, China, Europe (validated in nine countries), Hong Kong, Japan, South Korea, Mexico, and Russia) were granted in this family. Patent applications in this family are pending in multiple jurisdictions, including, for example, the European Patent Organization, China, Japan, and Korea. Patents in this patent family are expected to expire in 2032, absent any patent term adjustments or extensions.

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 and nine foreign patents (Canada, Europe (validated in seven countries), and Hong Kong) were granted in this family. Patent applications in this family are pending in the United States and European Patent Organization. Patents in this patent family are expected to expire in 2032, absent any patent term adjustment or extension.

Additionally, we own one patent family relating to GRI-0729 and related methods of using the same to treat diseases. Four United States and 13 foreign patents (Canada, Europe (validated in 11 countries), and Hong Kong) have been granted in this family. Patents in this patent family are expected to expire in 2032, absent any patent term adjustment or extension.

We also own one patent family with claims directed to GRI-0124 and related methods of using the same to treat diseases. Fourteen foreign patents (Taiwan, Australia, China, Europe (validated in seven countries), Hong Kong, Israel, Mexico and Russia) were granted in this family. Patent applications in this family are pending, for example, in the United States, United Arab Emirates, Brazil, China, Japan, Russia, Canada, Hong Kong and South Korea. Patents in this patent family are expected to expire in 2035, absent any patent term adjustment or extension.

We continually assess and refine our intellectual property strategy as we develop new technologies and therapeutic 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 United States patents may be extended for delays incurred due to compliance with the 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 therapeutic candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those therapeutic 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 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 United States Department of Justice (the "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 ("GLP") 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 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 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.

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. The FDA reviews the application to determine, among other things, whether the proposed product is safe and effective for its intended use, whether it has an acceptable purity profile and whether the product is being manufactured in accordance with cGMPs.

Under the goals and policies agreed to by the FDA under PDUFA, the FDA 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 applicant 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 in 2012, Congress created a new regulatory program for therapeutic 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 drug 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. All promotional materials for drug products being considered and approved under the accelerated approval program are subject to prior review by the FDA. 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. More recently, the Drug Supply Chain Security Act (the DSCSA), was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States. The DSCSA mandated phased-in 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, 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 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. It remains to be seen whether the FTC, other governmental agencies, pharmaceutical manufacturers, or other stakeholders continue to prioritize the policy issue of “improper” patent listings and whether significant litigation will develop in this area.

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 (the "BPCA"), certain therapeutic 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.

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, 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 (the "ACA"), among other things, amended the intent requirement of the federal Anti-Kickback Statute (the "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 FTCA, 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 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 Medicines and Healthcare products Regulatory Agency (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 (the "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 (the "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 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 EU 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. The Windsor Framework is expected to apply as of January 1, 2025 and will change the existing system under the Northern Ireland Protocol, including the regulation of pharmaceutical products in the United Kingdom. Specifically, the MHRA will be responsible for approving all medicines intended to be marketed in the United Kingdom (i.e., Great Britain and Northern Ireland), while the EMA will no longer be 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 that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. 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 current congressional session, numerous PBM reforms are being 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 will negotiate 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 agreements to conduct price negotiations with pharmaceutical manufacturers in October 2023. 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. Those lawsuits are currently ongoing.

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.

State laws protecting health and personal information are becoming increasingly stringent. For example, the California Confidentiality of Medical Information Act imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. The CCPA mirrors a number of the key provisions of the GDPR described below. The CCPA establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. The CPRA became effective on January 1, 2023, strengthening elements of the CCPA. Since passage of the CCPA, several other states (e.g., Connecticut, Colorado, Virginia, Delaware, Florida, Iowa, Montana, Oregon, Tennessee, Texas and Utah) have also enacted comprehensive consumer privacy laws that include key differences from California's law, further complicating compliance by industry and other stakeholders. Other states in the United States are considering privacy laws similar to the CCPA.

In Europe, the GDPR went into effect in May 2018, implementing a broad data protection framework that expanded the scope of EU data protection law, including to non- EU entities that process, or control the processing of, personal data relating to individuals located in the EU, including clinical trial data. The GDPR sets out a number of requirements that must be complied with when handling the personal data of EU-based data subjects including: providing expanded disclosures about how their personal data will be used; higher standards for organizations to demonstrate that they have obtained valid consent or have another legal basis in place to justify their data processing activities; the obligation to appoint data protection officers in certain circumstances; new rights for individuals to be "forgotten" and rights to data portability, as well as enhanced current rights (e.g. access requests); the principal of accountability and demonstrating compliance through policies, procedures, training and audit; and a new mandatory data breach regime. In particular, medical or health data, genetic data and biometric data where the latter is used to uniquely identify an individual are all classified as "special category" data under the GDPR and afforded greater protection and require additional 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 the EU 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. The GDPR also prohibits the international transfer of personal data from the EU to countries outside of the EU unless made to a country deemed to have adequate data privacy laws by the European Commission or made through an approved data transfer mechanism. On July 16, 2020, the Court of Justice of the European Union ("CJEU"), issued a landmark opinion in the case Maximilian Schrems vs. Facebook (Case C-311/18), called Schrems II. This decision (a) calls into question commonly relied upon data transfer mechanisms as between the EU Member States and the United States (such as the Standard Contractual Clauses) and (b) invalidates the EU-U.S. Privacy Shield on which many companies had relied as an acceptable mechanism for transferring such data from the EU to the United States.

On July 10, 2023, the European Commission adopted an adequacy decision for a new mechanism for transferring data from the EU to the United States – the EU-US Data Privacy Framework (the Framework). The Framework provides individuals in the EU with several new rights, including the right to obtain access to their data, or obtain correction or deletion of incorrect or unlawfully handled data. The adequacy decision followed the signing of an executive order introducing new binding safeguards to address the points raised in the Schrems II decision. Notably, the new obligations were geared to ensure that data can be accessed by US intelligence agencies only to the extent necessary and proportionate and to establish an independent and impartial redress mechanism to handle complaints from Europeans concerning the collection of their data for national security purposes. The European Commission will continually review developments in the United States along with its adequacy decision. Adequacy decisions can be adapted or even withdrawn in the event of developments affecting the level of protection in the applicable jurisdiction. Future actions of EU data protection authorities are difficult to predict. Some customers or other service providers may respond to these evolving laws and regulations by asking us to make certain privacy or data-related contractual commitments that we are unable or unwilling to make. This could lead to the loss of current or prospective customers or other business relationships.

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.

United States Foreign Corrupt Practices Act

In general, the Foreign Corrupt Practices Act of 1977, as amended (the "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 June 17, 2024, GRI had 3 employees of which all were full-time employees. 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 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 Merger Sub, Merger Sub was merged with and into GRI, with GRI surviving the Merger as a wholly owned subsidiary of the Company. In connection with the Merger, and prior to the Effective Time, the Company effected a reverse stock split of the Company's common stock at a ratio of 1-for-30. Also, in connection with the Closing, the Company amended its certificate of incorporation and bylaws 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 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 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*. The information contained in, and that can be accessed through, our website is not incorporated into and is not part of this prospectus.

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.

MANAGEMENT

Executive Officers, Key Employees and Directors

The following table provides information regarding our executive officers and directors as of June 17, 2024:

Name	Age	Position
Executive Officers:		
W. Marc Hertz, Ph.D.	54	President, Chief Executive Officer and Director
Leanne Kelly	47	Chief Financial Officer
Vipin Kumar Chaturvedi, Ph.D.	64	Chief Scientific Officer
Albert Agro, Ph.D.	59	Chief Medical Officer
Non-Employee Directors:		
David Szekeres	50	Chair of the Board
David Baker	59	Director
Roelof Rongen	58	Director
Camilla V. Simpson, M.Sc.	52	Director

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 Multimeric Biotherapeutics since 2008. Dr. Hertz has also held several senior positions at companies in the biotechnology industry since 1998. Dr. Hertz received his B.Sc. 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 in April 2023. She brings over 20 years of experience leading private and publicly traded companies across life science, technology and e-Commerce sectors with a foundation in public accounting. From May 2021 until the Closing, she served as Chief Financial Officer of Vallon. From 2016 to 2021, she served as Controller and Executive Director, Global Financial Reporting at OptiNose, Inc., a $74 million 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 B.Sc. 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, served as a member of its board of directors and as Chairperson of its scientific advisory board. Dr. Chaturvedi served as GRI Operations' Chief Scientific Officer from 2009 to 2017 and from 2022 to April 2023. Dr. Chaturvedi has served as a Professor of Medicine, Laboratory of Immune Regulation at the University of California, San Diego since April 2015. In 2015, Dr. Chaturvedi co-founded Simomics, UK, a simulation software company, and served as a non-executive director on its board of directors from 2015 to July 2022. Additionally, Dr. Chaturvedi has served on the board of directors of Vidur Discoveries, LLC, a consulting company, since 2009. Dr. Chaturvedi obtained his undergraduate degree in biology from the Kanpur

University, India, his Masters 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 a consultant to the Company with the title 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 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 of Cynapsus from June 2012 to September 2016. Additionally, Dr. Agro currently serves as an assistant professor in the Department of Pathology and Molecular Medicine at McMaster University. 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. 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 Connect Biopharma in June 2024 and serves as President. Prior to this, he served as Chief Operating Officer and Head of Finance at Heron Therapeutics, Inc. from March 2016 to August 2023. Mr. Szekeres served as Chief Business Officer, Principal Financial Officer and General Counsel at Regulus Therapeutics Inc. from 2014 to 2016. Mr. Szekeres also served as head of Mergers and Acquisitions, Securities and Governance at Life Technologies Corporation from 2008 through its acquisition by Thermo Fisher Scientific in February 2014. Mr. Szekeres currently serves on Sanford Burnham Prebys' board of directors. He served on the board of directors of Edico Genome Inc. from March 2014 until its acquisition by Illumina, Inc. in 2018 and Patara Pharma from October 2014 until its acquisition by Roivant Sciences Ltd. in 2018. Mr. Szekeres received his B.A. 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 member of boards of directors of companies in the biotechnology and biotherapeutic industries 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 Vallon's 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. Prior to being appointed Vallon's President and Chief Executive Officer, he served as a consultant to Vallon since January 15, 2018. He previously served as the Interim Chief Executive Officer and Chief Commercial Officer of Alcobra Ltd. (now known as Arcturus Therapeutics Holdings Inc.), where he oversaw the development of ADAIR. Prior to joining Alcobra Ltd., he worked at Shire Pharmaceuticals ("Shire") 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 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's service as Vallon's President and Chief Executive Officer and his extensive expertise in the biotechnology industry qualify 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 R&D/Commercial Development leader with extensive experience across many therapeutic areas and

functions. Mr. Rongen has served as Chief Executive Officer of gene-therapy company, Adolore BioTherapeutics, since July 2022, Managing Partner of AsteRx Pharma Consulting since September 2018 and Founder/Chief Executive Officer of Innovative Molecules since June 2019. In 2012, he founded and progressed Matinas BioPharma, an omega-3 and lipid-crystal nano-particle drug delivery company, 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 biotech/pharmaceutical consultant at The Wilkerson Group (acquired by IBM). Mr. Rongen received a Master of Science in Engineering in Molecular Sciences (with a Biotechnology/Bio-Process Technology focus) graduate degree from Wageningen University in the Netherlands and an MBA 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, Inc.'s board of directors since October 2017. Since April 2021, Ms. Simpson has served as Chief Executive Officer of Zehna Therapeutics, an early stage biotech and spin-out from the Cleveland Clinic. Since April 2019, Ms. Simpson has served as Managing Member and President of Rare Strategic, LLC where she provides strategic advice and consulting services to biotech 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 Pharmaceutical Inc. ("BioMarin") where she was responsible for corporate and R&D 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, she ultimately held the position of Vice President Regulatory Affairs Early Development and Business Development. Ms. Simpson holds a B.Sc. from University College Galway, Ireland, a B.Sc. Hons. from Kingston University, UK and an M.Sc. with distinction from the 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 may also choose to form certain committees, such as a compensation and an audit committee.

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 2024;
- 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 2025; 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 twelve 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 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.

Our Board expects to delegate various responsibilities and authority to committees as generally described below. 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 registration statement. We have included our website address in this registration statement 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 chair 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. 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 Mr. 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's 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 chair 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 2015 Plan and 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;
- 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 chair 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 CEO and other executive officer succession planning, and
- developing and recommending governance guidelines for the Company.

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 Chairman and Chief Executive Officer. Dr. Hertz will serve as Chief Executive Officer of the Company and as a member of the Company's Board. Mr. Szekeres will serve as the Chairman of the Company's 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 Company's Board, and the non-executive directors led by Mr. Szekeres in his role as a non-executive Chairman.

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 ours. 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 serving an equivalent function that has one or more officers serving 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, in 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.

EXECUTIVE AND DIRECTOR COMPENSATION

Our named executive officers for the year ended December 31, 2023 were:

- W. Marc Hertz, Ph.D., our Chief Executive Officer;
- Leanne Kelly, our Chief Financial Officer;
- Albert Agro, Ph.D., our Chief Medical Officer; and
- David Baker, our former Chief Executive Officer.

Summary Compensation Table

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, 2023 and 2022.

Name and Principal Position	Year	Salary ($)	Stock Awards ($)[1]	Option Awards ($)[2]	Non-Equity Incentive Compensation ($)[3]	All Other Compensation ($)	Total ($)
W. Marc Hertz, Ph.D.	2023	404,447	—	—	437,500	67	842,014
President and Chief Executive Officer	2022	343,750 [4][5]	—	—	—	—	343,750
Leanne M. Kelly	2023	304,063	—	114,347	237,500	9,367 [6]	665,277
Chief Financial Officer	2022	283,893	20,820	210,428	150,000	8,400 [6]	673,541
Albert Agro, Ph.D.	2023	162,500	—	—	113,750	130,736 [7]	406,986
Chief Medical Officer	2022	—	—	—	—	—	—
David Baker[9]	2023	144,577	—	89,264	75,000	988,211 [8][10]	1,297,051
Former President and Chief Executive Officer	2022	417,266	20,820	251,494	210,000	19,983 [10]	919,564

(1) The amounts in this column represent the aggregate grant date fair value of the restricted stock units (RSUs) 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 GRI's audited consolidated financial statements (Note 3. *Summary of Significant Accounting Policies - Stock-Based Compensation* and Note 11. *Stock-Based Compensation*) included in our Annual Report on Form 10-K for the year-ended December 31, 2023. In accordance with SEC rules, the grant date fair value of any award subject to a performance condition is based upon the probable outcome of the performance conditions. RSU awards with performance conditions that have been deemed not probable of achievement as of the grant date have not been included in this column as no compensation expense has been recognized under ASC Topic 718 during the year ended December 31, 2023. In December 2022, the RSU awards granted to Mr. Baker and Ms. Kelly were cancelled. Compensation expense equal to the grant date fair value of the cancelled awards expected to vest at the date of cancellation was recognized under ASC Topic 718.

(2) 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 GRI's audited consolidated financial statements (Note 3. *Summary of Significant Accounting Policies - Stock-Based Compensation* and Note 11. *Stock-Based Compensation*) included in our Annual Report on Form 10-K for the year-ended December 31, 2023, as filed with the SEC.

(3) 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 Officer and Director Compensation - Elements of Compensation - Bonuses and Non-Equity Incentive Plan Compensation*" below.

(4) Dr. Hertz was issued 4,054 restricted shares of GRI Operations common stock on December 7, 2022, of which 3,024 shares were issued in lieu of $275,250 of salary earned from January 1, 2022 through September 30, 2022 and foregone at the election of Dr. Hertz. Dr. Hertz also received $68,500 of salary paid in cash. The remaining restricted shares issued on December 7, 2022 related to salary earned in 2021.

(5) The amount included for restricted stock awards represents represent the aggregate grant date fair value for such stock awards computed in accordance with FASB ASC Topic 718. The shares vested upon the completion of the Merger.

(6) The amounts reflect matching contributions to the named executive officers' accounts under our SIMPLE IRA plan.

(7) The amounts reflect consulting fees paid to Dr. Agro prior to July 1, 2023, the date of his employment with GRI,

(8) The amounts reflect matching contributions to the named executive officer's account under Vallon's SIMPLE IRA plan, an auto allowance and amounts paid with respect to short and long-term disability and life insurance for the benefit of the named executive officer. The amounts reflect SIMPLE IRA matching contribution of $11,400 and $10,200 for 2023 and 2022, respectively; an auto allowance of $1,875 $6,000 in 2023 and 2022, respectively and insurance benefits of $1,991 and $7,983 in 2023 and 2022, respectively.

(9) Pursuant to the closing of the Merger on April 21, 2023, Mr. Baker resigned from the Company effective as of April 21, 2023.

(10) Includes $945,000 of severance payments (of which $603,750 was paid in 2023) pursuant to the terms of the separation agreement with Mr. Baker and his current employment agreement, as well as $27,945 in compensation for Mr. Baker's service as a director on our Board.

Elements of Compensation

2023 Base Salaries

On April 20, 2023, Dr. Hertz was appointed Chief Executive Officer and Ms. Kelly was appointed Chief Financial Officer of GRI, effective as of the Effective Time. The employment agreements with Dr. Hertz and Ms. Kelly provide for an annual base salary of $375,000 and $312,500, respectively. On July 1, 2023, Dr. Agro, our Chief Medical Officer, signed an employment agreement with the Company, which provided for an annual base salary of $325,000. On June 17, 2024, pursuant to that certain Amendment No. 1 to Employment Agreement (the "Agro Amendment"), between the Company and Dr. Agro, Dr. Agro's annual base salary was reduced to $100,000.

Bonuses and Non-Equity Incentive Plan Compensation

On April 20, 2023, Dr. Hertz was appointed Chief Executive Officer and Ms. Kelly was appointed Chief Financial Officer of GRI, effective as of the Effective Time. Pursuant to his employment agreement, Dr. Hertz is eligible to receive a discretionary annual performance bonus with a target bonus equal to 50% of his then current annual base salary. Pursuant to her employment agreement, Ms. Kelly is eligible to receive a discretionary annual performance bonus with a target bonus equal to 20% of her then current annual base salary for the first year of her employment and 35% of her then current annual base salary thereafter, a signing bonus of $100,000 and a retention bonus of $50,000, to be paid on the first anniversary of the Closing. Pursuant to his employment agreement, Dr. Agro was eligible to receive a discretionary annual performance bonus with a target bonus equal to 35% of his then current annual base salary. As a result of the Agro Amendment, Dr. Agro's employment agreement no longer provides for a discretionary annual performance bonus.

In addition to annual performance bonuses, in December 2022, Ms. Kelly was granted a bonus of $75,000, which was paid upon the Closing.

Prior to the Merger, Dr. Hertz's bonus awards were determined at the discretion of the GRI Operations Board. In March 2021, Dr. Hertz was granted a bonus of $250,000, which was paid upon the Closing.

Option Awards Granted During 2023

On September 26, 2023, pursuant to her employment agreement with GRI, Ms. Kelly was granted an option to purchase 915 shares of our Common Stock at an exercise price of $138.32.

Qualified Retirement Plan

We do not maintain any retirement, deferred compensation, pension or profit-sharing plans.

Employment Agreements

We have entered into an employment agreement with each of our named executive officers. The employment agreements with Dr. Hertz and Ms. Kelly 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 with Dr. Hertz and Ms. Kelly, each of each Dr. Hertz's and Ms. Kelly's base salary and target bonus will be reviewed periodically by our compensation committee or Board. These 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."

Dr. Agro's employment agreement, as amended by the Agro Amendment, provides that Dr. Agro will receive an annual base salary of $100,000 and does not provide for any cash performance bonus. Dr. Agro's employment agreement may be terminated by either the Company or Dr. Agro upon thirty (30) days' prior written notice to the other party.

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 agreements with each named executive officer other than Dr. Hertz also include 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 GRI named executive officers service terminates, that named executive officer (other than Dr. Agro) 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 (other than Dr. Agro) 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:

- continued base salary for a period of 18 months, 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 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.

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:

- continued base salary for a period of 12 months, 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.

Albert Agro, Ph.D.

Pursuant to his employment agreement with us, if Dr. Agro's employment were terminated for any reason, the Company will pay to Dr. Agro the portion of his annual base salary earned through the effective day of termination, as well as any unreimbursed business expenses.

Outstanding Equity Awards at 2023 Fiscal Year-End

Stock Option Awards

The following table sets forth the outstanding stock option awards as of December 31, 2023, 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. All equity awards granted to Leanne Kelly and David Baker for the year ended December 31, 2023 were made pursuant to the A&R 2018 Plan. Each vested, unexpired and unexercised option to purchase shares of our Common Stock outstanding immediately prior to the Merger continued to remain outstanding following the Effective Time in accordance with its terms. Each unvested, unexpired and unexercised option to purchase shares of our Common Stock outstanding immediately prior to the Merger was cancelled for no consideration at the Effective Time.

	Option Awards[3]				
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
Leanne Kelly	11	—	—	9,991.80	5/14/2031
Chief Financial Officer	4	—	—	15,369.90	2/15/2032
		915[1]		138.32	9/22/2033
David Baker	16	—	—	5,023.20	10/1/2028
Former Chief Executive Officer	22	—	—	6,006.00	2/5/2029
	16	—	—	9,991.80	5/14/2031
	5	—	—	15,369.90	2/15/2032
	31	347[2]	—	263.90	8/10/2023

(1) The stock options award will vest 25% on the first anniversary of the vesting start date (September 22, 2023) and 2.083% (1/48th of such shares) for each subsequent month that the executive remains employed with us.
(2) The stock option award will vest as to 8.33% on the date of grant (8/10/2023) and 8.33% (1/12th of such shares) for each subsequent full quarter that Mr. Baker remains on the Board.
(3) Drs. Hertz and Agro had no outstanding option or stock awards as of December 31, 2023.

Director Compensation

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.

Effective as of August 10, 2023, 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.
- 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, 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 10, 2023 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 our Common Stock equal to the quotient obtained by dividing $50,000 by the closing price of our Common Stock on the date of such annual meeting, which generally will vest in quarterly installments over one year.

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

GRI Director Compensation

The following table provides information on compensation paid to our non-employee directors in 2023:

	Fees Earned or Paid in Cash ($)	Option Awards ($)[1][3]	Total ($)
David Baker	27,945	89,264 [2]	117,209
Roelof Rongen	40,171	89,264 [2]	129,435
Camilla V. Simpson, M.Sc.	45,062	89,264 [2]	134,325
David Szekeres	63,575	89,264 [2]	152,839

(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 our audited consolidated financial statements (Note 3. *Summary of Significant Accounting Policies - Stock-Based Compensation* and Note 11. *Stock-Based Compensation*) included in our Annual Report on Form 10-K for the year-ended December 31, 2023, as filed with the SEC.

(2) Options to purchase 378 shares of Common Stock were granted on August 10, 2023 and vest as to 8.33% on the date of grant and 8.33% (1/12th of such shares) for each subsequent full quarter that the director remains on the Board.

(3) The following table shows the aggregate number of outstanding shares of Common Stock underlying outstanding option and stock awards held by our non-employee directors as of December 31, 2023:

Name	Outstanding Option Awards
David Baker	378
Roelof Rongen	378
Camilla V. Simpson M.Sc.	378
David Szekeres	378

Vallon Director Compensation

The following table provides information on compensation paid to Vallon non-employee directors in 2023, prior to their resignation upon the completion of the Merger:

	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	Total ($)
Richard Ammer	9,123	—	—	9,123
Meenu Karson	15,205	—	—	15,205
Joseph Payne	12,164	—	—	12,164
Marella Thorell	37,640	—	—	37,640

Equity Compensation Plan Information

The following table sets forth information regarding our equity compensation plans as of December 31, 2023:

Plan category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted average exercise price of outstanding options (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]	2,503	$ 3,593.85	2,381 [2]
Equity compensation plans not approved by security holders	—	—	—
Total	2,503	$ 3,593.85	2,381

(1) The number of shares of our Common Stock authorized under the 2018 Plan automatically increases on January 1st of each year until the expiration of the 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.

(2) In connection with the Merger, on April 20, 2023, the stockholders of the Company approved the Amended and Restated GRI Bio, Inc. 2018 Equity Incentive Plan (formerly known as the Vallon Pharmaceuticals, Inc. 2018 Equity Incentive Plan) to, among other things, increase the aggregate number of shares by 1,856 shares to 2,381 shares of Common Stock for issuance as awards under the plan.

Description of Amended and Restated GRI Bio, Inc. 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, formerly the Vallon Pharmaceuticals, Inc. 2018 Equity Incentive Plan (the "A&R 2018 Plan"). The A&R 2018 Plan became effective on April 21, 2023, with the stockholders approving the amendment to the A&R 2018 Plan (i) to increase the aggregate number of shares by 1,856 shares to 2,381 shares of Company Common Stock for issuance as awards under the A&R 2018 Plan, (ii) to increase the aggregate maximum number of shares of Company Common Stock that may be issued pursuant to the exercise of incentive stock options under the A&R 2018 Plan to 29,304 shares, (iii) to extend the term of the A&R 2018 Plan through January 1, 2033, (iv) to prohibit any action that would be treated as a "repricing" of an award without further approval by the stockholders of Company, and (v) to revise the limits on awards to non-employee directors as follows: the aggregate grant date fair value of shares granted to any non-employee director under the A&R 2018 Plan and any other cash compensation paid to any non-employee director in any calendar year may not exceed $0.75 million; increased to $1.0 million in the year in which such non-employee director initially joins the Board.

The A&R 2018 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock, performance units, performance shares, RSUs, 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, 2024 and ending on and including January 1, 2033, equal to the less over (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.

Description of GRI Bio, Inc. 2015 Equity Incentive Plan

The 2015 Plan was approved by GRI Operations' stockholders on July 10, 2015. In accordance with the Merger Agreement, on April 21, 2023, the Company assumed the 2015 Plan and the outstanding awards granted thereunder at the Effective Time. The 2015 Plan is administered by the Board or a committee designated by the Board. The 2015 Plan further authorizes the administrator to amend the exercise price and terms of certain awards thereunder. No new awards may be issued under the 2015 Plan. As of December 31, 2023, no awards were outstanding under the 2015 Plan.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

In addition to the director and executive officer compensation arrangements discussed in "Executive Officer and Director Compensation," since January 1, 2021, we and GRI Operations have engaged in the following transactions in which the amount involved exceeded the lesser of $120,000 or 1% of the average of our total assets amounts for the years ended December 31, 2023 and 2022, and in which any director, executive officer or holder of more than 5% of our voting securities, whom we refer to as our principal stockholders, or affiliates or immediate family members of our directors, executive officers and principal stockholders, had or will have a material interest. We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

2021 Convertible Note Financing

In January 2021, Vallon entered into a Convertible Promissory Note Purchase Agreement with certain existing stockholders, including Salmon Pharma and David Baker, Vallon's Chief Executive Officer, pursuant to which Vallon issued convertible promissory notes ("2021 Convertible Notes") for cash proceeds of $350,000. The 2021 Convertible Notes bear an interest rate of 7.0% per annum, non-compounding, and had a maturity date of September 30, 2021. The 2021 Convertible Notes were convertible into shares of Vallon capital stock offered to investors in any subsequent equity financing, or Qualified Financing (as defined therein), after the date of their issuance in which we issued any of our equity securities and were convertible at a 20.0% discount to the price per share offered in such Qualified Financing.

On February 12, 2021, Vallon consummated the initial public offering ("IPO") of Vallon common stock, which was considered a Qualified Financing. Accordingly, the 2021 Convertible Notes converted into an aggregate of 140 shares of Vallon common stock immediately prior to the closing of the IPO at a conversion price of $2,496.00 per share.

TEP Convertible Promissory Note

In November 2018, GRI Operations and TEP Biotech, LLC ("TEP") entered into a convertible note and warrant purchase agreement pursuant to which TEP agreed to fund up to $5.0 million to GRI Operations in exchange for a convertible promissory note (the "TEP Note") and a warrant to purchase up to 7,417 shares of GRI Operations common stock at an exercise price of $0.01 per share. The TEP Note was secured by GRI Operations' assets and accrues simple interest on the outstanding principal balance at a rate of 12% per annum. The total outstanding principal and accrued interest balance was initially due on the earlier of GRI Operations' next financing (as defined therein) and May 2, 2020 (the "Maturity Date").

Amendments to TEP Note

In December 2019, GRI Operations and TEP amended the TEP Note. In lieu of TEP funding the second $2.5 million tranche, TEP made a first additional advance of $0.5 million to GRI in exchange for a convertible promissory note, a warrant to purchase up to 5,073 shares of GRI Operations common stock at an exercise price of $0.01 per share, and the assignment of GRI Operations' rights under a certain call option agreement. The call option agreement, which was entered into in 2015, provided GRI Operations with the right to repurchase up to 11,538 shares of GRI Operations common stock held by the counterparty for $91.00 per share at any time before April 1, 2025.

In July 2020, the TEP Note maturity date was extended to August 31, 2020, and in March 2021, TEP agreed to forbear on its available right to exercise remedies on account of GRI Operations' failure to pay the past due principal and accrued interest balance until October 31, 2021.

In May 2021, GRI Operations and TEP further amended the TEP Note, and TEP agreed to make a second additional advance of $0.5 million to GRI Operations in exchange for a convertible promissory note with separate, modified conversion options.

In July 2022, GRI Operations and TEP further amended the TEP Note, and TEP agreed to make a third additional advance of $125,000 to GRI Operations in exchange for a convertible promissory note and a warrant to purchase up to 343 shares of GRI Operations common stock at an exercise price of $0.01 per share.

Conversion of TEP Note

In December 2022, in connection with the execution of the Merger Agreement, the TEP Note converted in full into 45,604 shares of GRI Operations common stock pursuant to a conversion agreement executed by GRI and TEP. Upon conversion, TEP became a beneficial owner of more than 5% of GRI Operations common stock.

Equity Financing

Between December 13, 2022 and May 8, 2023 we entered into securities purchase agreements, senior secured notes, the Equity Warrants and the Exchange Warrants with Altium. See “Prospectus Summary—Equity Financing” and “Prospectus Summary—Merger Transaction.”

Employment Agreements

We have entered into employment agreements with certain of our executive officers. See “Executive and Director Compensation”.

Equity Grants

We have granted stock options to certain of our executive officers and members of our Board. See “Executive and Director Compensation”.

Director and Executive Officer Compensation

See “Executive and Director Compensation” for a discussion of payments and options granted to our named executive officers and non-employee directors.

Indemnification Agreements with Officers and Directors and Directors’ and Officers’ Liability Insurance

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. We also maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act.

Related Party Transaction Policy

Our written related party transactions policy states that our employees, officers and directors, and any members of the immediate family of and any entity affiliated with any of the foregoing persons are not permitted to enter into a material related party transaction with us without the review and approval of our audit committee. The policy provides that our general counsel, or, if we do not then have a general counsel, our principal executive, financial, or accounting officer (each a “Designated Officer”), must be notified of any request for us to enter into a transaction with such parties in which the amount involved exceeds $120,000 as well as of the facts and circumstances of the proposed transaction. Should an employee of the Company become aware of a related party transaction, regardless

of whether such employee is a party to such transaction, such employee will report the related party transaction to the Designated Officer. The Designated Officer shall report such related party transaction to the audit committee for review. In approving or rejecting any such proposal, our audit committee considers the relevant facts and circumstances available and deemed relevant to the committee, including, but not limited to, (i) whether the transaction was undertaken in the ordinary course of business; (ii) whether the related party transaction was initiated by us, a subsidiary, or the related party; (iii) whether the transaction with the related party is proposed to be, or was, entered into on terms no less favorable to the company than terms that could have been reached with an unrelated third party; (iv) the purpose of, and the potential benefits to us of, the related party transaction; (v) the approximate dollar value of the amount involved in the related party transaction, particularly as it relates to the related party; (vi) the related party's interest in the related party transaction; (vii) whether the related party transaction would impair the independence of an otherwise independent director; and (viii) any other information regarding the related party transaction or the related party that would be material to investors in light of the circumstances of the particular transaction.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information known to us regarding beneficial ownership of our capital stock as of June 17, 2024 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 June 17, 2024. 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 543,775 shares of Common Stock deemed to be outstanding as of June 17, 2024, which number of shares has been adjusted to reflect the Reverse Stock Splits.

	Common Stock Beneficially Owned	
Name and Address of Beneficial Owner	**Number of Shares of Beneficial Ownership**	**Percentage of Total Common Stock**
Directors and Named Executive Officers[1]		
W. Marc Hertz, Ph.D.[2]	4,236	*
Leanne Kelly[3]	17	*
David Baker[4]	220	*
Roelof Rongen[5]	158	*
Camilla V. Simpson, M.Sc.[5]	158	*
David Szekeres[5]	158	*
All directors and executive officers as a group (8 persons) [6]	8,025	1.60 %

* Represents beneficial ownership of less than one percent of our outstanding Common Stock.
(1) 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.
(2) Consists of 4,236 shares of Common Stock.
(3) Consists of (i) 2 shares of Common Stock and (ii) 15 shares of Common Stock issuable pursuant to stock options exercisable within 60 days of June 13, 2024.
(4) Consists of (i) 3 shares of Common Stock and (ii) 217 shares of Common Stock issuable pursuant to stock options exercisable within 60 days of June 13, 2024.
(5) Consists of 158 shares of Common Stock issuable pursuant to stock options exercisable within 60 days of June 13, 2024.
(6) Consists of (i) the shares of Common Stock described in footnotes (2) through (5) above, (ii) 1,892 shares of Common Stock held by Vipin Kumar Chaturvedi, Ph.D., and (iii) 1,892 shares of Common Stock held by Albert Agro, Ph.D.

DESCRIPTION OF CAPITAL STOCK

General

Our authorized capital stock consists of 250,000,000 shares of Common Stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share, all of which shares of preferred stock are undesignated. Unless otherwise noted, all references to the share and per share amounts below reflect the Reverse Stock Splits.

As of June 17, 2024, 543,775 shares of Common Stock and no shares of preferred stock were outstanding and held by 17 stockholders of record.

Common Stock

The holders of shares of our Common Stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our Common Stock do not have any cumulative voting rights. Holders of our Common Stock are entitled to receive ratably any dividends declared by the Board out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our Common Stock has no preemptive rights, conversion rights, or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our Common Stock are entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock.

Preferred Stock

The Board has the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of Common Stock. The issuance of our preferred stock could adversely affect the voting power of holders of Common Stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of the Company or other corporate action. No shares of preferred stock are issued or outstanding, and we have no present plan to issue any shares of preferred stock.

Warrants

Pursuant to the Bridge SPA, on April 21, 2023, the Bridge Warrants held by Altium were exchanged for the Exchange Warrants. The Exchange Warrants were exercisable at any time on or after the applicable issuance date and have a term of 60 months from the date all shares underlying the Exchange Warrants are freely tradable. The exercise price of the Exchange Warrants was subject to adjustment for splits and similar recapitalization events. As of June 17, 2024, the Exchange Warrants have been fully exercised on a cashless basis.

Pursuant to the Equity SPA, on May 8, 2023, the Company issued to Altium (i) Series A-1 Warrants to purchase 13,947 shares of Common Stock with an initial exercise price of $1,229.41 per share, (ii) Series A-2 Warrants to purchase 12,552 shares of Common Stock with an initial exercise price of $1,341.34 per share (all of which have since been exercised, as described under the heading “Warrant Exercises” in Item 15 of Part II of this registration statement) and (iii) Series T Warrants to purchase (x) 8,950 shares of Common Stock at an exercise price of $1,117.48 per share and (y) if the Series T Warrants are exercised in full by paying the Aggregate Exercise Price (as defined therein) in cash, an additional amount of Series A-1 Warrants and Series A-2 Warrants, each to purchase 8,950 shares of Common Stock at their respective exercise price. The Series A-1 Warrants have a term of 60 months from the date all shares underlying the Series A-1 Warrants are freely tradable, and the Series A-2 Warrants and Series T Warrants have a term of 24 months from the date all shares underlying the Series A-2 Warrants and Series

T Warrants, respectively, are freely tradable. The Company may force the exercise of the Series T Warrants only subject to the satisfaction of certain equity conditions. These equity conditions include a requirement that shares of our Common Stock have a reported weighted average price of at least $838.11 per share for the periods set forth in the Series T Warrants. The equity conditions for the forced exercise of the Series T Warrants are not currently met. As of June 17, 2024, all of the Series A-1 and Series A-2 Warrants have been exercised.

The Equity SPA, Exchange Warrants and Equity Warrants also contain (or contained) customary 4.99%/9.99% beneficial ownership limitations, and Altium will be prohibited from receiving shares of our Common Stock from escrow or upon exercise of any Exchange Warrants or Equity Warrants, as applicable, to the extent that immediately prior to or after giving effect to receipt of these shares, Altium, together with its affiliates or other attribution parties would beneficially own more than 4.99%/9.99%, as applicable, of the total number of shares of our common stock then issued and outstanding. In that situation, the escrow agent will hold the shares in excess of the ownership limitation in abeyance for the benefit of the Investor pending compliance with the beneficial ownership limitation.

Additionally, the Equity Warrants have a cashless exercise provision providing that if on any trading day following the earlier of (i) 240 days following the Closing or (ii) the deadline under the registration rights agreement for having a registration statement registering the applicable underlying warrant shares for resale declared effective (such earlier date, the “Trigger Date”), a registration statement covering the resale of the warrant shares that are the subject of an exercise notice is unavailable, such Equity Warrant may be exercised on a cashless basis and receive shares of Common Stock pursuant to the formula therein. The Series A-2 Warrants also have an alternate cashless exercise provision providing that if on any trading day following the Trigger Date, the weighted average price of the Common Stock is less than 90% of the exercise price of the Series A-2 Warrants, then the holder of the Series A-2 Warrant may exercise the Series A-2 Warrants on a cashless basis and receive one share of Common Stock for each underlying Series A-2 Warrant share. The exercise price of the Series A-1 Warrants was subject to adjustment for certain dilutive issuances, including adjustment pursuant to which the exercise price may be further reduced by the value of the warrants issued in this offering as set forth and further described in the Series A-1 Warrants, and the exercise prices and number of shares issuable upon exercise of the Equity Warrants are subject to adjustment for reverse stock splits and similar recapitalization events. The Equity Warrants also contain certain rights with regard to asset distributions and fundamental transactions.

Pursuant to the Purchase Agreement, on February 1, 2024, we agreed to issue and sell, in a public offering, (i) 25,419 Shares of Common Stock, (ii) 359,196 February 2024 Pre-Funded Warrants exercisable for an aggregate of 359,196 shares of Common Stock (all of which have since been exercised), (iii) 384,615 Series B-1 Common Warrants exercisable for an aggregate of 384,615 shares of Common Stock, and (iv) 384,615 Series B-2 Common Warrants exercisable for an aggregate of 384,615 shares of Common Stock. The securities were offered in combinations of (a) one 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 $14.30 (less $0.0013 for each February 2024 Pre-Funded Warrant). As of June 17, 2024, all of the February 2024 Pre-Funded Warrants have been exercised.

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 $0.0013. Each Series B-1 Common Warrant is exercisable into one share of Common Stock at a price per share of $14.30 (as may be adjusted from time to time in accordance with the terms thereof) 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 $14.30 (as may be adjusted from time to time in accordance with the terms thereof) for the 18-month period after February 6, 2024, the date of issuance. In connection with the issuance of the securities pursuant to the 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 since been exercised.

As of June 17, 2024, there were a total of (i) 26,850 shares of Common Stock directly or indirectly underlying the Equity Warrants (including (a) 8,950 shares of Common Stock underlying Series A-1 Warrants to purchase shares of Common Stock, which Series A-1 Warrants are issuable upon exercise of Series T Warrants, assuming that the Series T Warrants have been exercised in full by paying the Aggregate Exercise Price in cash, (b) 8,950 shares of Common Stock underlying Series A-2 Warrants to purchase shares of Common Stock, which Series A-2 Warrants

are issuable upon exercise of the Series T Warrants, assuming the Series T Warrants have been exercised in full by paying the aggregate exercise price in cash and (c) 8,950 shares of Common Stock underlying the Series T Warrants to purchase shares of Common Stock), (ii) 769,210 shares of Common Stock directly or indirectly underlying the Series B Warrants and (iii) 343 shares of Common Stock directly or indirectly underlying other outstanding warrants to purchase Common Stock.

Registration Rights

Altium is entitled to rights with respect to registration of the shares of Common Stock held by it or issuable to it under the Securities Act. These rights are provided under the terms of a registration rights agreement between the Company and Altium. The registration rights agreement requires the Company to file a resale registration statement (the "Resale Registration Statement") with respect to the maximum number of shares of Common Stock held by or issuable to Altium pursuant to the Equity Warrants and the Exchange Warrants (the "Registrable Securities") within 15 business days after a demand for registration is made pursuant to the Registration Rights Agreement.

Subject to limited exceptions, if the Company fails to file and obtain and maintain effectiveness of the Resale Registration Statement(s) required under the registration rights agreement, then the Company shall be obligated to pay to each affected holder of Registrable Securities an amount equal to 1.5% of the aggregate purchase price of such holder's Registrable Securities whether or not included in such Resale Registration Statement on the date of such failure and 1.5% on every thirtieth day thereafter (pro-rated for periods of less than 30 days) until the date such failure is cured.

On October 13, 2023, we filed a registration statement on Form S-3 for the offer and resale of the Registrable Securities, as amended by a Pre-Effective Amendment No. 1 to Form S-3 on Form S-1, filed on December 4, 2023, which was declared effective by the SEC on December 15, 2023.

Indemnification

The registration rights granted in the registration rights agreement are subject to customary cross-indemnification and contribution provisions, under which we are obligated to indemnify holders of Registrable Securities in the event of material misstatements or omissions in the Resale Registration Statement(s) attributable to the Company, and they are obligated to indemnify the Company in an amount not to exceed the net proceeds to such holder as a result of the sale of Registrable Securities pursuant to such registration statement for material misstatements or omissions in the Resale Registration Statement(s) attributable to them in reliance upon and in conformity with written information furnished to the Company by such holders expressly for use in connection with such Registration Statement.

Expiration of Registration Rights

The Company must use its reasonable best efforts to maintain the effectiveness of the Resale Registration Statement until the earlier of (i) the date as of which Altium may sell all of the Registrable Securities covered by the applicable Resale Registration Statement(s) without restriction or limitation pursuant to Rule 144 and without the requirement to be in compliance with Rule 144(c)(1) (or any successor thereto) or (ii) the date on which Altium has sold all of the Registrable Securities covered by the applicable Resale Registration Statement(s).

Anti-Takeover Effects of our Amended and Restated Certificate of Incorporation, Amended and Restated Bylaws and Delaware Law

Our Amended and Restated Certificate of Incorporation, as amended and Amended and Restated Bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of the Company and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with the Board rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board Composition and Filling Vacancies

Our Amended and Restated Certificate of Incorporation provides for the division of the Board into three classes serving staggered three-year terms, with one class being elected each year. Our Amended and Restated Certificate of Incorporation provides that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on the Board, however occurring, including a vacancy resulting from an increase in the size of the Board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of the Board.

No Written Consent of Stockholders

Our Amended and Restated Certificate of Incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our Amended and Restated Bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of Stockholders

Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws provide that only the Company's chief executive officer, chairperson of the Board, and a majority of the members of the Board then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our Amended and Restated Bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements

Our Amended and Restated Bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to the Company's corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at the Company's principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our Amended and Restated Bylaws specify the requirements as to form and content of all notices to stockholders. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Any amendment of our Amended and Restated Certificate of Incorporation must first be approved by a majority of the Board, and if required by law or our Amended and Restated Certificate of Incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to removal of our directors, and the amendment of our Amended and Restated Bylaws must be approved by not less than 66 2/3% of the outstanding shares entitled to vote on the amendment. Our Amended and Restated Bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in our Amended and Restated Bylaws; and may also be amended by the affirmative vote of 66 2/3% of the outstanding shares entitled to vote on the amendment.

Preferred Stock

Our Amended and Restated Certificate of Incorporation provides for 10,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable the Board to discourage an attempt to obtain control of the Company by means of a merger, tender offer, proxy contest or otherwise. For

example, if in the due exercise of its fiduciary obligations, the Board were to determine that a takeover proposal is not in the best interests of our stockholders, the Board could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our Amended and Restated Certificate of Incorporation grants the Board broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of Common Stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of the Company.

Choice of Forum

Our Amended and Restated Certificate of Incorporation provides that unless we consent in writing to 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 the Company or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our Amended and Restated Certificate of Incorporation or our Amended and Restated 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 of the State of Delaware having personal jurisdiction over the indispensable parties named as defendants therein. 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.

Our Amended and Restated Certificate of Incorporation further provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.

In addition, our Amended and Restated Certificate of Incorporation provides that any person or entity purchasing or otherwise acquiring any interest in shares of our Common Stock is deemed to have notice of and consented to the foregoing provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation and bylaws has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable.

Section 203 of the DGCL

We are subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by the board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Listing

Our Common Stock is listed on The Nasdaq Capital Market under the trading symbol “GRI.”

Transfer Agent and Registrar

Our transfer agent and registrar for our Common Stock is Broadridge Corporate Issuer Solutions, Inc. The transfer agent and registrar’s address is 51 Mercedes Way, Edgewood, NY 11717.

DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering up to shares of Common Stock, together with Warrants to purchase up to shares of Common Stock. We are also offering Pre-Funded Warrants to purchase shares of Common Stock to those purchasers, whose purchase of shares of Common Stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding Common Stock following the consummation of this offering in lieu of the shares of our Common Stock that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%). Each Pre-Funded Warrant will be exercisable for one share of Common Stock. Each Pre-Funded Warrant is being issued together with the same Warrant described above being issued with each share of Common Stock. The shares of Common Stock or Pre-Funded Warrants, as the case may be, and the accompanying Warrants, can only be purchased together in this offering, but the shares of Common Stock and Pre-Funded Warrants and accompanying Warrants are immediately separable and will be issued separately in this offering. We are also registering the shares of Common Stock issuable from time to time upon exercise of the Pre-Funded Warrants and Warrants offered hereby.

Common Stock

The material terms and provisions of our Common Stock are described under the caption “Description of Capital Stock.”

Warrants

The following summary of certain terms and provisions of the Warrants included with the shares of Common Stock and the Pre-Funded Warrants that are being issued hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Warrants, the form of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of warrant for a complete description of the terms and conditions of the Warrants.

Duration, Exercise Price and Form

Each Warrant offered hereby will have an exercise price of $ per share and will be exercisable beginning on the effective date of the Warrant Stockholder Approval, provided however, if the Pricing Conditions are met, the Warrants will be exercisable upon the Initial Exercise Date. The Warrants will expire on the anniversary of the Initial Exercise Date. The exercise price and number of shares of Common Stock issuable upon exercise of the Warrants is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our Common Stock and the exercise price. The Warrants will be issued separately from the Common Stock and Pre-Funded Warrants and may be transferred separately immediately thereafter.

We intend to promptly, and in no event later than days after the consummation of this offering, seek stockholder approval for the issuance of shares of Common Stock issuable upon exercise of the Warrants but we cannot assure you that such stockholder approval will be obtained, provided, however, that, if and only if the Pricing Conditions are satisfied, then we will not seek Warrant Stockholder Approval. We have agreed with the investors in this offering that, if we do not obtain stockholder approval for the issuance of the shares of Common Stock upon exercise of the Warrants at the first stockholder meeting for such purpose after this offering, we will call a stockholder meeting every days thereafter until the earlier of the date we obtain such approval or the Warrants are no longer outstanding, provided, however, that, if and only if the Pricing Conditions are satisfied, then we will not seek Warrant Stockholder Approval.

Exercisability

The Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our Common Stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the Warrant to the extent that the holder would own more than 4.99% (or, at the election of the purchaser prior to the issuance of the warrants, 9.99%) of the outstanding Common Stock

immediately after exercise. Following the issuance of the Warrants, upon notice from the holder to us, the holder may increase or decrease the amount of beneficial ownership of outstanding Common Stock after exercising the holder's Warrants up to 9.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants and in accordance with the rules and regulations of the SEC, provided that any increase in the beneficial ownership limitation shall not be effective until sixty-one (61) days following notice to us.

Cashless Exercise

If, at the time a holder exercises its Warrants, a registration statement registering the issuance of the shares of Common Stock underlying the Warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of Common Stock determined according to a formula set forth in the Warrants.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the Warrants. Rather, the number of shares of Common Stock to be issued will be rounded up to the next whole share or we will pay a cash adjustment equal to such fraction multiplied by the exercise price to the holder.

Transferability

Subject to applicable laws, a Warrant may be transferred at the option of the holder upon surrender of the Warrant to us together with the appropriate instruments of transfer.

Trading Market and Listing

There is no trading market available for the Warrants on any securities exchange or nationally recognized trading system, and we do not expect a trading market to develop. We do not intend to list the Warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the warrants will be extremely limited. The Common Stock issuable upon exercise of the Warrants is currently listed on The Nasdaq Capital Market.

Rights as a Stockholder

Except as otherwise provided in the Warrants or by virtue of such holder's ownership of shares of our Common Stock, the holders of the Warrants do not have the rights or privileges of holders of our Common Stock, including any voting rights, until they exercise their Warrants.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Warrants and generally including any reorganization, recapitalization or reclassification of our Common Stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of greater than 50% of our outstanding Common Stock, or any person or group becoming the beneficial owner of greater than 50% of the voting power represented by our outstanding Common Stock, the holders of the Warrants will be entitled to receive upon exercise of the Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Warrants immediately prior to such fundamental transaction. In addition, in certain circumstances, upon a fundamental transaction, the holder of the Warrants will have the right to require us to repurchase its Warrants at the Black-Scholes value; provided, however, that, if the fundamental transaction is not within our control, including not approved by our Board, then the holder will only be entitled to receive the same type or form of consideration (and in the same proportion), at the Black-Scholes value of the unexercised portion of the Warrant that is being offered and paid to the holders of our Common Stock in connection with the fundamental transaction.

Waivers and Amendments

The Warrants may be modified or amended, or the provisions thereof waived, with the written consent of the holder of such Warrant and us.

Pre-Funded Warrants

The following summary of certain terms and provisions of the Pre-Funded Warrants that are being issued hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Pre-Funded Warrant, the form of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of Pre-Funded Warrant for a complete description of the terms and conditions of the Pre-Funded Warrants.

Duration, Exercise Price and Form

Each Pre-Funded Warrant offered hereby will have an initial exercise price per share equal to $0.0001. The Pre-Funded Warrants will be immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. The exercise price and number of shares of Common Stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our Common Stock and the exercise price. The Pre-Funded Warrants will be issued separately from the accompanying Warrants.

Exercisability

The Pre-Funded Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our Common Stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the Pre-Funded Warrant to the extent that the holder would own more than 4.99% (or, at the election of the purchaser prior to the issuance of the Pre-Funded Warrant, 9.99%) of the outstanding Common Stock immediately after exercise. Following the issuance of the Pre-Funded Warrants, upon notice from the holder to us, the holder may increase or decrease the amount of beneficial ownership of outstanding Common Stock after exercising the holder's Pre-Funded Warrants up to 9.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrants and in accordance with the rules and regulations of the SEC. Purchasers of Pre-Funded Warrants in this offering may also elect prior to the issuance of the Pre-Funded Warrants to have the initial exercise limitation set at 9.99% of our outstanding Common Stock, provided that any increase in the beneficial ownership limitation shall not be effective until sixty-one (61) days following notice to us.

Cashless Exercise

In lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of Common Stock determined according to a formula set forth in the Pre-Funded Warrants.

Fractional Shares

No fractional shares of Common Stock will be issued upon the exercise of the Pre-Funded Warrants. Rather, the number of shares of Common Stock to be issued will be rounded up to the next whole share or we will pay a cash adjustment to such fraction multiplied by the exercise price to the holder.

Transferability

Subject to applicable law, the Pre-Funded Warrants may be transferred at the option of the holder upon surrender of the Pre-Funded Warrants to us together with the appropriate instruments of transfer.

Trading Market and Listing

There is no trading market available for the Pre-Funded Warrants on any securities exchange or nationally recognized trading system, and we do not expect a trading market to develop. We do not intend to list the Pre-Funded Warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the Pre-Funded Warrants will be extremely limited. The Common Stock issuable upon exercise of the Pre-Funded Warrants is currently listed on The Nasdaq Capital Market.

Rights as a Stockholder

Except as otherwise provided in the Pre-Funded Warrants or by virtue of such holder's ownership of shares of our Common Stock, the holders of the Pre-Funded Warrants do not have the rights or privileges of holders of our Common Stock, including any voting rights, until they exercise their Pre-Funded Warrants. The Pre-Funded Warrants will provide that holders have the right to participate in distributions or dividends paid on our Common Stock.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Pre-Funded Warrants and generally including any reorganization, recapitalization or reclassification of our Common Stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of greater than 50% of our outstanding Common Stock, or any person or group becoming the beneficial owner of greater than 50% of the voting power represented by our outstanding Common Stock, the holders of the Pre-Funded Warrants will be entitled to receive upon exercise of the Pre-Funded Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Pre-Funded Warrants immediately prior to such fundamental transaction.

Waivers and Amendments

The Pre-Funded Warrants may be modified or amended, or the provisions thereof waived, with the written consent of the holder of such Pre-Funded Warrant and us.

Placement Agent Warrants

We have also agreed to issue to the Placement Agent or its designees as compensation in connection with this offering, the Placement Agent Warrants to purchase up to shares of Common Stock as compensation in connection with this offering. The Placement Agent Warrants will be exercisable beginning on the effective date of the Warrant Stockholder Approval, provided however, if the Pricing Conditions are met, such Placement Agent Warrants will be exercisable upon issuance and will have substantially the same terms as the Warrants described above, except that the Placement Agent Warrants will have an exercise price of $ per share (representing % of the combined public offering price per share and accompanying Warrants) and a termination date that will be five years from the commencement of the sales pursuant to this offering. See "Plan of Distribution" below.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO HOLDERS OF COMMON STOCK AND WARRANTS

The following discussion is a summary of certain material U.S. federal income tax consequences of the purchase, ownership and disposition of the shares of Common Stock and Pre-Funded Warrants and accompanying Warrants or components thereof, which we refer to collectively as the "Securities," issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or foreign tax laws are not discussed. This discussion is based on the Internal Revenue Code of 1986, as amended (the "Code"), Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service (the "IRS") in effect as of the date of this offering. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a holder of the Securities. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position regarding the tax consequences of the purchase, ownership and disposition of the Securities.

This discussion is limited to holders that hold the Securities as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a holder's particular circumstances, including the impact of the alternative minimum tax or the unearned income Medicare contribution tax. In addition, it does not address consequences relevant to holders subject to particular rules, including, without limitation:

- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons holding the Securities as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell the Securities under the constructive sale provisions of the Code;
- persons for whom our stock and pre-funded warrants constitutes "qualified small business stock" within the meaning of Section 1202 of the Code;
- persons who hold or receive the Securities pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to the stock being taken into account in an "applicable financial statement" (as defined in the Code);
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds; and
- tax-qualified retirement plans.

If a partnership (or other entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds the Securities, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding

the Securities and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT INTENDED AS LEGAL OR TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF THE SECURITIES ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Allocation of Purchase Price

Each share of Common Stock or Pre-Funded Warrant, as applicable, and accompanying Warrant will be treated for U.S. federal income tax purposes as an investment unit consisting of one share of our Common Stock or Pre-Funded Warrant, as applicable, and accompanying Warrant to purchase our Common Stock. In determining their tax basis for the Common Stock or Pre-Funded Warrant and the Warrant constituting an investment unit, holders of securities should allocate their purchase price for the investment unit between the Common Stock or Pre-Funded Warrant, as applicable, and the Warrant on the basis of their relative fair market values at the time of issuance. The Company does not intend to advise holders of the securities with respect to this determination, and holders of the securities are advised to consult their tax and financial advisors with respect to the relative fair market values of the Common Stock or Pre-Funded Warrant, as applicable, and the Warrants for U.S. federal income tax purposes.

Treatment of Pre-Funded Warrants

Although not free from doubt, a Pre-Funded Warrant should be treated as a share of our Common Stock for U.S. federal income tax purposes, and a holder of Pre-Funded Warrants should generally be taxed in the same manner as a holder of Common Stock, as described below. Accordingly, no gain or loss should be recognized (other than with respect to cash paid in lieu of a fractional share) upon the exercise of a Pre-Funded Warrant (except in the case of a cashless exercise, the treatment of which for U.S. federal income tax purposes is not clear) and, upon exercise, the holding period of a Pre-Funded Warrant should carry over to the share of Common Stock received. Similarly, the tax basis of the Pre-Funded Warrant should carry over to the share of Common Stock received upon exercise, increased by the exercise price of $0.0001. The discussion below assumes the characterization described above is respected for U.S. federal income tax purposes. Holders should consult their tax advisors regarding the risks associated with the acquisition of Pre-Funded Warrants pursuant to this offering (including alternative characterizations).

Tax Considerations Applicable to U.S. Holders

Definition of a U.S. Holder

For purposes of this discussion, a “U.S. holder” is any beneficial owner of the Securities that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more United States persons (within the meaning of Section 7701(a)(30) of the Code), or (2) has made a valid election under applicable Treasury Regulations to be treated as a United States person for U.S. federal income tax purposes.

Sale or Other Taxable Disposition of Common Stock or Pre-Funded Warrants

Upon the sale, exchange or other taxable disposition of the Common Stock or Pre-Funded Warrants, a U.S. holder generally will recognize capital gain or loss equal to the difference between (i) the amount of cash and the fair market value of any property received upon the sale, exchange or other taxable disposition and (ii) such U.S. holder's adjusted tax basis in the Common Stock or Pre-Funded Warrant. Such capital gain or loss will be long- term capital gain or loss if the U.S. holder's holding period in such Common Stock or Pre-Funded Warrant is more than one year at the time of the sale, exchange or other taxable disposition. Long-term capital gains recognized by certain non-corporate U.S. holders, including individuals, generally will be subject to reduced rates of U.S. federal income tax. The deductibility of capital losses is subject to certain limitations.

Sale or Other Disposition, Exercise or Expiration of Warrants

Upon the sale or other disposition of a warrant (other than by exercise), a U.S. holder will generally recognize capital gain or loss equal to the difference between the amount realized on the sale or other disposition and the U.S. holder's tax basis in the warrant. This capital gain or loss will be long-term capital gain or loss if the U.S. holder's holding period in such warrant is more than one year at the time of the sale or other disposition. The deductibility of capital losses is subject to certain limitations.

In general, a U.S. holder will not be required to recognize income, gain or loss upon exercise of a warrant for its exercise price (except to the extent the U.S. holder receives a cash payment for a such fractional share that would otherwise have been issuable upon exercise of the warrant, which will be treated as a sale as described above under "Sale or Other Taxable Disposition of Common Stock or Pre-Funded Warrants"). A U.S. holder's tax basis in a share of Common Stock received upon exercise of warrants will be equal to the sum of (i) the U.S. holder's tax basis in the warrants exchanged therefor and (ii) the exercise price of such warrants. A U.S. holder's holding period in the shares of Common Stock received upon exercise will commence on the day after such U.S. holder exercises the warrants. U.S. holders are urged to consult their tax advisors as to the consequences of an exercise of a warrant on a cashless basis, including with respect to their holding period and tax basis in the Common Stock received.

If a warrant expires without being exercised, a U.S. holder will recognize a capital loss in an amount equal to such holder's tax basis in the warrant. Such loss will be long-term capital loss if, at the time of the expiration, the U.S. holder's holding period in such warrant is more than one year. The deductibility of capital losses is subject to certain limitations.

Constructive Dividends on Common Warrants or Pre-Funded Warrants

As described in the section entitled "Dividend Policy," we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. However, if at any time during the period in which a U.S. holder holds warrants or pre-funded warrants, we were to pay a taxable dividend to our stockholders and, in accordance with an anti-dilution provisions of the warrants or pre-funded warrants, the exercise price thereof were decreased, that decrease would be deemed to be the payment of a taxable dividend to a U.S. holder of the warrants or pre-funded warrants, as applicable, to the extent of our earnings and profits, notwithstanding the fact that such holder will not receive a cash payment. If the exercise price is adjusted in certain other circumstances or other adjustments are made (or in certain circumstances, there is a failure to make adjustments), such adjustments may also result in the deemed payment of a taxable dividend to a U.S. holder. In addition, a holder of a warrant or pre-funded warrant may, in some circumstances, be deemed to have received a distribution subject to U.S. federal income tax as a result of an adjustment or the non-occurrence of an adjustment to the exercise price or number of shares of Common Stock issuable upon exercise of the warrant or pre-funded warrant. U.S. holders should consult their tax advisors regarding the proper treatment of any adjustments to the warrants and pre-funded warrants.

We are currently required to report the amount of any deemed distributions on our website or to the IRS and to holders not exempt from reporting. The IRS has proposed regulations addressing the amount and timing of deemed distributions, as well as obligations of withholding agents and filing and notice obligations of issuers in respect of such deemed distributions. If adopted as proposed, the regulations would generally provide that (i) the amount of a deemed distribution is the excess of the fair market value of the right to acquire stock immediately after the exercise price adjustment over the fair market value of the right to acquire stock (after the exercise price adjustment) without

the adjustment, (ii) the deemed distribution occurs at the earlier of the date the adjustment occurs under the terms of the instrument and the date of the distribution of cash or property that results in the deemed distribution and (iii) we are required to report the amount of any deemed distributions on our website or to the IRS and to all holders (including holders that would otherwise be exempt from reporting). The final regulations will be effective for deemed distributions occurring on or after the date of adoption, but holders and withholding agents may rely on them prior to that date under certain circumstances.

Information Reporting and Backup Withholding

A U.S. holder may be subject to information reporting and backup withholding (currently at a rate of 24%) when such holder receives payments on the Common Stock or Pre-Funded Warrants or Warrants (including constructive dividends) or receives proceeds from the sale or other taxable disposition of Common Stock, Pre-Funded Warrants or Warrants. Certain U.S. holders are exempt from backup withholding, including corporations and certain tax-exempt organizations. A U.S. holder will be subject to backup withholding if such holder is not otherwise exempt and such holder:

- fails to furnish the holder's taxpayer identification number, which for an individual is ordinarily his or her social security number;
- furnishes an incorrect taxpayer identification number;
- is notified by the IRS that the holder previously failed to properly report payments of interest or dividends;
- or fails to certify under penalties of perjury that the holder has furnished a correct taxpayer identification number and that the IRS has not notified the holder that the holder is subject to backup withholding.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a U.S. holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS. U.S. holders should consult their tax advisors regarding their qualification for an exemption from backup withholding and the procedures for obtaining such an exemption.

Tax Considerations Applicable to Non-U.S. Holders

For purposes of this discussion, a "non-U.S. holder" is a beneficial owner of the Securities that is neither a U.S. holder nor an entity treated as a partnership for U.S. federal income tax purposes.

Distributions

As described in the section entitled "Dividend Policy," we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. However, if we do make distributions of cash or property (other than certain distributions of Common Stock) on our Common Stock or Pre-Funded Warrants, such will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a non-U.S. holder's adjusted tax basis in its Common Stock or Pre-Funded Warrants, but not below zero. Any excess will be treated as capital gain and will be treated as described below in the section relating to the sale or disposition of our Common Stock, Pre-Funded Warrants or Warrants. Because we may not know the extent to which a distribution is a dividend for U.S. federal income tax purposes at the time it is made, for purposes of the withholding rules discussed below we or the applicable withholding agent may treat the entire distribution as a dividend.

Subject to the discussion below on backup withholding and foreign accounts, dividends paid to a non-U.S. holder of our Common Stock or Pre-Funded Warrants that are not effectively connected with the non-U.S. holder's conduct of a trade or business within the United States will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty).

Non-U.S. holders will be entitled to a reduction in or an exemption from withholding on dividends as a result of either (a) an applicable income tax treaty or (b) the non-U.S. holder holding our Common Stock or Pre-Funded

Warrants in connection with the conduct of a trade or business within the United States and dividends being effectively connected with that trade or business. To claim such a reduction in or exemption from withholding, the non-U.S. holder must provide the applicable withholding agent with a properly executed (a) IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) claiming an exemption from or reduction of the withholding tax under the benefit of an income tax treaty between the United States and the country in which the non-U.S. holder resides or is established, or (b) IRS Form W-8ECI stating that the dividends are not subject to withholding tax because they are effectively connected with the conduct by the non-U.S. holder of a trade or business within the United States, as may be applicable. These certifications must be provided to the applicable withholding agent prior to the payment of dividends and must be updated periodically. Non-U.S. holders that do not timely provide the applicable withholding agent with the required certification, but that qualify for a reduced rate under an applicable income tax treaty, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

If dividends paid to a non-U.S. holder are effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such dividends are attributable), then, although exempt from U.S. federal withholding tax (provided the non-U.S. holder provides appropriate certification, as described above), the non-U.S. holder will be subject to U.S. federal income tax on such dividends on a net income basis at the regular graduated U.S. federal income tax rates. In addition, a non-U.S. holder that is a corporation may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits for the taxable year that are attributable to such dividends, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

Exercise of Common Warrants or Pre-Funded Warrants

A non-U.S. holder generally will not be subject to U.S. federal income tax on the exercise of warrants or pre-funded warrants into shares of common stock. Non-U.S. holders are urged to consult their tax advisors as to the consequences of an exercise of a warrant on a cashless basis, including with respect to their holding period and tax basis in the common stock received.

Sale or Other Disposition of Common Stock, Pre-Funded Warrants or Common Warrants

Subject to the discussions below on backup withholding and foreign accounts, a non-U.S. holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other disposition of our Common Stock, Pre-Funded Warrants or Warrants unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such gain is attributable);
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our Common Stock, Pre-Funded Warrants or Warrants constitute U.S. real property interests ("USRPIs") by reason of our status as a U.S. real property holding corporation ("USRPHC") for U.S. federal income tax purposes.

Gain described in the first bullet point above will generally be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates. A non-U.S. holder that is a foreign corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

A non-U.S. holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on any gain derived from the disposition, which may be offset by certain U.S.-source capital losses of the non-U.S. holder (even though the individual is not

considered a resident of the United States) provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we are not currently and do not anticipate becoming a USRPHC. Because the determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of our other business assets and our non-U.S. real property interests, however, there can be no assurance we are not a USRPHC or will not become one in the future.

Non-U.S. holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Constructive Dividends on Common Warrants or Pre-Funded Warrants

As described in the section entitled "Dividend Policy," we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. However, if at any time during the period in which a non-U.S. holder holds warrants or pre-funded warrants we were to pay a taxable dividend to our stockholders and, in accordance with the anti-dilution provisions of the warrants or pre-funded warrants, the exercise price of the warrants were decreased, that decrease would be deemed to be the payment of a taxable dividend to a non-U.S. holder to the extent of our earnings and profits, notwithstanding the fact that such holder will not receive a cash payment. If the exercise price is adjusted in certain other circumstances (or in certain circumstances, there is a failure to make adjustments), such adjustments may also result in the deemed payment of a taxable dividend to a non-U.S. holder. Any resulting withholding tax attributable to deemed dividends may be collected from other amounts payable or distributable to the non-U.S. holder. Non-U.S. holders should consult their tax advisors regarding the proper treatment of any adjustments to the warrants and pre-funded warrants.

Information Reporting and Backup Withholding

Subject to the discussion below on foreign accounts, a non-U.S. holder will not be subject to backup withholding with respect to distributions on our Common Stock or Pre-Funded Warrants we make to the non-U.S. holder (including constructive dividends with respect to Warrants and Pre-Funded Warrants), provided the applicable withholding agent does not have actual knowledge or reason to know such holder is a United States person and the holder certifies its non-U.S. status, such as by providing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or other applicable certification. However, information returns generally will be filed with the IRS in connection with any distributions (including deemed distributions) made on our Common Stock, Pre-Funded Warrants and Warrants to the non-U.S. holder, regardless of whether any tax was actually withheld. Copies of these information returns may also be made available under the provisions of a specific treaty or agreement to the tax authorities of the country in which the non-U.S. holder resides or is established.

Information reporting and backup withholding may apply to the proceeds of a sale or other taxable disposition of our Common Stock, Pre-Funded Warrants or Warrants within the United States, and information reporting may (although backup withholding generally will not) apply to the proceeds of a sale or other taxable disposition of our Common Stock, Pre-Funded Warrants or Warrants outside the United States conducted through certain U.S.-related financial intermediaries, in each case, unless the beneficial owner certifies under penalty of perjury that it is a non-U.S. holder on IRS Form W-8BEN or W-8BEN-E, or other applicable form (and the payor does not have actual knowledge or reason to know that the beneficial owner is a U.S. person) or such owner otherwise establishes an exemption. Proceeds of a disposition of our Common Stock, Pre-Funded Warrants or Warrants conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a non-U.S. holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act ("FATCA")) on certain types of payments made to non-U.S.

financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends (including deemed dividends) paid on our Common Stock, Pre-Funded Warrants or Warrants, or (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of our Common Stock, Pre-Funded Warrants or Warrants paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends (including deemed dividends). Because we may not know the extent to which a distribution is a dividend for U.S. federal income tax purposes at the time it is made, for purposes of these withholding rules we or the applicable withholding agent may treat the entire distribution as a dividend. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of our Common Stock, Pre-Funded Warrants or Warrants on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued. Prospective investors should consult their tax advisors regarding the potential application of these withholding provisions.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS TAX ADVISORS REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR SECURITIES, AS WELL AS TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, NON-U.S. OR U.S. FEDERAL NON-INCOME TAX LAWS.

PLAN OF DISTRIBUTION

Pursuant to an engagement agreement, dated , 2024 (the "Engagement Agreement"), we have engaged (the "Placement Agent") to act as our exclusive placement agent to solicit offers to purchase the securities offered pursuant to this prospectus on a "reasonable best efforts" basis. The Engagement Agreement does not give rise to any commitment by the Placement Agent to purchase any of our securities, and the Placement Agent will have no authority to bind us by virtue of the Engagement Agreement. The Placement Agent is not purchasing or selling any of the securities offered by us under this prospectus, nor is it required to arrange for the purchase or sale of any specific number or dollar amount of securities. This is a best efforts offering, and there is no minimum offering amount required as a condition to the closing of this offering. The Placement Agent has agreed to use reasonable best efforts to arrange for the sale of the securities by us. Therefore, we may not sell all of the shares of Common Stock, Pre-Funded Warrants and Warrants being offered. The terms of this offering are subject to market conditions and negotiations between us, the Placement Agent and prospective investors. The Placement Agent does not guarantee that it will be able to raise new capital in any prospective offering. The Placement Agent may engage sub-agents or selected dealers to assist with the offering.

Investors purchasing securities offered hereby will have the option to execute a securities purchase agreement with us. In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers which enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. The ability to pursue a claim for breach of contract is material to larger purchasers in this offering as a means to enforce the following covenants uniquely available to them under the securities purchase agreement: (i) a covenant to not enter into variable rate financings for a period of following the closing of the offering, subject to certain exceptions; and (ii) a covenant to not enter into any equity financings for days from closing of the offering, subject to certain exceptions. The nature of the representations, warranties and covenants in the securities purchase agreements shall include:

- standard issuer representations and warranties on matters such as organization, qualification, authorization, no conflict, no governmental filings required, current in SEC filings, no litigation, labor or other compliance issues, environmental, intellectual property and title matters and compliance with various laws such as the Foreign Corrupt Practices Act; and
- covenants regarding matters such as registration of warrant shares, no integration with other offerings, filing of a Current Report on Form 8-K to disclose entering into these securities purchase agreements, no stockholder rights plans, no material nonpublic information, use of proceeds, indemnification of purchasers, reservation and listing of shares of Common Stock and no subsequent equity sales for .

Delivery of the shares of Common Stock, the Warrants and the Pre-Funded Warrants, if any, offered hereby is expected to occur on or about , 2024, subject to the satisfaction of certain customary closing conditions.

Fees and Expenses

We have agreed to pay the Placement Agent a total cash fee equal to % of the gross proceeds of this offering and a management fee equal to % of the gross proceeds raised in this offering. We will also pay the Placement Agent a non-accountable expense allowance of $ and up to $ for the expenses of its clearing firm and will reimburse the Placement Agent's legal fees and expenses in an amount up to $. We estimate the total offering expenses of this offering that will be payable by us, excluding the Placement Agent's fees and expenses, will be approximately $ million. After deducting the Placement Agent's fees and our estimated offering expenses, we expect the net proceeds from this offering to be approximately $ million.

The following table shows the per share and total cash fees we will pay to the Placement Agent in connection with the sale of the Common Stock, the Warrants and the Pre-Funded Warrants pursuant to this prospectus.

	Per Share and Accompanying Warrants	Per Pre-Funded Warrant and Accompanying Warrants	Total
Combined public offering price			
Placement Agent fees			
Proceeds to us, before expenses			

Placement Agent Warrants

We have agreed to grant Placement Agent Warrants to the Placement Agent to purchase a number of shares of our Common Stock equal to % of the aggregate number of shares of Common Stock and Pre-Funded Warrants sold to the investors in this offering. The Placement Agent Warrants will have an exercise price of $ ( ) % of the combined public offering price per share of Common Stock and accompanying Warrant) and will terminate on the fifth anniversary of the commencement of sales in this offering. The Placement Agent Warrants are registered on the registration statement of which this prospectus is a part. The form of the Placement Agent Warrant will be included as an exhibit to this registration statement of which this prospectus forms a part.

The Placement Agent Warrants provide for customary anti-dilution provisions (for share dividends, splits and recapitalizations and the like) consistent with FINRA Rule 5110. Pursuant to FINRA Rule 5110(e), the Placement Agent Warrants and any shares issuable thereunder shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of commencement of sales of this offering, except the transfer of any security: (i) by operation of law or by reason of reorganization of the issuer; (ii) to any FINRA member firm participating in the offering and the officers, partners, registered persons or affiliates thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period; (iii) if the aggregate amount of our securities held by the Placement Agent persons does not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund and the participating members in the aggregate do not own more than 10% of the equity in the fund; (v) the exercise or conversion of any security, if all securities remain subject to the lock-up restriction set forth above for the remainder of the time period; (vi) if we meet the registration requirements of Forms S-3, F-3 or F-10; or (vii) back to us in a transaction exempt from registration under the Securities Act.

Right of First Refusal

We have granted the Placement Agent a right of first refusal for a period of twelve (12) months following the closing of this offering to act as sole book-running manager, sole underwriter or sole Placement Agent for each and every future public or private offering or other capital-raising financing of equity or equity-linked securities using an underwriter or placement agent by us or any of our successors or subsidiaries, subject to certain exceptions. Notwithstanding anything to the contrary contained in this paragraph, in accordance with FINRA Rule 5110(g)(6)(A)(i), any such right of first refusal described in this paragraph shall not have a duration of more than three years from the commencement of sales of the first offering or the termination date of the term of the Engagement Agreement.

Tail

We have also agreed to pay the Placement Agent a tail fee equal to (i) a cash fee of % raised in any financing subject to the tail provision, and (ii) warrant coverage equal to % of the aggregate number of shares of Common Stock (or Common Stock equivalent) placed in any offering financing subject to the tail provision, as applicable to such financing, provided that in each case (i) or (ii) such compensation shall not apply to the gross proceeds received by us upon exercise or conversion in the ordinary course of any warrants or other convertible securities issued as part of the offering (other than Pre-Funded Warrants), if any investor, who was contacted by the

Placement Agent or introduced to us during the term of its engagement, provides us with capital in any public or private offering or other financing or capital raising transaction during the 12-month period following expiration or termination of our engagement of the Placement Agent, subject to certain exceptions.

Other Relationships

From time to time, the Placement Agent may provide in the future, various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which it may receive customary fees and commissions. Except as disclosed in this prospectus, we have no present arrangements with the Placement Agent for any services.

In addition, in the ordinary course of their business activities, the Placement Agent and its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The Placement Agent and its affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Determination of Offering Price

The combined public offering price per share and accompanying Warrant and the combined public offering price per Pre-Funded Warrant and accompanying Warrant we are offering, and the exercise prices and other terms of the Warrants were negotiated between us and the investors, in consultation with the Placement Agent based on the trading of our Common Stock prior to this offering, among other things. Other factors considered in determining the offering prices of the securities we are offering and the exercise prices and other terms of the Warrants include the history and prospects of our company, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.

Lock-Up Agreements

We and each of our officers and directors have agreed with the Placement Agent to be subject to a lock-up period of ( ) days following the date of closing of the offering pursuant to this prospectus. This means that, during the applicable lock-up period, we and such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any of our shares of Common Stock or any securities convertible into, or exercisable or exchangeable for, shares of Common Stock, subject to customary exceptions. The Placement Agent may waive the terms of these lock-up agreements in its sole discretion and without notice. In addition, we have agreed to not issue any securities that are subject to a price reset based on the trading prices of our Common Stock or upon a specified or contingent event in the future or enter into any agreement to issue securities at a future determined price for a period of following the closing date of this offering, subject to an exception. The Placement Agent may waive this prohibition in its sole discretion and without notice.

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock is Broadridge Corporate Issuer Solutions, Inc. There is no established public trading market for Common Stock, the Warrants and the Pre-Funded Warrants, and we do not plan on making an application to list the Warrants or the Pre-Funded Warrants on Nasdaq, any national securities exchange or other nationally recognized trading system. We will act as the registrar and transfer agent for the Warrants and the Pre-Funded Warrants.

Nasdaq Listing

Our Common Stock is currently listed on The Nasdaq Capital Market under the symbol “GRI.” On June 17, 2024, the reported closing price per share of our Common Stock was $2.8613 (as adjusted for the Reverse Stock

Splits). We do not plan to list the Warrants or the Pre-Funded Warrants on The Nasdaq Capital Market or any other securities exchange or trading market.

Indemnification

We have agreed to indemnify the Placement Agent against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the Placement Agent may be required to make with respect to any of these liabilities.

Regulation M

The Placement Agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act and any fees received by it and any profit realized on the sale of the securities by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The Placement Agent will be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 10b- 5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the Placement Agent. Under these rules and regulations, the Placement Agent may not (i) engage in any stabilization activity in connection with our securities; and (ii) bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until they have completed their participation in the distribution.

Electronic Offer, Sale and Distribution of Securities

A prospectus in electronic format may be made available on the websites maintained by the Placement Agent, if any, participating in this offering and the Placement Agent may distribute prospectuses electronically. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or the Placement Agent, and should not be relied upon by investors.

LEGAL MATTERS

The validity of the securities offered by this prospectus will be passed upon for us by Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C., San Diego, California. Certain legal matters will be passed upon for the Placement Agent by .

EXPERTS

The consolidated financial statements of GRI Bio, Inc. as of and for the years ended December 31, 2023 and 2022 included in this registration statement have been audited by Sadler, Gibb & Associates LLC, an independent registered public accounting firm,as stated in their report appearing herein (which report expresses an unmodified opinion and includes an emphasis-of-matter paragraph relating to GRI's ability to continue as a going concern), and are included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1, including exhibits and schedules, under the Securities Act that registers the securities covered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all the information contained in the registration statement and the exhibits and schedules filed as part of the registration statement. For further information with respect to us and our securities, we refer you to the registration statement and the exhibits and schedules filed as part of the registration statement. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, we refer you to the copies of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit.

We file our annual, quarterly and current reports, proxy statements and other information with the SEC under the Exchange Act. You can read our SEC filings, including the registration statement, at the SEC's website at w*ww.sec.gov*.

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

Our website address is *www.gribio.com*. The information contained in, and that can be accessed through, our website is not incorporated into and is not part of this prospectus.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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 sheets of GRI Bio, Inc. ("the Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph Regarding Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that 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 financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

Our audits included performing procedures to assess the risks of material misstatement of the 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 audits 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 audits provide a reasonable basis for our opinion.

/s/ Sadler, Gibb & Associates, LLC

We have served as the Company's auditor since 2022.

Draper, UT
March 28, 2024 except for the effects of the reverse stock split described in Note 15, as to which the date is June 18, 2024.

GRI Bio, Inc.

Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 1,808	$ 9
Prepaid expenses and other current assets	1,126	303
Total current assets	2,934	312
Property and equipment, net	8	4
Operating lease right-of-use assets	14	67
Total assets	$ 2,956	$ 383
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,410	$ 1,294
Accrued expenses	1,270	36
Advances from employees	—	5
Warrant liability	3	—
Bridge promissory note, net	—	602
Operating lease liabilities, current	14	57
Total current liabilities	2,697	1,994
Operating lease liabilities, non-current	—	14
Total liabilities	2,697	2,008
Commitments and contingencies (Note 13)		
Stockholders' equity (deficit):		
Common stock, $0.0001 par value; 250,000,000 shares authorized; 49,663 and 10,987 shares issued and outstanding as of December 31, 2023 and 2022, respectively	—	—
Additional paid-in-capital	31,792	16,871
Accumulated deficit	(31,533)	(18,496)
Total stockholders' equity (deficit)	259	(1,625)
Total liabilities and stockholders' equity (deficit)	$ 2,956	$ 383

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,	
	2023	**2022**
Operating expenses:		
Research and development	$ 3,232	$ 242
General and administrative	8,155	1,997
Total operating expenses	11,387	2,239
Loss from operations	(11,387)	(2,239)
Other income	250	—
Change in fair value of warrant liability	182	—
Loss on extinguishment of debt	—	(325)
Interest expense, net	(2,082)	(653)
Net loss	$ (13,037)	$ (3,217)
Net loss per share of common stock, basic and diluted	$ (367.20)	$ (324.31)
Weighted-average common shares outstanding, basic and diluted	35,504	9,923

See accompanying notes to consolidated financial statements.

GRI Bio, Inc.

Consolidated Statements of Changes in Stockholders' Equity (Deficit)
(in thousands, except shares)

	Redeemable Common Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance, December 31, 2021	85	$ 124	9,357	$ —	$ 10,431	$ (15,279)	$ (4,848)
Stock-based compensation expense	—	—	—	—	25	—	25
Issuance of warrants and non-contingent beneficial conversion feature in connection with convertible promissory note	—	—	—	—	60	—	60
Issuance of warrants in connection with non-convertible promissory note	—	—	—	—	30	—	30
Conversion of convertible promissory note	—	—	1,705	—	5,337	—	5,337
Restricted stock awards issued in satisfaction of accrued compensation	—	—	—	—	417	—	417
Issuance of warrants in connection with the issuance of a bridge promissory note	—	—	—	—	571	—	571
Redemption of redeemable common stock	(85)	(124)	(85)	—	—	—	—
Vesting of restricted stock	—	—	10	—	—	—	—
Net loss	—	—	—	—	—	(3,217)	(3,217)
Balance, December 31, 2022	—	$ —	10,987	$ —	$ 16,871	$ (18,496)	$ (1,625)
Stock-based compensation expense	—	—	—	—	388	—	388
Restricted stock vesting	—	—	1,807	—	—	—	—
Warrant issuance	—	—	—	—	532	—	532
Warrant exercise	—	—	17,658	—	12	—	12
Issuance of common stock in pre-closing financing	—	—	13,350	—	11,721	—	11,721
Issuance of common stock for settlement of bridge note	—	—	596	—	3,333	—	3,333
Issuance of common stock for reverse recapitalization expenses	—	—	335	—	1,875	—	1,875
Issuance of common stock to Vallon stockholders in reverse recapitalization	—	—	4,930	—	(2,940)	—	(2,940)
Net loss	—	—	—	—	—	(13,037)	(13,037)
Balance, December 31, 2023	—	$ —	49,663	$ —	$ 31,792	$ (31,533)	$ 259

See accompanying notes to consolidated financial statements.

GRI Bio, Inc.

Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (13,037)	$ (3,217)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation expense	4	3
Amortization of debt discounts and issuance costs	2,104	217
Stock-based compensation expense	388	25
Loss on extinguishment of debt	—	325
Change in fair value of warrant liability	(182)	—
Reduction in operating lease right of use assets	53	47
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(547)	(35)
Accounts payable	2,159	897
Accrued expenses	125	696
Operating lease liabilities	(57)	(43)
Cash used in operating activities	(8,990)	(1,085)
Investing activities:		
Purchase of property and equipment	(8)	(3)
Cash used in investing activities	(8)	(3)
Financing activities:		
Advances from employees	190	35
Repayment of advances from employees	(195)	(30)
Proceeds from issuance of non-convertible promissory note	—	125
Repayment of non-convertible promissory note	—	(125)
Proceeds from issuance of convertible promissory note	—	125
Repayment of convertible promissory note	—	(125)
Proceeds from issuance of bridge promissory note	1,250	1,250
Proceeds from issuance of common stock in pre-closing financing	12,250	—
Proceeds from warrant exercise	12	—
Cash acquired in reverse recapitalization	941	—
Payment of reverse recapitalization costs	(2,984)	—
Payment of deferred stock issuance costs	(517)	(111)
Payment of debt issuance costs	(150)	(13)
Redemption of redeemable common stock	—	(124)
Cash provided by financing activities	10,797	1,007
Net increase (decrease) in cash and cash equivalents	1,799	(81)
Cash and cash equivalents at beginning of period	9	90
Cash and cash equivalents at end of period	$ 1,808	$ 9
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ —	$ 33
Supplemental disclosure or noncash activities:		
Issuance of stock for repayment of bridge loan	$ 3,333	$ —
Non-contingent beneficial conversion feature on convertible promissory note	$ —	$ 60
Restricted stock awards issued in satisfaction of accrued compensation	$ —	$ 417

Recognition of debt discount and additional paid-in-capital for warrants issued in connection with promissory notes	$	532	$	601
Conversion of promissory note	$	—	$	5,337
Net liabilities acquired in connection with reverse recapitalization	$	3,881	$	—
Debt and deferred stock issuance costs included in accounts payable and accrued expenses	$	226	$	340
Issuance of stock for payment of reverse recapitalization costs	$	1,875	$	—
Issuance of warrants for payment of stock issuance costs	$	18	$	—

See accompanying notes to consolidated financial statements

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.

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 lead product candidate, GRI-0621, is an oral inhibitor of type 1 Natural Killer T (iNKT) 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 Natural Killer T (NKT) cells and is being developed for the treatment of autoimmune disorders, with much of its preclinical work in Systemic Lupus Erythematosus (SLE) or lupus and multiple sclerosis (MS).

Reverse Merger with Vallon Pharmaceuticals, Inc.

On April 21, 2023, pursuant to the Agreement and Plan of Merger, dated as of December 13, 2022, as amended on February 17, 2023 (the Merger Agreement), by and among the Company, GRI Bio Operations, Inc., formerly known as GRI Bio, Inc. (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 Operations (the Merger), with GRI Operations surviving the Merger as a wholly owned subsidiary of the Company. In connection with the Merger, and immediately prior to the effective time of the Merger (the Effective Time), the Company effected a reverse stock split of its common stock at a ratio of 1 for 30 (the April 2023 Reverse Stock Split). 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 and together with the April 2023 Reverse Stock Split, the Reverse Stock Splits)). Unless otherwise noted, all references to share and per share amounts in these financial statements reflect the Reverse Stock Splits. Also, in connection with the closing of the Merger (the Closing), the Company changed its name from "Vallon Pharmaceuticals, Inc." to "GRI Bio, Inc."

Basis of Presentation

As discussed in Note 4, the Merger was accounted for as reverse recapitalization under which the historical financial statements of the Company prior to the Merger are the historical financial statements of the accounting acquirer, GRI Operations. All common stock, per share and related information presented in the consolidated financial statements and notes prior to the Merger has been retroactively adjusted to reflect the Exchange Ratio (as defined below) and Reverse Stock Splits for all periods presented, to the extent applicable.

Reverse Stock Splits

On April 21, 2023, in connection with the Merger, and immediately prior to the Effective Time, the Company effected the April 2023 Reverse Stock Split. On January 30, 2024, the Company effected the January 2024 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 1 for 30 reverse stock split and the one-for-seven reverse stock split for all periods presented.

2. LIQUIDITY

These 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 $ 31,533 in accumulated deficit through December 31, 2023. The Company has financed its working capital requirements to date through the issuance of equity and debt securities. As of December 31, 2023, the Company had cash of approximately $1,808.

In connection with signing the Merger Agreement, the Company, GRI Operations and Altium Growth Fund, LP (Altium) entered into a Securities Purchase Agreement, dated December 13, 2022 (the Equity SPA), pursuant to which Altium agreed to invest $12,250 in cash and cancel any outstanding principal and accrued interest on the Bridge Notes (as defined below) in return for the issuance of shares of GRI Operations common stock immediately prior to the consummation of the Merger. Pursuant to the Equity SPA, immediately prior to the Closing, GRI Operations issued 74,584 shares of GRI Operations common stock (the Initial Shares) to Altium and 298,339 shares of GRI Operations common stock (the Additional Shares) into escrow with an escrow agent for net proceeds of $11,704, after deducting offering expenses of $ 546.

At the closing, pursuant to the Merger, the Initial Shares converted into an aggregate of 2,789 shares of the Company's Common Stock, par value $0.0001 per share (Common Stock) and the Additional Shares converted into an aggregate of 11,157 shares of the Common Stock. On May 8, 2023, in accordance with the terms of the Equity SPA, the Company and Altium authorized the escrow agent to, subject to beneficial ownership limitations, disburse to Altium all of the shares of the Common Stock issued in exchange for the Additional Shares.

On February 1, 2024, the Company entered into a securities purchase agreement (the Purchase Agreement), pursuant to which the Company agreed to issue and sell, in a public offering (the Offering), (i) 25,419 shares (the Shares) of Common Stock, (ii) 359,196 pre-funded warrants (the Pre-Funded Warrants) exercisable for an aggregate of 359,196 shares of Common Stock, (iii) 384,615 Series B-1 common warrants (the Series B-1 Common Warrants) exercisable for an aggregate of 384,615 shares of Common Stock, and (iv) 384,615 Series B-2 common warrants (the Series B-2 Common Warrants, and together with the Series B-1 Common Warrants, the Common Warrants) exercisable for an aggregate of 384,615 shares of Common Stock for gross proceeds of $5,500. The Common Warrants together with the Pre-Funded Warrants are referred to in this Annual Report on Form 10-K for the year ended December 31, 2023 (Annual Report) as the "Warrants." The securities were offered in combinations of (a) one Share or one 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 $ 14.30 (less $0.0013 for each Pre-Funded Warrant).

Subject to certain ownership limitations, the Warrants are exercisable upon issuance. Each Pre-Funded Warrant is exercisable for one share of Common Stock at a price per share of $0.0013 and does not expire. Each Series B-1 Common Warrant is exercisable into one share of Common Stock at a price per share of $14.30 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 $14.30 for an 18-month period after February 6, 2024 the date of issuance. In connection with the issuance of the securities pursuant to the 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.

Based on the Company's current operating plan, the Company believes that its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements into the second half of 2024.

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 Series T Warrants issued in connection with the Merger are not presently subject to forced exercise by the Company as the equity conditions for their forced exercise, which include (among other things) a requirement that shares of the Common Stock have a value weighted average price of at least $838.11 per share for the periods specified in the Series T Warrants, are not met. The Company intends to raise capital through additional issuances of equity securities and/or short-term or long-term debt arrangements, 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, the embedded derivative of convertible notes, warrant issuance and subsequent revaluations, valuation allowances relating to deferred tax assets, revenue recognition, accrued expenses and estimation of the incremental borrowing rate for the finance lease. If actual results differ from the Company’s estimates, or to the extent these estimates are adjusted in future periods, the Company’s results of operations could either benefit from, or be adversely affected by, any such change in estimate.

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, 2023 and 2022 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 $1,224 at December 31, 2023. The Company’s cash balance as of December 31, 2022 was fully insured.

Fair Value Measurements

The Company follows ASC 820, *Fair Value Measurements and Disclosures* (ASC 820), to measure the fair value of its financial statements and disclosures about fair value of its financial instruments. ASC 820 establishes a framework for measuring fair value in GAAP, and expands disclosures about 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 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, 2023, 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 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, 2023, 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 in connection with a securities purchase agreement. Vallon evaluated the 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 warrants related to the reduction of the exercise price in certain circumstances precludes the warrants from being accounted for as components of equity. As a result, the warrants are recorded as a liability on the balance sheet. Vallon recorded the fair value of the warrants upon issuance using a Black-Scholes valuation model.

The Company is required to revalue the warrants at each reporting date with any changes in fair value recorded in its statement of operations. The valuation of the 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 warrants liabilities is reflected in the statement of operations for the year ended December 31, 2023.

Deferred Stock Issuance Costs

Deferred stock issuance costs represent incremental legal 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.

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. Leases may be classified as finance leases or operating leases. 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.

The Company classifies a lease as a finance lease when one or more of the following criteria are met: (i) the lease transfers ownership of the underlying asset to the Company by the end of the lease term, (ii) the lease grants an option to purchase the underlying asset that the Company is reasonably certain to exercise, (iii) the lease term is for the major part of the remaining useful life of the underlying asset, (iv) the present value of the sum of the lease payments equals or exceeds substantially all of the fair value of the underlying asset, or (v) the underlying asset is of such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term. The Company did not have any finance leases as of December 31, 2023 and 2022. A lease that does not meet any of these criteria is classified as an operating lease.

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 (i.e., a period of time not included in the original lease agreement) 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.

Debt Discounts

The relative fair values of warrants and common shares issued and call option rights assigned in connection with principal advances under promissory notes, the increases in fair values of embedded conversion options in connection with convertible promissory note modifications, and the intrinsic values of non-contingent beneficial conversion features were recorded as debt discounts that are amortized as additional interest expense over the estimated terms of the notes using the effective interest method.

Debt Issuance Costs

Debt issuance costs represent incremental legal costs and other costs incurred that are directly attributable to issuing debt. The costs are included as a direct reduction of the carrying amount of the respective liability and are amortized as additional interest expense over the estimated term of the debt using the effective interest method.

Warrant Liability

The Company evaluated the warrants issued in connection with the May 2022 registered direct financing (Note 10) 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 warrants related to the reduction of the exercise price in certain circumstances precludes the warrants from being accounted for as components of equity. As the warrants meet the definition of a derivative as contemplated in ASC 815, the warrants are recorded as derivative liabilities on the accompanying consolidated balance sheets and measured at fair value at inception and at each reporting date in accordance with ASC 820, Fair Value Measurement, with changes in fair value recognized in the accompanying consolidated statements of operations in the period of change. The derivative liabilities will ultimately be converted into the Common Stock when the warrants are exercised, or will be extinguished upon expiry of the warrant term. Upon exercise, the intrinsic value of the shares issued is transferred to stockholders' equity. The difference between the intrinsic value of the stock issued and the fair value of the warrant is recorded as gain or loss on the exchange in the accompanying consolidated statements of operations in the period of exercise.

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. In considering the fair value of the underlying stock when the Company granted options, the Company considered several factors including the fair values established by market transactions. Stock option-based compensation includes estimates and judgments of when stock options might be exercised and stock price volatility. The timing of option exercises is out of the Company's control and depends upon a number of factors including the Company's market value and the financial objectives of the option holders. These estimates can have a material impact on the stock compensation expense but will have no impact on the cash flows. The estimation of share-based awards that will ultimately vest requires judgment, and to the extent

actual results or updated estimates differ from original estimates, such amounts are recorded as a cumulative adjustment in the period the estimates are revised. The Company uses the expected term, rather than the contractual term, for both employee and consultant options issued.

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, 2023 and 2022, the Company concluded 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 based on the weighted average number of shares of common stock outstanding during each year. Diluted net loss per common share is computed based on the weighted average number of shares of common stock outstanding during each year, plus the dilutive effect of options considered to be outstanding during each year, in accordance with ASC 260, *Earnings Per Share*. As the Company had a net loss in each of the years ended December 31, 2023 and 2022, 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,	
	2023	**2022**
Stock options	2,511	983
Warrants	1,767	626
Restricted stock with repurchase rights	—	1,808
	4,278	3,417

Recent 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 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.

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. 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.

On January 1, 2022, the Company adopted ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)* (ASU 2020-06). ASU 2020-06 address issues identified as a result of the complexity associated with applying GAAP for certain financial instruments with characteristics of liabilities and equity.The amendments focused on amending the guidance on convertible instruments and the guidance on the derivatives scope exception for contracts in an entity's own equity. The adoption of this standard did not have a material impact on the Company's financial statements.

4. MERGER WITH VALLON

On April 21, 2023, pursuant to the Merger Agreement, Merger Sub was merged with and into Private GRI, with Private GRI surviving the Merger as a wholly owned subsidiary of the Company. In connection with the Closing, the Company amended its certificate of incorporation and bylaws to change its name from "Vallon Pharmaceuticals, Inc." to "GRI Bio, Inc."

At the Effective Time:

(1) Each share of GRI Operations Common Stock (GRI Operations Common Stock) outstanding immediately prior to the Effective Time, including any shares of GRI Operations Common Stock issued pursuant to the Equity Financing (as defined below) automatically converted solely into the right to receive a number of shares of the Company's common stock equal to 0.0374 (the Exchange Ratio).

(2) Each option to purchase shares of GRI Operations Common Stock (each, a GRI Operations Option) outstanding and unexercised immediately prior to the Effective Time under the (the GRI Operations Plan, whether or not vested, converted into and became an option to purchase shares of Common Stock, and the Company assumed the GRI Operations Plan and each such GRI Operations Option in accordance with the terms of the GRI Operations Plan (the Assumed Options). The number of shares of Common Stock subject to each Assumed Option was determined by multiplying (i) the number of shares of GRI Operations Common Stock that were subject to such GRI Operations Option, as in effect immediately prior to the Effective Time, by (ii) the Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of Common Stock. The per share exercise price for the Common Stock issuable upon exercise of each Assumed Option was determined by dividing (A) the per share exercise price of such Assumed Option, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio and rounding the resulting per share exercise price up to the nearest whole cent. Any restriction on the exercise of any Assumed Option continued in full force and effect and the term, exercisability, vesting schedule and any other provisions of such Assumed Option otherwise remained unchanged.

(3) Each warrant to purchase shares of GRI Operations Common Stock (the GRI Operations Warrants) outstanding immediately prior to the Effective Time was assumed by the Company and converted into a warrant to purchase Common Stock (the Assumed Warrants) and thereafter (i) each Assumed Warrant became exercisable solely for shares of Common Stock; (ii) the number of shares of Common Stock subject to each Assumed Warrant was determined by multiplying (A) the number of shares of GRI Operations Common Stock that were subject to such GRI Operations Warrant, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of Common Stock; (iii) the per share exercise price for the Common Stock issuable upon exercise of each Assumed Warrant was determined by dividing (A) the exercise price per share of the GRI Operations Common Stock subject to such GRI Operations Warrant, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio, and rounding the resulting exercise price up to the nearest whole cent.

(4) The Bridge Warrants (Note 9) were exchanged for warrants (the Exchange Warrants) to purchase an aggregate of 4,632 shares of the Company's common stock. The Exchange Warrants contain substantively similar terms to the Bridge Warrants, and have an initial exercise price equal to $1,340.43 per share. The Exchange warrants have been fully exercised on a cashless basis.

(5) All rights with respect to GRI Operations restricted stock awards were assumed by the Company and converted into Company restricted stock awards with the number of shares subject to each restricted stock

award multiplied by the Exchange Ratio and rounding the resulting number down to the nearest whole number of shares of the Company's common stock. The term, exercisability, vesting schedule and other provisions of the GRI Operations restricted stock awards otherwise remained unchanged.

The Merger is accounted for as a reverse recapitalization under GAAP because the primary assets of Vallon were cash and cash equivalents. For accounting purposes, GRI Operations has been determined to be the accounting acquirer based upon the terms of the Merger and other factors including: (i) the equity holders of GRI Operations immediately prior to the Merger owned, or held rights to acquire, in the aggregate approximately 85% of the outstanding shares of the Company's common stock and the Company's stockholders immediately prior to the Merger owned approximately 15% of the outstanding shares of the Company's common stock (ii) GRI Operations holds the majority (4 out of 5) of board seats of the combined company, and (iii) GRI Operations management holds the majority of key positions in the management of the combined company. Immediately after the Merger, there were 32,487 shares of the Company's common stock outstanding.

The following table shows the net liabilities assumed in the Merger:

	April 21, 2023
Cash and cash equivalents	$ 941
Prepaid and other assets	310
Accounts payable and accrued expenses	(4,190)
Total net liabilities assumed	(2,939)
Plus: Transaction costs	(2,984)
Total net liabilities assumed plus transaction costs	$ (5,923)

In addition to the transaction costs noted above, at the Effective Time, 335 shares of the Common Stock were issued to GRI Operations' financial advisor for services related to the Merger.

5. FAIR VALUE MEASUREMENTS

The Company applies the guidance in ASC 820 to account for financial assets and liabilities measured on a recurring basis. Fair value is measured as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that is determined based on assumptions that market participants would use in pricing an asset or liability.

The Company uses a fair value hierarchy, which distinguishes between assumptions based on market data (observable inputs) and an entity's own assumptions (unobservable inputs). The guidance requires that fair value measurements be classified and disclosed in one of the following 3 categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liabilities.

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

Determining which category an asset or liability falls within the hierarchy requires significant judgment. The Company evaluates its hierarchy disclosures each reporting period. There were no transfers between Level 1, 2 and 3 during the year ended December 31, 2023.

The following table presents, for each of the fair value hierarchy levels required under ASC 820, the Company's liabilities that are measured at fair value on a recurring basis as of December 31, 2023:

	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Liabilities:			
Warrant liability	$ —	$ —	$ 3

As of December 31, 2022, the Company had no assets or liabilities measured at fair value on a recurring basis.

The following table presents the changes is the fair value of the Level 3 liability:

	Warrant Liability
Fair value as of December 31, 2022	$ —
Fair value at April 21, 2023 (date of Merger)	185
Change in valuation	(182)
Balance as of December 31, 2023	$ 3

The Black-Scholes valuation model was used to estimate the fair value of the warrants with the following assumptions:

	December 31, 2023
Volatility	171.0 %
Expected term in years	2.5
Dividend rate	0.0 %
Risk-free interest rate	4.12 %

6. PROPERTY AND EQUIPMENT

	December 31,	
	2023	2022
Computer equipment	$ 21	$ 13
Furniture and fixtures	13	13
	34	26
Accumulated depreciation	(26)	(22)
	$ 8	$ 4

Depreciation expense related to property and equipment was $ 4 and $3 for the years ended December 31, 2023 and 2022, respectively.

7. 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:

	Balance Sheet Line Item	December 31, 2023	December 31, 2022
Non-current operating lease assets	Other assets	$ 14	$ 67
Operating lease liabilities:			
Current operating lease liabilities	Other current liabilities	14	57
Non-current operating lease liabilities	Other liabilities	—	14
Total operating lease liabilities		$ 14	$ 71

Future minimum lease payments are due as follows:

	December 31, 2023
2024	14
Total	14
Less: Imputed interest	—
Present value of operating lease liabilities	$ 14

Operating lease costs were $59 for each of the years ended December 31, 2023 and 2022, 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 $ 65 and $54 for the years ended December 31, 2023 and 2022, respectively. This amount is included in operating activities in the consolidated statements of cash flows.

8. ACCRUED EXPENSES

Accrued expenses consisted of:

	December 31, 2023	December 31, 2022
Accrued expenses:		
Research and development	$ 93	$ —
General and administrative	441	—
Payroll and related	736	33
Other	—	3
Total accrued expenses	$ 1,270	$ 36

9. PROMISSORY NOTES

Bridge Financing

In connection with signing the Merger Agreement, GRI Operations entered into a Securities Purchase Agreement, dated as of December 13, 2022 (Bridge SPA), with Altium, pursuant to which GRI Operations issued senior secured promissory notes (Bridge Notes) in the aggregate principal amount of $3,333, in exchange for an aggregate purchase price of $2,500.

The Bridge Notes were issued in two closings: (i) the first closing for $ 1,667 in aggregate principal amount (in exchange for an aggregate purchase price of $1,250) closed on December 14, 2022; and (ii) the second closing for

$1,667 in aggregate principal amount (in exchange for an aggregate purchase price of $1,250) closed on March 9, 2023. The Bridge Notes were secured by a lien on all of the Company's assets.

In addition, upon the funding of each tranche, Altium received warrants to purchase an aggregate of 13,763 shares of the Common Stock (the Bridge Warrants). The Bridge Warrants had an exercise price of $121.03 per share, were exercisable at any time on or after the applicable issuance date and had a term of 60 months from the date all shares underlying the Bridge Warrants were freely tradable.

The $1,250 of proceeds from the first closing were allocated to the Bridge Notes and Bridge Warrants based on their relative fair values as of the commitment date, resulting in an allocation of $679 and $571, respectively. The $1,250 of proceeds from the second closing were allocated to the Bridge Notes and Bridge Warrants based on their relative fair values as of the commitment date, resulting in an allocation of $718 and $532, respectively.

In addition to the Bridge SPA, and also in connection with signing the Merger Agreement, the Company, GRI Operations and Altium entered into the Equity SPA (Note 10) pursuant to which Altium agreed to invest $12,250 in cash and cancel any outstanding principal and accrued interest on the Bridge Notes in return for the issuance of shares of GRI Operations' common stock immediately prior to the consummation of the Merger.

On April 21, 2023, the Company completed the Merger and the outstanding principal and accrued interest on the Bridge Notes was cancelled and the Bridge Warrants were exchanged for the Exchange Warrants. The Exchange Warrants contain substantively similar terms to the Bridge Warrants, and have an initial exercise price equal to $1,340.43 per share subject to adjustments for splits and recapitalization events.

The Bridge Notes were accounted for as share-settled debt under the accounting guidance in ASC 835-30 and, as such, the initial net carrying amounts were accreted to the redemption amounts using the effective interest method. The Company incurred debt issuance costs of $205 during the year ended December 31, 2022 and $90 during the year ended December 31, 2023 related to its issuance of debt under the Bridge SPA. Unamortized debt discounts and debt issuance costs totaled $1,065 as of December 31, 2022. Interest expense stemming from amortization of debt discounts and issuance costs was $2,104 for the year ended December 31, 2023.

TEP Note

In November 2018, GRI Operations and TEP Biotech, LLC (TEP) entered into a convertible note and warrant purchase agreement pursuant to which TEP agreed to fund up to $5,000 to GRI Operations in exchange for a convertible promissory note (the TEP Note) and a warrant to purchase up to 277 shares of GRI Operations' common stock at an exercise price of $0.01 per share. The TEP Note was secured by GRI Operations' assets and accrued simple interest on the outstanding principal balance at a rate of 12% per annum. The total outstanding principal and accrued interest balance was initially due on the earlier of GRI Operations' next financing, as defined, and May 2, 2020. The initial $2,500 tranche under the TEP Note was funded upon execution of the agreement in November 2018.

In December 2019, GRI Operations and TEP amended the TEP Note. In lieu of TEP funding the second $ 2,500 tranche, TEP made a first additional advance of $500 to GRI Operations in exchange for a convertible promissory note, a warrant to purchase up to 189 shares of GRI Operations' common stock at an exercise price of $0.01 per share, and the assignment of GRI Operations' rights under a certain call option agreement. The call option agreement, which was entered into in 2015, provided GRI Operations' with the right to repurchase up to 436 shares of GRI Operations' common stock held by the counterparty for $2,433.34 per share at any time before April 1, 2025.

In July 2020, the TEP Note maturity date was extended to August 31, 2020, and in March 2021, TEP agreed to forbear on its available right to exercise remedies on account of GRI Operations' failure to pay the past due principal and accrued interest balance until October 31, 2021.

In May 2021, GRI Operations and TEP amended the TEP Note, and TEP agreed to make a second additional advance of $ 500 to GRI Operations in exchange for a convertible promissory note with separate, modified conversion options.

In July 2022, GRI Operations and TEP further amended the TEP Note, and TEP agreed to make a third additional advance of $ 125 to GRI Operations in exchange for a convertible promissory note and a warrant to purchase up to 12 shares of GRI Operations' common stock at an exercise price of $0.01 per share.

In October 2022, GRI Operations and TEP entered into a conversion agreement pursuant to which, effective upon the full execution of the Merger Agreement (Note 4), $3,500 of outstanding principal under the TEP Note together with $ 650 of related accrued interest was to automatically convert into 1,705 shares of GRI Operations' common stock at a conversion price of $ 2,433.34 per share. Further, upon the closing of the first tranche of the Bridge Notes, GRI Operations was to repay, in cash, the $125 third additional advance under the TEP Note along with the $ 15 of related accrued interest. Upon issuance of the 1,705 conversion shares and payment of the $ 140 principal and accrued interest balance, GRI Operations would fully satisfy all of its obligations under the TEP Note.

In December 2022, upon the full execution of the Merger Agreement and the closing of the first tranche of the Bridge Notes GRI Operations issued the 1,705 conversion shares and paid the $ 140 principal and accrued interest balance as per the terms of the conversion agreement. The share numbers and exercise or conversion prices in this section of Note 9 entitled "TEP Note" reflect the Exchange Ratio retroactively.

As part of the conversion, the $4,150 of converted principal and accrued interest, along with $ 863 of related forfeited accrued interest through the conversion date, were credited to stockholders' deficit. Interest expense recognized on the TEP Note was $352 for the year ended December 31, 2022.

10. STOCKHOLDERS EQUITY (DEFICIT)

Common Stock

In connection with signing the Merger Agreement, the Company, GRI Operations and Altium entered the Equity SPA pursuant to which Altium agreed to invest $12,250 in cash and cancel any outstanding principal and accrued interest on the Bridge Notes in return for the issuance of shares of GRI Operations' common stock immediately prior to the consummation of the Merger. Pursuant to the Equity SPA, immediately prior to the Closing, GRI Operations issued 74,584 shares of GRI Operations' common stock (the Initial Shares) to Altium and 298,339 shares of GRI Operations' common stock (the Additional Shares) into escrow with an escrow agent for net proceeds of $11,704, after deducting offering expenses of $ 546.

At the closing, pursuant to the Merger, the Initial Shares converted into an aggregate of 2,789 shares of the Common Stock and the Additional Shares converted into an aggregate of 11,157 shares of the Common Stock. On May 8, 2023, in accordance with the terms of the Equity SPA, the Company and Altium authorized the escrow agent to, subject to beneficial ownership limitations, disburse to Altium all of the shares of the Common Stock issued in exchange for the Additional Shares.

Redeemable Common Stock

In November 2018, GRI Operations entered into an agreement with a stockholder pursuant to which the stockholder had the right to require GRI Operations to purchase all or a portion of 85 shares of GRI Operations' common stock held by the stockholder for $ 1,445.08 per share (the Put Right). The Put Right was exercisable (i) for a period commencing thirty days prior to the day Private GRI completed an equity or debt financing and ending fifteen business days thereafter, or (ii) at any time following a breach of the agreement by Private GRI.

In December 2022, the stockholder exercised the Put Right and GRI Operations redeemed the 85 shares of GRI Operations' common stock for $ 124 ($1,445.08 per share). The redeemed shares were retired by GRI Operations. The share numbers and exercise or conversion prices in this section of Note 10 entitled "Redeemable Common Stock" reflect the Exchange Ratio retroactively.

Common Stock Warrants

Pursuant to the Equity SPA, on May 8, 2023, the Company issued to Altium (i) Series A-1 Warrants to purchase 13,947 shares of the Common Stock at an exercise price of $1,229.41, (ii) Series A-2 Warrants to purchase 12,552 shares of the Common Stock at an exercise price of $ 1,341.34 , and (iii) Series T Warrants to purchase (x) 8,950

shares of the Common Stock at an exercise price of $ 1,117.48 and (y) upon exercise of the Series T Warrants, 8,950 additional Series A-1 Warrants and Series A-2 Warrants, each to purchase 8,950 shares of the Common Stock at an exercise price of $ 1,229.41 and $1,341.34, respectively (collectively, the Equity Warrants).

The Series A-1 Warrants have a term of 60 months from the date all shares underlying the Series A-1 Warrants are freely tradable. The A-2 warrants have a 2-year term and expire in June 2025. Series T Warrants have a term of 24 months from the date all shares underlying Series T Warrants are freely tradable. As noted in Note 2. *Liquidity*, the Company may force the exercise of the Series T Warrants subject to the satisfaction of certain equity conditions. The Equity Warrants include certain contingent cashless exercise features and contain certain other rights with regard to asset distributions and fundamental transactions. The exercise price of the Series A-1 Warrants is subject to adjustment for certain dilutive issuances, and all of the Equity Warrants are subject to standard antidilution adjustments. As of December 31, 2023, all of the A-2 Warrants had been exercised and all of the A-1 Warrants and T Warrants were outstanding. The Equity Warrants were classified as equity and the allocated fair value of $5,675 is included in additional paid in capital.

Pursuant to the Bridge SPA, upon the funding of each tranche of the Bridge Note, Altium received the Bridge Warrants. The Bridge Warrants had an exercise price of $121.03 per share, were exercisable at any time on or after the applicable issuance date and had a term of 60 months from the date all shares underlying the Bridge Warrants are freely tradable. Upon the completion of the Merger the Bridge Warrants were exchanged for the Exchange Warrants to purchase an aggregate of 4,632 shares of the Common Stock. The Exchange Warrants contain substantively similar terms to the Bridge Warrants, and have an initial exercise price equal to $1,340.43 per share subject to adjustments for splits and recapitalization events. All of the Bridge Warrants had been exercised as of December 31, 2023. The Bridge Warrants were classified as equity and the allocated fair value of $2,860 is included in additional paid in capital.

In connection with the Closing, GRI Operations granted its financial advisor warrants (the Advisor Warrants) to purchase shares of GRI Operations' common stock, which, at the Effective Time, became exercisable for an aggregate of 26 shares of the Common Stock at an exercise price of $ 5,586.49 per share. The Advisor Warrants have a five-year term. All of the Advisor Warrants were outstanding as of December 31, 2023. The Advisor Warrants were classified as equity and the fair value of $18 is included in additional paid in capital.

The Black-Scholes option-pricing model was used to estimate the fair value of the Equity Warrants, the Exchange Warrants and the Advisor Warrants with the following weighted-average assumptions:

Volatility	167.6 %
Expected term in years	1.69
Dividend rate	0.0 %
Risk-free interest rate	4.37 %

In May 2022, Vallon issued warrants to purchase an aggregate of 1,355 shares of common stock at an exercise price of $ 2,561.65 per share in connection with a securities purchase agreement. The warrants have a five-year term. The warrants were classified as a liability and are revalued at each balance sheet date. The fair value of $3 as of December 31, 2023 is reflected in warrant liability on the accompanying consolidated balance sheets (Note 5).

In connection with Vallon’s initial public offering in February 2021, Vallon granted the underwriters warrants (the Underwriters' Warrants) to purchase an aggregate of 42 shares of common stock at an exercise price of 27,300.00 per share. The Underwriters’ Warrants have a five-year term.

As of December 31, 2023, the Company had the following warrants outstanding to purchase common stock.

Number of Shares	Exercise Price per Share	Expiration Date
8,950	$1,117.48	December 2025
42	$27,300.00	February 2026
271	$2,561.65	May 2027
13	$0.01	July 2027
26	$5,586.49	April 2028
13,947	$1,229.41	December 2028

11. STOCK-BASED COMPENSATION

2015 Equity Incentive Plan

GRI Operations adopted the GRI Bio, Inc. 2015 Equity Incentive Plan, as amended (the GRI Operations Plan), that provided GRI Operations with the ability to grant stock options, restricted stock awards and other equity-based awards to employees, directors, and consultants. Stock options granted under the GRI Operations Plan generally had a contractual life of up to 10 years. Upon completion of the Merger, the Company assumed the GRI Operations Plan and 982 outstanding and unexercised options issued thereunder, and ceased granting awards under the GRI Operations Plan.

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, formerly the Vallon Pharmaceuticals, Inc. 2018 Equity Incentive Plan (the A&R 2018 Plan). The A&R 2018 Plan had previously been approved by the Company's Board, subject to stockholder approval. The A&R 2018 Plan became effective on April 21, 2023, with the stockholders approving the amendment to the A&R 2018 Plan to, among other things, (i) to increase the aggregate number of shares by 1,856 shares to 2,381 shares of the Common Stock for issuance as awards under the A&R 2018 Plan, (ii) to extend the term of the A&R 2018 Plan through January 1, 2033, (iii) to prohibit any action that would be treated as a "repricing" of an award without further approval by the stockholders of Company, and (iv) to revise the limits on awards to non-employee directors.

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, 2023, awards granted under the A&R 2018 Plan representing the right to purchase or contingent right to receive up to an aggregate of 2,503 shares of the Common Stock were outstanding and 2,381 shares of the 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, 2024 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 Common Stock outstanding on the final day of the immediately preceding calendar year.

The Company recorded stock-based compensation related to stock options issued under the GRI Operations Plan and A&R 2018 Plan in the following expense categories of its accompanying statements of operations for the years ended December 31, 2023 and 2022:

	For the Year Ended December 31,	
	2023	2022
Research and development	$ —	$ —
General and administrative	388	25
Total	$ 388	$ 25

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, which is the vesting period for certain performance-based awards. The Company records expense for performance-based awards if it 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, 2023:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at December 31, 2022	1,232	$ 3,593.85	4.71
Granted	2,427	$ 216.56	
Exercised	—	—	
Forfeited	(1,156)	$ 3,263.98	
Outstanding at December 31, 2023	2,503	$ 471.45	9.55
Exercisable at December 31, 2023	328	$ 2,198.07	8.81
Vested and expected to vest at December 31, 2023	2,503	$ 471.45	9.55

As of December 31, 2023, all of the outstanding and exercisable stock options were out of the money and therefore had no intrinsic value. At December 31, 2023, the unrecognized compensation cost related to unvested stock options expected to vest was $424. This unrecognized compensation is expected to be recognized over a weighted-average amortization period of 2.9 years.

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,	
	2023	2022
Volatility	129.54 %	90.39 %
Expected term in years	5.84	5.98
Dividend rate	0.00 %	0.00 %
Risk-free interest rate	4.34 %	2.00 %
Fair value of common stock on grant date	$ 193.90	$ 351.26

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.

12. ASSET PURCHASE AGREEMENT

On August 22, 2023, the Company entered into Asset Purchase Agreement (the Aardvark Agreement) with Aardvark Therapeutics, Inc. (Aardvark), pursuant to which Aardvark agreed to purchase (i) the Company's license agreement with Medice Arzneimittel Pűtter GmbH & Co. KG, dated January 6, 2020, (ii) certain patents related to the Company's ADAIR product candidate, and (iii) files (of contract manufacturing and FDA correspondence) for a formulation described in IND No. 133072, ADAIR for the Treatment of ADHD and Narcolepsy, filed with the United States Food and Drug Administration. Under the terms of the Aardvark Agreement, the Company received an upfront cash payment of $250, which was recognized as other income. The Company is also eligible to receive potential additional milestone payments contingent upon Aardvark achieving certain future ADAIR regulatory and sales milestones. Other than the upfront payment, the Company does not anticipate the receipt of any milestone payments from Aardvark in the near term, which potential milestone payments may or may not be achieved, paid or received in the future.

13. COMMITMENTS AND CONTINGENCIES

Employment Agreements

The Company has entered into employment contracts with 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.

14. 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,	
	2023	2022
Expected income tax benefit at the federal statutory rate	21.0 %	21.0 %
State and local taxes, net of federal benefit	8.4	7.7
Non-deductible items and other	(12.1)	(11.0)
Research and development credits	1.1	—
Change in valuation allowance	(18.4)	(17.7)
Total	— %	— %

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,	
	2023	2022
Deferred tax assets:		
Federal and state net operating loss carryforwards	$ 12,848	$ 3,211
Share based compensation	166	177
Accruals and other	255	16
Lease liabilities	—	20
Capitalized research and development costs	1,099	91
Research and development tax credits	153	—
Gross deferred tax assets	14,521	3,515
Less: deferred tax liabilities	—	(19)
Less: valuation allowance	(14,521)	(3,496)
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, 2023 and 2022. The Company increased its valuation allowance by approximately $11,025 for the year ended December 31, 2023. The Company intends to maintain a valuation allowance until sufficient positive evidence exists to support a reversal of the allowance.

As of December 31, 2023, the Company had federal, state and local net operating loss carryforwards of $ 45,185, $29,552, and $17,772, respectively; $39,061 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 begin to expire in 2024. As of December 31, 2023, the Company had federal and state research and development tax credit carryforwards of $136 and $17, respectively. The federal credit carryforwards begin to expire in 2043, the state credit carryforwards do not expire. 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 files income tax returns in the US federal jurisdiction as well as California, Pennsylvania and Philadelphia. The tax years 2020 to 2023 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, 2023 and 2022, 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.

15. SUBSEQUENT EVENTS

Recapitalization

On January 30, 2024, the Company effected the January 2024 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-seven reverse stock split for all periods presented.

Securities Purchase Agreement

On February 1, 2024, the Company entered into the Purchase Agreement, pursuant to which the Company agreed to issue and sell, in the Offering, (i) 25,419 Shares of the Common Stock, (ii) 359,196 Pre-Funded Warrants exercisable for an aggregate of 359,196 shares of Common Stock, (iii) 384,615 Series B-1 Common Warrants exercisable for an aggregate of 384,615 shares of Common Stock, and (iv) 384,615 Series B-2 Common Warrants exercisable for an aggregate of 384,615 shares of Common Stock for gross proceeds of $ 5,500. The securities are being offered in combinations of (a) one Share or one 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 $14.30 (less $0.0013 for each Pre-Funded Warrant).

Subject to certain ownership limitations, the Warrants were exercisable upon issuance. Each Pre-Funded Warrant is exercisable for one Share of Common Stock at a price per share of $0.0013 and does not expire. Each Series B-1 Common Warrant is exercisable into one Share of Common Stock at a price per share of $14.30 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 $ 14.30 for an 18-month period after February 6, 2024, the date of issuance. In connection with the issuance of the securities pursuant to the 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.

On June 17, 2024, the Company effected a one-for-thirteen reverses stock split (the June 2024 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 June 2024 Reverse Stock Split.

GRI Bio, Inc.

Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	March 31, 2024	December 31, 2023
Assets	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 4,091	$ 1,808
Prepaid expenses and other current assets	337	1,126
Total current assets	4,428	2,934
Property and equipment, net	7	8
Operating lease right-of-use assets	152	14
Total assets	$ 4,587	$ 2,956
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 637	$ 1,410
Accrued expenses	999	1,270
Warrant liability	1	3
Operating lease liabilities, current	43	14
Total current liabilities	1,680	2,697
Operating lease liabilities, non-current	109	—
Total liabilities	1,789	2,697
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock, $0.0001 par value; 250,000,000 shares authorized as of March 31, 2024 and December 31, 2023; 245,875 and 49,663 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	—	—
Additional paid-in-capital	36,218	31,792
Accumulated deficit	(33,420)	(31,533)
Total stockholders' equity	2,798	259
Total liabilities and stockholders' equity	$ 4,587	$ 2,956

See accompanying notes to unaudited interim consolidated financial statements.

GRI Bio, Inc.

Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2024	**2023**
Operating expenses:		
Research and development	933	116
General and administrative	962	872
Total operating expenses	1,895	988
Loss from operations	(1,895)	(988)
Change in fair value of warrant liability	2	—
Interest income (expense), net	6	(1,162)
Net loss	$ (1,887)	$ (2,150)
Net loss per share of common stock, basic and diluted	$ (5.94)	$ (15.04)
Weighted-average common shares outstanding, basic and diluted	317,474	142,988

See accompanying notes to unaudited interim consolidated financial statements.

GRI Bio, Inc.

Consolidated Statements of Changes in Stockholders' Equity (Deficit)
(in thousands, except shares)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Deficit
	Shares	Amount			
Balance, December 31, 2022	10,987	$ —	$ 16,871	$ (18,496)	$ (1,625)
Stock-based compensation	—	—	13	—	13
Restricted stock vesting	5	—	—	—	—
Warrant issuance	—	—	532	—	532
Net loss	—	—	—	(2,150)	(2,150)
Balance, March 31, 2023	10,992	$ —	$ 17,416	$ (20,646)	$ (3,230)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Equity
	Shares	Amount			
Balance, December 31, 2023	49,663	$ —	$ 31,792	$ (31,533)	$ 259
Stock-based compensation	—	—	37	—	37
Fractional share adjustment	(19)	—	—	—	—
Issuance of common stock and prefunded warrants in financing	25,419	—	4,389	—	4,389
Prefunded warrant exercise	170,812	—	—	—	—
Net loss	—	—	—	(1,887)	(1,887)
Balance, March 31, 2024	245,875	$ —	$ 36,218	$ (33,420)	$ 2,798

See accompanying notes to unaudited interim consolidated financial statements.

GRI Bio, Inc.

Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Operating activities:		
Net loss	$ (1,887)	$ (2,150)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation expense	1	1
Amortization of debt discounts and issuance costs	—	1,161
Stock-based compensation expense	37	13
Change in fair value of warrant liability	(2)	—
Reduction in operating lease right of use assets	14	12
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	564	28
Accounts payable	(744)	408
Accrued expenses	(172)	(36)
Operating lease liabilities	(14)	(16)
Cash used in operating activities	(2,203)	(579)
Financing activities:		
Advances from employees	—	190
Repayment of advances from employees	—	(195)
Proceeds from issuance of bridge promissory note	—	1,250
Proceeds from issuance of common stock and prefunded warrants	5,500	—
Payment of stock issuance costs	(1,014)	(110)
Payment of debt issuance costs	—	(105)
Cash provided by financing activities	4,486	1,030
Net increase in cash and cash equivalents	2,283	451
Cash and cash equivalents at beginning of period	1,808	9
Cash and cash equivalents at end of period	$ 4,091	$ 460
Supplemental disclosure of non-cash financing activities:		
Recognition of debt discount and additional paid-in-capital for issuance of warrants in connection with the issuance of promissory notes	$ —	$ 532
Recognition of right of use assets and lease liabilities	$ 152	$ —
Debt and stock issuance costs included in accounts payable	$ 97	$ 45
Property and equipment purchases included in accounts payable	$ —	$ 8

See accompanying notes to unaudited interim consolidated financial statements.

GRI Bio, Inc.

Notes to Unaudited Interim 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.

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 lead product candidate, GRI-0621, is an oral inhibitor of type 1 Natural Killer T (iNKT) 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 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 (SLE) or lupus and multiple sclerosis (MS).

Reverse Merger with Vallon Pharmaceuticals, Inc.

On April 21, 2023, pursuant to the Agreement and Plan of Merger, dated as of December 13, 2022, as amended on February 17, 2023 (the Merger Agreement), by and among the Company, GRI Bio Operations, Inc., formerly known as GRI Bio, Inc. (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 Operations (the Merger), with GRI Operations surviving the Merger as a wholly owned subsidiary of the Company (Note 4). In connection with the closing of the Merger (the Closing), the Company amended its certificate of incorporation and amended its bylaws to change its name from "Vallon Pharmaceuticals, Inc." to "GRI Bio, Inc."

Recapitalization

In connection with the Merger, and immediately prior to the effective time of the Merger (the Effective Time), the Company effected a reverse stock split of its common stock, par value $0.0001 (Common Stock), at a ratio of 1-for-30 (the April 2023 Reverse Stock Split). 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 and together with the April 2023 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.

Basis of Presentation

As discussed in Note 4, the Merger was accounted for as reverse recapitalization under which the historical financial statements of the Company prior to the Merger are the historical financial statements of the accounting acquirer, GRI Operations. All Common Stock, per share and related information presented in the consolidated financial statements and notes prior to the Merger has been retroactively adjusted to reflect the Exchange Ratio (as defined below) and the Reverse Stock Splits for all periods presented, to the extent applicable.

2. LIQUIDITY

These unaudited interim 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 $33,420 in accumulated deficit through March 31, 2024. The Company has financed its working capital requirements to date through the issuance of equity and debt securities. As of March 31, 2024, the Company had cash of approximately $4,091.

In connection with signing the Merger Agreement, the Company, GRI Operations and Altium Growth Fund, LP (Altium) entered into a Securities Purchase Agreement, dated December 13, 2022 (the Equity SPA), pursuant to which Altium agreed to invest $12,250 in cash and cancel any outstanding principal and accrued interest on the Bridge Notes (as defined below) in return for the issuance of shares of GRI Operations common stock (GRI Operations Common Stock) immediately prior to the consummation of the Merger. Pursuant to the Equity SPA, immediately prior to the Closing, GRI Operations issued 74,584 shares of GRI Operations Common Stock (the Initial Shares) to Altium and 298,339 shares of GRI Operations Common Stock (the Additional Shares) into escrow with an escrow agent for net proceeds of $11,704, after deducting offering expenses of $ 546.

At the Closing, pursuant to the Merger, the Initial Shares converted into an aggregate of 2,789 shares of the Company's Common Stock and the Additional Shares converted into an aggregate of 11,157 shares of the Company's Common Stock. On May 8, 2023, in accordance with the terms of the Equity SPA, the Company and Altium authorized the escrow agent to, subject to beneficial ownership limitations, disburse to Altium all of the shares of the Company's Common Stock issued in exchange for the Additional Shares.

On February 1, 2024, the Company entered into a securities purchase agreement (the Purchase Agreement), pursuant to which the Company agreed to issue and sell, in a public offering, (i) 25,419 shares (the Shares) of Common Stock, (ii) 359,196 pre-funded warrants (the Pre-Funded Warrants) exercisable for an aggregate of 359,196 shares of Common Stock, (iii) 384,615 Series B-1 common warrants (the Series B-1 Common Warrants) exercisable for an aggregate of 384,615 shares of Common Stock, and (iv) 384,615 Series B-2 common warrants (the Series B-2 Common Warrants, and together with the Series B-1 Common Warrants, the Common Warrants) exercisable for an aggregate of 384,615 shares of Common Stock for net proceeds of $4,389, after deducting offering expenses of $ 1,110. The Common Warrants together with the Pre-Funded Warrants are referred to as the "Warrants." The securities were offered in combinations of (a) one Share or one 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 $ 14.30 (less $0.0013 for each Pre-Funded Warrant).

Subject to certain ownership limitations, the Warrants became exercisable upon issuance. Each Pre-Funded Warrant is exercisable for one share of Common Stock at a price per share of $0.0013 and does not expire. Each Series B-1 Common Warrant is exercisable into one share of Common Stock at a price per share of $14.30 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 $14.30 for an 18-month period after February 6, 2024 the date of issuance. In connection with the issuance of the Shares and Warrants pursuant to the 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.

Based on the Company's current operating plan, the Company believes that its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements into the third quarter of 2024.

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 Series T Warrants issued in connection with the Merger are not presently subject to forced exercise by the Company as the equity conditions for their forced exercise, which include (among other things) a requirement that shares of Common Stock have a value weighted average price of at least $838.11 per share for the periods specified in the Series T Warrants, are not met. The Company intends to raise capital through additional issuances of equity securities and/or short-term or long-term debt arrangements, 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. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accompanying unaudited interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial periods and pursuant to the rules of the Securities and Exchange Commission (the SEC). Any reference in the accompanying unaudited interim financial statements to "authoritative guidance" is meant to refer to GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) of the Financial Accounting Standards Board (FASB). The December 31, 2023 balance sheet was derived from the Company's audited consolidated financial statements.

In the opinion of management, the unaudited interim consolidated financial statements furnished herein include all normal and recurring adjustments considered necessary to present fairly the Company's financial position as of March 31, 2024, and the consolidated results of operations and consolidated stockholders' equity for the three months ended March 31, 2024 and 2023 and consolidated cash flows for the three months ended March 31, 2024 and 2023. Consolidated results of operations for the three months ended March 31, 2024, are not necessarily indicative of the consolidated operating results that may be expected for the year ending December 31, 2024. The unaudited interim consolidated financial statements, presented herein, do not contain the required disclosures under GAAP for annual consolidated financial statements. The accompanying unaudited interim consolidated financial statements should be read in conjunction with the annual audited consolidated financial statements and related notes as of and for the year ended December 31, 2023, included in the Company's Annual Report on Form 10-K filed with the SEC on March 28, 2024.

Principles of Consolidation

The unaudited interim 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.

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 March 31, 2024, 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 balance sheets for cash, 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 March 31, 2024, 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 in connection with a securities purchase agreement. Vallon evaluated the 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 warrants related to the reduction of the exercise price in certain circumstances precluded the warrants from being accounted for as components of equity. As a result, the warrants were recorded as a liability on the balance sheet. Vallon recorded the fair value of the warrants upon issuance using a Black-Scholes valuation model.

The Company is required to revalue the warrants at each reporting date with any changes in fair value recorded in its statement of operations. The valuation of the 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 warrants liabilities is reflected in the statement of operations for the three months ended March 31, 2024.

Net Loss Per Common Share

Basic and diluted net loss per common share is computed based on the weighted average number of shares of common stock outstanding during each year. Diluted net loss per common share is computed based on the weighted average number of shares of common stock outstanding during each year, plus the dilutive effect of options considered to be outstanding during each year, in accordance with ASC 260, *Earnings Per Share*. As the Company had a net loss in each of the three months ended March 31, 2024 and 2023, 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:

	March 31,	
	2024	2023
Stock options	2,511	983
Warrants	792,196	1,140
Restricted stock with repurchase rights	—	1,803
	794,707	3,926

Recent Accounting Pronouncements

The Company considered the applicability and impact of all ASUs issued during the quarter ended March 31, 2024 and each was determined to be either not applicable or expected to have minimal impact on these consolidated financial statements.

4. MERGER WITH VALLON

On April 21, 2023, pursuant to the Merger Agreement, Merger Sub was merged with and into GRI Operations, with GRI Operations surviving the Merger as a wholly owned subsidiary of the Company. In connection with the Closing, the Company amended its certificate of incorporation and bylaws to change its name from "Vallon Pharmaceuticals, Inc." to "GRI Bio, Inc."

At the Effective Time:

(1) Each share of GRI Operations Common Stock outstanding immediately prior to the Effective Time, including any shares of GRI Operations Common Stock issued pursuant to the Equity SPA automatically converted solely into the right to receive a number of shares of the Company's Common Stock equal to 0.0374 (the Exchange Ratio).

(2) Each option to purchase shares of GRI Operations Common Stock (each, a GRI Operations Option) outstanding and unexercised immediately prior to the Effective Time under the GRI Bio, Inc. 2015 Equity Incentive Plan, as amended (the GRI Operations Plan), whether or not vested, converted into and became an option to purchase shares of the Company's Common Stock, and the Company assumed the GRI Operations Plan and each such GRI Operations Option in accordance with the terms of the GRI Operations Plan (the Assumed Options). The number of shares of Common Stock subject to each Assumed Option was determined by multiplying (i) the number of shares of GRI Operations Common Stock that were subject to such GRI Operations Option, as in effect immediately prior to the Effective Time, by (ii) the Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of Common Stock. The per share exercise price for the Common Stock issuable upon exercise of each Assumed Option was determined by dividing (A) the per share exercise price of such Assumed Option, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio and rounding the resulting per share exercise price up to the nearest whole cent. Any restriction on the exercise of any Assumed Option continued in full force and effect and the term, exercisability, vesting schedule, and any other provisions of such Assumed Option otherwise remained unchanged.

(3) Each warrant to purchase shares of GRI Operations Common Stock (the GRI Operations Warrants) outstanding immediately prior to the Effective Time was assumed by the Company and converted into a warrant to purchase shares of Common Stock (the Assumed Warrants) and thereafter (i) each Assumed Warrant became exercisable solely for shares of the Common Stock; (ii) the number of shares of Common Stock subject to each Assumed Warrant was determined by multiplying (A) the number of shares of GRI Operations Common Stock that were subject to such GRI Operations Warrant, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of Common Stock; (iii) the per share exercise price for shares of Common Stock issuable upon exercise of each Assumed Warrant was determined by dividing (A) the exercise price per share of GRI Operations Common Stock subject to such GRI Operations Warrant, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio, and rounding the resulting exercise price up to the nearest whole cent.

(4) The Bridge Warrants (Note 8) were exchanged for warrants (the Exchange Warrants) to purchase an aggregate of 4,632 shares of the Company's Common Stock. The Exchange Warrants contain substantively similar terms to the Bridge Warrants, and have an initial exercise price equal to $1,340.43 per share.

(5) All rights with respect to GRI Operations restricted stock awards were assumed by the Company and converted into Company restricted stock awards with the number of shares subject to each restricted stock award multiplied by the Exchange Ratio and rounding the resulting number down to the nearest whole number of shares of the Company's Common Stock. The term, exercisability, vesting schedule and other provisions of the GRI Operations restricted stock awards otherwise remained unchanged.

The Merger was accounted for as a reverse recapitalization under GAAP because the primary assets of Vallon were cash and cash equivalents. For accounting purposes, GRI Operations was determined to be the accounting acquirer based upon the terms of the Merger and other factors including: (i) the equity holders of GRI Operations immediately prior to the Merger owned, or held rights to acquire, in the aggregate approximately 85% of the outstanding shares of the Company's Common Stock and the Company's stockholders immediately prior to the Merger owned approximately 15% of the outstanding shares of the Company's Common Stock (ii) GRI Operations holds the majority (4 out of 5) of board seats of the combined company, and (iii) GRI Operations' management holds the majority of key positions in the management of the combined company. Immediately after the Merger, there were 32,487 shares of the Company's Common Stock outstanding.

The following table shows the net liabilities assumed in the Merger:

	April 21, 2023
Cash and cash equivalents	$ 941
Prepaid and other assets	310
Accounts payable and accrued expenses	(4,190)
Total net liabilities assumed	(2,939)
Plus: Transaction costs	(2,984)
Total net liabilities assumed plus transaction costs	$ (5,923)

In addition to the transaction costs noted above, at the Effective Time, 335 shares of Common Stock were issued to GRI Operations' financial advisor for services related to the Merger.

5. FAIR VALUE MEASUREMENTS

The Company applies the guidance in ASC 820 to account for financial assets and liabilities measured on a recurring basis. Fair value is measured as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that is determined based on assumptions that market participants would use in pricing an asset or liability.

The Company uses a fair value hierarchy, which distinguishes between assumptions based on market data (observable inputs) and an entity's own assumptions (unobservable inputs). The guidance requires that fair value measurements be classified and disclosed in one of the following 3 categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liabilities; and

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

Determining which category an asset or liability falls within the hierarchy requires significant judgment. The Company evaluates its hierarchy disclosures each reporting period. There were no transfers between Level 1, 2 and 3 during the three months ended March 31, 2024.

The following table presents, for each of the fair value hierarchy levels required under ASC 820, the Company's liabilities that are measured at fair value on a recurring basis at March 31, 2024:

	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Liabilities:			
Warrant liability	$ —	$ —	$ 1
Total liabilities	$ —	$ —	$ 1

The following table presents the changes in the fair value of the Level 3 liability:

	Warrant Liability
Fair value as of December 31, 2023	$ 3
Change in valuation	(2)
Fair value as of March 31, 2024	$ 1

The Black-Scholes valuation model was used to estimate the fair value of the warrants with the following weighted-average assumptions:

	March 31, 2024	December 31, 2023
Volatility	211.9 %	171.0 %
Expected term in years	2.5	2.5
Dividend rate	0.0 %	0.0 %
Risk-free interest rate	4.50 %	4.12 %

6. PROPERTY AND EQUIPMENT

	March 31, 2024	December 31, 2023
Computer equipment	$ 21	$ 21
Furniture and fixtures	13	13
	34	34
Accumulated depreciation	(27)	(26)
	$ 7	$ 8

Depreciation expense related to property and equipment was $ 1 for each of the three months ended March 31, 2024 and 2023.

7. ACCRUED EXPENSES

Accrued expenses consist of the following:

	March 31, 2024	December 31, 2023
Research and development	$ 191	$ 93
General and administrative	52	441
Payroll and related	756	736
Total accrued expenses	$ 999	$ 1,270

8. PROMISSORY NOTES

Bridge Financing

In connection with signing the Merger Agreement, GRI Operations entered into a Securities Purchase Agreement, dated as of December 13, 2022 (the Bridge SPA), with Altium, pursuant to which GRI Operations issued senior secured promissory notes (Bridge Notes) in the aggregate principal amount of $3,333, in exchange for an aggregate purchase price of $ 2,500.

The Bridge Notes were issued in two closings: (i) the first closing for $ 1,667 in aggregate principal amount (in exchange for an aggregate purchase price of $1,250) closed on December 14, 2022; and (ii) the second closing for

$1,667 in aggregate principal amount (in exchange for an aggregate purchase price of $1,250) closed on March 9, 2023. The Bridge Notes were secured by a lien on all of the Company's assets.

In addition, upon the funding of each tranche, Altium received warrants to purchase an aggregate of 13,763 shares of Common Stock (the Bridge Warrants). The Bridge Warrants had an exercise price of $121.03 per share, were exercisable at any time on or after the applicable issuance date and had a term of 60 months from the date all shares underlying the Bridge Warrants were freely tradable.

The $1,250 of proceeds from the first closing were allocated to the Bridge Notes and Bridge Warrants based on their relative fair values as of the commitment date, resulting in an allocation of $679 and $571, respectively. The $1,250 of proceeds from the second closing were allocated to the Bridge Notes and Bridge Warrants based on their relative fair values as of the commitment date, resulting in an allocation of $718 and $532, respectively.

In addition to the Bridge SPA, and also in connection with signing the Merger Agreement, the Company, GRI Operations and Altium entered into the Equity SPA (Note 9) pursuant to which Altium agreed to invest $12,250 in cash and cancel any outstanding principal and accrued interest on the Bridge Notes in return for the issuance of shares of GRI Operations' Common Stock immediately prior to the consummation of the Merger.

On April 21, 2023, the Company completed the Merger and the outstanding principal and accrued interest on the Bridge Notes was cancelled and the Bridge Warrants were exchanged for the Exchange Warrants. The Exchange Warrants contain substantively similar terms to the Bridge Warrants, and have an initial exercise price equal to $1,340.43 per share subject to adjustments for splits and recapitalization events.

The Bridge Notes were accounted for as share-settled debt under the accounting guidance in ASC 835-30 and, as such, the initial net carrying amounts were accreted to the redemption amounts using the effective interest method. The Company incurred $295 of debt issuance costs related to its issuance of debt under the Bridge SPA, of which $90 was incurred during the three months ended March 31, 2023. Interest expense stemming from amortization of debt discounts and issuance costs was $1,161 for the three months ended March 31, 2023.

9. STOCKHOLDERS' EQUITY

In connection with signing the Merger Agreement, the Company, GRI Operations and Altium entered the Equity SPA pursuant to which Altium agreed to invest $12,250 in cash and cancel any outstanding principal and accrued interest on the Bridge Notes in return for the issuance of shares of GRI Operations' Common Stock immediately prior to the consummation of the Merger. Pursuant to the Equity SPA, immediately prior to the Closing, GRI Operations issued the Initial Shares to Altium and the Additional Shares into escrow with an escrow agent for net proceeds of $11,704, after deducting offering expenses of $546.

At the Closing, pursuant to the Merger, the Initial Shares converted into an aggregate of 2,789 shares of Common Stock and the Additional Shares converted into an aggregate of 11,157 shares of Common Stock. On May 8, 2023, in accordance with the terms of the Equity SPA, the Company and Altium authorized the escrow agent to, subject to beneficial ownership limitations, disburse to Altium all of the shares of the Common Stock issued in exchange for the Additional Shares.

On February 1, 2024, the Company entered into the Purchase Agreement, pursuant to which the Company agreed to issue and sell, in the Offering, (i) 25,419 Shares of the Common Stock, (ii) 359,196 Pre-Funded Warrants exercisable for an aggregate of 359,196 shares of Common Stock, (iii) 384,615 Series B-1 Common Warrants exercisable for an aggregate of 384,615 shares of Common Stock, and (iv) 384,615 Series B-2 Common Warrants exercisable for an aggregate of 384,615 shares of Common Stock for net proceeds of $ 4,389, after deducting offering expenses of $ 1,110. The securities were offered in combinations of (a) one Share or one 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 $14.30 (less $0.0013 for each Pre-Funded Warrant).

Subject to certain ownership limitations, the Warrants were exercisable upon issuance. Each Pre-Funded Warrant is exercisable for one Share of Common Stock at a price per share of $0.0013 and does not expire. Each Series B-1 Common Warrant is exercisable into one Share of Common Stock at a price per share of $14.30 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 $14.30 for an 18-month period after February 6, 2024, the date of issuance. The Warrants were classified as equity and the allocated fair value of $4,279 is included in additional paid in capital.

The Company determined that the amount paid for the 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 Purchase Agreement, the exercise price of the Series A-1 Warrants issued in connection with the Merger was reduced to par, or $0.0001, per share pursuant to the terms of the Series A-1 Warrants.

As of March 31, 2024, the Company had the following warrants outstanding to purchase Common Stock.

Number of Shares	Exercise Price per Share	Expiration Date
188,385	$0.0013	Do not expire
384,615	$14.30	August 2025
8,950	$1,117.48	December 2025
42	$27,300.00	February 2026
271	$2,561.65	May 2027
13	$0.01	July 2027
26	$5,586.49	April 2028
13,947	$0.0001	December 2028
384,615	$14.30	February 2029

10. STOCK-BASED COMPENSATION

2015 Equity Incentive Plan

GRI Operations adopted the GRI Operations Plan, that provided GRI Operations with the ability to grant stock options, restricted stock awards and other equity-based awards to employees, directors, and consultants. Upon completion of the Merger, the Company assumed the GRI Operations Plan and 982 outstanding and unexercised options issued thereunder, and ceased granting awards under the GRI Operations Plan. As of March 31, 2024, no options remain outstanding under the GRI Operations Plan.

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, formerly the Vallon Pharmaceuticals, Inc. 2018 Equity Incentive Plan (the A&R 2018 Plan). The A&R 2018 Plan had previously been approved by the Company's board of directors, subject to stockholder approval. The A&R 2018 Plan became effective on April 21, 2023, with the stockholders approving the amendment to the A&R 2018 Plan to, among other things, (i) to increase the aggregate number of shares by 1,856 shares to 2,381 shares of the Company's Common Stock for issuance as awards under the A&R 2018 Plan, (ii) to extend the term of the A&R 2018 Plan through January 1, 2033, (iii) to prohibit any action that would be treated as a "repricing" of an award without further approval by the stockholders of Company, and (iv) to revise the limits on awards to non-employee directors.

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 March 31, 2024, awards granted under the A&R 2018 Plan representing the right to purchase or contingent right to receive up to an aggregate of 2,503 shares of the Company's Common Stock were outstanding and 4,367 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, 2024 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 GRI Operations Plan and the A&R 2018 Plan in the following expense categories of its accompanying consolidated statements of operations for the three months ended March 31, 2024 and 2023:

	For the Three Months Ended March 31,	
	2024	2023
Research and development	$ —	$ —
General and administrative	37	13
Total	$ 37	$ 13

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 three months ended March 31, 2024:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at December 31, 2023	2,503	$ 471.45	9.55
Granted	—		
Exercised	—		
Forfeited/cancelled	—		
Outstanding at March 31, 2024	2,503	$ 471.45	9.30
Exercisable at March 31, 2024	456	$ 1,655.14	8.78
Vested and expected to vest at March 31, 2024	2,503	$ 471.45	9.30

As of March 31, 2024, all of the outstanding and exercisable stock options were out of the money and therefore had no intrinsic value. At March 31, 2024, the unrecognized compensation cost related to unvested stock options expected to vest was $350. This unrecognized compensation is expected to be recognized over a weighted-average amortization period of 2.72 years.

No equity-based awards were granted during the three months ended March 31, 2024 and 2023.

11. COMMITMENTS AND CONTINGENCIES

Employment Agreements

The Company has entered into employment contracts with 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.

12. SUBSEQUENT EVENTS

On June 17, 2024, the Company effected a one-for-thirteen reverses stock split (the June 2024 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 June 2024 Reverse Stock Split.

Up to Shares of Common Stock and accompanying Warrants to Purchase Up to Shares of Common Stock

or

Up to Pre-Funded Warrants to Purchase Up to Shares of Common Stock and accompanying Warrants to Purchase Up to Shares of Common Stock

Up to Placement Agent Warrants to Purchase Up to Shares of Common Stock

Up to Shares of Common Stock Issuable Upon Exercise of the Warrants, Pre-Funded Warrants and Placement Agent Warrants

PRELIMINARY PROSPECTUS

, 2024

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

The following table sets forth the costs and expenses, other than underwriting discounts and commissions, paid or payable in connection with the sale and distribution of the securities being registered. All amounts are estimates except the SEC registration fee and the FINRA filing fee.

	Amount
SEC registration fee	$ 3,697.38
FINRA filing fee	(1)
Printing and engraving expenses	(1)
Legal fees and expenses	(1)
Accountants' fees and expenses	(1)
Miscellaneous expenses	(1)
Total	$ (1)

(1) To be filed by amendment.

ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS.

Section 145 of the General Corporation Law of the State of Delaware (the "DGCL") 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. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of 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 intend to enter into such agreements with our executive 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.

We also maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act.

ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES.

In the three years preceding the filing of this registration statement, we have issued the following securities that were not registered under the Securities Act.

2022 Warrants

On May 13, 2022, the Company entered into the Securities Purchase Agreement with certain investors for the sale in a private placement of up to 271 unregistered warrants to purchase one share of our Common Stock, as well as the sale in a registered direct offering of 271 of our shares of Common Stock. The foregoing share numbers have been adjusted to reflect the Reverse Stock Splits. Ladenburg Thalmann & Co. Inc. served as the placement agent for the Company.

On May 17, 2022, the Company closed on the private placement and the registered direct offering. The gross proceeds from the private placement and registered direct offering were approximately $3.9 million, before deducting fees payable to the placement agent and other estimated offering expenses payable by the Company.

Warrant Exercises

Between November 9, 2023 and November 27, 2023, we issued 12,552 shares of our Common Stock pursuant to the exercise of Series A-2 Warrants on a cashless basis pursuant to the alternate cashless exercise feature described therein.

On May 21, 2024, we issued 13,947 shares of our Common Stock pursuant to the cash exercise of Series A-1 Warrants.

The sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance on (i) Section 4(a)(2) of the Securities Act (and Regulation D promulgated thereunder) as transactions by an issuer not involving any public offering or (ii) Section 3(a)(9) as a transaction in which a security is exchanged by the issuer with its existing security holders exclusively where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange, as applicable. Except as otherwise described above, none of the foregoing transactions involved any underwriters or any public offering. All recipients received or had, through their relationships with us, adequate access to information about us. As necessary, the recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to,

or for sale in connection with, any distribution thereof, and appropriate legends were affixed to the securities issued in these transactions.

ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) Exhibits.

Exhibit No.	Description	Filed Herewith	Form	Incorporated by Reference File No.	Date Filed
1.1	At The Market Offering Agreement, by and between the Company and H.C. Wainwright & Co., LLC, dated as of May 20, 2024.		8-K	001-40034	05/20/2024
2.1Δ	Agreement and Plan of Merger, by and among the Company, GRI Bio Operations, Inc. and Vallon Merger Sub, Inc., dated as of December 13, 2022.		8-K	001-40034	12/13/2022
2.2	Amendment to Agreement and Plan of Merger, by and among the Company, GRI Bio Operations, Inc., and Vallon Merger Sub, Inc., dated as of February 17, 2023.		S-4/A	333-268977	2/24/2023
3.1	Amended and Restated Certificate of Incorporation , as amended.	X			
3.2	Amended and Restated Bylaws.		8-K/A	001-40034	5/26/2023
4.1	Specimen Common Stock Certificate.		S-1	333-249636	10/23/2020
4.2Δ	Registration Rights Agreement, by and between the Company and the investor party thereto, dated as of December 13, 2022.		8-K	001-40034	12/13/2022
4.3	Form of Bridge Warrant.		8-K	001-40034	5/13/2022
4.4	Form of Amendment No. 1 to Common Stock Purchase Warrant.		8-K	001-40034	7/26/2022
4.5	Form of Equity Warrant.		8-K	001-40034	12/13/2022
4.6	Form of Exchange Warrant.		8-K	001-40034	12/13/2022
4.7Δ	Form of Senior Secured Note of GRI Bio Operations, Inc.		S-4	333-268977	12/23/2022
4.8	Warrant to Purchase Stock issued to TEP Biotech, LLC, dated as of November 2, 2018.		S-4	333-268977	12/23/2022
4.9	Warrant to Purchase Stock issued to TEP Biotech, LLC, dated as of December 3, 2019.		S-4	333-268977	12/23/2022
4.10	Warrant to Purchase Stock issued to TEP Biotech, LLC, dated as of July 7, 2022.		S-4	333-268977	12/23/2022
4.11	Warrant to Purchase Stock issued to Oppel Greeff, dated as of July 7, 2022.		S-4	333-268977	12/23/2022
4.12	Form of Amendment to 2022 Warrant to Purchase Stock.		S-4/A	333-268977	1/27/2023
4.13Δ	Securities Purchase Agreement, by and between GRI Bio Operations, Inc. and Altium Growth Fund, LP, dated as of December 13, 2022.		8-K	001-40034	12/13/2022
4.14Δ	Securities Purchase Agreement, by and among the Company, GRI Bio Operations, Inc. and Altium Growth Fund, LP, dated as of December 13, 2022.		8-K	001-40034	12/13/2022
4.15Δ	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	333-268977	3/6/2023
4.16	Investor's Rights Agreement, by and between the Company and Salmon Pharma GmbH, dated as of July 25, 2019.		S-1	333-249636	10/23/2020

4.17Δ	Voting Agreement, by and among the Company and certain of its stockholders, dated as of December 30 2020.	S-1	333-249636	10/23/2020
4.18	Form of Pre-Funded Warrant.	8-K	001-40034	2/02/2024
4.19	Form of Series B-1 Common Warrant.	8-K	001-40034	2/02/2024
4.20	Form of Series B-2 Common Warrant.	8-K	001-40034	2/02/2024
4.21*	Form of Pre-Funded Warrant.			
4.22*	Form of Warrant.			
4.23*	Form of Placement Agent Warrant.			
5.1*	Opinion of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.			
10.1#	A&R 2018 Equity Incentive Plan.	10-Q	001-40034	05/15/2023
10.2#	Form of Nonqualified Stock Option Agreement under the Company's 2018 Equity Incentive Plan.	S-1	333-249636	10/23/2020
10.3#	Form of Incentive Stock Option Agreement under the Company's 2018 Equity Incentive Plan.	S-1	333-249636	10/23/2020
10.4#	GRI Bio Operations, Inc. 2015 Equity Incentive Plan.	S-4	333-268977	12/23/2022
10.5	License Agreement, by and between the Company and MEDICE Arzneimittel Putter GmbH & Co. KG, dated as of January 6, 2020.	S-1	333-249636	10/23/2020
10.6	Form of Company Support Agreement, by and between GRI Bio Operations, Inc. and each of the parties named in each agreement therein, dated as of December 13, 2022.	8-K	001-40034	12/13/2022
10.7	Form of GRI Bio Operations, Inc. Support Agreement, by and between the Company and each of the parties named in each agreement therein., dated as of December 13, 2022.	8-K	001-40034	12/13/2022
10.8	Placement Agency Agreement, by and between the Company and Ladenburg Thalmann & Co., Inc., dated as of May 13, 2022.	8-K	001-40034	5/13/2022
10.9Δ	Securities Purchase Agreement, by and between the Company and each purchaser identified on the signature pages thereto, dated as of May 13, 2022.	8-K	001-40034	5/13/2022
10.10Δ	Amendment No. 1 to Securities Purchase Agreement, by and between the Company and each purchaser identified on the signature pages thereto, dated as of July 25, 2022.	8-K	001-40034	7/26/2022
10.11#	Incentive Stock Option Agreement, by and between GRI Bio Operations, Inc. and Sean Edwards, dated as of November 4, 2016.	S-4	333-268977	12/23/2022
10.12#	Nonqualified Stock Option Agreement, by and between GRI Bio Operations, Inc. and Rohit Loomba, dated as of November 4, 2016.	S-4	333-268977	12/23/2022
10.13#	Nonqualified Stock Option Agreement, by and between GRI Bio Operations, Inc. and Gerald Yakatan, dated as of November 4, 2016.	S-4	333-268977	12/23/2022
10.14#Δ	Restricted Stock Purchase Agreement, by and between GRI Bio Operations, Inc. and Albert Agro, dated as of November 1, 2009.	S-4	333-268977	12/23/2022
10.15#	Restricted Stock Award Agreement, by and between GRI Bio Operations, Inc. and Albert Agro, dated as of April 2, 2015, as amended by the Amendment to the Restricted Stock Award Agreement, by and between GRI Bio Operations, Inc. and Albert Agro, dated as of December 7, 2022.	S-4	333-268977	12/23/2022

10.16#Δ	Restricted Stock Purchase Agreement, by and between GRI Bio Operations, Inc. and Vipin Kumar Chaturvedi, dated as of March 28, 2009.	S-4	333-268977	12/23/2022
10.17#	Restricted Stock Award Agreement, by and between GRI Bio Operations, Inc. and Vipin Kumar Chaturvedi, dated as of April 2, 2015, as amended by the Amendment to the Restricted Stock Award Agreement, by and between GRI Bio Operations, Inc. and Vipin Kumar Chaturvedi, dated as of December 7, 2022.	S-4	333-268977	12/23/2022
10.18#	Restricted Stock Award Agreement, by and between GRI Bio Operations, Inc. and Sean Edwards, dated as of March 31, 2021.	S-4	333-268977	12/23/2022
10.19#	Restricted Stock Award Agreement, by and between GRI Bio Operations, Inc. and Sean Edwards, dated as of December 7, 2022.	S-4	333-268977	12/23/2022
10.20#Δ	Restricted Stock Purchase Agreement, by and between GRI Bio Operations, Inc. and W. Marc Hertz, dated as of March 28, 2009.	S-4	333-268977	12/23/2022
10.21#	Restricted Stock Award Agreement, by and between GRI Bio Operations, Inc. and W. Marc Hertz, dated as of April 2, 2015, as amended by the Amendment to the Restricted Stock Award Agreement, by and between GRI Bio Operations, Inc. and W. Marc Hertz, dated as of December 7, 2022.	S-4	333-268977	12/23/2022
10.22#	Restricted Stock Award Agreement, by and between GRI Bio Operations, Inc. and W. Marc Hertz, dated as of March 31, 2021.	S-4	333-268977	12/23/2022
10.23#	Restricted Stock Award Agreement, by and between GRI Bio Operations, Inc. and W. Marc Hertz, dated as of December 7, 2022.	S-4	333-268977	12/23/2022
10.24#	Consulting and Clinical Advisory Board Agreement, by and between GRI Bio Operations, Inc. and Rohit Loomba, M.D., dated as of June 3, 2016.	S-4	333-268977	12/23/2022
10.25#	Consulting and Scientific Advisory Board Agreement, by and between GRI Bio Operations, Inc. and Vipin Kumar Chaturvedi, personally or through Vidur Discoveries LLC, dated as of October 31, 2018.	S-4	333-268977	12/23/2022
10.26Δ	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.	S-4	333-268977	12/23/2022
10.27	Clawback Policy.	10-Q	001-40034	11/14/2023
10.28#	Amended and Restated Non-Employee Director Compensation Program.	S-1/A	333-274972	12/4/2023
10.29	Form of Indemnification Agreement.	8-K	001-40034	4/21/2023
10.30#	Employment Agreement, by and between GRI Bio Operations, Inc. and Marc Hertz, Ph.D., dated as of February 20, 2023.	S-4/A	333-268977	2/24/2023
10.31#	Employment Agreement, by and between GRI Bio Operations, Inc. and Leanne M. Kelly, dated as of February 20, 2023.	S-4/A	333-268977	2/24/2023
10.32#	Employment Agreement, by and between GRI Bio Operations, Inc. and Vipin Kumar Chaturvedi, dated as of February 20, 2023.	S-4/A	333-268977	2/24/2023
10.33#	Employment Agreement, by and between the Company and Albert Agro, Ph.D., dated as of July 1, 2023.	10-Q	001-40034	8/14/2023

10.34#	Amendment No. 1 to Employment Agreement, by and between the Company and Albert Agro, Ph.D., dated as of June 17, 2024.		8-K	001-40034	6/18/2024
10.35Δ	Asset Purchase Agreement, by and between the Company and Aardvark Therapeutics, Inc., dated as of August 22, 2023.		8-K	001-40034	8/23/2023
10.36Δ	Form of Securities Purchase Agreement, dated as of February 1, 2024, between GRI Bio, Inc. and each purchaser named in the signature pages thereto.		8-K	001-40034	2/02/2024
10.37	Placement Agency Agreement, dated as of February 1, 2024, by and between GRI Bio, Inc. and A.G.P./Alliance Global Partners.		8-K	001-40034	2/02/2024
10.38*	Form of Securities Purchase Agreement.				
21.1	Subsidiaries of the registrant.		S-1/A	333-274972	12/4/2023
23.1	Consent of Sadler, Gibb & Associates, LLC, Independent Registered Public Accounting Firm.	X			
23.2*	Consent of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. (included in Exhibit 5.1).				
24.1	Power of Attorney (included on signature page to this registration statement).	X			
101.INS	iXBRL Instance Document				
101.SCH	iXBRL Taxonomy Extension Schema Document				
101.CAL	iXBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	iXBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	iXBRL Taxonomy Extension Label Linkbase Document				
101.PRE	iXBRL Taxonomy Extension Presentation Linkbase Document				
107	Filing Fee Table	X			

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

Δ 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.

* To be filed by amendment

(b) Financial Statement Schedules.

No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or notes.

ITEM 17. UNDERTAKINGS.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933,

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of

prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement, and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

Provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(6) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of

expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(7) The undersigned registrant hereby undertakes that:

(i) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(ii) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in La Jolla, California, on this 18th day of June, 2024.

GRI BIO, INC.

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

SIGNATURES AND POWER OF ATTORNEY

We, the undersigned directors and officers of GRI Bio, Inc., hereby severally constitute and appoint W. Marc Hertz, Ph.D. and Leanne Kelly, and each of them singly, our true and lawful attorneys, with full power to them, and to each of them singly, to sign for us and in our names in the capacities indicated below, the registration statement on Form S-1 filed herewith, and any and all pre-effective and post-effective amendments to said registration statement, and any registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, in connection with the registration under the Securities Act of 1933, as amended, of equity securities of GRI Bio, Inc., and to file or cause to be filed the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys, 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 connection therewith, as fully to all intents and purposes as each of us might or could do in person, and hereby ratifying and confirming all that said attorneys, and each of them, or their substitute or substitutes, shall do or cause to be done by virtue of this Power of Attorney.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons 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)	June 18, 2024
/s/ Leanne Kelly Leanne Kelly	Chief Financial Officer (Principal Financial and Accounting Officer)	June 18, 2024
/s/ David Szekeres David Szekeres	Director and Chairperson of the Board	June 18, 2024
/s/ David Baker David Baker	Director	June 18, 2024
/s/ Roelof Rongen Roelof Rongen	Director	June 18, 2024
/s/ Camilla V. Simpson, M.Sc. Camilla V. Simpson, M.Sc.	Director	June 18, 2024

Exhibit 107

Calculation of Filing Fee Tables

Form S-1
(Form Type)

GRI Bio, Inc.
(Exact Name of Each Registrant as Specified in its Charter)

Table 1: Newly Registered and Carry Forward Securities

Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price [1]	Fee Rate	Amount of Registration Fee
Equity	Common Stock, par value $0.0001 per share [2]	457(o)			$ 6,000,000	0.00014760	$ 885.60
Other	Pre-Funded Warrants to purchase Common Stock [3]	Other			-		(3)
Equity	Common Stock underlying the Pre-Funded Warrants [3]	457(o)			-		(3)
Other	Warrants to purchase Common Stock	Other			-		(4)
Equity	Common Stock underlying the Warrants to purchase Common Stock	457(o)			$ 6,000,000	0.00014760	$ 885.60
Other	Placement Agent Warrants to purchase Common Stock	Other			-		(4)(5)
Equity	Common Stock underlying the Placement Agent Warrants to purchase Common Stock	457(o)			$ 525,000	0.00014760	$ 77.49
Total Offering Amounts					$ 12,525,000	0.00014760	$ 1,848.69
Total Fees Previously Paid							-
Total Fee Offsets							-
Net Fee Due							$ 1,848.69

(1) Estimated solely for the purpose of calculating the amount of the registration fee in pursuant to Rule 457(o) under the Securities Act of 1933, as amended (the "Securities Act").

(2) Pursuant to Rule 416 under the Securities Act, this registration statement shall also cover any additional shares of the registrant's securities that become issuable by reason of any share splits, share dividends or similar transactions.

(3) The proposed maximum aggregate offering price of the Common Stock will be reduced on a dollar-for-dollar basis based on the offering price of any Pre-Funded Warrants issued in the offering, and the proposed maximum aggregate offering price of the Pre-Funded Warrants to be issued in the offering will be reduced on a dollar-for-dollar basis based on the offering price of any Common Stock issued in the offering. Accordingly, the proposed maximum aggregate offering price of the Common Stock and Pre-Funded Warrants (including the Common Stock issuable upon exercise of the Pre-Funded Warrants), if any, is $6,000,000.

(4) No separate registration fee is payable pursuant to Rule 457(g) under the Securities Act.

(5) Represents Warrants issuable to the Placement Agent, or its designees, to purchase a number of shares of Common Stock equal to 7.0% of the aggregate number of shares of Common Stock and Pre-Funded Warrants being offered in this offering, at an exercise price equal to 125% of the combined public offering price per share of Common Stock and accompanying Warrant.

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
Delivered 01:14 PM 02/10/2021

(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

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the inclusion in this Registration Statement on Form S-1 of GRI Bio, Inc. to be filed on or about June 18, 2024 of our report dated March 28, 2024, on our audits of the GRI Bio, Inc. financial statements as of December 31, 2023 and 2022 and for each of the years then ended. We also consent to the reference to our firm under the caption “Experts” in this Registration Statement on Form S-1/A.

/s/ Sadler, Gibb & Associates, LLC

Draper, UT
June 18, 2024