

**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): March 10, 2022



VIRIDIAN THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36483
(Commission
File Number)

47-1187261
(IRS Employer
Identification No.)

221 Crescent Street, Suite 401
Waltham, MA
(Address of principal executive offices)

02453
(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 March 10, 2022, Viridian Therapeutics, Inc., issued a press release reporting financial results for the fourth quarter and year ended December 31, 2021.

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 and 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 March 10, 2022
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: March 10, 2022

By: /s/ Jonathan Violin

Jonathan Violin

President, Chief Executive Officer, and Director



**VIRIDIAN THERAPEUTICS REPORTS FOURTH QUARTER AND FULL YEAR 2021
FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATES**

— *Ongoing Phase 1/2 clinical trial for VRDN-001, an IGF-1R antibody for the treatment of Thyroid Eye Disease, is on track to report top line proof of concept data in the second quarter of 2022* —

— *VRDN-002, a distinct IGF-1R antibody incorporating validated half-life extension technology, expected to deliver top line Phase 1 clinical data in mid-2022* —

— *Strong cash and investment position of \$197 million; current cash runway expected to fund operations into 2024* —

— *Conference call today at 4:30 p.m. ET* —

Waltham, Mass., March 10, 2022 — Viridian Therapeutics, Inc. (NASDAQ: VRDN), a biotechnology company advancing new treatments for patients suffering from serious diseases underserved by current therapies, today announced financial results for the fourth quarter and year ended December 31, 2021 and provided corporate updates.

“In 2020, we created Viridian to engineer and advance novel therapeutic antibodies to improve patient care. We are committed to a patient-centric model of innovation, leveraging proven biology and technology to efficiently design medicines that meet the needs of patients and healthcare providers,” stated Jonathan Violin, Ph.D., President and CEO of Viridian Therapeutics. “With two open INDs for VRDN-001 and VRDN-002, we have meaningfully advanced our pipeline of therapeutic candidates for the treatment of thyroid eye disease (TED). We aim to deliver novel treatment options that expand settings of care and reduce the burden of disease for TED patients.”

Fourth Quarter 2021 and Recent Highlights

VRDN-001: Viridian’s most advanced product candidate, VRDN-001, is a differentiated humanized monoclonal antibody that binds and blocks the insulin-like growth factor-1 receptor (IGF-1R) signaling pathway with sub-nanomolar affinity. This mechanism of action is clinically and commercially validated for the treatment of TED. The Company’s ongoing first clinical trial for VRDN-001 is a Phase 1/2 proof of concept study that includes multiple randomized, placebo-controlled cohorts of TED patients designed to assess the potential for VRDN-001 to provide rapid improvement of signs and symptoms of TED, including proptosis. The Company expects to announce top line proof of concept clinical data in the second quarter of 2022 from the trial, which includes TED patients in two randomized, placebo-controlled cohorts. The protocol for this trial allows for additional patient cohorts, as informed by the initial proof of concept data, to assess differing treatment paradigms that may offer advantages over currently available therapies and mitigate patient treatment burden.

VRDN-002: Viridian's second product candidate, VRDN-002, is a distinct, next-generation IGF-1R antibody incorporating half-life extension technology and is designed to support administration as a convenient, low-volume, subcutaneous (SC) injection for the treatment of TED. In January 2022, Viridian announced the United States Food and Drug Administration (FDA) acceptance of its investigational new drug (IND) application. The Company is proceeding with its planned first-in-human Phase 1 clinical trial of VRDN-002, which is a single ascending dose trial to explore safety, tolerability, pharmacokinetics and pharmacodynamics of intravenously administered VRDN-002 in healthy volunteers. The Company expects to announce data from this Phase 1 trial in mid-2022. Results from this trial will inform the feasibility of a low-volume and/or low-frequency SC dosing paradigm for TED patients. The Company believes a low-volume SC injection could improve convenience for patients and physicians, mitigate treatment burdens, and expand the settings of care for TED therapies.

Commenting on the planned TED data readouts in 2022, Violin continued, "We believe 2022 will be a transformational year in Viridian's evolution. We expect to achieve several key milestones this year, including announcing top line data from our Phase 1/2 proof of concept trial for VRDN-001 in the second quarter of 2022, and top line data from our Phase 1 trial for VRDN-002 in mid-2022. The data from both trials will provide valuable insights that will guide our later stage development plans for VRDN-001 and VRDN-002."

Discovery Pipeline: Viridian's strategy includes expanding its pipeline beyond IGF-1R and TED with a focus on opportunities that will leverage validated mechanisms and technologies to bring new therapeutic options to patients underserved by today's available medicines. The most advanced of these programs is VRDN-004, a therapeutic monoclonal antibody program currently in discovery stage for an undisclosed rare disease. In addition, VRDN-005 is a discovery-stage program for another undisclosed indication in which the Company believes patient care can be advanced with a novel therapeutic monoclonal antibody.

Fourth Quarter and Full Year 2021 Financial Results

Cash Position: Cash, cash equivalents and short-term investments were \$197 million as of December 31, 2021, compared to \$127.6 million as of December 31, 2020. The Company believes that its current cash, cash equivalents and short-term investments will be sufficient to fund its operations into 2024.

R&D Expenses: Research and development expenses were \$22.4 million during the fourth quarter of 2021 and \$56.9 million for the year ended December 31, 2021, compared to \$15.3 million and \$28.3 million, respectively, for the same periods last year. The annual increase in research and development expenses was primarily driven by the advancement of the Company's lead programs, including expenses related to manufacturing and IND-enabling studies. This increase was partially offset by a decrease in clinical trial expenses in the fourth quarter of 2021.

G&A Expenses: General and administrative expenses were \$6.9 million during the fourth quarter of 2021 and \$25.8 million for the year ended December 31, 2021, compared to \$5.5 million and \$13.3 million, respectively, for the same periods last year. The annual increase in general and administrative expenses was driven by increases in personnel related costs, including severance, share-based compensation charges, and consulting expenses.

Net Loss: The Company's net loss was \$28.9 million for the fourth quarter of 2021 and \$79.4 million for the year ended December 31, 2021, compared to \$90.7 million and \$110.7 million for the same periods last year, respectively. The Company's 2020 net loss includes acquired in-process R&D (IPR&D) expense of \$69.9 million. Acquired IPR&D expense resulted from the acquisition of private company Viridian in October 2020. The acquisition cost allocated to acquire IPR&D with no alternative future use was recorded as an expense at the acquisition date. No acquired IPR&D expenses were incurred during the year ended December 31, 2021.

Shares Outstanding: As of December 31, 2021, Viridian had approximately 42,829,137 shares of common stock outstanding on an as-converted basis, which included 23,924,004 shares of common stock outstanding and an aggregate of approximately 18,905,133 shares of common stock issuable upon the conversion of 260,437 and 23,126 shares of Series A and Series B preferred stock, respectively.

Fourth Quarter and Full Year 2021 Financial Results Conference Call

Viridian's management will host a conference call today at 4:30 p.m. ET to discuss the financial results and recent corporate developments. The dial-in number for the conference call is 1-877-407-0789 for domestic participants and 1-201-689-8562 for international participants, with Conference ID #13727096.

A live webcast of the conference call can be accessed through the "[Events](#)" page in the Investors section of the [Viridian Therapeutics website](#). Following the live webcast, an archived version of the call will also be available on the website.

About Viridian Therapeutics, Inc.

[Viridian Therapeutics](#) is a biotechnology company advancing new treatments for patients suffering from serious diseases but underserved by today's therapies. Viridian's most advanced program, VRDN-001, is a differentiated humanized monoclonal antibody targeting insulin-like growth factor-1 receptor (IGF-1R), a clinically and commercially validated target for the treatment of thyroid eye disease (TED). Viridian's second product candidate, VRDN-002, is a distinct anti-IGF-1R antibody that incorporates half-life extension technology and is designed to support administration as a convenient, low-volume, subcutaneous injection. TED is a debilitating autoimmune disease that causes inflammation and fibrosis within the orbit of the eye which can cause double vision, pain, and potential blindness. Patients with severe disease often require multiple remedial surgeries to the orbit, eye muscles and eyelids. Viridian is based in Waltham, Massachusetts.

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 our expectations, plans and intentions. Forward-looking statements include, without limitation, statements regarding the Company's expectations and guidance regarding its business plans and objectives for its product candidates and pipeline, including the therapeutic potential and clinical benefits thereof, the sufficiency of the Company's financial position and its projected cash runway, the timing, progress and plans for the Company's ongoing and future research and clinical development programs, trial protocols for ongoing clinical trials, and expectations regarding the timing for data. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our 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: uncertainty and potential delays related to clinical drug development; the duration and impact of regulatory delays in our clinical programs; manufacturing risks; 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 future operating results and financial performance; the timing of pre-clinical and clinical trial activities and reporting results from same; the effects from the COVID-19 pandemic on the Company's research, development and business activities and operating results, including those risks set forth under the caption "Risk Factors" in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 5, 2021 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 we, nor our 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 our views as of any date subsequent to the date hereof.

VIRIDIAN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

VIRIDIAN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)