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

August 15, 2022

- Positive initial clinical data from ongoing Phase 1/2 Trial evaluating VRDN-001 in patients with Thyroid Eye Disease (TED) -

- VRDN-002 achieved a substantially extended half-life of 30-40 days in healthy volunteers with a sustained IGF-1 response and a favorable safety and tolerability profile -

- Ended 2Q 2022 with cash, cash equivalents and short-term investments of $161 million, in addition to $75M credit facility, provide cash runway into 2024

- Conference call today at 8:00 a.m. ET -

WALTHAM, Mass., Aug. 15, 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 second quarter ending June 30, 2022 and provided corporate updates.

Earlier today in a separate news release, the Company announced positive initial clinical data from the first cohort of the ongoing Phase 1/2 clinical trial of VRDN-001, an IGF-1R antibody, in patients with thyroid eye disease (TED). In addition, Viridian announced positive topline data from a first-in-human Phase 1 clinical trial of intravenously administered VRDN-002 in healthy volunteers.

“We believe today’s positive initial VRDN-001 data for the treatment of Thyroid Eye Disease is transformative for Viridian and significantly advances our goal of improving patient care in TED. VRDN-001 delivered a rapid, compelling and clinically meaningful improvement at week 6 across all efficacy measures of TED: proptosis, clinical activity score, and diplopia, exceeding results from any prior TED trials,” said Jonathan Violin, Ph.D., President and CEO of Viridian Therapeutics. “We look forward to quickly advancing VRDN-001, which we believe can be a best-in-class IV therapy for patients, to Phase 3. In addition, promising initial VRDN-002 data, together with the unveiling of VRDN-003, an extended half-life version of VRDN-001, significantly advances our subcutaneous (SC) strategy. We expect to advance either VRDN-002 or VRDN-003 into registrational trials by year end 2023 based on clinical data from the two programs and expect to initiate our SC Phase 3 program in early 2024.”

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 expected 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 planned 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 patients, 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 Program: VRDN-002 and VRDN-003

- VRDN-002 will advance to a proof-of-concept trial in TED, evaluating 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 for the second quarter of 2023 with proof-of-concept data expected in the fourth quarter of 2023.
- By the end of 2023, the Company expects to 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.

Conference call and webcast
The Company will host a conference call today at 8:00 a.m. ET to discuss the topline data for VRDN-001 and VRDN-002. The Viridian management team will be joined by Raymond Douglas, M.D., Ph.D., Director of the Thyroid Eye Disease Program at Cedars-Sinai Medical Center. The dial-in number for the conference call is 1-877-407-0789 for domestic participants and 1-201-689-8562 for international participants. The conference ID is 13730501. 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.

Second Quarter 2022 Financial Results

Cash Position: Cash, cash equivalents and short-term investments were $161.2 million as of June 30, 2022, compared with $197 million as of December 31, 2021. The Company believes that its current cash, cash equivalents and short-term investments, in addition to its $75M credit facility, will be sufficient to fund its operations into 2024.

During the second quarter 2022, 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.

R&D Expenses: Research and development expenses were $21.7 million during the second quarter of 2022, compared with $12.6 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, as well as costs related to our preclinical programs. These increases were offset by expenses related to manufacturing costs for VRDN-001 and VRDN-002 that were incurred in the second quarter of 2021. Research and development expenses were $39.5 million during the six months ended June 30, 2022, compared with $26.4 million for the same period last year. The increase in research and development expenses was primarily driven by personnel related costs, license fees, clinical trial costs for VRDN-001 and VRDN-002, as well as costs related to our preclinical programs. These increases were offset by expenses related to manufacturing and IND-enabling studies for VRDN-001 and VRDN-002 that were incurred in the same period last year.

G&A Expenses: General and administrative expenses were $8.1 million during the second quarter of 2022, compared with $6.5 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.
General and administrative expenses were $16.5 million during the six months ended June 30, 2022, compared with $12.7 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 $29.5 million for the second quarter of 2022, compared with $18.0 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 June 30, 2022, Viridian had approximately 42,909,027 shares of common stock outstanding on an as-converted basis, which included 28,463,980 shares of common stock outstanding and an aggregate of approximately 14,445,047 shares of common stock issuable upon the conversion of 193,539 and 23,126 shares of Series A and Series B preferred stock, respectively.

About Viridian Therapeutics
Viridian Therapeutics is a biotechnology company advancing new treatments for patients suffering from serious diseases underserved by current therapies. Viridian's most advanced program, VRDN-001, is a differentiated 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). VRDN-002 is a distinct anti-IGF-1R antibody and incorporates half-life extension technology. VRDN-003 is an extended half-life version of VRDN-001. Both VRDN-002 and VRDN-003 are designed for administration as convenient, low-volume, subcutaneous injections. TED is a debilitating autoimmune disease that causes inflammation and fibrosis within the orbit of the eye which can cause double vision, pain, and potential blindness. 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 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 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.

VIRIDIAN THERAPEUTICS, INC.
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,	
	2022	2021	2022	2021
Revenue:				
Collaboration Revenue - related party	$ 256	$ 1,090	$ 472	$ 2,541
Operating Expenses:				
Research and development	21,712	12,565	39,458	26,371
General and administrative	8,108	6,523	16,467	12,683
Total operating expenses	29,820	19,088	55,925	39,054
Loss from operations	(29,564)	(17,998)	(55,453)	(36,513)
Other income				
Interest and other income	227	34	423	89
Interest expense	(154)	—	(154)	—
Net loss	(29,491)	(17,964)	(55,184)	(36,424)
Change in unrealized loss on investments	(142)	9	(920)	(4)
Comprehensive loss	$ (29,633)	$ (17,955)	$ (56,104)	$ (36,428)
Net loss	$ (29,491)	$ (17,964)	$ (55,184)	$ (36,424)
Net loss per share, basic and diluted	$ (1.06)	$ (2.21)	$ (2.05)	$ (5.04)
Weighted-average shares used to compute basic and diluted loss per share	27,762,257	8,106,765	26,948,692	7,226,447

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

	June 30,	December 31,
	2022	2021
Cash and cash equivalents	$ 161,207	$ 196,965
Other assets	8,607	6,744
Total assets	**$ 169,814**	**$ 203,709**
Total liabilities	27,916	15,993
Total stockholders' equity	141,898	187,716
Total liabilities and stockholders' equity	**$ 169,814**	**$ 203,709**

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