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

November 13, 2023

- THRIVE and THRIVE-2 clinical trials are continuing to enroll active and chronic thyroid eye disease (TED) patients; expected delivery of topline clinical results for both clinical trials on track for 2024 -

- Timing for the selection of lead subcutaneous TED program is on track for the end of 2023 -

- Advancing recently announced novel preclinical portfolio of potentially best-in-class neonatal Fc receptor (FcRn) inhibitors with the broad potential to treat autoimmune diseases -

- Announced the appointment of Stephen Mahoney as President and Chief Executive Officer -

- Closed a private placement of approximately $185 million with new and existing investors to fund pipeline development and extend operating cash runway into 2026 -

WALTHAM, Mass.--(BUSINESS WIRE)--Nov. 13, 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 third quarter ended September 30, 2023.

“We are focused on driving execution of our potentially best-in-class anti-IGF-1R therapies to reach meaningful clinical readouts in our intravenous and subcutaneous TED franchise,” said Steve Mahoney, President and CEO of Viridian Therapeutics. “We recently reiterated our expectations for our timelines and unveiled our novel anti-FcRn portfolio for autoimmune diseases with our first investigational new drug (IND) submission for this program planned by year end 2024. Finally, our recent closing of a private placement for approximately $185 million enables our allocation of capital to the most value-creating results for patients and shareholders.”

Program Highlights

Thyroid eye disease (TED)

Intravenous TED Program: VRDN-001

Viridian’s lead product candidate, VRDN-001, is a monoclonal antibody that acts as a full antagonist of insulin-like growth factor-1 receptor (IGF-1R), a clinically and commercially validated target for TED that has a current US annual market opportunity of approximately $2 billion. Intravenous VRDN-001 is being evaluated in two Phase 3 clinical trials, THRIVE and THRIVE-2, for the treatment of active and chronic TED, respectively.

- The ongoing THRIVE Phase 3 clinical trial of VRDN-001 in patients with active TED continues to enroll patients with topline results expected in mid-2024.
- THRIVE-2, a Phase 3 clinical trial of VRDN-001 in patients with chronic TED, is active and enrolling patients with topline results anticipated by year end 2024.
- THRIVE and THRIVE-2 are each designed to compare a five-dose treatment arm of VRDN-001, dosed three weeks apart, to placebo. This five-dose VRDN-001 regimen features fewer infusions and a shorter time per infusion compared to the currently marketed IGF-1R inhibitor.
- In a Phase 1/2 clinical trial, intravenous VRDN-001 was shown to improve the signs and symptoms of TED at six weeks in patients with active and chronic disease after receiving two infusions of VRDN-001 in all dose cohorts and was generally well-tolerated.

Subcutaneous TED Programs: VRDN-001, VRDN-002, and VRDN-003

Subcutaneous VRDN-001 is the same monoclonal antibody as the intravenous program formulated for subcutaneous delivery. VRDN-002 constitutes a different novel monoclonal antibody targeting IGF-1R and is engineered to have an extended half-life to allow for less frequent dosing. VRDN-003 combines the same binding domain from VRDN-001 with the same engineered extended half-life of VRDN-002. The company is conducting Phase 1 clinical trials in healthy volunteers with subcutaneous VRDN-001, VRDN-002, and VRDN-003 to evaluate each program’s pharmacokinetics and safety.

- Enrollment has been completed in the Phase 1 clinical trials to evaluate the pharmacokinetics and safety of subcutaneous VRDN-001, VRDN-002, and VRDN-003 in healthy volunteers, and data are expected in the fourth quarter of 2023.
- Viridian is on track to select its lead subcutaneous program by year end 2023 and plans to disclose available subcutaneous data for VRDN-001, VRDN-002 and VRDN-003 supporting this program selection for a potentially best-in-class anti-IGF-1R product candidate.
- Viridian entered into a subcutaneous autoinjector supply agreement with Ypsomed in October 2023 to support its development of convenient subcutaneous therapies for the treatment of TED.

Autoimmune Diseases

Next Generation FcRn Portfolio: VRDN-006 and VRDN-008

Viridian is developing a portfolio of engineered FcRn inhibitors. FcRn inhibition has the potential to treat a broad array of autoimmune diseases, representing a significant commercial opportunity. VRDN-006 is a highly selective Fc fragment. VRDN-008 is a novel, first-in-class FcRn inhibitor that aims to pair immunoglobulin G (IgG) suppression with extended half-life technology.

- VRDN-006 showed specificity for blocking FcRn-IgG interactions in non-human primates while showing no decreases in albumin or increases in low-density lipoprotein (LDL) levels.
- VRDN-008, with its extended half-life, has the potential to more deeply and durably suppress IgG as compared to existing anti-FcRn therapies and pipeline candidates.
- The company is designing both VRDN-006 and VRDN-008 to be convenient, self-administered, subcutaneous products.
- Viridian plans to file an IND for VRDN-006 by year end 2024 and anticipates sharing additional details on both programs in 2024.

Corporate Highlights

- In October 2023, the Company appointed Stephen Mahoney as President and Chief Executive Officer and a member of the Board of Directors. Mr. Mahoney brings more than two decades of experience in the biopharmaceutical industry where he has held a number of strategic, operational, financial, business development, and legal roles with regional and global responsibilities.
- In October 2023, along with Mr. Mahoney's appointment, the company also hired Thomas Beetham as Chief Operating Officer, and Shan Wu, Ph.D., as Chief Business Officer. Each has worked with Mr. Mahoney in prior companies and will strengthen Viridian's management team.

Financial Results

- **Cash Position**: Cash, cash equivalents, and short-term investments were $313 million as of September 30, 2023, compared with $334.3 million as of June 30, 2023. On November 1, 2023, the company closed a private placement financing that resulted in gross proceeds of approximately $185 million, before deducting offering expenses. The company believes that its current cash, cash equivalents, and short-term investments, including proceeds from the private placement, will be sufficient to fund its operations into 2026.
- **R&D Expenses:** Research and development expenses were $30.4 million during the third quarter of 2023, compared with $22.1 million for the same period last year. Research and development expenses for the third quarter of 2023 include increased costs related to ongoing clinical trials. Other drivers for the increase in research and development expenses include personnel-related costs including share-based compensation.
- **G&A Expenses:** General and administrative expenses were $20.9 million during the third quarter of 2023, compared with $8.9 million for the same period last year. The increase in general and administrative expenses was driven by personnel-related costs, including share-based compensation and severance costs, as well as market research, accounting and other professional fees.
- **Net Loss:** The company's net loss was $47.7 million for the third quarter of 2023, compared with $28.9 million for the same period last year. The increase in net loss was driven by the increase in operating expenses described above.
- **Shares outstanding:** Following the closing of its private placement financings, as of the date hereof, Viridian had approximately 73,650,891 shares of common stock outstanding on an as-converted basis, which included 52,586,039 shares of common stock and an aggregate of approximately 21,064,852 shares of common stock issuable upon the conversion of 172,435 and 143,522 shares of Series A and Series B preferred stock, respectively.

Viridian will not be hosting a conference call to discuss its third quarter financial results.

About Viridian Therapeutics

Viridian 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 two global Phase 3 clinical trials (THRIVE and THRIVE-2) to evaluate the safety and efficacy of VRDN-001 in patients with active and chronic TED. Simultaneously, the company is developing its subcutaneous program strategy with the goal of providing a potentially more conveniently administered therapy to patients with TED. In addition to its TED portfolio, Viridian is advancing a novel portfolio of neonatal Fc receptor (FcRn) inhibitors, VRDN-006 and VRDN-008, which has the potential to be developed in multiple autoimmune diseases. Viridian is also developing additional 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 X.

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 potential for VRDN-006 and VRDN-008; 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 IND filings; expectations regarding the timing for enrollment and 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 plan regarding selection of a lead SC program candidate; competition from other therapies or products; estimates of market size; 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 November 13, 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue:				
Collaboration Revenue - related party	$ 72	$ 1,195	$ 242	$ 1,667
Total revenue	72	1,195	242	1,667
Operating Expenses:				
Research and development	30,385	22,119	121,208	61,577
General and administrative	20,911	8,861	62,006	25,328
Total operating expenses	51,296	30,980	183,214	86,905
Loss from operations	(51,224)	(29,785)	(182,972)	(85,238)
Other income				
Interest and other income	4,164	1,044	13,029	1,467
Interest and other expense	(600)	(164)	(931)	(318)
Net loss	(47,660)	(28,905)	(170,874)	(84,089)
Change in unrealized gain (loss) on investments	109	137	326	(783)
Comprehensive loss	$ (47,551)	$ (28,768)	$ (170,548)	$ (84,872)
Net loss	$ (47,660)	$ (28,905)	$ (170,874)	$ (84,089)
Net loss per share, basic and diluted	$ (1.09)	$ (0.86)	$ (3.97)	$ (2.88)
Weighted-average shares used to compute basic and diluted loss per share	43,654,577	33,742,076	43,057,658	29,238,247

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

	September 30, 2023	December 31, 2022
Cash, cash equivalents and short-term investments	$ 313,007	$ 424,550
Other assets	15,750	10,541
Total assets	**$ 328,757**	**$ 435,091**

Total liabilities	45,181	40,027
Total stockholders' equity	283,576	395,064
Total liabilities and stockholders' equity	**$ 328,757**	**$ 435,091**

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