Viridian Therapeutics Reports First Quarter 2022 Financial Results and Provides Corporate Updates

May 12, 2022

-- Phase 1/2 clinical trial for VRDN-001 currently recruiting Thyroid Eye Disease (TED) patients at sites in the U.S. and Canada; top line proof of concept data expected in the third quarter of 2022 --

-- Interim results for VRDN-001 in healthy volunteers show saturation of IGF-1 response at doses as low as 3 mg/kg, supporting potential efficacy of lower doses in TED --

-- Adverse events reported to date for VRDN-001 in healthy volunteers are generally comparable to placebo, with no drug related events of hyperglycemia, hearing loss, or muscle spasms reported at any dose including top dose of 20 mg/kg --

-- VRDN-002 Phase 1 clinical trial dose escalation complete: First-In-Human, healthy volunteer trial for VRDN-002 on track for top line data in the third quarter of 2022--

-- Ended 1Q 2022 with cash, cash equivalents and short-term investments of $175 million, expected to fund operations into 2024 --

-- Conference call today at 4:30 p.m. ET --

WALTHAM, Mass., May 12, 2022 (GLOBE NEWSWIRE) -- Viridian Therapeutics, Inc. (NASDAQ: VRDN), a biotechnology company advancing new treatments for patients suffering from serious diseases underserved by current therapies, today announced financial results for the first quarter ending March 31, 2022 and provided corporate updates, including interim results for the healthy volunteer portion of the Company's ongoing proof of concept trial of VRDN-001 in Thyroid Eye Disease (TED).

"Our ongoing VRDN-001 and VRDN-002 clinical trials are poised to deliver data in the coming months that we believe will transform Viridian and significantly advance our goal of improving patient care in Thyroid Eye Disease," said Jonathan Violin, Ph.D., President and CEO of Viridian Therapeutics. "Our first clinical results are highly encouraging. The VRDN-001 healthy volunteer interim data show saturation of IGF-1 response at all doses tested, confirming robust IGF-1R inhibition as seen in our preclinical data, with an excellent safety and tolerability profile. We look forward to seeing the first efficacy data from TED patients soon."

First Quarter 2022 and Recent Highlights

VRDN-001: Viridian's most advanced product candidate VRDN-001 is a differentiated humanized monoclonal antibody that binds and blocks the insulin-like growth factor-1 receptor (IGF-1R) with sub-nanomolar affinity. This mechanism of action is clinically and commercially validated for the treatment of TED. The Company's ongoing first clinical trial for VRDN-001 is a Phase 1/2 proof of concept study that includes multiple randomized, placebo-controlled cohorts of TED patients. The trial is designed to assess the potential for VRDN-001 to provide rapid improvement of signs and symptoms of TED at six weeks, after two intravenous (IV) infusions of VRDN-001. The Company expects to announce top line proof of concept clinical data from two patient cohorts in the third quarter of 2022.

Dose escalation and healthy volunteer enrollment is complete, and the Company continues to enroll TED patients at sites in the U.S. and Canada. Each TED cohort includes eight patients randomized in a 3:1 ratio to receive VRDN-001 or placebo. The first cohort is evaluating two infusions of 10 mg/kg VRDN-001; the second cohort is evaluating two infusions of 20 mg/kg VRDN-001.

The healthy volunteer portion of the trial includes doses of 3 mg/kg, 10 mg/kg and 20 mg/kg in 13 subjects. No drug related adverse events associated with hyperglycemia, hearing loss or muscle spasms have been reported to date. Other adverse events have been generally comparable to placebo; to date, there have been no infusion reactions or serious adverse events. Interim data for plasma levels of IGF-1, a biomarker for target engagement, show a rapid increase that saturated after the first infusion at levels that were similar for all doses tested, including 3 mg/kg. Based on these results the Company now plans to enroll a cohort of TED patients at a dose of 3 mg/kg following the completion of the 10 mg/kg and 20 mg/kg cohorts in this trial. The Company expects to report top-line data from the 3 mg/kg cohort in the fourth quarter of 2022.

"The interim healthy volunteer data suggests robust activity of VRDN-001 at doses from 3 mg/kg to 20 mg/kg, with excellent safety and tolerability based on our observations to date. In TED patients we are assessing safety and tolerability as well as multiple efficacy endpoints and expect to report top line data on proptosis, clinical activity score and diplopia," said Dr. Barrett Katz, M.D., M.B.A., Chief Medical Officer of Viridian Therapeutics. "These efficacy measurements will be assessed at six weeks, after two infusions of VRDN-001. We will report the same endpoints used to evaluate teprotumumab, focusing on mean change from baseline in proptosis reduction, but will also report proptosis responder rate, clinical activity score, and diplopia."

VRDN-002: Viridian's second product candidate, VRDN-002, is a distinct, next-generation IGF-1R antibody incorporating half-life extension technology, designed to support administration as a convenient, low-volume, subcutaneous injection for the treatment of TED. In March 2022, Viridian announced dosing of the first subject in a first-in-human, healthy volunteer Phase 1 clinical trial evaluating VRDN-002. This is a single ascending dose trial to explore safety, tolerability, pharmacokinetics and pharmacodynamics of intravenously administered VRDN-002 at doses of 3 mg/kg, 10 mg/kg, and 20 mg/kg in up to 16 healthy volunteers. The Company has completed dose escalation and expects to announce top line data from this Phase 1 trial in the third quarter of 2022. Results from this trial will confirm the feasibility of a low-volume subcutaneous dosing paradigm for TED patients; the company is planning a SC proof of concept trial in TED patients as the next step in VRDN-002 development. The Company believes a low-volume subcutaneous injection would improve convenience for patients and physicians, mitigate treatment burdens, and expand the settings of care for TED therapies.

Discovery Pipeline: Viridian's pipeline expansion is focused on additional opportunities that leverage validated mechanisms and technologies in therapeutic areas 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. VRDN-005 is a second discovery-stage program for another undisclosed indication in which the Company believes patient care can be advanced with a novel therapeutic monoclonal antibody.

First Quarter 2022 Financial Results

Cash Position: Cash, cash equivalents and short-term investments were $175 million as of March 31, 2022, compared with $197 million as of December 31, 2021.

After the first quarter ended, the Company entered into a debt financing agreement with Hercules Capital, Inc. for up to $75 million. Under the terms of the agreement, Viridian drew an initial $5 million at closing.

An additional $20 million is available at the Company's request through June 15, 2023, with an additional $25 million available upon the Company's achievement of certain milestones, and the remaining $25 million available subject to final lender approval. The Company is under no obligation to draw funds in the future.

Excluding this $75 million credit facility, 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 were $17.7 million during the first quarter of 2022, compared with $13.8 million for the same period last year. The increase in research and development expenses was primarily driven by personnel related costs, license fees and clinical trial costs for VRDN-001 and VRDN-002. These increases were offset by expenses related to manufacturing and IND-enabling studies for VRDN-001 and VRDN-002 that were incurred in the first quarter of 2021.

G&A Expenses: General and administrative expenses were $8.4 million during the first quarter of 2022, compared with $6.2 million for the same period last year. 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 $25.7 million for the first quarter of 2022, compared with $18.5 million for the same period last year. The increase in net loss was driven by increased operating costs, as described above, as well as lower revenue from our collaboration with Zenas in the first quarter of 2022 compared to 2021.

Shares Outstanding: As of March 31, 2022, Viridian had approximately 42,883,007 shares of common stock outstanding on an as-converted basis, which included 27,169,422 shares of common stock outstanding and an aggregate of approximately 15,713,585 shares of common stock issuable upon the conversion of 212,566 and 23,126 shares of Series A and Series B preferred stock, respectively.

First Quarter 2022 Financial Results Conference Call

Viridian's management will host a conference call today at 4:30 p.m. ET to discuss the financial results and recent corporate developments. The dial-in number for the conference call is 1-877-270-2148 for domestic participants and 1-412-902-6510 for international participants. A live webcast of the conference call can be accessed through the "Events" page in the Investors section of the Viridian Therapeutics website. Following the live webcast, an archived version of the call will also be available on the website.

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 humanized 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). 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. TED is a debilitating autoimmune disease that causes inflammation and fibrosis within the orbit and behind 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 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, trial design and protocols for ongoing clinical trials, and expectations regarding the timing of top line data for the VRDN-001 and VRDN-002 programs, the safety and efficacy of the Company's product candidates, and the unpredictable relationship between preclinical study results and clinical study results. 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 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 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.

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

	Three Months Ended March 31,	
	2022	**2021**
Revenue:		
Collaboration Revenue - related party	$ 216	$ 1,451
Total revenue	216	1,451
Operating Expenses:		
Research and development	17,746	13,806
General and administrative	8,359	6,160
Total operating expenses	26,105	19,966
Loss from operations	(25,889)	(18,515)
Other income		
Interest and other income	196	55
Net loss	(25,693)	(18,460)
Change in unrealized loss on investments	(778)	(13)
Comprehensive loss	$ (26,471)	$ (18,473)
Net loss	$ (25,693)	$ (18,460)
Net loss per share, basic and diluted	$ (0.98)	$ (2.91)
Weighted-average shares used to compute basic and diluted loss per share	26,126,092	6,336,347

VIRIDIAN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(amounts in thousands)
(unaudited)

	March 31, 2022	**December 31, 2021**
Cash and cash equivalents	$ 30,858	$ 42,299
Short-term investments	$ 144,570	$ 154,666
Total assets	$ 183,165	$ 203,709
Total liabilities	$ 16,523	$ 15,993
Total stockholders' equity	$ 166,642	$ 187,716
Total liabilities and stockholders' equity	$ 183,165	$ 203,709

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Source: Viridian Therapeutics, Inc