Viridian Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Updates

March 8, 2023

- Positive data reported from ongoing Phase 1/2 trial evaluating low-dose VRDN-001 in patients with thyroid eye disease (TED) -

- First patient enrolled in 'THRIVE' Phase 3 trial in patients with active TED, with results expected in mid-2024 -

- Initial results from the proof-of-concept study of VRDN-001 in patients with chronic TED are expected in the second quarter of 2023 -

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

WALTHAM, Mass., March 08, 2023 (GLOBE NEWSWIRE) -- 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 for the fourth quarter and full year ended December 31, 2022.

"2022 was a productive year for Viridian, as we made significant progress and reached multiple important milestones in our TED program with VRDN-001, our lead product candidate. Building on this positive momentum, we are strategically positioned to continue the advancement of our pipeline of TED programs in 2023," said Scott Myers, President and CEO of Viridian Therapeutics. "As part of my recent appointment as CEO, I look forward to advancing our recently initiated THRIVE Phase 3 trial of VRDN-001 in patients with active TED, generating data in patients with chronic TED, continuing the development of our subcutaneous programs, and beginning to establish our commercial capabilities. These activities support our overall goal to build a fully integrated biopharmaceutical company."

Added Mr. Myers: "We also look forward to providing additional details on one of our preclinical programs later this year. Our preclinical programs have the potential to expand our current pipeline beyond TED and build on our strategy of developing best-in-class medicines that address known limitations of current therapies."

Program highlights

Thyroid eye disease (TED)

Intravenous (IV) program: VRDN-001
Viridian's lead product candidate, VRDN-001, is a monoclonal antibody believed to act 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.

- In January 2023, the Company announced positive data from the third, low-dose cohort in its ongoing Phase 1/2 clinical trial of VRDN-001 in patients with active TED.
- In December 2022, the Company announced that the first patient was enrolled in its THRIVE Phase 3 trial evaluating the efficacy and safety of VRDN-001 in patients with active TED, with topline results expected in the middle of 2024.
- Clinical and non-clinical presentations of VRDN-001 are expected at the 49th Annual Meeting of the North American Neuro-Ophthalmology Society (NANOS) from March 11th to 16th, 2023, in Orlando, Florida.
- Initial results from the proof-of-concept study of VRDN-001 in patients with chronic TED are expected in the second quarter of 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.

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. All three candidates have the potential to be developed into a convenient, SC, self-administered pen device. 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.

- In January 2023, the Company announced that updated pharmacokinetic (PK) modeling support feasibility of ongoing development of a self-administered pen for SC administration, and a planned dosing interval of up to once monthly for its SC program candidates.
- A clinical poster presentation of VRDN-002 Phase 1 data in healthy volunteers is expected at the 49th Annual Meeting of NANOS from March 11th to 16th, 2023 in Orlando, Florida.
- The filing of the investigational new drug application (IND) for VRDN-003 with the US Food and Drug Administration (FDA)

is planned for the second quarter of 2023.

- The Company plans to initiate Phase 1 trials in healthy volunteers for both VRDN-003 and VRDN-001 SC, with topline results expected in the fourth quarter of 2023.
- VRDN-002 proof-of-concept trial results in patients with active TED are expected by year-end 2023.
- The Company expects to select its lead SC program by year-end 2023 and advance the selected SC program into a pivotal trial in the middle of 2024.

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.

Corporate highlights

- In February 2023, the Company appointed Scott Myers as President and Chief Executive Officer and a member of the Board of Directors. Mr. Myers has more than 30 years of biopharmaceutical and medical technology experience and has held global executive leadership and director roles at numerous commercial- and development-stage biopharmaceutical companies.
- In November 2022, Viridian promoted and hired the following senior executives:
    - Deepa Rajagopalan, M.D., was promoted to Chief Product and Strategy Officer after joining the Company in 2021 to lead new product and portfolio development. Dr. Rajagopalan is focused on advancing the Company's pre-approval commercialization planning efforts for TED and market development activities for its discovery-stage pipeline.
    - Rob Henderson, Ph.D., was promoted to Chief Scientific Officer after joining the Company in 2021 as Senior Vice President of Research. As Chief Scientific Officer, Dr. Henderson leads all nonclinical science and research at Viridian.
    - Todd James joined Viridian as Senior Vice President, Corporate Affairs and Investor Relations. Mr. James served in a similar position at Acceleron Pharma from 2015 until its acquisition by Merck in 2021.

Financial results

- **Cash Position:** Cash, cash equivalents, and short-term investments were $424.6 million as of December 31, 2022, compared with $431.3 million as of September 30, 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 $39.3 million during the fourth quarter of 2022, compared with $22.4 million for the same period last year. The increase in research and development expenses was primarily driven by an increase in chemistry, manufacturing, and controls (CMC) expenses, preclinical costs, expenses related to milestones and upfront payments, as well as personnel costs. Research and development expenses were $100.9 million during the 12 months ended December 31, 2022, compared with $56.9 million for the same period last year. The increase in research and development expenses was primarily driven by clinical trial and preclinical costs, expenses related to milestones and upfront payments, and CMC expenses.
- **G&A Expenses:** General and administrative expenses were $9.9 million during the fourth quarter of 2022, compared with $6.9 million for the same period last year. The increase in general and administrative expenses was driven by increases in personnel-related costs and consulting expenses. General and administrative expenses were $35.2 million during the 12 months ended December 31, 2022, compared with $25.8 million for the same period last year.
- **Net Loss:** The Company's net loss was $45.8 million for the fourth quarter of 2022, compared with $28.9 million for the same period last year. The increase in net loss was driven by increased operating costs, as described above.
- **Shares outstanding:** As of March 1, 2023, Viridian had approximately 57,748,362 shares of common stock outstanding on an as-converted basis, which included 42,837,951 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 fourth quarter and full year 2022 financial results today, Wednesday, March 8 at 8:00 a.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 1-877-407-0789 (domestic) or 1-201-689-8562 (international) and reference code 13736278. 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 intravenously administered VRDN-001 program, the Company is advancing two candidates for its subcutaneous strategy with the goal of providing a more conveniently administered therapy to patients with TED. Viridian is 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.

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; 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 11, 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.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(amounts in thousands, except share and per share data)
(unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
Revenue:				
Collaboration Revenue - related party	$ 105	$ 214	$ 1,772	$ 2,963
Total revenue	105	214	1,772	2,963
Operating Expenses:				
Research and development	39,317	22,394	100,894	56,886
General and administrative	9,854	6,901	35,182	25,805
Total operating expenses	49,171	29,295	136,076	82,691
Loss from operations	(49,066)	(29,081)	(134,304)	(79,728)
Other income				
Interest and other income	3,449	138	4,916	318
Interest expense	(168)	(3)	(486)	(3)
Net loss	(45,785)	(28,946)	(129,874)	(79,413)
Change in unrealized loss on investments	300	(154)	(233)	(149)

Comprehensive loss	$ (45,485)	$ (29,100)	$ (130,107)	$ (79,562)
Net loss	$ (45,785)	$ (28,946)	$ (129,874)	$ (79,413)
Net loss per share, basic and diluted	$ (1.13)	$ (1.31)	$ (4.05)	$ (6.66)
Weighted-average shares used to compute basic and diluted loss per share	40,541,507	22,109,530	32,087,293	11,918,712

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

	December 31,	
	2022	**2021**
Cash, cash equivalents, and short-term investments	$ 424,550	$ 196,965
Other assets	10,541	6,744
Total assets	**$ 435,091**	**$ 203,709**
Total liabilities	40,027	15,993
Total stockholders' equity	395,064	187,716
Total liabilities and stockholders' equity	**$ 435,091**	**$ 203,709**

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Source: Viridian Therapeutics, Inc