Viridian Therapeutics Reports Second Quarter 2021 Financial Results and Provides Corporate Updates

August 11, 2021

- *Completed a successful pre-IND meeting with the FDA for VRDN-001, a differentiated monoclonal antibody targeting IGF-1R for the treatment of Thyroid Eye Disease*
- *On track to submit an IND filing with the FDA for VRDN-001 in the fourth quarter of 2021 and for key proof of concept clinical data in Thyroid Eye Disease patients in the second quarter of 2022*
- *First VRDN-001 clinical trial data has potential to show rapid and substantial reduction in proptosis, the defining symptom of Thyroid Eye Disease*
- *Multiple abstracts accepted for upcoming presentation at the American Thyroid Association (ATA) Annual Meeting, highlighting preclinical data for Viridian's differentiated IGF-1R antibodies*
- *Strengthened management team with appointments of Kristian Humer as Chief Financial Officer and Chief Business Officer and Deepa Rajagopalan, M.D. as SVP of New Product and Portfolio Development*
- *Reported $109 million in cash, cash equivalents and short-term investments as of June 30, 2021, providing cash runway into 2024*

WALTHAM, Mass., Aug. 11, 2021 (GLOBE NEWSWIRE) -- Viridian Therapeutics, Inc. (Nasdaq: VRDN) (the "Company" or "Viridian"), a biopharmaceutical company advancing new treatments for patients suffering from serious diseases and underserved by current therapies, today announced financial results for the second quarter ended June 30, 2021, and provided corporate updates.

"We continue to make rapid progress with our lead TED program, VRDN-001," said Jonathan Violin, Ph.D., President and Chief Executive Officer of Viridian. "Following a highly collaborative pre-IND dialogue with the FDA for VRDN-001, we remain on track to submit IND filings for both VRDN-001 and VRDN-002 to the FDA in the fourth quarter of 2021. This would put us on track to report key Phase 1/ 2 proof of concept clinical data in TED patients in the second quarter of 2022 for VRDN-001, quickly followed by Phase 1 first-in-human data in mid-year 2022 for VRDN-002. We are also progressing our discovery programs as we expand our pipeline beyond IGF-1R and TED, advancing our strategy to discover and develop novel and differentiated monoclonal antibodies."

Second Quarter 2021 and Recent Highlights

VRDN-001: Viridian's most advanced product candidate is VRDN-001, 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). This antibody has previously been studied in over 100 oncology patients as AVE1642, informing plans for rapid development in TED. The Company recently completed a successful pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA) and gained alignment on initial development plans and the proposed design for a randomized, placebo-controlled Phase 1/ 2 clinical proof of concept trial. This trial will evaluate safety, tolerability, and efficacy with the potential for clinically meaningful improvement in proptosis, the defining characteristic of TED, previously shown to be improved by IGF-1R blockade. The protocol allows for flexibility to subsequently assess multiple doses and treatment regimens to inform product profiles that may be superior to currently available therapies. The Company remains on track to file an IND in the fourth quarter of 2021, with initial proof of concept clinical data in TED patients expected in the second quarter of 2022.

VRDN-002: 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. IND-enabling activities remain on track with plans to file an IND by the end of 2021. The Company expects to initiate clinical development with a Phase 1 single ascending dose trial to explore safety, tolerability, pharmacokinetics, and target engagement of intravenous VRDN-002 in healthy volunteers. Data from this trial are expected by mid-year 2022, and could demonstrate feasibility of a low-volume and/or low-frequency dosing paradigm. In parallel, formulation development is on track to support initiation of a clinical trial evaluating low-volume subcutaneous injection of VRDN-002 in 2022. The Company believes a low-volume subcutaneous injection could improve convenience for patients and physicians, mitigate treatment burdens, and expand the settings of care for TED therapies.

Discovery Pipeline: Viridian's corporate development strategy includes expanding its discovery pipeline beyond IGF-1R and TED, with a focus on opportunities that will leverage validated mechanisms, technologies, and modalities to bring new therapeutic options to patients underserved by today's available medicines. The most advanced of these programs is VRDN-004, a therapeutic monoclonal antibody program currently in discovery stage. The Company continues to evaluate additional opportunities to expand its product pipeline for rare disease indications and remains focused on opportunities to leverage validated mechanisms and technologies to bring new therapeutic options to patients underserved by current therapies.

Scientific Presentations: The Company announced that it will present preclinical data on VRDN-001 and VRDN-002 at the American Thyroid Association (ATA) Annual Meeting, which will be held virtually from September 30 to October 3, 2021. Details of the Company's presentations will be announced in the coming weeks.

Appointments:

- Kristian Humer appointed Chief Financial Officer and Chief Business Officer in July 2021. He brings more than 20 years of life science investment banking, mergers and acquisitions, and partnering experience to Viridian. Most recently, Mr. Humer served as Managing Director of Banking, Capital Markets & Advisory for the Global Healthcare team at Citigroup, Inc.

- Deepa Rajagopalan, M.D., appointed Senior Vice President of New Product and Portfolio Development, in July 2021. Most recently, Dr. Rajagopalan served as Vice President of New Products at Intercept Pharmaceuticals, and previously held roles at Alexion Pharmaceuticals and Bain & Company.

- Jennifer Moses, CPA, appointed to the Company's Board of Directors and as Chair of the Company's Audit Committee in July 2021. Ms. Moses is the Chief Financial Officer of G1 Therapeutics. Prior to G1 Therapeutics, she was a partner at Rankin McKenzie, LLC, and previously held roles of increasing responsibility at Deloitte.

Second Quarter 2021 Financial Results

Cash Position: Cash, cash equivalents and short-term investments were $109.3 million as of June 30, 2021, compared to $127.6 million as of December 31, 2020. 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 increased by $8.8 million to $12.6 million during the second quarter of 2021, compared to $3.8 million during the second quarter of 2020. The increase in research and development expenses was primarily driven by the advancement of the Company's lead programs, including expenses related to manufacturing and IND enabling studies. This increase was partially offset by a decrease in clinical trial expenses in the second quarter of 2021.

G&A Expenses: General and administrative expenses increased by $3.8 million to $6.5 million during the second quarter of 2021, compared to $2.7 million during the second quarter of 2020. 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 $18.0 million for the second quarter of 2021, compared to $6.4 million for the second quarter of 2020.

Shares Outstanding: As of August 10, 2021, Viridian had approximately 31,294,508 shares of common stock outstanding on an as-converted basis, which included 9,542,087 shares of common stock and approximately 21,752,421 shares of common stock issuable upon the conversion of 326,270 shares of preferred stock.

About Viridian Therapeutics, Inc.

Viridian Therapeutics is a biotechnology company advancing new treatments for patients suffering from serious diseases and underserved by today's 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), a debilitating auto-immune disease that causes inflammation and fibrosis within the orbit of 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. Learn more about Viridian and its programs at www.viridiantherapeutics.com.

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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, strategies, 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, its projected cash runway, the timing, progress and plans for the Company's ongoing and future research and clinical development programs, future regulatory interactions, expectations regarding the timing for data, and the timing of the Company's IND filings for VRDN-001 and VRDN-002. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our clinical results and other future conditions. 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. We may not actually achieve the forecasts disclosed in our forward-looking statements, and you should not place undue reliance on our 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; and 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 26, 2021, the Company's other periodic reports 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
Collaboration revenue - related party	$ 1,090	$ —	$ 2,541	$ —
Collaboration revenue	—	—	—	681
Grant revenue	—	168	—	315
Total revenue	1,090	168	2,541	996
Operating expenses:				
Research and development	12,565	3,836	26,371	9,939
General and administrative	6,523	2,706	12,683	5,429
Total operating expenses	19,088	6,542	39,054	15,368
Loss from operations	(17,998)	(6,374)	(36,513)	(14,372)
Other income (expense):				
Interest and other income	34	33	89	128
Interest and other expense	—	(94)	—	(235)
Net loss	(17,964)	(6,435)	(36,424)	(14,479)
Change in unrealized gain (loss) on investments	9	—	(4)	—
Comprehensive loss	$ (17,955)	$ (6,435)	$ (36,428)	$ (14,479)
Net loss	$ (17,964)	$ (6,435)	$ (36,424)	$ (14,479)
Net loss per share, basic and diluted	$ (2.21)	$ (1.82)	$ (5.04)	$ (4.41)
Weighted-average shares used to compute basic and diluted net loss per share	8,106,765	3,538,490	7,226,447	3,285,123

VIRIDIAN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)
(unaudited)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 27,704	$ 45,897
Short-term investments	81,597	81,742
Prepaid expenses and other current assets	4,110	1,972
Unbilled revenue - related party	2,051	—
Total current assets	115,462	129,611
Property and equipment, net	298	309
Operating lease right-of-use asset, net	1,567	478
Other assets - related party	778	856
Other assets	97	1
Total assets	$ 118,202	$ 131,255
Liabilities and Stockholders' Equity		

Current liabilities:		
Accounts payable	$ 2,392	$ 670
Accrued liabilities	14,150	9,703
Current portion of deferred revenue - related party	288	301
Total current liabilities	16,830	10,674
Other liabilities - related party	1,293	501
Other liabilities	1,167	43
Total liabilities	19,290	11,218
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, series A non-voting convertible preferred stock, $0.01 par value; 435,000 shares authorized; 340,219 and 398,487 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	154,363	180,801
Preferred stock, $0.01 par value; 5,000,000 shares authorized; 0 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	—	—
Common stock, $0.01 par value; 200,000,000 shares authorized; 8,608,886 and 4,231,135 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	86	42
Additional paid-in capital	259,786	218,089
Accumulated other comprehensive loss	(12)	(8)
Accumulated deficit	(315,311)	(278,887)
Total stockholders' equity	98,912	120,037
Total liabilities and stockholders' equity	$ 118,202	$ 131,255