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

August 8, 2023

- Reported positive topline data from proof-of-concept study of VRDN-001 in patients with chronic thyroid eye disease (TED) -

- THRIVE Phase 3 trial in patients with active TED amended to reflect Viridian's confidence in 5-infusion treatment regimen and key stakeholder feedback on evolving TED treatment paradigm –

- THRIVE-2 Phase 3 trial in patients with chronic TED expected to start in the third quarter of 2023 –

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

WALTHAM, Mass.--(BUSINESS WIRE)--Aug. 8, 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 second quarter ended June 30, 2023.

"Last month, we established proof-of-concept for VRDN-001 in patients with chronic TED, marking an exciting milestone for the Company and building on the compelling data we previously reported in active TED. VRDN-001 demonstrated profound clinical activity in chronic TED patients after only two infusions, confirming this candidate's ability to potentially be an effective therapy in active and chronic TED," said Scott Myers, President and CEO of Viridian Therapeutics. "We are also quickly advancing our potential first-in-class subcutaneous TED program and are proud to announce that our Phase 1 trial for VRDN-001 SC in healthy volunteers is fully enrolled. In addition, our Phase 1 trial for VRDN-003 SC has been initiated and is now enrolling healthy volunteers."

Added Mr. Myers: "The significant strides we have made with our TED program this quarter lay the foundation for us to execute on all upcoming key milestones. We remain committed to initiating our Phase 3 THRIVE-2 trial of VRDN-001 in chronic TED patients during the third quarter – our second pivotal trial for this candidate – and selecting our lead subcutaneous program by year-end."

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.

- Preliminary data from the ongoing Phase 1/2 trial of VRDN-001 demonstrated clinically meaningful and rapid improvement in signs and symptoms of chronic TED at week 6 after receiving two infusions of VRDN-001 10 mg/kg or 3 mg/kg. VRDN-001 was generally well tolerated in both dose cohorts.
- The THRIVE Phase 3 trial evaluating the efficacy and safety of VRDN-001 in patients with active TED was amended to include the VRDN-001 5-infusion treatment regimen and placebo arms only with the primary endpoint assessment at week 15. Topline results from the THRIVE Phase 3 trial are expected in the middle of 2024.
- 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 third quarter 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, each with the potential to be developed into a convenient, SC, self-administered pen device.

- The VRDN-001 SC Phase 1 trial in healthy volunteers was initiated and is fully enrolled.
- Viridian recently initiated the Phase 1 trial in healthy volunteers evaluating IV and SC cohorts of VRDN-003.
- Viridian expects the initiation of a SC pen device supply agreement with an experienced drug delivery device manufacturer in the second half of 2023.
- The Company expects topline results from its Phase 1 trials, evaluating VRDN-001 and VRDN-003 SC in healthy volunteers, in the fourth quarter of 2023.
- Viridian plans 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.

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.

Financial results

- **Cash Position**: Cash, cash equivalents, and short-term investments were $334.3 million as of June 30, 2023, compared with $373.9 million as of March 31, 2023. 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 $40.1 million during the second quarter of 2023, compared with $21.7 million for the same period last year. Research and development expenses for the second quarter of 2023 include costs related to manufacturing costs for various programs as well as costs related to ongoing clinical trials. Other drivers for the increase in research and development expenses include: personnel-related costs (including share-based compensation) and license costs.
- **G&A Expenses:** General and administrative expenses were $19.3 million during the second quarter of 2023, compared with $8.1 million for the same period last year. The increase in general and administrative expenses was driven by personnel-related costs including share-based compensation, as well as market research, accounting and other professional fees.
- **Net Loss:** The Company's net loss was $55.1 million for the second quarter of 2023, compared with $29.5 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 August 1, 2023, Viridian had approximately 43,631,098 shares of common stock outstanding on an as-converted basis, which included 58,541,509 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

As noted on the Company's VRDN-001 Phase 1/2 data call in July, the Company will not be hosting a conference call to discuss its second quarter financial results. The Company will resume hosting a regular quarterly earnings call in November for its third quarter 2023 financial results.

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 is conducting 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 planning a second Phase 3 trial, called THRIVE-2, to evaluate the safety and efficacy of VRDN-001 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 our expectations, plans and intentions. Forward-looking statements include, without limitation, statements regarding our expectations, strategies, plans and intentions. 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: the potential efficacy and safety of VRDN-001, VRDN-002, and VRDN-003 for the treatment of Thyroid Eye Disease (TED), the relationship between the results from the positive data from the ongoing Phase 1/2 clinical trial of VRDN-001 in patients with chronic TED and the results of ongoing or future clinical trials; the timing, progress and plans for our ongoing or future research, pre-clinical and clinical development programs; trial protocols for ongoing clinical trials; expectations regarding the timing for data; uncertainty and potential delays related to clinical drug development; the duration and impact of regulatory delays in our clinical programs; the timing of and our ability to obtain and maintain regulatory approvals for our therapeutic candidates, including VRDN-001, VRDN-002, and VRDN-003; manufacturing risks; our ability to develop a subcutaneous formulation (SC); our plan regarding a lead SC program candidate; our expectations regarding a pen device supply partnership; 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; our financial position and its projected cash runway; our future operating results and financial performance; the clinical utility of our therapeutic candidates and our intellectual property position; 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 our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 10, 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue:				
Collaboration Revenue - related party	$ 72	$ 256	$ 170	$ 472
Total revenue	72	256	170	472
Operating Expenses:				
Research and development	40,083	21,712	90,823	39,458
General and administrative	19,264	8,108	41,095	16,467
Total operating expenses	59,347	29,820	131,918	55,925
Loss from operations	(59,275)	(29,564)	(131,748)	(55,453)
Other income				
Interest and other income	4,378	227	8,865	423
Interest expense	(166)	(154)	(331)	(154)
Net loss	(55,063)	(29,491)	(123,214)	(55,184)
Change in unrealized loss on investments	1	(142)	217	(920)
Comprehensive loss	$ (55,062)	$ (29,633)	$ (122,997)	$ (56,104)
Net loss	$ (55,063)	$ (29,491)	$ (123,214)	$ (55,184)
Net loss per share, basic and diluted	$ (1.27)	$ (1.06)	$ (2.88)	$ (2.05)
Weighted-average shares used to compute basic and diluted loss per share	43,253,457	27,762,257	42,753,476	26,948,692

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

	June 30, 2023	December 31, 2022
Cash, cash equivalents and short-term investments	$334,291	$ 424,550
Other assets	17,176	10,541
Total assets	**$351,467**	**$ 435,091**
Total liabilities	35,610	40,027
Total stockholders' equity	315,857	395,064
Total liabilities and stockholders' equity	**$351,467**	**$ 435,091**

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