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): May 9, 2023

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 401 **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 obligations 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 May 9, 2023, Viridian Therapeutics, Inc. (the "Company"), issued a press release reporting financial results for the three months ended March 31, 2023.

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 (the "Securities Act"), 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 May 9, 2023
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: May 9, 2023

By: /s/ Scott Myers
Scott Myers
President, Chief Executive Officer, and Director

Viridian Therapeutics Reports First Quarter 2023 Financial Results and Provides Corporate Update

- Topline data from proof-of-concept study of VRDN-001 in patients with chronic thyroid eye disease (TED) are expected in June/July 2023 -

- Selection of lead subcutaneous (SC) program in TED planned for year-end 2023 -

- Company adds multiple senior executives to its leadership team, including its first Chief Commercial Officer, as part of its ongoing growth -

- Conference call today at 4:30pm ET -

WALTHAM, Mass., May 9, 2023 -- Viridian Therapeutics, Inc. (NASDAQ: VRDN), a biotechnology company focused on discovering and developing potential best-in-class medicines for serious and rare diseases, today announced financial results and provided a corporate update for the first quarter ended March 31, 2023.

“This is an important year for Viridian as we prepare to report topline data from our proof-of-concept study examining VRDN-001 in patients with chronic TED, and later this year, initiate our THRIVE-2 Phase 3 trial, select our lead SC program, and disclose details of at least one of our preclinical programs,” said Scott Myers, President and CEO of Viridian Therapeutics. “We began 2023 building significant momentum with the VRDN-001 low dose data update in patients with active TED. We added several senior executives to our leadership team, marking a critical step in our mission to deliver potential best-in-class medicines for patients and becoming a fully integrated biopharmaceutical company.”

Program highlights

Thyroid eye disease (TED)

Intravenous (IV) program: VRDN-001
Viridian’s lead product candidate, VRDN-001, is a monoclonal antibody which acts as a full antagonist of insulin-like growth factor-1 receptor (IGF-1R). VRDN-001 is being evaluated in clinical trials for the treatment of active and chronic TED.

- Data from the Phase 1/2 clinical trial of VRDN-001 in patients with active TED were highlighted in an oral presentation at the Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO 2023) in April.
- The VRDN-001 proof-of-concept study in patients with chronic TED is fully enrolled, with topline data from the 10 mg/kg and 3 mg/kg dose cohorts expected in June or July 2023.
- Initiation of the THRIVE-2 Phase 3 trial evaluating the efficacy and safety of VRDN-001 in patients with chronic TED is planned for the middle of 2023, with topline results expected by year-end 2024.
- The THRIVE Phase 3 trial evaluating the efficacy and safety of VRDN-001 in patients with active TED remains ongoing, with topline results expected in the middle of 2024.

Subcutaneous (SC) programs: VRDN-001, VRDN-002, and VRDN-003
The Company is advancing VRDN-001, VRDN-002, and VRDN-003 as SC program candidates, each with the potential to be developed into a convenient, SC, self-administered pen device. Viridian believes that VRDN-001 IV’s low-dose data support its potential as a SC candidate. VRDN-002 is a novel anti-IGF-1R monoclonal antibody incorporating half-life extension technology. VRDN-003 is an anti-IGF-1R

monoclonal antibody with the same amino acid sequence as VRDN-001, except for the addition of the half-life extension technology that is incorporated in VRDN-002.

- Preclinical and clinical posters of VRDN-002 were presented at ARVO 2023 in April.
- Two preclinical posters of VRDN-003 were presented at ARVO 2023 in April.
- Viridian plans to file the investigational new drug application (IND) for VRDN-003 with the US Food and Drug Administration (FDA) in the second quarter of 2023.
- The Company expects topline results from Phase 1 trials evaluating VRDN-003 and VRDN-001 SC in healthy volunteers in the fourth quarter of 2023.
- The Company expects to select its lead SC program based on the preclinical and clinical data available across all three programs by year-end 2023, and plans to advance the selected SC program into a pivotal trial in the middle of 2024.
- Viridian believes that the differentiated mechanism of action for VRDN-003 and VRDN-001 SC acting as full-antagonists of IGF-1R have the highest potential to bring the best SC product profile to patients in the long term.
- The VRDN-002 trial in patients with TED will proceed in 2024 only if VRDN-002 is selected as the lead SC program at the end of 2023.

Preclinical programs in autoimmune and rare disease

VRDN-004, VRDN-005, and VRDN-006

- Viridian is developing multiple preclinical assets in rare and autoimmune diseases. The Company plans to announce additional information on at least one of these programs in 2023.
- Viridian entered a partnership to utilize Enable Injections' enFuse® on-body drug delivery system for one of its preclinical programs outside of thyroid eye disease.

Corporate highlights

- During the first quarter of 2023, Viridian hired the following senior executives:
    - Tony Casciano joined Viridian as Chief Commercial Officer (CCO), where he will establish and lead all functions and activities related to commercialization. Mr. Casciano previously served as CEO and member of the board of directors of Teal Bio, and prior to that, served as the Chief Operating Officer and CCO of AMAG Pharmaceuticals. Prior to AMAG, Mr. Casciano spent 16 years leading various commercial functions with increased levels of responsibility at Sanofi and Genzyme.
    - Thomas Ciulla, M.D., MBA, joined Viridian as Chief Development Officer (CDO) where he will lead the clinical development efforts for all TED programs. Dr. Ciulla currently serves as the Chief Medical Advisor and the Chair of the Scientific Advisory Board at Clearside BioMedical, where he previously served as Chief Medical Officer and CDO. Prior to Clearside, Dr. Ciulla held senior leadership roles at Spark Therapeutics and Ophthotech Corporation.
    - Felix Geissler, M.D., Ph.D, joined Viridian as Senior Vice President, Medical Affairs, where he will lead and direct the development and execution of the medical affairs

strategy. Previously, Dr. Geissler served as Vice President, Medical Affairs at Curis, and prior to that, served in a similar position at Horizon Therapeutics.

- Erik Kupperman, Ph.D, joined Viridian as Vice President, Program Leadership. Dr. Kupperman will assist the TED and broader pipeline teams to develop global asset strategies. Dr. Kupperman has held similar positions at Alexion, Takeda, and Millennium Pharmaceuticals.

Financial results

- **Cash Position**: Cash, cash equivalents, and short-term investments were $373.9 million as of March 31, 2023, compared with $424.6 million as of December 31, 2022. 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 2025.

- **R&D Expenses:** Research and development expenses were $50.7 million during the first quarter of 2023, compared with $17.7 million for the same period last year. Research and development expenses for the first quarter of 2023 include a one-time $15.0 million upfront payment to Enable Injections in consideration for the rights granted to Viridian to utilize Enable Injections' enFuse® on-body drug delivery system. Other drivers for the increase in research and development expenses include: higher chemistry, manufacturing and controls (CMC) expenses in preparation for the IND application for VRDN-003 as well as development activities; higher personnel costs due to an increase in headcount; and higher preclinical costs due to early-stage collaboration expenses.

- **G&A Expenses:** General and administrative expenses were $21.8 million during the first quarter of 2023, compared with $8.4 million for the same period last year. The increase in general and administrative expenses was driven by an increase in personnel costs, including share-based compensation due to an increase in headcount as well as severance costs related to the separation agreement with the Company's former Chief Executive Officer.

- **Net Loss:** The Company's net loss was $68.2 million for the first quarter of 2023, compared with $25.7 million for the same period last year. The increase in net loss was driven by the increase in operating expenses described above.

- **Shares outstanding:** As of May 1, 2023, Viridian had approximately 58,039,558 shares of common stock outstanding on an as-converted basis, which included 43,129,147 shares of common stock and an aggregate of approximately 14,910,411 shares of common stock issuable upon the conversion of 172,435 and 51,210 shares of Series A and Series B preferred stock, respectively.

Conference call and webcast

The Company will host a webcast and conference call to discuss its first quarter 2023 financial results and provide a corporate update today, Tuesday, May 9, 2023 at 4:30 p.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 1-888-330-3622 (domestic) or 1-646-960-0662 (international) and reference code 3961606. A replay of the webcast will be available following the completion of the event.

About Viridian Therapeutics

Viridian Therapeutics 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 engineering enables it to develop 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 recently initiated its first global Phase 3 trial called 'THRIVE' to evaluate the safety and efficacy of VRDN-001 in patients with active TED. Viridian is also evaluating VRDN-001 in a Phase 2 proof-of-concept trial in patients with chronic TED. In addition to its program for intravenously administered VRDN-001, the Company is advancing three candidates for its subcutaneous strategy with the goal of providing a more conveniently administered therapy to patients with TED. Viridian is also developing multiple preclinical assets in autoimmune and rare diseases.

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

Note regarding 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 the Company's expectations, plans and intentions. Forward-looking statements include, without limitation, statements regarding the Company's expectations, strategies, plans and intentions. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on the Company's current beliefs, expectations, and assumptions. 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: the potential efficacy and safety of VRDN-001, VRDN-002 and VRDN-003 for the treatment of TED; the relationship between the results from the positive data from the Phase 1/2 clinical trial of VRDN-001 and the results of ongoing or future clinical trials; the timing, progress and plans for the Company's ongoing and future research and clinical development programs; expectations regarding the timing for data; uncertainty and potential delays related to clinical drug development; the duration and impact of regulatory delays in the Company's clinical programs; manufacturing risks; the Company's ability to develop a subcutaneous formulation; the Company's ability to build a fully integrated biopharmaceutical company; competition from other therapies or products; other matters that could affect the sufficiency of existing cash, cash equivalents and short-term investments to fund operations; the Company's financial position and its projected cash runway; the Company's future operating results and financial performance; the timing of pre-clinical and clinical trial activities and reporting results from same, including those risks set forth under the caption "Risk Factors" in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 9, 2023 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,	
	2023	**2022**
Revenue:		
Collaboration Revenue - related party	$ 98	$ 216
Total revenue	98	216
Operating Expenses:		
Research and development	50,740	17,746
General and administrative	21,831	8,359
Total operating expenses	72,571	26,105
Loss from operations	(72,473)	(25,889)
Other income		
Interest and other income	4,487	196
Interest expense	(165)	—
Net loss	(68,151)	(25,693)
Change in unrealized loss on investments	216	(778)
Comprehensive loss	$ (67,935)	$ (26,471)
Net loss	$ (68,151)	$ (25,693)
Net loss per share, basic and diluted	$ (1.61)	$ (0.98)
Weighted-average shares used to compute basic and diluted loss per share	42,242,309	26,126,092

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

	March 31, 2023	**December 31, 2022**
Cash, cash equivalents, and short-term investments	$ 373,858	$ 424,550
Other assets	12,784	10,541
Total assets	**$ 386,642**	**$ 435,091**
Total liabilities	36,093	40,027
Total stockholders' equity	350,549	395,064
Total liabilities and stockholders' equity	**$ 386,642**	**$ 435,091**

Contacts
Source: Viridian Therapeutics, Inc.

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