

**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): November 4, 2021



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

203 Crescent Street, Building 17, Suite 102B, Waltham, MA 02453
(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.

Section 2 - Financial Information**Item 2.02 Results of Operations and Financial Condition.**

On November 4, 2021, Viridian Therapeutics, Inc., issued a press release reporting financial results for the three months ended September 30, 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.

Section 9 - Financial Statements and Exhibits**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits.

Exhibit Number	Exhibit Description
99.1	Press release, dated November 4, 2021
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: November 4, 2021

By: /s/ Jonathan Violin
Jonathan Violin
President, Chief Executive Officer, and Director



VIRIDIAN THERAPEUTICS REPORTS THIRD QUARTER 2021 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATES

- Submitted an investigational new drug (IND) application to the FDA for VRDN-001, an IGF-1R antibody for the treatment of Thyroid Eye Disease (TED) and expect to report Phase 1/2 proof of concept clinical data in TED patients in the second quarter of 2022
- VRDN-002, a distinct IGF-1R antibody incorporating validated half-life extension technology, remains on track for an IND filing before year end 2021, and to deliver initial clinical data in mid-2022
- Strong financial position after successful follow-on financing with pro forma cash position of \$213.8 million to support continued company and pipeline expansion. Current cash runway expected to fund operations into 2024

Waltham, Mass., November 4, 2021 — Viridian Therapeutics, Inc. (NASDAQ: VRDN) (the “Company” or “Viridian”), a biotechnology company advancing new treatments for patients suffering from serious diseases underserved by today’s therapies, today announced financial results for the third quarter ended September 30, 2021, and provided corporate updates.

“In the third quarter, we made substantial progress strengthening the Company with key leadership hires, a successful financing, and our recent submission of an IND for VRDN-001 for the treatment of Thyroid Eye Disease,” stated Jonathan Violin, Ph.D., Viridian’s President and CEO. “Our pipeline is rapidly advancing, and we remain on track to report clinical data from our VRDN-001 and VRDN-002 programs in the second quarter of 2022 and mid-year 2022, respectively. In addition, we continue to advance our discovery pipeline to broaden our portfolio of potential best in class therapeutics.”

Third Quarter 2021 and Recent Highlights

VRDN-001: Viridian’s most advanced product candidate is VRDN-001, a differentiated monoclonal antibody targeting insulin-like growth factor-1 receptor (IGF-1R), a clinically and commercially validated target for the treatment of TED. This antibody has previously been studied in over 100 oncology patients as AVE1642, informing plans for rapid development in TED. The Company recently submitted an IND application for VRDN-001 to the United States Food and Drug Administration (FDA). The Company is planning to initiate a randomized, placebo-controlled Phase 1/2 clinical trial of VRDN-001 evaluating safety, tolerability, and efficacy. The proposed clinical trial protocol allows for flexibility to assess multiple doses and treatment regimens to inform product profiles that may be superior to currently available therapies. The Company believes this clinical trial could provide key proof of concept data showing clinically meaningful improvements in signs and symptoms of TED, such as proptosis, the defining characteristic of TED, previously shown to be improved by IGF-1R blockade. The Company expects to announce top line proof of concept clinical data in the second quarter of 2022 from the trial that includes TED patients in two randomized, placebo-controlled cohorts.

VRDN-002: 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. IND-enabling activities remain on track with plans to file an IND by the end of 2021. The Company expects to initiate clinical development with a Phase 1 single ascending dose trial to explore safety, tolerability, pharmacokinetics, and target engagement of intravenous VRDN-002 in healthy volunteers. Top line data from this trial are expected to be announced in mid-year 2022 and could support feasibility of a low-volume injection and/or low-frequency dosing paradigm. In parallel, formulation development is on track to support initiation of a clinical trial evaluating low-volume subcutaneous injection of VRDN-002 in 2022. The Company believes a low-volume subcutaneous injection could improve convenience for patients and physicians, mitigate treatment burdens, and expand the settings of care for TED therapies.

Discovery Pipeline: Viridian's corporate development 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. The Company continues to evaluate additional opportunities to expand its product pipeline for rare disease indications.

Completed Financing: In September 2021, Viridian announced the closing of an underwritten public offering of 7,344,543 shares of its common stock, which included the exercise in full by the underwriters of their option to purchase up to 1,159,089 additional shares of common stock, at a public offering price of \$11.00 per share and 23,126 shares of Series B preferred stock at a public offering price of \$733.37 per share, which are convertible into approximately 1,541,810 shares of common stock, subject to beneficial ownership conversion limits. The net proceeds to Viridian from the offering were approximately \$91.9 million after deducting underwriting discounts, commissions, and other offering expenses.

Scientific Presentations: The Company presented two posters featuring preclinical data on VRDN-001 and VRDN-002 at the 90th Annual Meeting of the American Thyroid Association (ATA):

- The VRDN-001 poster showed that the antibody bound IGF-1R with high affinity and inhibited IGF-1R signaling with high potency. The in vitro profile of VRDN-001 suggests favorable efficacy and/or exposure requirements for the treatment of TED patients. The full poster is available at ([click here](#)).
- The VRDN-002 poster showed that the antibody demonstrated a desirable PK profile in non-human primates, suggesting potential utility for the treatment of TED. The prolonged half-life of VRDN-002 suggests potential administration as a low-volume, convenient subcutaneous injection, or as an intravenous infusion requiring fewer or less frequent treatments vs. conventional therapeutic IgG antibodies. The full poster is available at ([click here](#)).

Management and Board of Directors Appointments:

- Kristian Humer was appointed Chief Financial Officer and Chief Business Officer in July 2021. He brings more than 20 years of life science investment banking, mergers and acquisitions, and partnering experience to Viridian. Most recently, Mr. Humer served as Managing Director of Banking, Capital Markets & Advisory for the Global Healthcare team at Citigroup, Inc.
- Deepa Rajagopalan, M.D. was appointed Senior Vice President of New Product and Portfolio Development in July 2021. Most recently, Dr. Rajagopalan served as Vice President of New Products at Intercept Pharmaceuticals, and previously held roles at Alexion Pharmaceuticals and Bain & Company.
- Jennifer Moses, CPA was appointed to the Company's Board of Directors and as Chair of the Company's Audit Committee in July 2021. Ms. Moses is the Chief Financial Officer of G1 Therapeutics. Prior to G1 Therapeutics, she was a partner at Rankin McKenzie, LLC, and previously held roles of increasing responsibility at Deloitte.

Third Quarter 2021 Financial Results

Cash Position: Cash, cash equivalents and short-term investments were \$213.8 million as of September 30, 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 increased by \$5 million to \$8.1 million during the third quarter of 2021, compared to \$3.1 million during the third quarter of 2020. The 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 third quarter of 2021.

G&A Expenses: General and administrative expenses increased by \$2.3 million to \$6.2 million during the third quarter of 2021, compared to \$3.9 million during the third quarter of 2020. The 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 \$14.03 million for the third quarter of 2021, compared to \$5.5 million for the third quarter of 2020.

Shares Outstanding: As of November 3, 2021, Viridian had approximately 42,365,036 shares of common stock outstanding on an as-converted basis, which included 21,722,349 shares of common stock and approximately 20,642,687 shares of common stock issuable upon the conversion of 286,499 and 23,126 shares of Series A and Series B preferred stock respectively.

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 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). 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 safety and efficacy profiles of VRDN-001 and VRDN-002, 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, planned trial designs, future regulatory interactions, the timing of the Company's IND filing for VRDN-002 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 August 12, 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Collaboration revenue (related party, \$2,541 and \$0 at September 30, 2021 and December 31, 2020, respectively)	\$ 208	\$ —	\$ 2,749	\$ 681
Grant revenue	—	—	—	315
Total revenue	<u>208</u>	<u>—</u>	<u>2,749</u>	<u>996</u>
Operating expenses:				
Research and development	8,121	3,111	34,492	13,050
General and administrative	6,221	2,299	18,904	7,728
Total operating expenses	<u>14,342</u>	<u>5,410</u>	<u>53,396</u>	<u>20,778</u>
Loss from operations	<u>(14,134)</u>	<u>(5,410)</u>	<u>(50,647)</u>	<u>(19,782)</u>
Other income (expense):				
Interest and other income	91	9	180	137
Interest and other expense	—	(93)	—	(328)
Net loss	<u>(14,043)</u>	<u>(5,494)</u>	<u>(50,467)</u>	<u>(19,973)</u>
Change in unrealized gain (loss) on investments	9	—	5	—
Comprehensive loss	<u>\$ (14,034)</u>	<u>\$ (5,494)</u>	<u>\$ (50,462)</u>	<u>\$ (19,973)</u>
Net loss	<u>\$ (14,043)</u>	<u>\$ (5,494)</u>	<u>\$ (50,467)</u>	<u>\$ (19,973)</u>
Net loss per share, basic and diluted	<u>\$ (1.25)</u>	<u>\$ (1.48)</u>	<u>\$ (5.95)</u>	<u>\$ (5.82)</u>
Weighted-average shares used to compute basic and diluted net loss per share	<u>11,183,578</u>	<u>3,719,186</u>	<u>8,487,485</u>	<u>3,430,867</u>

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

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 138,875	\$ 45,897
Short-term investments	74,937	81,742
Prepaid expenses and other current assets	3,649	1,972
Unbilled revenue	\$ 479	—
Total current assets	217,940	129,611
Property and equipment, net	347	309
Operating lease right-of-use asset, net	1,461	478
Other assets—related party	—	856
Other assets	1,457	1
Total assets	\$ 221,205	\$ 131,255
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,731	\$ 670
Accrued liabilities	10,320	9,703
Current portion of deferred revenue (related party, \$301 at Dec. 2020)	288	301
Total current liabilities	14,339	10,674
Other liabilities—related party	—	501
Other liabilities	2,275	43
Total liabilities	16,614	11,218
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, series A non-voting convertible preferred stock, \$0.01 par value; 435,000 shares authorized; 321,334 and 398,487 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	145,794	180,801
Preferred stock, series B non-voting convertible preferred stock, \$0.01 par value; 5,000,000 shares authorized; 23,126 and 0 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	15,669	—
Common stock, \$0.01 par value; 200,000,000 shares authorized; 19,376,634 and 4,231,135 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	194	42
Additional paid-in capital	372,291	218,089
Accumulated other comprehensive loss	(3)	(8)
Accumulated deficit	(329,354)	(278,887)
Total stockholders' equity	204,591	120,037
Total liabilities and stockholders' equity	\$ 221,205	\$ 131,255