



NEWS RELEASE

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

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- Robust execution with multiple upcoming near-term milestones, including planned Biologics License Application (BLA) submission for veligrotug on track in 2H 2025 and expected U.S. commercial launch in 2026 -
- Breakthrough Therapy Designation (BTD) for veligrotug announced in May 2025, a designation granted by the Food and Drug Administration (FDA) to drug candidates where clinical evidence shows they may offer substantial improvement over existing therapies -
- Veligrotug showed a strong durability of proptosis response and continued to be generally well-tolerated at 52 weeks in THRIVE -
- Announced exclusive license agreement with Kissei Pharmaceutical to develop and commercialize veligrotug and VRDN-003 in Japan for \$70 million upfront and potential future milestones up to \$315 million and royalties -
- Cash position of \$563.4 million as of June 30, 2025, supporting cash runway into 2H 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 second quarter ended June 30, 2025.

“Veligrotug’s recent Breakthrough Therapy Designation as well as the continued and consistent performance of veligrotug across all of the endpoints and timepoints in our pivotal clinical trials, including the latest update on durability of response, showcase the momentum Viridian is building as we approach our planned BLA filing and expected commercial launch,” said Steve Mahoney, Viridian’s President and CEO. “We are making extraordinary

progress on our commercial preparation and we plan to be launch-ready on a Priority Review designation timeline, if we receive it. In parallel to U.S. commercial launch planning, the recently announced license agreement with Kissei to develop and commercialize veligrotug and VRDN-003 in Japan further validates the value of our TED programs and the potential broad global opportunities in front of us. Overall, we are very pleased with our progress across our portfolio, including continuing to advance our FcRn inhibitors, VRDN-006 and VRDN-008, and look forward to sharing the outcomes from our upcoming milestones.”

Recent Business Highlights

Veligrotug for Active and Chronic Thyroid Eye Disease

- Positive Pivotal Trial Readouts. Veligrotug achieved all primary and secondary endpoints across proptosis, Clinical Activity Score (CAS), and diplopia in each of its two pivotal phase 3 clinical trials, THRIVE and THRIVE-2 for patients with active and chronic TED respectively.
- Robust Clinical Profile. This is the first and only drug candidate in chronic TED to demonstrate statistically significant and clinically meaningful improvement and resolution of diplopia in a global phase 3 clinical trial to date.
- Generally Well Tolerated Safety Profile. Veligrotug was generally well-tolerated in its pivotal phase 3 clinical trials, THRIVE and THRIVE-2.
- Breakthrough Therapy Designation. The FDA granted Breakthrough Therapy Designation (BTD) to veligrotug for the treatment of TED.
 - Our application was based on veligrotug’s (i) consistent and robust improvement and resolution of diplopia in chronic TED, and (ii) rapid onset of proptosis response.
 - BTD supports eligibility for Priority Review which, if received, could accelerate our timing for veli commercial launch.
- Durability of Response. Demonstrated positive long-term durability data in THRIVE, with 70% of proptosis responders at 15 weeks maintaining that response at 52 weeks, which is 40 weeks after patients received their last dose in the clinical trial.
- Biologics License Application. Viridian is on track to submit a BLA to the U.S. FDA in the second half of 2025 and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in the first half of 2026.

VRDN-003 for Active and Chronic Thyroid Eye Disease

- Topline Data – Pivotal Clinical Trials. Anticipate topline data from both REVEAL-1 and REVEAL-2 in the first half of 2026; BLA submission planned for year-end 2026.
- Planned Commercial Profile. Plan to launch VRDN-003, if approved, with a commercially validated, low-volume

autoinjector designed for patients to infrequently self-administer at home.

Japan Licensing with Kissei Pharmaceutical

- As **announced** in July, Viridian entered into an exclusive license agreement with Kissei Pharmaceutical to develop and commercialize veligrotug and VRDN-003 in Japan.
 - Viridian will receive an upfront cash payment of \$70 million, with the potential to receive an additional \$315 million in development, regulatory, and commercial milestones.
 - Viridian also receives tiered royalties on net sales in Japan with percentages ranging from the 20s to mid-30s.
 - Kissei will be responsible for all development, regulatory, and commercialization activities, and associated costs, in Japan.

FcRn Inhibitor Portfolio

- VRDN-006 Healthy Volunteer Data. Viridian expects data from the VRDN-006 phase 1 clinical trial in healthy volunteers in Q3 2025, including proof-of-concept IgG reduction
- VRDN-008 Investigational New Drug (IND). Submission on track for year-end 2025
 - As previously disclosed, after a single, high dose in non-human primates, VRDN-008 showed a longer half-life head-to-head versus efgartigimod and a more sustained IgG reduction.

Expected Upcoming Milestones

- Veligrotug
 - BLA submission in second half 2025
 - U.S. commercial launch in 2026, if approved
 - MAA submission in first half 2026
- VRDN-003
 - Topline data in first half 2026
- VRDN-006
 - Healthy volunteer clinical data in Q3 2025
- VRDN-008
 - IND submission year-end 2025

Financial Results

- Cash Position: Cash, cash equivalents, and short-term investments were \$563.4 million as of June 30, 2025,

compared with \$636.6 million as of March 31, 2025. 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 \$86.6 million during the three months ended June 30, 2025, compared to \$56.2 million during the three months ended June 30, 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 \$20.2 million during the three months ended June 30, 2025, compared to \$16.1 million during the three months ended June 30, 2024. The increase was driven by increased costs associated with preparatory commercial activities for veligrotug, as well as increased legal, accounting, and other professional service costs and personnel-related costs to support the growing organization.
- **Shares Outstanding:** As of June 30, 2025, Viridian had 100,320,386 shares of common stock outstanding on an as-converted basis, which included 81,651,186 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) and a portfolio of inhibitors to the neonatal Fc receptor (FcRn). In TED, the company is conducting a pivotal program for veligrotug, 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. For the FcRn portfolio, Viridian is developing VRDN-006, a Fc fragment that inhibits FcRn, and VRDN-008, a half-life extended FcRn inhibitor.

About Veligrotug

Veligrotug is an intravenously 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. Based on clinical data to date, veligrotug has demonstrated robust clinical activity and was generally well-tolerated.

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. Both THRIVE and THRIVE-2 reported positive topline data, meeting all the primary and secondary endpoints of each study. 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.

About VRDN-003

VRDN-003 is a subcutaneously delivered, half-life extended, potential best-in-class anti-IGF-1R antibody. VRDN-003 has the same binding domain as veligrotug and was engineered to have a longer half-life. In a phase 1 healthy volunteer clinical trial, VRDN-003 showed a half-life of 40-50 days, 4-5x that of veligrotug. Pharmacokinetics modeling predicted that VRDN-003 exposure levels after Q4W and Q8W dosing achieve the range of veligrotug exposures that showed robust clinical activity in a two-infusion phase 2 clinical trial in TED. Viridian is conducting a pivotal program for VRDN-003, including two phase 3 clinical trials assessing VRDN-003 dosed Q4W and Q8W in active and chronic TED, REVEAL-1 and REVEAL-2, respectively.

About VRDN-006 and VRDN-008

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. Viridian is studying VRDN-006 in a first-in-human phase 1 clinical trial in healthy volunteers.

VRDN-008 is a half-life extended 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. VRDN-008 showed a longer half-life than efgartigimod and led to a more sustained IgG reduction after a single, high dose in non-human primates.

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 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 impact of Breakthrough Therapy Designation, including eligibility for Priority Review, or any other FDA designations; the potential utility, efficacy, potency, safety, clinical benefits, clinical response, convenience, and number of indications of veligrotug, VRDN-003, VRDN-006, and VRDN-008, including Viridian's view of the strength of the THRIVE durability and safety resolution data and veligrotug's robust clinical profile; 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; Viridian's expectations regarding the potential commercialization of veligrotug and VRDN-003, if approved, including the anticipated U.S. launch of veligrotug in 2026, plans to launch VRDN-003 with a low-volume autoinjector, and in Japan under the agreement with Kissei; Viridian's partnership with Kissei, including that it supports the potential for broad global opportunities; Viridian's ability to receive development, regulatory, and commercial milestone payments and receive royalties on the commercial sale of our product candidates, if approved, pursuant to the agreement with Kissei; 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 June 30,		Six Months Ended June 30, 2025	
	2025	2024	2025	2024
Revenue:				
Collaboration Revenue - related party	\$ 75	\$ 72	\$ 147	\$ 144
Total revenue	75	72	147	144
Operating Expenses:				
Research and development	86,626	56,193	163,461	97,136
General and administrative	20,216	16,066	37,319	31,091
Total operating expenses	106,842	72,259	200,780	128,227
Loss from operations	(106,767)	(72,187)	(200,633)	(128,083)
Other income (expense)				
Interest and other income	6,546	7,791	14,086	15,732
Interest and other expense	(514)	(597)	(1,100)	(1,184)
Net loss	(100,735)	(64,993)	(187,647)	(113,535)
Change in unrealized gain (loss) on investments	(176)	(176)	79	(881)
Comprehensive loss	\$ (100,911)	\$ (65,169)	\$ (187,568)	\$ (114,416)
Net loss allocated to common stock	\$ (81,978)	\$ (49,453)	\$ (152,664)	\$ (85,481)
Net loss per share, basic and diluted, common	\$ (1.00)	\$ (0.77)	\$ (1.87)	\$ (1.37)
Weighted-average common shares outstanding used to compute basic and diluted loss per share	81,593,463	63,854,514	81,471,496	62,476,777
Net loss allocated to Series A preferred stock	\$ (9,034)	\$ (8,129)	\$ (16,848)	\$ (14,962)
Net loss per share, basic and diluted, Series A preferred stock	\$ (66.99)	\$ (51.63)	\$ (124.93)	\$ (91.22)
Weighted-average Series A preferred stock outstanding used to compute basic and diluted loss per share	134,864	157,435	134,864	164,029
Net loss allocated to Series B preferred stock	\$ (9,723)	\$ (7,411)	\$ (18,135)	\$ (13,092)
Net loss per share, basic and diluted, Series B preferred stock	\$ (66.98)	\$ (51.64)	\$ (124.93)	\$ (91.22)
Weighted-average Series B preferred stock outstanding used to compute basic and diluted loss per share	145,160	143,522	145,160	143,522

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

	June 30, 2025	December 31, 2024
Cash, cash equivalents and short-term investments	\$ 563,356	\$ 717,584
Other assets	18,968	24,819
Total assets	\$ 582,324	\$ 742,403
Total liabilities	67,155	70,764
Total stockholders' equity	515,169	671,639
Total liabilities and stockholders' equity	\$ 582,324	\$ 742,403

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Source: Viridian Therapeutics, Inc.