UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 8, 2024

VIRIDIAN THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36483**	**47-1187261**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

221 Crescent Street, Suite 103A **Waltham, MA**	**02453**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 272-4600

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value	VRDN	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On August 8, 2024, Viridian Therapeutics, Inc. issued a press release reporting financial results for the quarter ended June 30, 2024.

The press release is attached hereto as Exhibit 99.1, which is furnished under Item 2.02 of this Current Report on Form 8-K and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits

(d) *Exhibits*.

Exhibit Number	Exhibit Description
99.1	Press release, dated August 8, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Viridian Therapeutics, Inc.

Date: August 8, 2024

By: /s/ Stephen Mahoney
Stephen Mahoney
President, Chief Executive Officer, and Director

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

- THRIVE VRDN-001 global phase 3 clinical trial in active thyroid eye disease (TED) remains on track for topline readout in September 2024 -

- THRIVE-2 VRDN-001 global phase 3 clinical trial in chronic TED topline readout expected year-end 2024; enrollment completed in July and exceeded its target -

- REVEAL-1 and REVEAL-2, global phase 3 clinical trials for subcutaneous VRDN-003 in patients with active and chronic TED, on track to initiate in August 2024 -

- Investigational New Drug (IND) submission for neonatal Fc receptor (FcRn) inhibitor VRDN-006 planned by year-end 2024; non-human primate (NHP) data anticipated for half-life extended FcRn inhibitor VRDN-008 in the second half of 2024 -

- Cash, cash equivalents, and short-term investments of $571.4 million as of June 30, 2024; provides cash runway into the second half of 2026 -

WALTHAM, Mass., August 8, 2024 — 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 second quarter ending June 30, 2024.

“Our team continues to execute across the board as shown by the progress we have made this quarter, and we are proud to report solid progress in our TED portfolio, with both VRDN-001 phase 3 trials, THRIVE and THRIVE-2, exceeding enrollment targets, and VRDN-003 trials, REVEAL-1 and REVEAL-2, planned to initiate this month,” said Steve Mahoney, Viridian President and Chief Executive Officer. “All timelines within our FcRn portfolio remain on track, and we anticipate submitting an IND for VRDN-006 by year-end, and reporting NHP data for VRDN-008 in the second half of the year. We look forward to delivering on these multiple key program milestones this year, beginning with our THRIVE readout next month.”

RECENT PROGRESS

Thyroid Eye Disease Portfolio

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

- **THRIVE-2 Completed and Exceeded Enrollment in July 2024**: The THRIVE-2 global phase 3 clinical trial in patients with chronic TED completed enrollment in July 2024 with a total of 188 patients, exceeding its enrollment target of 159 patients due to patient demand. Approximately 40% of the enrolled patients were from the US.
- **VRDN-001 Topline Data and BLA on Track:** Both VRDN-001 global phase 3 clinical studies, THRIVE and THRIVE-2, are on track for topline data readouts in September and by year-end 2024, respectively. Viridian anticipates submitting a Biologics License Application (BLA) in the second half of 2025, pending data, 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 antibody designed as a low-volume, infrequent, and self-administered subcutaneous injection

- **REVEAL-1 and REVEAL-2 on Track to Initiate in August:** REVEAL-1 and REVEAL-2 are randomized, double-masked, placebo-controlled, global phase 3 clinical trials assessing the efficacy and safety of VRDN-003 in patients with active and chronic TED, respectively. In each study, Viridian plans to administer VRDN-003 subcutaneously every 4 weeks or every 8 weeks and assess outcomes versus placebo. The trials are designed to have a primary endpoint of proptosis responder rate, based on the achievement of at least 2 mm improvement in proptosis from baseline at week 24, and additional secondary outcome measures including changes from baseline in proptosis, clinical activity score (CAS), and diplopia.
- **Topline Data and BLA in 2026**: Viridian anticipates topline data for both REVEAL-1 and REVEAL-2 to be available in the first half of 2026 to enable a potential BLA submission by the end of 2026. The company plans to launch VRDN-003 with a commercially available auto-injector pen, if approved.

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 $571.4 million as of June 30, 2024, compared with $613.2 million as of March 31, 2024. 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 $56.2 million during the quarter ended June 30, 2024, compared to $40.1 million during the quarter ended June 30, 2023. The increase in research and development expenses was driven by increased clinical trials costs associated with our ongoing THRIVE and THRIVE-2 clinical trials, as well as increased personnel costs to support our pipeline development.
- **G&A Expenses**: General and administrative expenses were $16.1 million during the quarter ended June 30, 2024, compared to $19.3 million during the quarter ended June 30, 2023. The decrease in general and administrative expenses was driven by a decrease in personnel-related costs, primarily due to decreased share-based compensation expense in the current year.
- **Net Loss**: The company's net loss was $65.0 million for the second quarter ended June 30, 2024, compared with $55.1 million for the same period last year.
- **Shares Outstanding:** As of June 30, 2024, Viridian had approximately 83,944,478 shares of common stock outstanding on an as-converted basis, which included 63,879,675 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.

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 is also advancing VRDN-003 as a potential best-in-class subcutaneous therapy for the treatment of TED, including two planned global phase 3 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," "continue," "could," "estimate," "expect," "intend," "may," "might," "on track," "plan," "potential," "predict," "project," "design," "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 REVEAL-1 and REVEAL-2, global phase 3 clinical trials for VRDN-003; milestones; timelines; anticipated data results and timing of their disclosure, including topline results; regulatory interactions and anticipated timing of regulatory submissions, including the anticipated IND submission for VRDN-006 and the anticipated BLA submission for VRDN-001; Viridian's expectation that its data package will support a BLA submission for VRDN-001 in the second half of 2025, pending data; Viridian's expectation that its data package will support a marketing authorization application in Europe for VRDN-001; clinical trial designs, including the REVEAL-1 and REVEAL-2, global phase 3 clinical trials for VRDN-003; Viridian's plans to launch VRDN-003 with a commercially available auto-injector pen, if approved; the potential utility, efficacy, potency, safety, clinical benefits, clinical response, convenience and number of indications of VRDN-001, VRDN-003, VRDN-006 and VRDN-008; Viridian's product candidates potentially being best-in-class; and that Viridian'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; 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, including adjustments that we may make to the VRDN-003 clinical trial designs as a result of the VRDN-001 data; 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; and those risks set forth under the caption "Risk Factors" in our most recent quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 8, 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue:				
Collaboration Revenue - related party	$ 72	$ 72	$ 144	$ 170
Total revenue	72	72	144	170
Operating Expenses:				
Research and development	56,193	40,083	97,136	90,823
General and administrative	16,066	19,264	31,091	41,095
Total operating expenses	72,259	59,347	128,227	131,918
Loss from operations	(72,187)	(59,275)	(128,083)	(131,748)
Other income				
Interest and other income	7,791	4,378	15,732	8,865
Interest and other expense	(597)	(166)	(1,184)	(331)
Net loss	(64,993)	(55,063)	(113,535)	(123,214)
Change in unrealized gain (loss) on investments	(176)	1	(881)	217
Comprehensive loss	$ (65,169)	$ (55,062)	$ (114,416)	$ (122,997)
Net loss	$ (64,993)	$ (55,063)	$ (113,535)	$ (123,214)
Net loss per share, basic and diluted	$ (1.02)	$ (1.27)	$ (1.82)	$ (2.88)
Weighted-average shares used to compute basic and diluted loss per share	63,854,514	43,253,457	62,476,777	42,753,476

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

	June 30, 2024	December 31, 2023
Cash, cash equivalents and short-term investments	$571,366	$ 477,370
Other assets	14,297	13,054
Total assets	**$585,663**	**$ 490,424**
Total liabilities	56,325	48,402
Total stockholders' equity	529,338	442,022
Total liabilities and stockholders' equity	**$585,663**	**$ 490,424**

Contact

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Source: Viridian Therapeutics, Inc.