



GRI Bio Reports Second Quarter 2024 Financial Results and Provides Corporate Update

Company focused on execution of lead program GRI-0621 for the treatment of Idiopathic Pulmonary Fibrosis (IPF)

GRI-0621 interim data readout of Phase 2a biomarker study on track for Q4 2024 and topline data on track for Q1 2025

LA JOLLA, CA, Aug. 14, 2024 (GLOBE NEWSWIRE) -- GRI Bio, Inc. (NASDAQ: GRI) ("GRI Bio" or the "Company"), a biotechnology company advancing an innovative pipeline of Natural Killer T (NKT) cell modulators for the treatment of inflammatory, fibrotic and autoimmune diseases, today reported its financial results for the second quarter ended June 30, 2024 and provided a corporate update.

"Our focus and priority remain on the successful execution of our Phase 2a biomarker study of GRI-0621 for the treatment of IPF, with interim data by the end of the year and topline data on track for Q1 2025. We are excited about this product candidate and its potential to address a significant area of unmet medical need," commented Marc Hertz, PhD, Chief Executive Officer of GRI Bio. "Additionally, we continue to generate encouraging data in our GRI-0803 program for the treatment of systemic lupus erythematosus. We currently estimate that we have cash to support our planned operations into the first quarter of 2025 with plans to raise additional funds to support our planned operations."

Recent Highlights

- Expanded intellectual property protection for proprietary NKT cell modulators with grant of Korea patent title, "*Prevention and Treatment of Inflammatory Conditions*;
- Closed a public offering with aggregate gross proceeds of \$4.0 million;
- Announced that the manuscript titled, "[*Type 1 invariant natural killer T cells drive lung fibrosis*](#)¹," has been published in the American Journal of Respiratory and Critical Care Medicine;
- [Presented positive preclinical data](#) demonstrating lead program GRI-0621 reduces the important inflammatory and fibrotic drivers in IPF.
- [Announced oral presentation](#) at the 8th Annual Idiopathic Pulmonary Fibrosis Summit being held August 20-22, 2024; and
- [Presented encouraging preclinical data](#) from the Company's preclinical studies of type 2 NKT activating molecules, GRI-0803 and GRI-0124 at the 14th International Congress on Autoimmunity.

GRI-0621: Type 1 invariant NKT (iNKT) antagonist in development for the treatment of IPF.

IPF is a rare chronic progressive pulmonary disease with abnormal scarring of the lung blocking the movement of oxygen into the bloodstream. Currently available treatments for IPF are limited with only two approved drugs that come with significant side-effects, limited compliance and no impact on overall survival² leaving significant opportunity to augment IPF treatment with a new therapeutic.

GRI Bio's lead program, GRI-0621, is a small molecule RAR- $\beta\gamma$ dual agonist that inhibits the activity of human iNKT cells. In preliminary trials to date and previous trials with the oral formulation, GRI-0621 has been shown to improve fibrosis in multiple disease models and improve liver function tests and other markers of inflammation and injury in patients.

The Company plans to leverage the 505(b)(2) regulatory pathway and has launched a Phase 2a biomarker study evaluating GRI-0621 for the treatment of IPF. For more information about the Phase 2a study, please visit clinicaltrials.gov and reference identifier NCT06331624.

Expected GRI-0621 Upcoming Milestones

- Q4 2024: Report interim data from Phase 2a biomarker study
- Q1 2025: Report topline results from Phase 2a biomarker study

GRI-0803: Novel activator of human type 2 NKT cells in development for the treatment of autoimmune disorders, with an initial focus on systemic lupus erythematosus (SLE).

SLE is an autoimmune disease in which the immune system attacks its own tissue and organs. SLE is the most common form of lupus. Current treatments are limited, consisting primarily of immunosuppressive therapies, with only two new therapies approved in the past 50 years.

GRI Bio's second asset in development, GRI-0803, is a novel activator of human type 2 NKT cells. Activation of type 2 NKT leads to a dendritic cell-mediated inhibition of iNKT cells. In the Company's preclinical studies, type 2 NKT activating molecules, GRI-0803 and GRI-0124, were observed to inhibit both murine and human iNKT cells. Oral administration of these type 2 NKT activating molecules was observed to inhibit lupus nephritis and to significantly improve overall survival. The Company is currently focusing its available resources on GRI-0621, but, pending additional funding, the GRI-0803 IND-enabling and Phase1 program will continue in 2025.

Summary of Financial Results for Second Quarter 2024

Net loss was \$2.4 million for the three months ended June 30, 2024.

Research and development expenses were \$0.9 million for each of the three-month periods ended June 30, 2024 and 2023, respectively.

General and administrative expenses were \$1.4 million and \$5.1 million for the three months ended June 30, 2024 and 2023, respectively.

As of June 30, 2024, the Company had cash and cash equivalents of approximately \$6.4 million. In June 2024, the Company closed a public offering with aggregate gross proceeds of \$4.0 million. 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 first quarter of 2025.

About GRI Bio, Inc.

GRI Bio is a clinical-stage biopharmaceutical company focused on fundamentally changing the way inflammatory, fibrotic and autoimmune diseases are treated. GRI Bio's therapies are designed to target the activity of NKT cells, which are key regulators earlier in the inflammatory cascade, to interrupt disease progression and restore the immune system to homeostasis. NKT cells are innate-like T cells that share properties of both NK and T cells and are a functional link between the innate and adaptive immune responses. Type 1 invariant (iNKT) cells play a critical role in propagating the injury, inflammatory response, and fibrosis observed in inflammatory and fibrotic indications. GRI Bio's lead program, GRI-0621, is an inhibitor of iNKT cell activity and is being developed as a novel oral therapeutic for the treatment of idiopathic pulmonary fibrosis, a serious disease with significant unmet need. The Company is also developing a pipeline of novel type 2 NKT agonists for the treatment of systemic lupus erythematosus. Additionally, with a library of over 500 proprietary compounds, GRI Bio has the ability to fuel a growing pipeline.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "target," "aim," "should," "will," "would," or the negative of these words or other similar

expressions. These forward-looking statements are based on the Company's current beliefs and expectations. Forward-looking statements include, but are not limited to, statements regarding: the Company's expectations with respect to development and commercialization of the Company's product candidates, the timing of initiation or completion of clinical trials and availability of resulting data, the potential benefits and impact of the Company's clinical trials and product candidates and any implication that the data or results observed in preclinical trials or earlier studies or trials will be indicative of results of later studies or clinical trials, the Company's beliefs and expectations regarding potential stakeholder value and future financial performance, the Company's beliefs about the timing and outcome of regulatory approvals and potential regulatory approval pathways, the Company's expected milestones for 2024, and the Company's beliefs and expectations regarding the sufficiency of its existing cash and cash equivalents to fund its planned operations, its ability to raise additional funds, which may not be available to the Company on acceptable terms or at all, its ability to resume development of GRI-0863 and capital expenditure requirements. Actual results may differ from the forward-looking statements expressed by the Company in this press release and consequently, you should not rely on these forward-looking statements as predictions of future events. These forward-looking statements are subject to inherent uncertainties, risks and assumptions that are difficult to predict, including, without limitation: (1) the inability to maintain the listing of the Company's common stock on Nasdaq and to comply with applicable listing requirements; (2) changes in applicable laws or regulations; (3) the inability of the Company to raise financing in the future; (4) the success, cost and timing of the Company's product development activities; (5) the inability of the Company to obtain and maintain regulatory clearance or approval for its respective products, and any related restrictions and limitations of any cleared or approved product; (6) the inability of the Company to identify, in-license or acquire additional technology; (7) the inability of the Company to compete with other companies currently marketing or engaged in the development of products and services that the Company is currently developing; (8) the size and growth potential of the markets for the Company's products and services, and their respective ability to serve those markets, either alone or in partnership with others; (9) the failure to achieve any milestones or receive any milestone payments under any agreements; (10) inaccuracy in the Company's estimates regarding expenses, future revenue, capital requirements and needs for and the ability to obtain additional financing; (11) the Company's ability to protect and enforce its intellectual property portfolio, including any newly issued patents; and (12) other risks and uncertainties indicated from time to time in the Company's filings with the U.S. Securities and Exchange Commission (the "SEC"), including the risks and uncertainties described in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K filed with the SEC on March 28, 2024 and subsequently filed reports. Forward-looking statements contained in this announcement are made as of this date, and the Company undertakes no duty to update such information except as required under applicable law.

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¹ <https://doi.org/10.1164/rccm.202402-0288LE>

² T. M. Maher *et al.*, Global incidence and prevalence of idiopathic pulmonary fibrosis. *Respir Res* **22**, 197 (2021)

