

GRI Bio, Inc.

Initiating Coverage with BUY and \$12 Target

Large market opportunities for its immune responses drugs to treat IPF and SLE. We believe expected positive clinical data in 2024/25 to be strong catalysts for stock.

Initiating with BUY: We are initiating coverage of GRI Bio with a BUY rating and a 12-month price target of \$12. GRI Bio is a clinical-stage biopharmaceutical company focused on diseases associated with dysregulated immune responses.

Focus on immune response regulations: GRI Bio's science is founded on the discovery that NKT (Natural killer T) cells and dysregulated (uncontrolled) immune responses can be reset by regulating the activity of NKT cells to potentially treat a broad array of acute and chronic conditions.

GRI-0621: The company's initial main focus is developing GRI-0621 for the treatment of IPF (Idiopathic Pulmonary Fibrosis). GRI-0621 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.

Phase 2a Trial for GRI-0621: In December 2023, the company commenced enrollment for its GRI-0621 Phase 2a Trial in Patients with IPF. This trial will be a twelve-week, multicenter, multinational, randomized, placebo-controlled trial in approximately 36 patients with IPF. This trial is expected to take about one year.

Key data expected in Q4 and Q1: The company currently expects interim data from the Phase 2a study in Q4 2024 and top-line data in Q1 2025.

GRI-0803: The company's second planned drug product is GRI-0803, which is a novel oral agonist (activates a receptor to produce a biological response) of type 2 Natural Killer T (type 2 NKT) cells. The company is developing GRI-0803 for the treatment of autoimmune disorders, with much of its preclinical work in SLE (systemic lupus erythematosus or lupus) and MS (multiple sclerosis).

IDE for GRI-0803 in 2025: The company expects to file an IND (Investigational New Drug Application) for GRI-0803 to treat Lupus in 2025.

Large market potential for IPF: Idiopathic pulmonary fibrosis is one of the most common and severe form of progressive PF. IPF is on the rise with more than 40,000 new cases diagnosed annually. More than 250,000 Americans are living with PF and ILD, of which IPF affects approximately 140,000 patients in the U.S.

Large market potential for Lupus: The Lupus Foundation of America estimates that 1.5 million Americans, and at least five million people worldwide, have a form of lupus. As many as 24,000 people in the U.S. are diagnosed with the disease each year.

Positive high risks versus high rewards: Overall, concerns outweighed by growth prospects and valuation. GRI Bio's 2 drugs still have long development and commercialization roads left and the high risks of clinical trials or commercial failures, but we believe the ~billion dollars market potential presents high rewards for the risks.

Very large upside potential: We note that GRI Bio stock is trading below cash value. The company's market capitalization is only ~\$1 million, but it has \$6 million in cash (as of Q2 2024). We believe investors are getting a near free option with very large upside potential if the company succeeds with only limited downside risks.

Current valuation attractive: We calculate a 12-month price target for shares of GRI Bio to be \$12 based on a NPV analysis, representing significant upside from the current share price. We believe this valuation appropriately balances out the company's high risks with its high growth prospects and large upside opportunities.

Company Description

Based in La Jolla, CA, GRI Bio is a clinical-stage biopharmaceutical company focused on diseases associated with dysregulated immune responses leading to inflammatory, fibrotic, and autoimmune disorders.

United States Healthcare

October 8, 2024

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Stock Data

Exchange:	NasdaqCM
52-week Range:	0.30 - 154.70
Shares Outstanding (million):	3.0
Market cap (\$million):	\$1
EV (\$million):	\$(5)
Debt (\$million):	\$0
Cash (\$million):	\$6
Avg. Daily Trading Vol. (\$million):	\$0.5
Float (million shares):	3
Short Interest (million shares):	0.1
Dividend, annual (yield):	\$0 (NA%)

Revenues (US\$ million)

	2023A (Cur.)	<u>2024E</u> (Cur.)	<u>2025E</u> (Cur.)
Q1 Mar	0A	0A	0E
Q2 Jun	0A	0A	0E
Q3 Sep	0A	0E	0E
Q4 Dec	<u>0A</u>	<u>0E</u>	<u>0E</u>
Total	0A	0E	0E
EV/Revs	N/A	N/A	N/A

Earnings per Share (pro forma)

	2023A	2024E	2025E
	<u>(Cur.)</u>	(Cur.)	(Cur.)
Q1 Mar	(195)A	(5.94)A	(0.69)E
Q2 Jun	(239)A	(4.92)A	(0.67)E
Q3 Sep	(47)A	(0.73)E	(0.65)E
Q4 Dec	(35)A	(0.71)E	(0.63)E
Total	(367)A	(4.97)E	(2.63)E
P/E	N/A	N/A	N/A

^{*}Reflects a 1:30 reverse stock split in April 2023.

Important Disclosures

Ascendiant Capital Markets LLC seeks to do business with companies covered by its research team. Consequently, investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making an investment decision.

For analyst certification and other important disclosures, refer to the Disclosure Section, located at the end of this report, beginning on page 36.

COVERAGE INITIATION

Rating: BUY

Ticker: GRI

Price: \$0.35

Target: \$12.00

^{*}Reflects a 1:7 reverse stock split in January 2024.

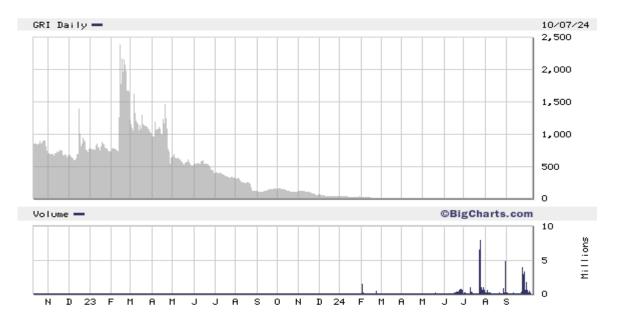
^{*}Reflects a 1:13 reverse stock split in June 2024.



Exhibit 1: GRI Bio, Inc. Stock Price (2-years since reverse merger)

Merger Announcement (with GRI Bio, Inc.) - 12/13/22

Merger Completion (to form GRI Bio, Inc.) - 4/21/23



^{*}Reflects a 1:30 reverse stock split in April 2023.

Source: https://bigcharts.marketwatch.com/

INVESTMENT THESIS

We are initiating coverage of GRI Bio with a BUY rating and a 12-month price target of \$12.

Based in La Jolla, CA, GRI Bio is a clinical-stage biopharmaceutical company focused on diseases associated with dysregulated immune responses leading to inflammatory, fibrotic, and autoimmune disorders. The company is discovering, developing, and commercializing innovative therapies that target serious diseases associated with dysregulated (uncontrolled) immune responses. The company has 2 main drugs in development (GRI-0621 for Idiopathic Pulmonary Fibrosis (IPF) and GRI-0803 for Systemic Lupus Erythematosus (SLE)).

The company's initial main focus is developing GRI-0621 for the treatment of IPF. GRI-0621 is an oral formulation of tazarotene, a prescription topical retinoid that is approved in the U.S. for the treatment of psoriasis and acne. GRI-0621 inhibits the activity of iNKT (invariant natural killer T) cells that have been shown to accumulate in IPF patients and other interstitial (fluid-filled space existing between a structural barrier, such as a cell membrane or the skin, and internal structures, such as organs) lung disease patients. It

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has been shown that activated iNKT cells are overexpressed in IPF, hepatic and other fibrotic conditions and are significantly correlated with chronic and advanced disease.

The company's second planned drug product is GRI-0803, which is a novel oral agonist (activates a receptor to produce a biological response) of type 2 Natural Killer T (type 2 NKT) cells. The company is developing GRI-0803 for the treatment of autoimmune disorders, with much of its preclinical work in SLE (systemic lupus erythematosus or lupus) and MS (multiple sclerosis).

Exhibit 2: GRI Bio, Inc.



A New Approach to Inflammatory Diseases

Summary

Elevating Clinical Stage Biotechnology Company Advancing Innovative Pipeline Across Multiple Orphan and High-Value Inflammatory, Fibrotic and Autoimmune Diseases

We Believe NKT Science is Compelling to Fundamental Institutional Investors and Big Pharma Partners

NKT Science

Leading NKT regulation technology targeting earlier in the inflammatory cascade to interrupt disease progression

High-Value Indications

Clinical pipeline in potential highvalue indications with multiple pipeline expansion opportunities

Proven Team

Team with proven NKT, immunology and drug development experience

Source: Company reports.

GRI Bio's science is founded on the discovery that NKT (Natural killer T) cells are a functional link between the innate and adaptive immune systems and that dysregulated (uncontrolled) immune responses can be reset by regulating the activity of NKT cells to potentially treat a broad array of acute and chronic conditions.



NKT cells share properties of both NK (Natural killer cells) and T (types of white blood cells) cells and are critical regulators of immune responses. NK cells provide rapid responses to virus-infected, stressed, tumor cells based on signals from activating and inhibitory receptors. NK cells can recognize and kill stressed cells in the absence of antibodies, allowing for a much faster immune reaction. T cells are types of white blood cells of the immune system and play a central role in the adaptive immune response.

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 and are critical for minimizing the damage caused by inflammatory responses. 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 and activated iNKT cells accumulate in the lungs of IPF, NASH and SLE patients, as well as other chronic inflammatory, fibrotic, and autoimmune disease populations.

Exhibit 3: GRI Bio Investment Highlights

Highlights

Advancing an Innovative Pipeline of NKT Cell Modulators for the Treatment of Inflammatory, Fibrotic and Autoimmune Diseases

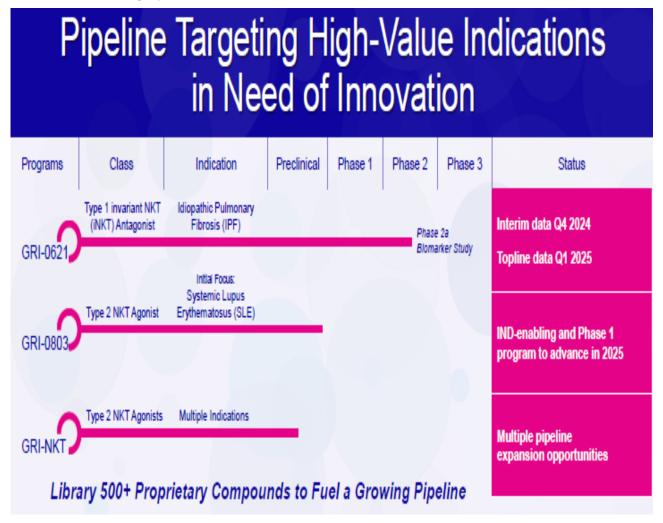
NKT Science	Innovative Small Molecules	High-Value Indications
Leveraging Natural Killer T (NKT) regulation to target earlier in the inflammatory cascade to interrupt disease progression	Small molecule drugs that act like cell therapy Provides favorable economics in manufacturing and dosing	~100K People in the US¹ Idiopathic Pulmonary Fibrosis ~160K People in the US² Systemic Lupus Erythematosus

a Leading Tyrosine Kinase Inhibitor with 2025 Projected Sales of \$5 Billion³

Source: Company report.



Exhibit 4: GRI Bio Drug Pipeline Timeline



Source: Company report.

Idiopathic pulmonary fibrosis is one of the most common and severe form of progressive PF. IPF is on the rise with more than 40,000 new cases diagnosed annually. More than 250,000 Americans are living with PF and ILD, of which IPF affects approximately 140,000 patients in the U.S. IPF primarily affects individuals between the ages of 65 and 70, and is expected to rise with an aging population. The median survival is between two to three years after diagnosis, and the average life expectancy is between three and five years.

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. Despite this, total worldwide sales of pirfenidone and nintedanib in 2019 were over \$1.2 billion and \$1.6 billion, respectively.

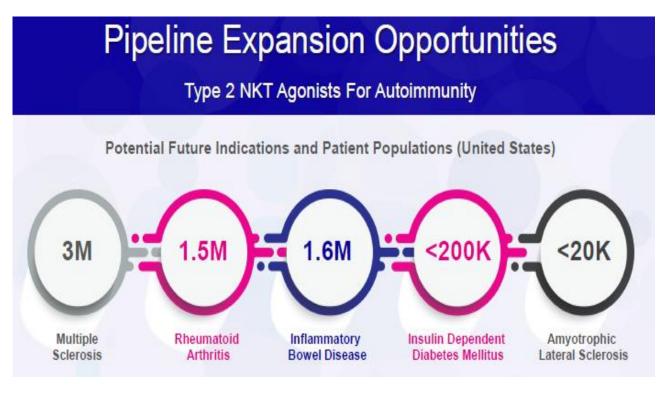
Systemic Lupus Erythematosus (SLE) is the most common type of lupus (~70% of all cases) and is usually what people refers to when talking about Lupus. The Lupus Foundation of America estimates that 1.5 million Americans, and at least five million people worldwide, have a form of lupus. As many as 24,000 people in the U.S. are diagnosed with the disease each year.



SLE is an autoimmune disease in which the immune system mistakenly attacks its own healthy tissues, especially joints and skin, but can affect almost every organ and tissue of the body causing widespread inflammation and tissue damage in the affected organs. It can affect the joints, skin, brain, lungs, kidneys, and blood vessels. The condition can be fatal, and often causes debilitating bouts of fatigue and pain that prevent nearly half of adult patients from working. In the U.S., around 80,000 – 100,000 patients suffer from kidney nephritis, one of the most serious manifestations of SLE, typically within five years of diagnosis. SLE predominantly affects women and often starts between the ages of 15 and 44.

Experts don't know what causes SLE. Many scientists believe that lupus develops in response to a combination of factors both inside and outside the body. This includes hormones, genetics, and environment. 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 so new treatment options are needed.

Exhibit 5: GRI Bio Pipeline Expansion Opportunities



Source: Company reports.

GRI Bio share price has been weak and volatile since the completion of its reverse merger on April 21, 2023. GRI Bio's share price was \$781.24 (split adjusted) on 4/23/23, but closed at \$35.04 on 12/29/23. So far in 2024, the stock has been weak at -99% (to the current share price of \$0.35 as of 10/7/24). Since 9/29/23 (in the past year), the stock has traded between \$0.30 (on 10/1/24) and \$161.98 (on 10/5/23).

We believe this stock price volatility is likely due to the high general stock price volatility with small/microcap biotechnology stocks particularly after a reverse merger event. We believe that there are near term catalysts that can drive the stock particularly for key clinical milestones (interim and top-line data for GRI-0621 in late 2024/early 2025 and start of clinical trials for GRI-0803 in 2025). As



the company is likely to make significant progress in its businesses over the next several years, we believe this will result in much improved visibility into future cash flows and higher share price.

Although it is very likely that the company will have to keep raising capital to achieve its product development goals, we believe that positive progress will make future financings accretive to current shareholders.

The company's near term plans over the next year is to advance GRI-0621 in its clinical trials towards a FDA approval for the treatment of IPF. We believe expected positive milestones and clinical data (particularly its expected late 2024 interim data from its Phase 2a study and top-line data in Q1 2025) and its IDE application for GRI-0803 for the treatment of SLE over the next year to be strong catalysts for stock.

Our investment thesis factors in an uncertain drug development process and very competitive industry which is offset by the very large potential upside opportunities created from a successful drug. We believe that the current valuation for GRI Bio has already factored in many of its risks (principally drug approval and successful commercialization) but is under valuing its overall growth prospects and product portfolio, resulting in a positive risk versus reward scenario for an investment in GRI Bio.

We believe the current valuation is attractive.

Based on our expectations and assumptions and our NPV analysis, we calculate a 12-month price target for shares of GRI Bio to be \$12, representing significant upside from current share price. We believe this valuation appropriately balances out the company's high risks with the company's high growth prospects and large upside opportunities. We acknowledge that GRI Bio is still at a very early stage in its drug development and product commercialization, but we believe key drug development milestones over the next year should be positive catalysts for the stock.

INVESTMENT RISKS

Long and Uncertain Drug Development Cycles

GRI Bio is highly dependent upon securing drug approvals for its products in order to sell them (produce revenue). The drug development cycle can be long (average of 12 years), expensive (average of \$350 million), complicated, and uncertain. On average only about 10% of drugs entering clinical trials ever make it to final approval. Because GRI Bio main drug candidates are still in early clinical development (GRI-0621 is in Phase 2a and GRI-0803 is pre-IND (Investigational New Drug Application)), there are significant risks and a long time horizon to receive FDA approval. We estimate that it likely at least two years before any of its drug therapies can receive FDA approval. With a high likelihood of binary outcomes (either success or failure), the risks are very high but the potential rewards can also be high as well.

Product Commercialization Risks

Even after obtaining drug approvals, there is still a chance that commercial success will not be achieved (due to competition, changes in the market, better or newer drugs or technologies, lack of reasonable reimbursements, or lack of market acceptance). While there are currently no good therapeutics to prevent or treat severe fibrotic lung diseases such as IPF and the current treatment options remains limited, there is the chance that other potential therapeutic treatments and options may be developed and launched before the company's drugs are launched. In addition, GRI Bio will need to replace existing therapies and treatments being used currently as standards of care. Like most health care drugs, the company will also need to get suitable insurance and government reimbursements for its products.

High Level of Competition

GRI Bio operates in a highly competitive environment and competes against a wide range of other biopharmaceutical companies that are attempting to replicate or already have comparable treatments as the company's drugs. Some of these competitors are much larger or have greater resources, and proprietary technology; which could result in lower projected sales for its drugs and higher



costs, reduced margins, and lowered profitability for the company. Even if GRI Bio were to be successful with its drug development, its products will have to compete with existing or new standards of care.

Concentrated Product Pipeline

The company is currently developing 2 drug therapeutics, one of which is currently in FDA clinical trials. If GRI Bio were to experience difficulties with development of its GRI-0621 and GRI-0803 drugs, then it may have a material negative impact on its business and financials as there are no meaningful products that are as far along in development which can offset.

Coronavirus and Economic Uncertainties

While healthcare costs tends to be less correlated with economic activity and income levels due to their nondiscretionary nature, major deterioration in economic conditions tends to result in an overall decline in consumer spending. This was demonstrated during the 2008 and 2009 Great Recession and global economic slowdown. While consumer spending levels and economic conditions have rebounded since and have been strong most of the 2010s, the global macroeconomic environment can change significantly quickly as was shown with the start of the COVID-19 pandemic in March 2020. Since then, due to huge government stimulus the U.S. economy has been very strong the past 4 years. However, the pandemic has still negatively impacted many businesses and has been a huge disruption to the U.S. (and global) economy. This includes biotechs as many have seen FDA drug development reviews, feedback, and approvals delayed along with disruptions in clinical trials. We note that the economy is currently back to normal, but potential economic weakness or volatility may result in depressed government, enterprise, and consumer spending levels; this may have a negative impact on GRI Bio, its business partners, government, and consumers.

Capital Markets Risks

We believe GRI Bio has enough cash to fund its operations into 2025 (Q1 (March) 2025), but we estimate that it will need to raise capital by Q4 2024 (December 2024). We believe that it will be at least several years before the company can be cash flow self-sufficient from operations. Many biopharmaceutical companies fund their operations from the sale of equity or debt capital until their products reach commercial success or until they sell off the commercial rights to other companies. Biopharmaceuticals ("biotechs") valuations tend to fluctuate widely, and though they are reasonably strong now (due to a strong M&A market for biotechs and large government funding for healthcare), there is always the chance that market interests and valuations for companies in this industry decline significantly. Share price weakness and volatility for small/micro cap and biotech stocks may make capital raising much more difficult and expensive.



VALUATION

We are initiating coverage of GRI Bio with a BUY rating and a 12-month price target of \$12.00, which is based on a NPV analysis. As the company is a clinical stage drug development company, it currently generates no revenue and significant losses so traditional valuation metrics are not useful. We believe a more accurate valuation should take into consideration the potential value of its drug product pipeline. We do acknowledge that this valuation is complex and requires a large number of forward assumptions that we have to estimate that may be imprecise and may vary significantly from actual results. This is particularly so for a company like GRI Bio which is still in early clinical trials work with its main drug (GRI-0621) and pre-clinical stage with its other drug (GRI-0803).

However, we believe our assumptions are fair and provide a reasonable basis for our valuation analysis. Our analysis considers future estimated revenue from each of its major drug product pipelines (based on estimated future sales, a probability rate of success, and discounted this back to a current value), mainly focused on its 2 drugs in development (GRI-0621 for Idiopathic Pulmonary Fibrosis (IPF) and GRI-0803 for Systemic Lupus Erythematosus (SLE)). We apply a high discount rate and a low probability of success to capture the high uncertainties associated generally with drugs in development. We then added up the values, made an assumption about future investments required and allocated the value based on current share count. Based on our NPV analysis, we arrived at our 12-month price target of \$12.00, which we believe appropriately balances out the company's risks with its high growth prospects.

GRI Bio share price has been weak and volatile since the completion of its reverse merger on April 21, 2023. GRI Bio's share price was \$781.24 (split adjusted) on 4/23/23, but closed at \$35.04 on 12/29/23. So far in 2024, the stock has been weak at -99% (to the current share price of \$0.35 as of 10/7/24). Since 9/29/23 (in the past year), the stock has traded between \$0.30 (on 10/1/24) and \$161.98 (on 10/5/23).

This is in contrast with general stock price weakness and volatility with small/microcap tech stocks in 2022 and then a sharp rebound in 2023 (Russell 2000 Index of small-cap U.S. stocks was -20% in 2022 and +19% in 2023). While the Russell 2000 Index has been strong in 2024 (+9% YTD and compares to the S&P500 +21% and NASDAQ +21%), it and small and micro-cap companies have remained volatile even as the overall stock market has been strong and positive.

We believe this stock price volatility is likely due to the high general stock price volatility with small/microcap biotechnology stocks particularly after a reverse merger event. We believe that there are near term catalysts that can drive the stock particularly for key clinical milestones (interim and top-line data for GRI-0621 in late 2024/early 2025 and start of clinical trials for GRI-0803 in 2025). As the company is likely to make significant progress in its businesses over the next several years, we believe this will result in much improved visibility into future cash flows and higher share price.

Although it is very likely that the company will have to keep raising capital to achieve its drug development goals, we believe that positive progress will make future financings accretive to current shareholders.

We expect valuations for GRI Bio to improve as visibility into cash flow generation becomes clearer (though we acknowledge that drug approvals and product commercialization is likely at least 2 years away), resulting in significant upside to the current share price. We also want to note that investor's interest in drug development companies are high with many companies in this area attributed high valuations due to the large market opportunities and numerous acquisitions at high valuations (particularly for Idiopathic Pulmonary Fibrosis (IPF) companies).



Exhibit 6: Company Valuation (DCF) (in \$ millions)

Valuation of Business Segments (in millions)

			% of			Discount	Esti	mated Annual	% of Market	N	Market Potential
Drug Products	Estima	ated NPV	Success	Ca	Iculated NPV	Rate		Sales	Share		per year
GRI-0621 - Idiopathic Pulmonary Fibrosis (IPF)	\$	57	25%	\$	229	35%	\$	80	20%	\$	400
GRI-0803 - Systemic Lupus Erythematosus (SLE)	\$	11	10%	\$	114	35%	\$	40	20%	\$	200
Total	\$	69									
Net cash	\$	6									
Estimated additional investments (& debt) required	\$	39									
Current Value for existing shareholders	\$	36									
Shares Outstanding (mils)		3									
Estimated Value per share	\$	12.00]								

Source: Ascendiant Capital Markets estimates.

Exhibit 7: GRI Bio, Inc. Stock Price (in 2024)



^{*}Reflects a 1:7 reverse stock split in January 2024.*Reflects a 1:13 reverse stock split in June 2024.

Source: https://bigcharts.marketwatch.com/



Exhibit 8: Recent Acquisitions in IPF Companies

		uisitions i for Signif		
Company	Partner	Stage (Year)	Upfront	Total Deal
Galápa gos	 GILEAD	Phase 3 (2019)	\$3.95B	\$3.96B plus \$1.1B investment undisclosed milestones
Promedior	Roche	Phase 2 (2019)	\$390M	\$1B milestones + royalties
bridge <mark>bio</mark>	Boehringer Ingelheim	Phase 1 (2019)	\$50.57M	\$1.25B milestones
🔀 Redx	AstraZeneca 2	Predinical (2020)	\$17M	\$360M + royalties
The DJS	abbvie	Preclinical (2022)		\$255M total payment
MORPHIC No. CRAPEUTIC	abbvie	Predinical (2018) Predinical (2020)	\$100M \$20M	R&D option agreement Upfront licensing fee for IPF program(s)
raviton	表德制药 DE PROMAKCILIDA	Predinical (2021)	NA	\$518M upfront, milestones

Source: Company report.

COMPANY

Based in La Jolla, CA, GRI Bio is a clinical-stage biopharmaceutical company focused on diseases associated with dysregulated immune responses leading to inflammatory, fibrotic, and autoimmune disorders. The company is discovering, developing, and commercializing innovative therapies that target serious diseases associated with dysregulated (uncontrolled) immune responses. The company has 2 main drugs in development (GRI-0621 for Idiopathic Pulmonary Fibrosis (IPF) and GRI-0803 for Systemic Lupus Erythematosus (SLE)).

The company's initial main focus is developing GRI-0621 for the treatment of IPF. GRI-0621 is an oral formulation of tazarotene, a prescription topical retinoid that is approved in the U.S. for the treatment of psoriasis and acne. GRI-0621 inhibits the activity of iNKT (invariant natural killer T) cells that have been shown to accumulate in IPF patients and other interstitial (fluid-filled space existing



between a structural barrier, such as a cell membrane or the skin, and internal structures, such as organs) lung disease patients. It has been shown that activated iNKT cells are overexpressed in IPF, hepatic and other fibrotic conditions and are significantly correlated with advanced disease.

The company's second planned drug product is GRI-0803, which is a novel oral agonist (activates a receptor to produce a biological response) of type 2 Natural Killer T (type 2 NKT) cells. The company is developing GRI-0803 for the treatment of autoimmune disorders, with much of its preclinical work in SLE (systemic lupus erythematosus or lupus) and MS (multiple sclerosis).

Vallon Pharmaceuticals, Inc. was a clinical-stage biopharmaceutical company focused on the development and commercialization of novel abuse-deterrent medications for CNS (central nervous system) disorders. The company was founded in 2018 and had its IPO in February 2021. In April 2022, Vallon commenced a search for strategic alternatives following disappointing clinical trial data for its drug candidate.

In December 2022, Vallon announced that it has entered into a definitive business combination agreement to acquire privately-held GRI Bio, Inc. (Legacy GRI). On April 21, 2023, the business combination was completed. Legacy GRI became the primary operations of the combined company and the name of the company was changed to GRI Bio, Inc. from Vallon Pharmaceuticals, Inc.

Legacy GRI was founded by three immunologists to pursue NKT cell research and drug development. The company was incorporated in 2009 under the name Glycoregimmune, Inc. and changed its name to GRI Bio, Inc. in 2015.

As of March 2024, GRI Bio had ~4 employees.

Management Team

W. Marc Hertz, Ph.D. (age 54) Chief Executive Officer - Mr. Hertz has served as President and CEO since April 2023. He co-founded GRI Operations in 2009 and served as CEO and Chairperson of its board of directors since its inception. In addition to his management positions, Mr. 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. Mr. Hertz has also held several senior positions at companies in the biotechnology industry since 1998. Mr. Hertz received his undergraduate degree in biology from Bowdoin College and his Ph.D. in immunology and microbiology from the University of Colorado Medical School.

Leanne Kelly (age 47) Chief Financial Officer — Ms. Kelly has served as CFO since the closing of the Merger in April 2023. She brings over 20 years of experience leading private and publicly traded companies across life science, technology and e-Commerce sectors. From May 2021 until the closing of the Merger, she served as the CFO of Vallon. From 2016 to 2021, she served as the Controller and Executive Director, Global Financial Reporting at OptiNose, Inc., a multi-million dollar revenue specialty pharmaceutical company. Over the course of her career, she has worked at Flower Orthopedics, Iroko Pharmaceuticals, LLC, Genaera Corporation, and as an auditor with KPMG LLP. Ms. Kelly received her Bachelor of Science degree in Business Economics from Lehigh University and is a licensed CPA (inactive status) in the state of Pennsylvania.



Exhibit 9: GRI Bio Management Team

Proven Leadership Team



DRUG PIPELINE

GRI Bio is a clinical-stage biopharmaceutical company focused on diseases associated with dysregulated immune responses leading to inflammatory, fibrotic, and autoimmune disorders. The company is discovering, developing, and commercializing innovative therapies that target serious diseases associated with dysregulated (uncontrolled) immune responses. The company has 2 main drugs in development (GRI-0621 for Idiopathic Pulmonary Fibrosis (IPF) and GRI-0803 for Systemic Lupus Erythematosus (SLE)). Besides GRI-0803, the company has a proprietary library of 500+ compounds.

The company's initial main focus is developing GRI-0621 for the treatment of IPF. GRI-0621 is an oral formulation of tazarotene, a prescription topical retinoid that is approved in the U.S. for the treatment of psoriasis and acne. GRI-0621 inhibits the activity of iNKT (invariant natural killer T) cells that have been shown to accumulate in IPF patients and other interstitial (fluid-filled space existing between a structural barrier, such as a cell membrane or the skin, and internal structures, such as organs) lung disease patients. It has been shown that activated iNKT cells are overexpressed in IPF, hepatic and other fibrotic conditions and are significantly correlated with chronic and advanced disease.

The company's second planned drug product is GRI-0803, which is a novel oral agonist (activates a receptor to produce a biological response) of type 2 Natural Killer T (type 2 NKT) cells. The company is developing GRI-0803 for the treatment of autoimmune disorders, with much of its preclinical work in SLE (systemic lupus erythematosus or lupus) and MS (multiple sclerosis).



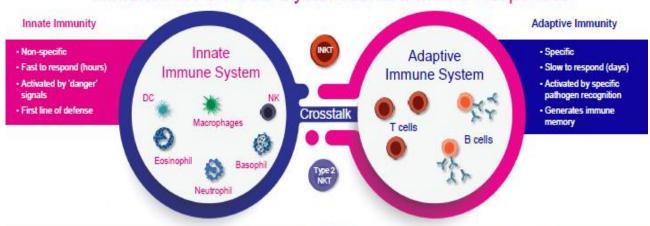
Exhibit 10: NKT Science

NKT SCIENCE:

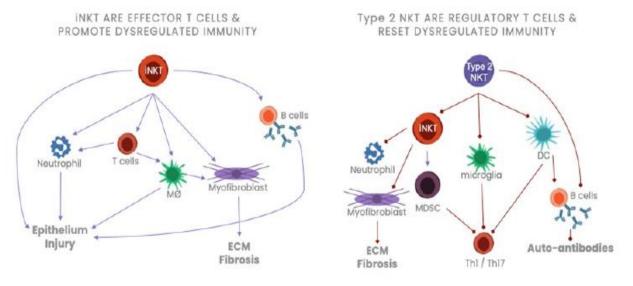
Target the Immune Response Earlier in the Inflammatory Cascade to Interrupt Disease Progression

NKT Cells for Immune Regulation

Novel Immune Mechanism to Regulate the Adaptive-Innate Immune Axis & Reset Dysfunctional Immune Responses



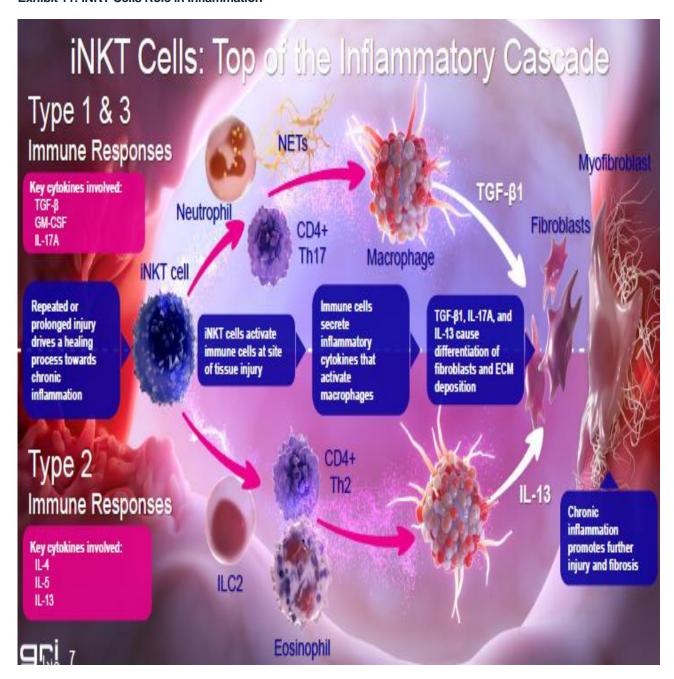
Regulating NKT Cells is a Selective Approach to Immunomodulation via Resetting the Immune Response



Source: Company reports.



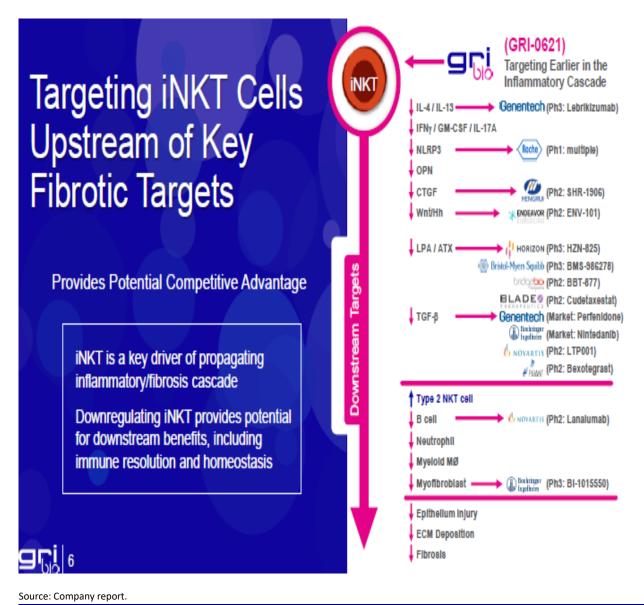
Exhibit 11: iNKT Cells Role in Inflammation



Source: Company reports.



Exhibit 12: Targeting iNKT Cells Upstream



GRI Bio is developing GRI-0621 to treat severe fibrotic lung diseases such as idiopathic pulmonary fibrosis (IPF). GRI-0621 is an oral gel capsule formulation of an FDA-approved topical dermatology product, tazarotene, a synthetic RAR-beta and gamma-selective agonist and potent inhibitor of iNKT cells. Tazarotene is approved in topical (on the skin) 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.

In preliminary data from its trials to date, and earlier trials with oral tazarotene, the company has observed GRI-0621 to be well-tolerated and to inhibit iNKT cell activity in subjects. It has been shown that activated iNKT are upregulated in IPF, primary sclerosing cholangitis (PSC), non-alcoholic steatohepatitis (NASH), alcoholic liver disease (ALD), systemic lupus erythematosus disease (SLE), multiple sclerosis (MS), ulcerative colitis (UC) patients, as well as other indications.



Exhibit 13: Good (Acute) vs. Bad (Chronic) Inflammation

TYPES OF INFLAMMATION

ACUTE "GOOD" INFLAMMATION

CHRONIC "BAD" INFLAMMATION



A <u>serious</u> threat triggers inflammation (a cut, bruise, infection, etc.)



A non-serious event triggers inflammation (eating a certain food, acne bacteria. etc.)



The body releases inflammatory compounds



The body releases inflammatory compounds



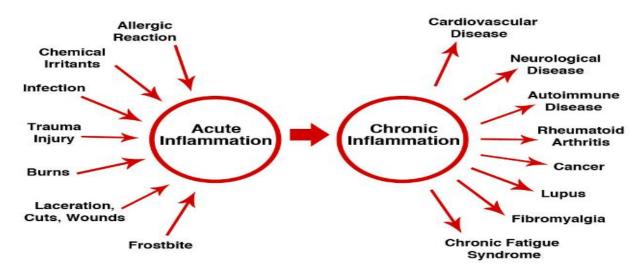
The job gets done & antiinflammatory compounds are released. The body goes back to business as usual



The body doesn't release anti-inflammatory compounds and keeps sending an inflammatory response

GoodGlow.co

Acute Vs. Chronic Inflammation



Source: Inside Out Health Wellness

Source: GoodGlow.co and Inside Out Health Wellness.



GRI Bio's science is founded on the discovery that NKT (Natural killer T) cells are a functional link between the innate and adaptive immune systems and that dysregulated (uncontrolled) immune responses can be reset by regulating the activity of NKT cells to potentially treat a broad array of acute and chronic conditions.

NKT cells share properties of both NK (Natural killer cells) and T (types of white blood cells) cells and are critical regulators of immune responses. NK cells provide rapid responses to virus-infected, stressed, tumor cells based on signals from activating and inhibitory receptors. NK cells can recognize and kill stressed cells in the absence of antibodies, allowing for a much faster immune reaction. T cells are types of white blood cells of the immune system and play a central role in the adaptive immune response.

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 and are critical for minimizing the damage caused by inflammatory responses. 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 and activated iNKT cells accumulate in the lungs of IPF, NASH and SLE patients, as well as other chronic inflammatory, fibrotic, and autoimmune disease populations.

Exhibit 14: GRI-0621 For Idiopathic Pulmonary Fibrosis (IPF)

GRI-0621

Idiopathic Pulmonary Fibrosis (IPF)

Ongoing Phase 2a biomarker study with interim data expected Q4 2024 and topline data Q1 2025

Leveraging FDA agreed 505(b)(2) regulatory pathway

Orphan indication with ~40K newly diagnosed cases annually¹

GRI-0621 is a small molecule RAR-βγ dual agonist that inhibits the activity of human iNKT cells. GRI-0621 has been shown to reduce aminotransferases and other LFTs in patients and improve fibrosis in multiple disease models. GRI is repurposing GRI-0621 as a once-daily oral capsule for the treatment of IPF with the potential to expand into additional fibrotic indications.

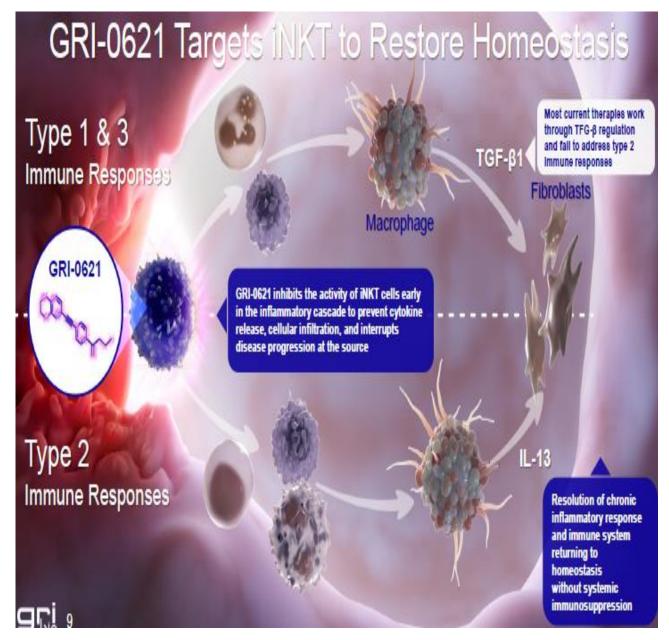
Key Highlights:

- Targets upstream in the inflammatory cascade providing potential for greater efficacy
- Favorable safety profile demonstrated in prior late stage studies
- iNKT inhibition demonstrated fibrosis resolution in multiple animal models
- Extensive IP protection with issued medical use patents and market LOE through 2036

Source: Company report.



Exhibit 15: GRI-0621 Targets iNKT To Restore Homeostasis (Normal Health)



Source: Company report.



There are over 200 types of interstitial lung diseases (ILD), which are characterized by varied amounts of inflammation, scarring, or both, that damage the ability of the lung to absorb oxygen from the air. Pulmonary fibrosis (PF) means scarring of the lung and can be seen in many types of ILD.

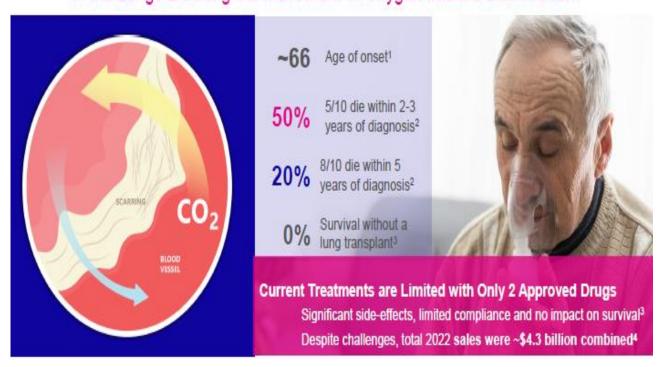
When a person is diagnosed with PF, sometimes a doctor is able to find the cause of the disease. In many cases a doctor cannot find a reason why a person has developed pulmonary fibrosis. When the cause of the disease is not known, the fibrosis may be termed "idiopathic."

Idiopathic Pulmonary Fibrosis (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.

Exhibit 16: Idiopathic Pulmonary Fibrosis

The Need in Idiopathic Pulmonary Fibrosis

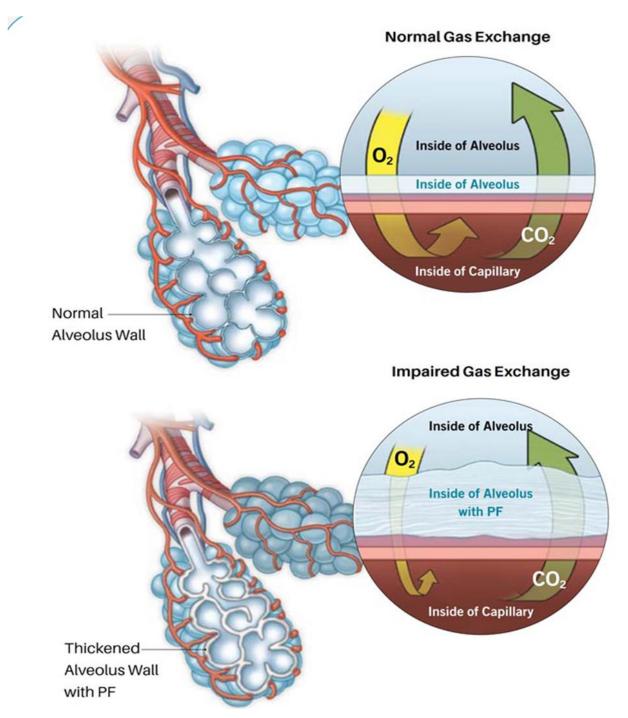
A Rare Chronic Progressive Pulmonary Disease with Abnormal Scarring of the Lungs Blocking the Movement of Oxygen into the Bloodstream



Source: Company reports.



Exhibit 17: Idiopathic Pulmonary Fibrosis (IPF)



Source: Pulmonary Fibrosis Foundation.



Idiopathic pulmonary fibrosis is one of the most common and severe form of progressive PF. IPF is on the rise with more than 40,000 new cases diagnosed annually. More than 250,000 Americans are living with PF and ILD, of which IPF affects approximately 140,000 patients in the U.S. IPF primarily affects individuals between the ages of 65 and 70, and is expected to rise with an aging population. The median survival is between two to three years after diagnosis, and the average life expectancy is between three and five years.

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. Despite this, total worldwide sales of pirfenidone and nintedanib in 2019 were over \$1.2 billion and \$1.6 billion, respectively.

Exhibit 18: GRI-0621 For IPF Benefits

GRI-0621 for the Treatment of Idiopathic Pulmonary Fibrosis

Small molecule RAR- $\beta\gamma$ dual agonist that inhibits the activity of human iNKT cells

iNKT inhibition demonstrated fibrosis resolution in multiple animal models

Established safety profile as an oral formulation

GRI-0621 is an oral formulation of an FDA-approved topical dermatology product, tazarotene

Prior late-stage studies of an oral formulation of tazarotene demonstrated favorable safety profile in ~1,700 subjects

Extensive IP protection with issued medical use patents and market LOE through 2036

Source: Company reports.



Exhibit 19: GRI-0621 Clinical Models

Targeting iNKT Cells Upstream of Key Fibrotic Targets Provides Potential Competitive Advantage

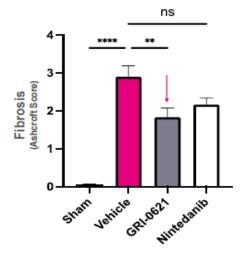
iNKT is a key driver of propagating inflammatory/fibrosis cascade

Downregulating iNKT provides potential for downstream benefits, including immune resolution and homeostasis

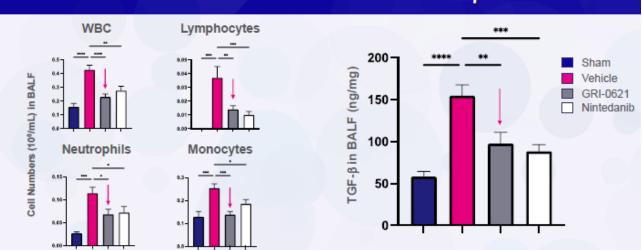
95 14

IPF Animal Model:

GRI-0621 significantly reduces inflammation, TGF- β , and fibrosis in a bleomycin model of pulmonary fibrosis and compares favorably to Nintedanib



Modulation of NKT Activity Inhibits Inflammation and TGF-β



Preclinical Data on Par with OFEV® (nintedanib), a Leading Tyrosine Kinase Inhibitor with 2025 Projected Sales of \$5 Billion¹

Source: Company reports.

Our Solution - GRI-0621





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 (invariant NKT cells) 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 the molecule was well tolerated.

In preclinical studies, animals lacking iNKT cells were observed to be protected from fibrosis in models of IPF, NASH, 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. Scientific literature suggests that there are common biological mechanisms that drive fibrosis in different tissues such as lung, liver, and kidney.

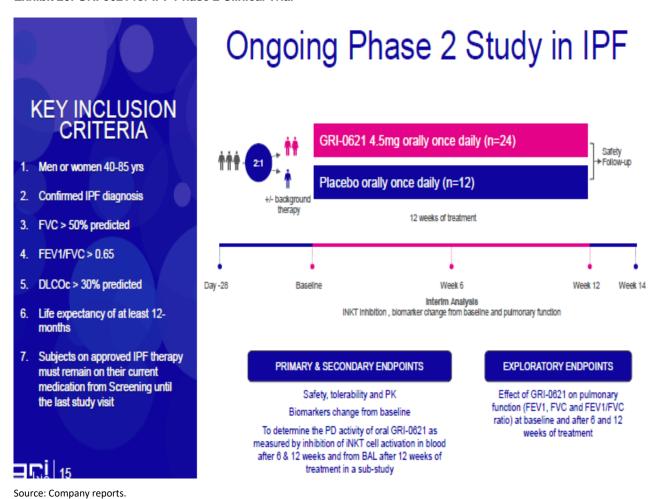
In December 2023, the company commenced enrollment for its GRI-0621 Phase 2a Trial in Patients with IPF. This trial will be a twelve-week, multicenter, multinational, randomized, placebo-controlled trial in approximately 36 patients with IPF. Weekly visits out to twelve weeks will evaluate safety, pharmacokinetics, 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. The company currently expects interim data in Q4 2024 and top-line data is expected in Q1 2025.

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



Exhibit 20: GRI-0621 for IPF Phase 2 Clinical Trial



The company is also developing GRI-0803, a novel orally administered activator of type 2 NKT (Natural killer T) cells, from which it observed therapeutic benefits in multiple models of autoimmunity. GRI-0803 has the potential to treat SLE and related kidney nephritis, MS, autoimmune hepatitis, and other autoimmune disorders. The company's initial focus for GRI-0803 is for Lupus.

Scientific studies have suggested that iNKT (Invariant natural killer T) cells 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 and in spontaneous models of lupus. Notably, activation of type 2 NKT leads to a dendritic cell-mediated inhibition of iNKT cells. In preclinical studies, GRI-0803 was observed to inhibit both murine and human iNKT cells.

GRI-0803 was observed to inhibit lupus nephritis and to significantly improve overall survival. 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. 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.

The company expects to file an IND (Investigational New Drug Application) for GRI-0803 to treat Lupus in 2025.



Exhibit 21: GRI-0803 For Systemic Lupus Erythematosus (SLE)

GRI-0803

Initial Focus on Systemic Lupus Erythematosus (SLE)

Novel activator of human type 2 NKT cells

Extensive IP protection with issued composition of matter and use patents and market LOE through 2038

GRI-0803 is a 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). Activation of type 2 NKT leads to a dendritic cell-mediated inhibition of iNKT cells. In our 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.

Key Highlights:

- Targets upstream in the inflammatory cascade providing potential for greater efficacy
- Oral administration in a spontaneous model of lupus nephritis demonstrated significant inhibition of proinflammatory cytokines, including IL-6 and IL-17; significant inhibition of autoantibodies; and improvement in overall and proteinuria-free survival

Advancing Toward the Clinic

IND-Enabling and Phase 1
Program to Advance in 2025

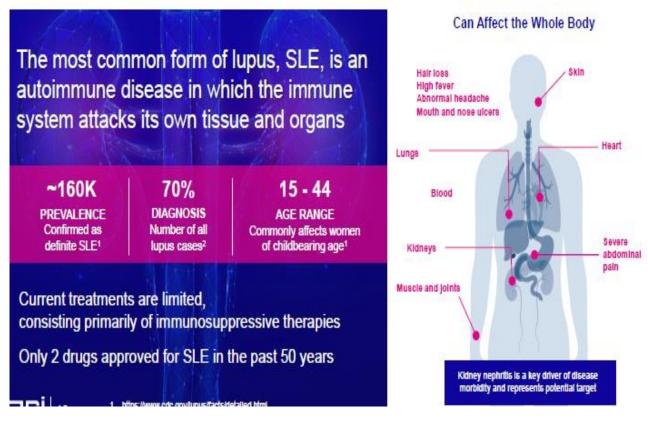
Steps Toward IND Filing Validate bioanalytical methods Complete cGMP manufacturing Complete toxicology studies

Source: Company reports.



Exhibit 22: Systemic Lupus Erythematosus (SLE)

The Need in Systemic Lupus Erythematosus



Source: Company reports.

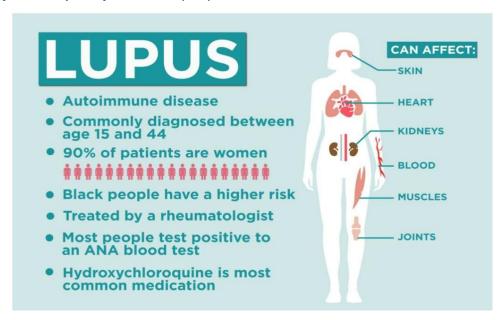
Systemic Lupus Erythematosus (SLE) is the most common type of lupus (~70% of all cases) and is usually what people refers to when talking about Lupus. The Lupus Foundation of America estimates that 1.5 million Americans, and at least five million people worldwide, have a form of lupus. As many as 24,000 people in the U.S. are diagnosed with the disease each year.

SLE is an autoimmune disease in which the immune system mistakenly attacks its own healthy tissues, especially joints and skin, but can affect almost every organ and tissue of the body causing widespread inflammation and tissue damage in the affected organs. It can affect the joints, skin, brain, lungs, kidneys, and blood vessels. The condition can be fatal, and often causes debilitating bouts of fatigue and pain that prevent nearly half of adult patients from working. In the U.S., around 80,000 – 100,000 patients suffer from kidney nephritis, one of the most serious manifestations of SLE, typically within five years of diagnosis. SLE predominantly affects women and often starts between the ages of 15 and 44.

Experts don't know what causes SLE. Many scientists believe that lupus develops in response to a combination of factors both inside and outside the body. This includes hormones, genetics, and environment. 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 so new treatment options are needed.

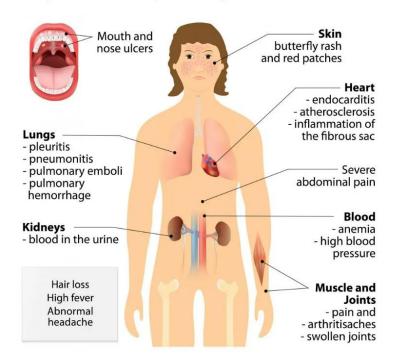


Exhibit 23: Systemic Lupus Erythematosus (SLE)



Source: https://creakyjoints.org/about-arthritis/lupus/lupus-overview/lupus-facts/

Systemic lupus erythematosus



Source: Medical News Today.



Exhibit 24: GRI Bio's Strategy

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 (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 first 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.

Source: Company reports.

FINANCIALS

GRI Bio's fiscal year ends on December 31. We expect its next earnings report (for Q3 2024 ending September 2024) to be in mid-November. Because the company is a clinical stage drug development company, it currently generates no revenue and significant losses as it funds its drug development.

On April 21, 2023, Vallon Pharmaceuticals, Inc. completed the acquisition of GRI Bio, Inc. (Legacy GRI). The deal was structured for Vallon shareholders to own ~17% of the combined shares of the company and Legacy GRI shareholders to own ~83%. The merger was accounted for as a reverse recapitalization ("reverse merger") so Vallon is treated as the acquired company and Legacy GRI is treated as the acquirer for financial reporting purposes (so historical financials before the merger were restated to reflect Legacy GRI's financials). The company has effected several reverse stock splits in 2023 and 2024, including a 1-for-30 in April 2023, a 1-for-7 in January 2024, and 1-for-13 in June 2024 (all of our historical and projected financials have been adjusted accordingly).



Exhibit 25: GRI Bio Historical and Projected Financials

FYE Dec 31				
(in millions except EPS)	2022A	2023A	2024E	2025E
Total Revenue	-	-	-	-
Research & development costs	0.2	3.2	3.8	4.0
Operating income (loss)	(2.2)	(11.4)	(8.6)	(8.8)
Net income (pro forma)	(3.2)	(13.0)	(8.5)	(8.8)
EPS	\$(324.31)	\$(367.21)	\$ (4.97)	\$ (2.63)

Source: Company reports and Ascendiant Capital Markets estimates.

Recent Results (fiscal Q2 2024 ending June 2024)

GRI Bio's recent financial performance is reflective of its developmental stage. In its Q2 2024 report (on August 14, 2024), the company reported no revenue and net loss was \$2.3 million. Operating expenses were \$2.3 million (up from \$1.9 million in Q1 2024), consisting mainly of drug development costs and general and administrative expenses. Q2 EPS was \$(4.92).

We note that in late 2024 the company plans to report interim data from its Phase 2a biomarker study for GRI-0621 for Idiopathic Pulmonary Fibrosis (IPF), with top-line data expected in Q1 2025. The company plans to file its IND application for GRI-0803 for the treatment of SLE (systemic lupus erythematosus or lupus) in 2025 with expected approval and the start of clinical trials in 2025.

The company does not provide specific quarterly financial guidance, but we believe that R&D expenses should remain relatively stable as the company continues clinical trial activities. Going forward, we believe operating expenses of ~\$2 million is a reasonable near term quarterly cash burn rate. The company expects continued progress on its drug development milestones in 2024/2025. We do not expect the company to experience revenue until its drugs make significant progress towards FDA approval (either from product sales or from the sales of drug marketing rights to new partners), which is likely at least two years away.

For 2024 (ending December 2024), we expect no revenues and a net loss of \$9 million and EPS of \$(4.37). For 2025 (ending December 2025), we expect no revenues and a net loss of \$9 million and EPS of \$(2.63).

We believe investors should be focused on its progress on its drug development, which will likely take at least two years before a potential FDA approval. We believe that the biggest potential variable in our financial model is the ability of the company to get FDA (or equivalent) approval for its GRI-0621 and GRI-0803 drugs under development. It is these approvals that are ultimately how GRI Bio will be able to finally be able to generate revenue. If the company can make significant progress towards these goals, then revenue and earnings will likely be able to grow significantly. However, if the company has difficulties in making progress towards getting drug approvals, then revenue and profitability may not be achieved or will likely grow at a moderate rate or even not at all. Even after drug approvals, GRI Bio faces a big challenge to successfully commercialize its products. However, given the lack of good treatment options to prevent or treat severe fibrotic lung diseases such as IPF and the current treatment options remains limited, we believe GRI Bio commercial prospects are very positive if it obtains FDA approval.

The company's balance sheet has \$6 million in cash and no debt as of June 2024. We believe GRI Bio has enough cash to fund its operations into Q1 2025 (March 2025), so we estimate that it will need to raise capital by Q4 2024 (December 2024).



Exhibit 26: Q2 2024 Financial Report (as of August 14, 2024)

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 — 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 fibrosis¹," 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.

Source: Company reports.

Exhibit 27: Upcoming Milestones (as of August 14, 2024)

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

Source: Company reports.



Exhibit 28: GRI Bio Financial Metrics

Recent Share Price (10/7/24) 52-Weeks Share Price (Low - High) Shares Outstanding	•	0.35 - 154.70 million
Market Capitalization Enterprise Value	*	million million
Cash (6/30/24)	\$6	million
Debt (6/30/24)	T -	\$0
2023A Revenue 2023A Net loss 2023A EPS		\$0 0 million (367.21)
2024E Revenue	:	\$0
2024E Net loss		million
2024E EPS	\$	(4.97)
2025E Revenue 2025E Net loss 2025E EPS		\$0 3 million (2.63)
	т	(/

Source: Company reports and Ascendiant Capital Markets estimates.



FINANCIAL MODEL

GRI Bio, Inc

GRI Bio, Inc.	M 00	L 00	0 00	D 00	2022	M 00	I 00	0 00	D 00	2000	M 01	l 0 1	0 61	D 01	2027	M 07	l 65	0 0-	D 05	2005
Income Statement (\$ mils)	Mar-22	Jun-22		Dec-22	2022	Mar-23	Jun-23	Sep-23	Dec-23	2023	Mar-24	Jun-24	Sep-24		2024				Dec-25	2025
Fiscal Year End: December 31	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3E	Q4E	FY-E	Q1E	Q2E	Q3E	Q4E	FY-E
Total Revenue	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Cost of Revenues	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Gross Profit	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Research & development	0.060	0.059	0.063	0.060	0.242	0.116	0.880	1.189	1.047	3.232	0.933	0.877	1.000	1.000	3.810	1.000	1.000	1.000	1.000	4.000
General & administrative	0.138	0.130	0.123	1.606	1.997	0.872	5.054	1.250	0.979	8.155	0.962	1.380	1.200	1.200	4.742	1.200	1.200	1.200	1.200	4.800
Restructuring and other					0.000					0.000					0.000					0.000
Total operating expenses	0.198	0.189	0.186	1.666	2.239	0.988	5.934	2.439	2.026	11.387	1.895	2.257	2.200	2.200	8.552	2.200	2.200	2.200	2.200	8.800
Operating income (loss)	(0.198)	(0.189)	(0.186)	(1.666)	(2.239)	(0.988)	(5.934)	(2.439)	(2.026)	(11.387)	(1.895)	(2.257)	(2.200)	(2.200)	(8.552)	(2.200)	(2.200)	(2.200)	(2.200)	(8.800
Interest income (expense)	(0.104)	(0.106)	(0.165)	(0.278)	(0.653)	(1.162)	(0.934)	0.006	0.01	(2.082)	0.006	0.006	0.000	0.000	0.012	0.000	0.000	0.000	0.000	0.000
Other income (expense)	(0.000)	(0.005)	(0.054)	(0.325)	(0.325)	(0.450)	0.122	0.296	0.014	0.432	0.002	0.001	0.000	0.000	0.003	0.000	0.000	0.000	0.000	0.000
Income before income taxes Income taxes	(0.302)	(0.295)	(0.351)	(2.269)	(3.217) 0.000	(2.150)	(6.746)	(2.137)	(2.004)	(13.037)	(1.887)	(2.250)	(2.200)	(2.200) 0.000	(8.537) 0.000	(2.200) 0.000	(2.200)	(2.200)	(2.200)	0.000
Net income (loss)	(0.302)	(0.295)	(0.351)	(2.269)	(3.217)	(2.150)	(6.746)	(2.137)	(2.004)	(13.037)	(1.887)	(2.250)			(8.537)		(2.200)		(2.200)	(8.800
Nonrecurring/noncash adjustme	ents (0.302)	(0.295)	(0.351)	(0.001) (2.270)	(0.001) (3.218)	(2.150)	0.000 (6.746)	(2.137)	(0.001) (2.005)	(0.001) (13.038)	(1.887)	(2.250)	(2.200)	(2.200)	0.000 (8.537)	(2.200)	(2.200)	(2.200)	(2.200)	0.000 (8.800
EBITDA																				
Shares, Basic	0.009	0.009	0.010	0.010	0.010	0.011	0.028	0.045	0.058	0.036	0.317	0.458	3.000	3.100	1.719	3.200	3.300	3,400	3.500	3.350
Shares, Diluted	0.009	0.009	0.010	0.010	0.010	0.011	0.028	0.045	0.058	0.036	0.317	0.458	3.000	3.100	1.719	3.200	3.300	3.400	3.500	3.350
EPS Basic (pro forma)	(\$32.28)	(\$31.53)	(\$35.64)	(\$230.52)	(\$324.31)	(\$195.47)	(\$239.37)	(\$47.15)	(\$34.57)	(\$367.21)	(\$5.94)	(\$4.92)	(\$0.73)	(\$0.71)	(\$4.97)	(\$0.69)	(\$0.67)	(\$0.65)	(\$0.63)	(\$2.63
EPS Diluted (pro forma)	(\$32.28)	(\$31.53)	(\$35.64)	(\$230.52)	(\$324.31)	(\$195.47)	(\$239.37)	(\$47.15)	(\$34.57)	(\$367.21)	(\$5.94)	(\$4.92)	(\$0.73)	(\$0.71)	(\$4.97)	(\$0.69)	(\$0.67)	(\$0.65)	(\$0.63)	(\$2.63
Margins Gross margin Research & development General & administrative Operating margin Tax rate, GAAP Net margin																				
Y/Y % change Total Revenue Gross margin Research & development General & administrative Operating income (loss) Net income (loss) EPS Diluted (pro forma)						93% 532% 399% 612% 506%	1392% 3788% 3040% 2187% 659%	1787% 916% 1211% 509% 32%	1645% -39% 22% -12% -85%	1236% 308% 409% 305% 13%	704% 10% 92% -12% -97%	0% -73% -62% -67% -98%	-4% -10% 3%	-4% 23% 9% 10% -98%	18% -42% -25% -35% -99%	7% 25% 16% 17% -88%	14% -13% -3% -2% -86%	0% 0% 0%	0% 0% 0% 0% -11%	5% 19 3% 39 -47%

Source: Company reports and Ascendiant Capital Markets estimates.

Reflects a 1:7 reverse stock split in January 2024 Reflects a 1:13 reverse stock split in June 2024



GRI Bio. Inc.

Balance Sheet (\$ mils)	Dec-22	Jun-23	Sep-23	Dec-23	Mar-24	Jun-24	Sep-24	Dec-24	Mar-25	Jun-25	Sep-25	Dec-25
Fiscal Year End: December 31	Q4A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3E	Q4E	Q1E	Q2E	Q3E	Q4E
Assets												
Cash and cash equivalents	0.009	4.799	3,488	1.808	4.091	6.353	4.190	2.027	(0.136)	(2.299)	(3.397)	(5.360
Short term investments	0.000	00	0.100	1.000		0.000	0.000	0.000	0.000	0.000	0.000	0.000
Deferred income taxes							0.000	0.000	0.000	0.000	0.000	0.000
Prepaid expenses and other	0.303	0.793	0.879	1.126	0.337	0.531	0.531	0.531	0.531	0.531	0.531	0.531
Total current assets	0.312	5.592	4.367	2.934	4.428	6.884	4.721	2.558	0.395	(1.768)	(2.866)	(4.829
Total current assets	0.312	3.332	4.507	2.334	4.420	0.004	4.721	2.550	0.555	(1.700)	(2.000)	(4.023
Property and equipment, net	0.004	0.009	0.009	0.008	0.007	0.006	0.006	0.006	0.006	0.006	0.006	0.006
Intangibles, net							0.000	0.000	0.000	0.000	0.000	0.000
Deferred income tax							0.000	0.000	0.000	0.000	0.000	0.000
Other Other	0.067	0.041	0.028	0.014	0.152	0.141	0.141	0.141	0.141	0.141	0.141	0.141
Total assets	0.383	5.642	4.404	2.956	4.587	7.031	4.868	2.705	0.542	(1.621)	(2.719)	(4.682
Liabilities and stockholders' equity												
Accounts payable	1,294	0.307	0.988	1.410	0.637	1.236	1,236	1.236	1,236	1,236	1,236	1.236
Accrued expenses	0.036	1.193	1.143	1.270	0.999	0.935	0.935	0.935	0.935	0.935	2.000	2.200
Deferred income tax	0.000				0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Warrant liabilities		0.063	0.018	0.003	0.001		0.000	0.000	0.000	0.000	0.000	0.000
Other	0.062	0.041	0.028	0.014	0.043	0.045	0.045	0.045	0.045	0.045	0.045	0.045
Short term debt	0.602			•.•.			0.000	0.000	0.000	0.000	0.000	0.000
Total current liabilities	1.994	1.604	2.177	2.697	1.680	2.216	2.216	2.216	2.216	2.216	3.281	3.481
Deferred income taxes							0.000	0.000	0.000	0.000	0.000	0.000
Warrant liabilities							0.000	0.000	0.000	0.000	0.000	0.000
Other long term liabilities	0.014				0.109	0.096	0.000	0.000	0.000	0.000	0.000	0.000
Long term debt	0.014				0.109	0.090	0.000	0.000	0.000	0.000	0.000	0.000
Total other liabilities	0.014	0.000	0.000	0.000	0.109	0.096	0.096	0.096	0.096	0.096	0.096	0.096
Preferred stock							0.000	0.000	0.000	0.000	0.000	0.000
Common stock							0.037	0.074	0.111	0.148	0.185	0.222
Additional paid-in capital	16.871	31.430	31.756	31.792	36.218	40.389	40.389	40.389	40.389	40.389	40.389	40.389
Retained earnings	(18.496)	(27.392)	(29.529)	(31.533)	(33.420)	(35.670)	(37.870)	(40.070)	(42.270)	(44.470)	(46.670)	(48.870
Other							0.000	0.000	0.000	0.000	0.000	0.000
Accumulated other comprehensive income							0.000	0.000	0.000	0.000	0.000	0.000
Total stockholders' equity	(1.625)	4.038	2.227	0.259	2.798	4.719	2.556	0.393	(1.770)	(3.933)	(6.096)	(8.259
Total stockholders' equity and liabilities	0.383	5.642	4.404	2.956	4.587	7.031	4.868	2.705	0.542	(1.621)	(2.719)	(4.682

Balance Sheet Drivers

Dalance Sheet Drivers												
	Dec-22	Jun-23	Sep-23	Dec-23	Mar-24	Jun-24	Sep-24	Dec-24	Mar-25	Jun-25	Sep-25	Dec-25
	Q4A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3E	Q4E	Q1E	Q2E	Q3E	Q4E
Book & Cash Value (per share)												
Book Value per Share (diluted)	-\$165.02	\$143.29	\$49.14	\$4.47	\$8.81	\$10.31	\$0.85	\$0.13	-\$0.55	-\$1.19	-\$1.79	-\$2.36
Cash per Share (diluted)	\$0.91	\$170.29	\$76.96	\$31.17	\$12.89	\$13.88	\$1.40	\$0.65	-\$0.04	-\$0.70	-\$1.00	-\$1.53
Net cash per Share (diluted)	-\$60.22	\$170.29	\$76.96	\$31.17	\$12.89	\$13.88	\$1.40	\$0.65	-\$0.04	-\$0.70	-\$1.00	-\$1.53

Source: Company reports and Ascendiant Capital Markets estimates



GRI Bio, Inc.

Cash Flow Statement (\$ mils)	Jun-22	Sep-22	Dec-22	2022	Mar-23	Jun-23	Sep-23	Dec-23	2023	Mar-24	Jun-24	Sep-24	Dec-24	2024	Mar-25	Jun-25	Sep-25	Dec-25	2025
iscal Year End: December 31	Q1&2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3E	Q4E	FY-E	Q1E	Q2E	Q3E	Q4E	FY-E
Cash flow from operating activities																			
Net income	(0.597)	(0.351)	(2.269)	(3.217)	(2.150)	(6.746)	(2.137)	(2.004)	(13.037)	(1.887)	(2.250)	(2.200)	(2.200)	(8.537)	(2.200)	(2.200)	(2.200)	(2.200)	(8.80
Depreciation	0.001	0.001	0.001	0.003	0.001	0.001	0.001	0.001	0.004	0.001	0.001			0.002					0.00
Amortization				0.000					0.000					0.000					0.00
Non-cash lease expense				0.000					0.000					0.000					0.00
Debt related amortization expense		0.045	0.172	0.217	1.161	0.943			2.104					0.000					0.00
Stock comp			0.025	0.025	0.013	0.013	0.326	0.036	0.388	0.037	0.037	0.037	0.037	0.148	0.037	0.037	0.037	0.037	0.14
Deferred income taxes				0.000					0.000			0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.00
Change in fair value of warrant liability				0.000		0.063	(0.045)	(0.200)	(0.182)	(0.002)	(0.001)			(0.003)					0.00
Lease	0.023	0.012	0.012	0.047	0.012	0.014	0.013	0.014	0.053	0.014	(0.141)			(0.127)					0.00
Inventory reserve				0.000					0.000					0.000					0.00
Accrued interest				0.000					0.000					0.000					0.00
Writedowns and impairments			0.325	0.325					0.000					0.000					0.0
Other gains/losses				0.000					0.000					0.000					0.00
Other				0.000					0.000					0.000					0.00
Changes in operating assets and liabilitie	s:																		
Prepaid expenses & other current ass	(0.008)	0.001	(0.028)	(0.035)	0.028	(0.778)	(0.086)	0.289	(0.547)	0.564	(0.194)	0.000	0.000	0.370	0.000	0.000	0.000	0.000	0.0
Income tax	(,		(,	0.000		(/	(,		0.000		(/			0.000					0.0
Other assets				0.000					0.000			0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.0
Accounts payable	0.079	(0.002)	0.820	0.897	0.408	3.771	0.681	(2.701)	2.159	(0.744)	0.344	0.000	0.000	(0.400)	0.000	0.000	0.000	0.000	0.0
Accrued expenses	0.409	0.181	0.106	0.696	(0.036)	1.193	(0.051)	(0.981)	0.125	(0.172)	(0.078)	0.000	0.000	(0.250)	0.000	0.000	1.065	0.200	1.26
Deferred revenue				0.000	(5.555)		(0.00.)	(0.00.)	0.000	(*****=/	(0.0.0)			0.000					0.00
Other liabilities	(0.023)	(0.012)	(0.008)	(0.043)	(0.016)	(0.014)	(0.013)	(0.014)	(0.057)	(0.014)	0.141	0.000	0.000	0.127	0.000	0.000	0.000	0.000	0.00
Net cash (used in) provided by opera	(0.116)	(0.125)	(0.844)	(1.085)	(0.579)	(1.540)	(1.311)		(8.990)	(2.203)	(2.141)	(2.163)	(2.163)	(8,670)	(2.163)	(2.163)	(1.098)	(1.963)	(7.38
Net cash (used in) provided by opera	(0.116)	(0.125)	(0.044)	(1.065)	(0.579)	(1.540)	(1.311)	(5.560)	(0.990)	(2.203)	(2.141)	(2.103)	(2.103)	(0.070)	(2.163)	(2.163)	(1.090)	(1.903)	(7.30
Cash flow from investing activities			(0.000)	(0.000)		(0.000)			(0.000)										
Purchases of property and equipment			(0.003)	(0.003)		(800.0)			(0.008)			0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.00
Purchases of short-term investments				0.000					0.000					0.000					0.00
Acquisitions				0.000					0.000					0.000					0.00
<u>Other</u>				0.000					0.000					0.000					0.00
Net cash used in investing activities	0.000	0.000	(0.003)	(0.003)	0.000	(800.0)	0.000	0.000	(0.008)	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.00
Cash flow from financing activities																			
Issuance of debt	0.035	0.250	1.000	1.285	1.440	0.000	(1.250)		0.190			0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.0
Repayment of debt		(0.030)	(0.013)	(0.043)	(0.195)				(0.195)					0.000					0.0
Issuance of stock			(0.235)	(0.235)	(0.215)	12.465	1.250		13.500	4.486	4.403	0.000	0.000	8.889	0.000	0.000	0.000	0.000	0.0
Proceeds from stock option exercises				0.000		0.012			0.012					0.000					0.0
Other				0.000		(6.590)	0.000	3.880	(2.710)					0.000					0.00
Dividends and distributions				0.000					0.000					0.000					0.00
Cash provided by (used in) financing	0.035	0.220	0.752	1.007	1.030	5.887	0.000	3.880	10.797	4.486	4.403	0.000	0.000	8.889	0.000	0.000	0.000	0.000	0.00
Effect of exchange rate on cash				0.000					0.000					0.000					0.0
Net increase (decrease) in cash and	(0.081)	0.095	(0.095)	(0.081)	0.451	4.339	(1.311)	(1.680)	1.799	2.283	2.262	(2.163)	(2.163)	0.219	(2.163)	(2.163)	(1.098)	(1.963)	(7.3
, ,	0.090	0.095	0.104	0.090	0.009	0.460	4.799	3.488	0.009	1.808	4.091	6.353	4.190	1.808	2.027	(0.136)	(2.299)	(3.397)	
Beginning cash and equivalents	0.090	0.009	0.104	0.090	0.009	0.460	4.799	3.488	0.009	1.808	6.353	0.353	4.190	1.808	2.02/	(0.136)	(2.299)	(3.397)	2.02

Source: Company reports and Ascendiant Capital Markets estimates



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GRI Bio, Inc.

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Total return is defined as price appreciation plus dividend yield.

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Rating	Count	Percent	Past 12 months	
			Count	Percent
Buy	55	98%	18	33%
Hold	Λ	0%	Λ	Λ%

Buy	55	98%	18	33%
Hold	0	0%	0	0%
Sell	1	2%	0	0%
Total	56	100%	18	32%

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