



NEWS RELEASE

Viridian Therapeutics Highlights Recent Progress and Reports First Quarter 2025 Financial Results

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- Biologics License Application (BLA) submission for veligrotug on track for second half 2025 with potential for U.S. launch in 2026; preparatory commercial activities underway -
- REVEAL-1 and REVEAL-2, phase 3 clinical trials assessing VRDN-003 in active and chronic thyroid eye disease (TED), are on track for topline data in the first half of 2026 -
- VRDN-006 clinical data in healthy volunteers on track for third quarter 2025 -
- VRDN-008, a bispecific neonatal Fc receptor (FcRn) inhibitor with an extended half-life, on track for an Investigational New Drug (IND) submission for year-end 2025 -
- Appointed Jeff Ajer, long-time Chief Commercial Officer of BioMarin, to Viridian's Board of Directors -
- Strong cash position of \$636.6 million as of March 31, 2025, which supports cash runway into the second half of 2027 -

WALTHAM, Mass.--(BUSINESS WIRE)-- Viridian Therapeutics, Inc. (Nasdaq: VRDN), a biotechnology company focused on discovering, developing and commercializing potential best-in-class medicines for serious and rare diseases, today reported recent business highlights and financial results for the first quarter ended March 31, 2025.

"We continue to execute across the portfolio as we work towards submitting the veligrotug BLA in the second half of 2025, advancing our VRDN-003 subcutaneous clinical trials with anticipated topline data from both trials in the first half of 2026, and delivering healthy volunteer data for our first FcRn program in the third quarter of 2025," said

Steve Mahoney, Viridian's President and CEO. "As we prepare for our transition to become a commercial organization, including the anticipated U.S. launch of veligrotug in 2026, we are excited to have added Jeff Ajer, an experienced commercial leader, to our Board of Directors. We believe the data from our two pivotal clinical trials support veligrotug having a differentiated clinical profile and believe it will be well-positioned to be the IV treatment-of-choice in TED. From a portfolio perspective, we are in many ways just getting started and we look forward to the potential of bringing new treatment options to TED patients as well as other autoimmune patients who may benefit from our anti-FcRn approaches."

TED Portfolio Progress

Veligrotug is an intravenously (IV) delivered, anti-insulin-like growth factor-1 receptor (IGF-1R) antibody in phase 3 development for thyroid eye disease, with the potential to be the IV treatment-of-choice for active and chronic TED patients.

- **BLA On Track for 2H 2025; European Medicines Agency (EMA) Marketing Authorization Application (MAA) Submission Expected 1H 2026:** Following achievement of all primary and secondary endpoints in two pivotal phase 3 clinical trials for patients with active and chronic TED, Viridian is on track to submit the veligrotug BLA to the U.S. Food and Drug Administration (FDA) in the second half of 2025 and a MAA to the EMA in the first half of 2026. Preparatory commercial activities are underway to support an anticipated commercial launch in 2026, if approved.
- **Robust Clinical Profile Based on Phase 3 Pivotal Data:** In its pivotal phase 3 clinical trials, THRIVE and THRIVE-2, veligrotug demonstrated a rapid onset of treatment effect and statistically significant and clinically meaningful reduction and resolution of diplopia. This is the first data set from a global phase 3 clinical trial in chronic TED patients to demonstrate statistically significant diplopia response and resolution. Veligrotug was generally well tolerated and had a low rate of hearing impairment, a key adverse event of interest, in both clinical trials.

VRDN-003 is a potential best-in-class, subcutaneous, half-life extended anti-IGF-1R antibody with the same binding domain as veligrotug.

- **Topline Data from Phase 3 Clinical Trials On Track for 1H 2026:** Viridian anticipates topline data from both REVEAL-1 and REVEAL-2 in the first half of 2026, with a BLA submission planned by year-end 2026. Patient enrollment and dosing continues in both phase 3 clinical trials. Viridian plans to launch VRDN-003, if approved, with a commercially available, low-volume autoinjector for patients to self-administer at home.

FcRn Inhibitor Portfolio Progress

FcRn inhibitors have the potential to treat a broad array of autoimmune diseases, representing multiple significant potential commercial market opportunities. The two currently marketed indications of myasthenia gravis (MG) and

chronic inflammatory demyelinating polyneuropathy (CIDP) alone are projected to have a market size close to \$10 billion by 2030. An additional 17 indications are currently in clinical development with an FcRn inhibitor, with dozens more autoimmune diseases thought to be addressable by these inhibitors, highlighting the breadth of the therapeutic area and potential commercial opportunity.

VRDN-006 is a highly selective Fc fragment which inhibits FcRn and is designed to be a convenient subcutaneous and self-administered option for patients.

- Proof-of-Concept Phase 1 Clinical Data On Track for Q3 2025: Viridian expects data from its phase 1 clinical trial in healthy volunteers in Q3 2025, including proof-of-concept IgG reduction.

VRDN-008 is a half-life extended bispecific FcRn inhibitor comprising an Fc fragment and an albumin-binding domain designed to prolong IgG suppression and provide a potentially best-in-class subcutaneous option for patients.

- IND On Track for Year-End 2025: As previously disclosed, VRDN-008 showed a longer half-life than efgartigimod and led to a more sustained IgG reduction after a single, high dose in NHPs. An IND submission for VRDN-008 is on track by year-end 2025.

Corporate Updates – Appointment of Jeff Ajer to Viridian’s Board of Directors

On April 7, Viridian **announced** the appointment of Jeff Ajer to the Company’s Board of Directors. Mr. Ajer was most recently the Executive Vice President and Chief Commercial Officer of BioMarin Pharmaceutical, Inc. and has more than 25 years of experience driving commercialization for rare diseases and specialty medicines. Mr. Ajer’s extensive commercial experience includes leading commercial planning for late-stage pipeline programs, multiple product launches, and establishing BioMarin’s commercial infrastructure and global footprint.

Upcoming Investor Conferences

Viridian will participate in the following upcoming investor conferences in May 2025. A live webcast of the presentation can be accessed under “Events and Presentations” on the Investors section of the Viridian website at **viridiantherapeutics.com**. A replay of the webcast will be available following the event.

- RBC Global Healthcare Conference: Presentation on Tuesday, May 20, 2025, at 1:35 p.m. ET in New York, New York.

Financial Results

- Cash Position: Cash, cash equivalents, and short-term investments were \$636.6 million as of March 31, 2025,

compared with \$717.6 million as of December 31, 2024. The company believes that its current cash, cash equivalents, and short-term investments will be sufficient to fund its currently planned operations into the second half of 2027.

- **R&D Expenses:** Research and development expenses were \$76.8 million during the three months ended March 31, 2025, compared to \$40.9 million during the three months ended March 31, 2024. The increase in research and development expenses was driven by increased costs associated with conducting more clinical trials than the same period last year, including multiple ongoing phase 3 clinical trials for both veligrotug and VRDN-003 and a phase 1 clinical trial for VRDN-006, as well as increased personnel-related costs as a result of increased headcount.
- **G&A Expenses:** General and administrative expenses were \$17.1 million during the three months ended March 31, 2025, compared to \$15.0 million during the three months ended March 31, 2024. The increase in general and administrative expenses was driven by increased costs associated with preparatory commercial activities for veligrotug, as well as increased legal, accounting, and other professional service costs to support the growing organization.
- **Shares Outstanding:** As of March 31, 2025, Viridian had 100,258,627 shares of common stock outstanding on an as-converted basis, which included 81,589,427 shares of common stock and an aggregate 18,669,200 shares of common stock issuable upon the conversion of 134,864 and 145,160 shares of Series A and Series B preferred stock, respectively.

About Viridian Therapeutics

Viridian is a biopharmaceutical company focused on discovering, developing and commercializing 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 veligrotug (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. Both THRIVE and THRIVE-2 reported positive topline data, meeting all the primary and secondary endpoints of each study. Viridian is also advancing VRDN-003 as a potential best-in-class subcutaneous therapy for the treatment of TED, including two ongoing global phase 3 pivotal clinical trials, REVEAL-1 and REVEAL-2, to evaluate the efficacy and safety of VRDN-003 in patients with active and chronic 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,” “become,” “continue,” “could,” “design,” “estimate,” “expect,” “intend,” “may,” “might,” “on track,” “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 development, clinical development, and anticipated commercialization of Viridian’s product candidates veligrotug (formerly VRDN-001), VRDN-003, VRDN-006, and VRDN-008; anticipated start dates of studies; anticipated data results and timing of their disclosure, including VRDN-003 topline data from the REVEAL-1 and REVEAL-2 trials in the first half of 2026 and anticipated VRDN-006 clinical data, including proof-of-concept IgG reduction data, in the third quarter of 2025; regulatory interactions and anticipated timing of regulatory submissions, including the anticipated BLA submissions for veligrotug in the second half of 2025 and VRDN-003 by year-end 2026, MAA submission for veligrotug in the first half of 2026, and IND submission for VRDN-008 by year-end 2025, pending data; the potential utility, efficacy, potency, safety, clinical benefits, clinical response, convenience, and number of indications of veligrotug, VRDN-003, VRDN-006, and VRDN-008; veligrotug’s potential to be the IV treatment-of-choice for active and chronic TED; potential market sizes and market opportunities, including for Viridian’s product candidates; Viridian’s product candidates potentially being best-in-class; whether veligrotug will serve an unmet need; Viridian’s expectations regarding the potential commercialization of veligrotug and VRDN-003, if approved, including the anticipated U.S. launch of veligrotug in 2026 and plans to launch VRDN-003 with a low-volume autoinjector; and that Viridian’s cash, cash equivalents and short-term investments will be sufficient to fund its operations into the second half of 2027.

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; that results or data from completed or ongoing clinical trials may not be representative of 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; changes to trial protocols for ongoing or new clinical trials; expectations and

changes regarding the timing for regulatory filings; regulatory interactions; expectations and changes 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; that our product candidates may not be commercially successful, if approved; and other risks described from time to time in the "Risk Factors" section of our filings with the Securities and Exchange Commission (SEC), including those described in our most recent Annual Report on Form 10-K or Quarterly Report on Form 10-Q, as applicable, and supplemented from time to time by our Current Reports on Form 8-K. 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,	
	2025	2024
Revenue:		
Collaboration Revenue - related party	\$ 72	\$ 72
Total revenue	72	72
Operating Expenses:		
Research and development	76,835	40,944
General and administrative	17,103	15,025
Total operating expenses	93,938	55,969
Loss from operations	(93,866)	(55,897)
Other income (expense)		
Interest and other income	7,540	7,942
Interest and other expense	(586)	(587)
Net loss	(86,912)	(48,542)
Change in unrealized gain (loss) on investments	255	(705)
Comprehensive loss	\$ (86,657)	\$ (49,247)
Net loss allocated to common stock	\$ (70,688)	\$ (36,150)
Net loss per share, basic and diluted, common	\$ (0.87)	\$ (0.59)
Weighted-average common shares outstanding used to compute basic and diluted loss per share	81,344,134	61,099,038
Net loss allocated to Series A preferred stock	\$ (7,814)	\$ (6,731)
Net loss per share, basic and diluted, Series A preferred stock	\$ (57.94)	\$ (39.45)
Weighted-average Series A preferred stock outstanding used to compute basic and diluted loss per share	134,864	170,621
Net loss allocated to Series B preferred stock	\$ (8,410)	\$ (5,661)

Net loss per share, basic and diluted, Series B preferred stock	\$	(57.94)	\$	(39.44)
Weighted-average Series B preferred stock outstanding used to compute basic and diluted loss per share		145,160		143,522

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

	March 31, 2025	December 31, 2024
Cash, cash equivalents and short-term investments	\$ 636,633	\$ 717,584
Other assets	24,348	24,819
Total assets	\$ 660,981	\$ 742,403
Total liabilities	56,508	70,764
Total stockholders' equity	604,473	671,639
Total liabilities and stockholders' equity	\$ 660,981	\$ 742,403

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Source: Viridian Therapeutics, Inc.