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 15, 2022

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 8.01 Other Events.

On August 15, 2022, Viridian Therapeutics, Inc. (the "Company") announced positive initial clinical data from the 10mg/kg cohort in its ongoing Phase 1/2 clinical trial of VRDN-001, an anti-IGF-1R antibody, in patients with active thyroid eye disease ("TED"). TED is a rare autoimmune disease in which the body's own immune system attacks the tissues around and behind the eyes causing inflammation, swelling, and damage, which develops into signs and symptoms of double vision, bulging eyes, and ocular pain. The double-blind, placebo-controlled Phase 1/2 trial is evaluating two infusions of VRDN-001 administered intravenously. The inclusion and exclusion criteria and the baseline patient characteristics for this trial are similar to prior TED clinical trials. Efficacy measurements include proptosis (bulging eyes), Clinical Activity Score ("CAS"), and diplopia (double vision), which are the same endpoints as measured in the clinical development of Tepezza®, the only approved therapy targeting IGF-1R in patients with TED.

Data from Ongoing VRDN-001 Phase 1/2 Proof-of-concept Trial

This ongoing trial is evaluating two infusions of VRDN-001, three weeks apart, with efficacy measured 6 weeks after the first dose. Each dose is evaluated in a cohort of 8 patients, randomized so that 6 patients receive VRDN-001 and 2 patients receive placebo. The first cohort evaluated a dose of 10mg/kg, with initial clinical data reported on August 15, 2022. The second cohort is evaluating a dose of 20mg/kg and enrollment is nearly complete, and the Company plans to report results at an upcoming medical meeting in the fourth quarter of 2022. A third cohort will evaluate a dose of 3mg/kg, with data anticipated in the fourth quarter of 2022.

Initial VRDN-001 Safety Data

VRDN-001 was well-tolerated by all patients treated at the 10mg/kg dose. There were no reported serious adverse events ("SAEs"), no patient discontinuations, and no hyperglycemia or infusion reactions as of August 9, 2022, the cutoff date for follow up observation. Two cases of mild muscle spasm were reported and did not require intervention. There was one report of "ringing in the ears" which resolved within two weeks without intervention.

In the ongoing second TED cohort, which is evaluating two infusions of 20mg/kg of VRDN-001, no adverse events of hyperglycemia, muscle spasm, hearing impairment, infusion reactions, or any serious adverse events were reported as of the cutoff date of August 9, 2022.

Initial VRDN-001 Clinical Activity Data

All patients in the 10mg/kg cohort were treated for two full cycles and were evaluated for proptosis, CAS, and diplopia.

The following clinical activity was observed at week 6:

<u>Proptosis</u>

- 83% proptosis responder rate, defined as a ≥2mm reduction in proptosis from baseline
- Rapid reduction with a median time to proptosis response of 3 weeks
- 2.4mm mean reduction in proptosis from baseline

<u>Clinical Activity Score (CAS)</u>

- 83% of patients achieved maximal or near-maximal therapeutic effect on CAS, defined as reaching a CAS of 0 or 1 on a 7-point composite measure of signs and symptoms of TED
- 4.3 point mean reduction in CAS from baseline

Overall Response

- 83% overall responder rate, defined as a ≥2mm reduction in proptosis and a ≥2 point reduction in CAS

Diplopia

- 75% complete resolution of diplopia, defined as patients with baseline diplopia who achieved a score of 0 on the Gorman Subjective Diplopia scale

First-in-human Data for VRDN-002

Earlier this year, the Company initiated a first-in-human Phase 1 clinical trial of VRDN-002, a novel monoclonal antibody that incorporates half-life extension technology and is designed to support administration as a convenient, low-volume, subcutaneous ("SC") injection for the treatment of TED patients. This single ascending dose trial explored safety, tolerability, pharmacokinetics and pharmacodynamics of intravenously administered VRDN-002 at doses of 3, 10, and 20mg/kg in 12 healthy volunteers.

The following results were observed:

- VRDN-002 achieved a substantially extended half-life of 30-40 days
- After a single IV dose of VRDN-002, plasma IGF-1 levels increased approximately 2.5-fold and were sustained throughout the measurement period of 84 days
- PK/PD analysis demonstrates the feasibility of a convenient, low-volume, subcutaneous injection paradigm of 2mL 300mg dosed Q2W or Q4W
- VRDN-002 was generally well tolerated with no reported adverse events of hyperglycemia, hearing impairment, muscle spasm, infusion reactions, or any SAEs

Clinical Plan and Future Milestones for Viridian TED Programs

Additional VRDN-001 Phase 1/2 Cohorts

- VRDN-001 20mg/kg cohort data presentation planned for a medical meeting in the fourth quarter of 2022. VRDN-001 3mg/kg cohort is expected to deliver data in the fourth quarter of 2022
- Additional VRDN-001 chronic TED proof-of-concept cohorts now planned to launch in the fourth quarter of 2022, with data in the first half of 2023

Global VRDN-001 Phase 3 Program in Active and Chronic TED

- First VRDN-001 double-blind, placebo-controlled Phase 3 trial (THRIVE), in active TED patients, expected to initiate by the end of 2022, with topline data expected in mid-year 2024. The trial will evaluate the 10mg/kg dose, with a rapid 30-minute infusion time, in two treatment regimens:
  - a standard 8-infusion Q3W regimen matching Tepezza dosing regimen
  - an accelerated 12-week, 5-infusion Q3W regimen, offering a 43% shorter, highly differentiated dosing regimen
- Second VRDN-001 double-blind, placebo-controlled Phase 3 trial (THRIVE-2), in chronic TED, expected to initiate in the first half of 2023 with topline data by the end of 2024
- THRIVE and THRIVE-2 trial results are expected to form the basis of both a biologics license application (BLA) in the US as well as a marketing authorization application (MAA) in the EU

SC Programs: VRDN-002 and VRDN-003

- VRDN-002 will advance to a proof-of-concept trial in TED, evaluating 2mL 300mg SC injection, dosed Q2W or Q4W, with data expected in the second half of 2023. Viridian is unveiling VRDN-003, an extended half-life version of VRDN-001. VRDN-003 builds upon the clinical performance of VRDN-001 by incorporating the same technology that enabled VRDN-002 to achieve its

substantially extended half-life. VRDN-003 has similar non-human primate half-life to VRDN-002 and is expected to match the VRDN-002 human half-life. IND filing for VRDN-003 is planned the second quarter of 2023 with proof-of-concept data expected in the fourth quarter of 2023

- By the end of 2023, the Company will select to advance either VRDN-002 or VRDN-003 into registrational trials based on clinical data from the two programs and plans to initiate a global Phase 3 program of a potentially best-in-class SC therapy for TED in early 2024

Note Regarding Forward-Looking Statements

This Current Report on Form 8-K 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 and VRDN-002 for the treatment of TED; the relationship between the results from the positive data from the ongoing Phase 1/2 clinical trial of VRDN-001 and the first-in-human Phase 1 clinical trial of VRDN-002 and results of ongoing and future clinical trials; the timing, progress and plans for the Company’s ongoing and future research and clinical development programs; trial protocols for ongoing clinical trials, including the clinical trials for VRDN-001 and VRDN 002; expectations regarding the timing for data, including the expected timing of additional data from the ongoing Phase 1/2 clinical trial of VRDN-001 and the first-in-human Phase 1 clinical trial of VRDN-002; uncertainty and potential delays related to clinical drug development; the duration and impact of regulatory delays in the Company’s 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 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; 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 the Company’s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (“SEC”) on August 15, 2022 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.

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 16, 2022

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