



NEWS RELEASE

Viridian Therapeutics Highlights Recent Progress and Reports First Quarter 2024 Financial Results

5/8/2024

- THRIVE VRDN-001 global phase 3 clinical trial in active thyroid eye disease (TED) completed and exceeded its target for enrollment in March 2024; topline readout expected in September 2024 -
- THRIVE-2 VRDN-001 global phase 3 clinical trial for patients with chronic TED remains on track for topline readout by year-end 2024 -
- Positive VRDN-003 Type C meeting held with the US Food and Drug Administration (FDA); pivotal program on track to start mid-year 2024 -
- VRDN-006 FcRn inhibitor remains on track for Investigational New Drug (IND) submission by year-end 2024; non-human primate data expected for VRDN-008, a half-life extended FcRn inhibitor, in the second half of 2024 -
- Conference call today at 8:00am ET -

WALTHAM, Mass.--(BUSINESS WIRE)-- Viridian Therapeutics, Inc. (NASDAQ: VRDN), a biotechnology company focused on discovering and developing potential best-in-class medicines for serious and rare diseases, today reported recent business highlights and financial results for the first quarter ending March 31, 2024.

"It has been a remarkable first quarter of execution as we made progress across our TED and neonatal Fc receptor (FcRn) inhibitor programs," said Steve Mahoney, Viridian President and Chief Executive Officer. "Rapidly completing and exceeding enrollment in THRIVE demonstrates the demand for new therapeutic options in TED and reflects our team's ability to execute as we look forward to delivering on the exciting catalysts in the year ahead. We remain on track for our key milestones across the portfolio as we aim to deliver on our corporate priorities for the benefit of

patients and our other stakeholders.”

RECENT PROGRESS

Thyroid Eye Disease Portfolio

VRDN-001, an intravenously delivered anti-insulin-like growth factor-1 receptor (IGF-1R) antibody

- THRIVE Enrollment Completed in March 2024, Topline Data Expected September 2024: The THRIVE phase 3 clinical trial in patients with active TED completed enrollment in March 2024, meeting and exceeding its enrollment target of 90 patients with patient demand driving a total enrollment of 113 patients. Approximately half of the enrolled patients were from the US and half from Europe.
- THRIVE-2 Topline Data On Track for Year-End 2024: The THRIVE-2 phase 3 clinical trial in patients with chronic TED continues to enroll and remains on track for topline readout by year-end 2024.
- VRDN-001 Safety Database and Preparation For Second Half 2025 Biologics License Application (BLA) Filing: To meet the safety database requirement for BLA filing, Viridian is actively enrolling patients into the recently initiated STRIVE clinical trial. STRIVE is a global study of VRDN-001 in TED patients that utilizes broad inclusion criteria (e.g., any severity or duration of disease) and is randomized 3:1 (10 mg/kg IV with an active control of 3 mg/kg IV). Viridian is also enrolling patients in an open label extension study for non-responders in THRIVE and THRIVE-2. Viridian anticipates filing a BLA in the second half of 2025, pending data, for marketing approval in TED and expects that its data package will support a marketing authorization application in Europe.

VRDN-003, a potential best-in-class, subcutaneous, half-life extended anti-IGF-1R product candidate designed to be a low-volume and infrequent subcutaneous injection

- Pivotal Program On Track For Mid-Year 2024 Initiation Following Positive FDA Meeting: Viridian completed a positive Type C meeting with the FDA to discuss the VRDN-003 pivotal development plan. The pivotal program remains on track to start mid-year 2024, and Viridian plans to provide additional details, including study designs, prior to the start of the program.

FcRn Inhibitor Portfolio

VRDN-006, a highly selective anti-FcRn Fc fragment designed to be a convenient subcutaneous and self-administered option for patients

- IND On Track for Year-End 2024: Viridian is on track to submit an IND application for VRDN-006 by year-end

2024.

VRDN-008, a half-life extended FcRn inhibitor designed to prolong IgG suppression and provide a potentially best-in-class subcutaneous option for patients

- NHP Data On Track for Second Half 2024: Viridian is on track to provide VRDN-008 non-human primate data, including PK and PD data, in the second half of 2024.
- Potential Best-in-Class Profile: As a half-life extended FcRn inhibitor, VRDN-008 has the potential to enable deeper and more durable suppression than existing therapies targeting FcRn.

FINANCIAL RESULTS

- Cash Position: Cash, cash equivalents, and short-term investments were \$613.2 million as of March 31, 2024, compared with \$477.4 million as of December 31, 2023. The company believes that its current cash, cash equivalents, and short-term investments will be sufficient to fund its operations into the second half of 2026.
- R&D Expenses: Research and development expenses were \$40.9 million during the quarter ended March 31, 2024, compared to \$50.7 million during the quarter ended March 31, 2023. The decrease in research and development expenses was driven by a \$15 million license fee incurred during the quarter ending March 31, 2023. This decrease was partially offset by increased clinical trials costs associated with our ongoing THRIVE and THRIVE-2 clinical trials, as well as increased personnel costs.
- G&A Expenses: General and administrative expenses were \$15.0 million during the quarter ended March 31, 2024, compared to \$21.8 million during the quarter ended March 31, 2023. The decrease in general and administrative expenses was driven by a reduction in severance and share-based compensation costs related to separation agreements with former executive officers entered into during the quarter ending March 31, 2023.
- Net Loss: The company's net loss was \$48.5 million for the first quarter ended March 31, 2024, compared with \$68.2 million for the same period last year.
- Shares Outstanding: As of March 31, 2024, Viridian had approximately 83,863,339 shares of common stock outstanding on an as-converted basis, which included 63,798,536 shares of common stock and an aggregate of approximately 20,064,803 shares of common stock issuable upon the conversion of 157,435 and 143,522 shares of Series A and Series B preferred stock, respectively.

CONFERENCE CALL AND WEBCAST

Viridian will host a webcast and conference call to discuss its first quarter 2024 financial results and provide a corporate update today, May 8, at 8:00 a.m. ET.

The webcast can be accessed under “Events and Presentations” on the Investors section of the Viridian website at viridiantherapeutics.com. To participate in the conference call, please dial 800-715-9871 (domestic) or 646-307-1963 (international) and reference code 7373356. A replay of the webcast will be available following the completion of the event.

About Viridian Therapeutics

Viridian is a biopharmaceutical company focused on engineering and developing potential best-in-class medicines for patients with serious and rare diseases. Viridian’s expertise in antibody discovery and protein engineering enables the development of differentiated therapeutic candidates for previously validated drug targets in commercially established disease areas.

Viridian is advancing multiple candidates in the clinic for the treatment of patients with thyroid eye disease (TED). The company is conducting a pivotal program for VRDN-001, including two global phase 3 clinical trials (THRIVE and THRIVE-2) to evaluate its efficacy and safety in patients with active and chronic TED. Viridian’s goal is to advance VRDN-001 as a potential best-in-class intravenous therapy followed by VRDN-003 as a potential best-in-class subcutaneous therapy for the treatment of TED.

In addition to its TED portfolio, Viridian is advancing a novel portfolio of neonatal Fc receptor (FcRn) inhibitors, including VRDN-006 and VRDN-008, which has the potential to be developed in multiple autoimmune diseases.

Viridian is based in Waltham, Massachusetts. For more information, please visit www.viridiantherapeutics.com. Follow Viridian on **LinkedIn** and **X**.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of words such as, but not limited to, “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would” or other similar terms or expressions that concern our expectations, plans and intentions. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations, and assumptions. Forward-looking statements include, without limitation, statements regarding: preclinical and clinical development of Viridian’s product candidates VRDN-001, VRDN-003, VRDN-006 and VRDN-008; anticipated start dates of studies, including the initiation date of the VRDN-003 pivotal program; alignment with regulatory authorities and anticipated regulatory submissions, including the anticipated IND submission for VRDN-006 and the anticipated BLA submission for VRDN-001;

Viridian's expectation that its data will support a BLA in the second half of 2025, pending data, for marketing approval in TED for VRDN-001; Viridian's expectation that its data package will support a marketing authorization application in Europe for VRDN-001; anticipated study designs and their disclosure; enrollment in Viridian's clinical studies; upcoming milestones and anticipated data results, including topline results; the potential utility, efficacy, potency, safety, clinical benefits, clinical response and convenience of VRDN-001, VRDN-003, VRDN-006 and VRDN-008; Viridian's product candidates potentially being best-in-class; and that the company's cash, cash equivalents and short-term investments will be sufficient to fund its operations into the second half of 2026. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. Such forward-looking statements are subject to a number of material risks and uncertainties including but not limited to: potential utility, efficacy, potency, safety, clinical benefits, clinical response and convenience of Viridian's product candidates; the relationship between the results from the positive data from completed or ongoing clinical trials and the results of ongoing or future clinical trials; that preliminary data may not be representative of final data; the timing, progress and plans for our ongoing or future research, preclinical and clinical development programs; trial protocols for ongoing clinical trials; expectations regarding the timing for regulatory filings; expectations regarding the timing for enrollment and data; uncertainty and potential delays related to clinical drug development; the duration and impact of regulatory delays in our clinical programs; the timing of and our ability to obtain and maintain regulatory approvals for our therapeutic candidates; manufacturing risks; competition from other therapies or products; estimates of market size; other matters that could affect the sufficiency of existing cash, cash equivalents and short-term investments to fund operations; our financial position and projected cash runway; our future operating results and financial performance; Viridian's intellectual property position; the timing of preclinical and clinical trial activities and reporting results from same; and those risks set forth under the caption "Risk Factors" in our most recent annual report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 27, 2024 and other subsequent disclosure documents filed with the SEC. Any forward-looking statement speaks only as of the date on which it was made. Neither the company, nor its affiliates, advisors, or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing the company's views as of any date subsequent to the date hereof.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(amounts in thousands, except share and per share data)
(unaudited)

Three Months Ended March 31,

	2024	2023
Revenue:		
Collaboration Revenue - related party	\$ 72	\$ 98
Total revenue	72	98
Operating Expenses:		
Research and development	40,944	50,740
General and administrative	15,025	21,831
Total operating expenses	55,969	72,571
Loss from operations	(55,897)	(72,473)
Other income		
Interest and other income	7,942	4,487
Interest and other expense	(587)	(165)
Net loss	(48,542)	(68,151)
Change in unrealized gain (loss) on investments	(705)	216
Comprehensive loss	\$ (49,247)	\$ (67,935)
Net loss	\$ (48,542)	\$ (68,151)
Net loss per share, basic and diluted	\$ (0.79)	\$ (1.61)
Weighted-average shares used to compute basic and diluted loss per share	61,099,038	42,242,309

Viridian Therapeutics, Inc.
Selected Financial Information
Condensed Consolidated Balance Sheets
(amounts in thousands)
(unaudited)

	March 31, 2024	December 31, 2023
Cash, cash equivalents and short-term investments	\$ 613,187	\$ 477,370
Other assets	17,194	13,054
Total assets	\$ 630,381	\$ 490,424
Total liabilities	47,851	48,402
Total stockholders' equity	582,530	442,022
Total liabilities and stockholders' equity	\$ 630,381	\$ 490,424

Source: Viridian Therapeutics, Inc.

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Source: Viridian Therapeutics, Inc.