NEWS RELEASE

Viridian Therapeutics Reports Third Quarter 2024 Financial Results and Recent Progress Including New FcRn Data

2024-11-12

- Reported positive topline phase 3 data for veligrotug from THRIVE in patients with active thyroid eye disease (TED); on track to report topline data from THRIVE-2 in chronic patients in December 2024 -

- Initiated two global phase 3 clinical trials of subcutaneous VRDN-003, REVEAL-1 and REVEAL-2 in August, in active and chronic TED, respectively; topline data anticipated in the first half of 2026 -

- New non-human primate (NHP) data for VRDN-008, a next-generation bispecific neonatal Fc receptor (FcRn) inhibitor, demonstrates a potential best-in-class pharmacokinetic (PK) and pharmacodynamic (PD) profile; Investigational New Drug (IND) submission is planned for year-end 2025 and proof-of-concept IgG reduction data in healthy volunteers is anticipated in the second half of 2026 -

- VRDN-006, a Fc fragment inhibitor of FcRn, remains on track for Investigational New Drug (IND) submission by year-end 2024; proof-of-concept IgG reduction data in healthy volunteers anticipated in the second half of 2025 -

- Net proceeds of $243.2 million from public offering in September 2024 extends cash runway into the second half of 2027; cash, cash equivalents, and short-term investments of $753.2 million as of September 30, 2024 -

WALTHAM, Mass.--(BUSINESS WIRE)-- Viridian Therapeutics, Inc. (NASDAQ: VRDN), a biotechnology company focused on discovering and developing potential best-in-class medicines for serious and rare diseases, today reported recent business highlights and financial results for the third quarter ending September 30, 2024.

“We had another exceedingly strong quarter of execution across our TED and FcRn portfolios,” said Steve Mahoney,

Viridian's President and Chief Executive Officer. "In TED, we reported highly-compelling and positive phase 3 data for veligrotug and eagerly anticipate the readout of THRIVE-2 in December. We also initiated both pivotal phase 3 clinical trials for VRDN-003, our next-generation subcutaneous IGF-1R inhibitor. For our FcRn inhibitor portfolio, we are thrilled today to share VRDN-008 NHP data for the first time, demonstrating a potential best-in-class pharmacokinetic and pharmacodynamic profile for this half-life extended bispecific FcRn inhibitor. Together with our Fc fragment approach with VRDN-006, we believe these programs in our FcRn portfolio will bring differentiated options for patients and each contribute to an exciting pipeline beyond TED. This quarter, we also further strengthened our cash position with a financing that allows us to accelerate our R&D pipeline and extend our cash runway into the second half of 2027."

RECENT TED PORTFOLIO PROGRESS

Veligrotug is an intravenously delivered anti-insulin-like growth factor-1 receptor (IGF-1R) antibody in phase 3 development for thyroid eye disease.

- Achieved All Primary and Secondary Endpoints in THRIVE: In September, Viridian **announced** positive topline results for veligrotug in THRIVE, a global phase 3 clinical trial in patients with active TED. Veligrotug met all of its primary and secondary endpoints after five infusions with high statistical significance ($p < 0.0001$) and was generally well-tolerated.
- THRIVE-2 Topline Data Readout on Track for December 2024: THRIVE-2 is a global phase 3 clinical trial assessing the efficacy and safety of veligrotug after five infusions in patients with chronic TED. THRIVE-2 completed enrollment in July 2024 with a total of 188 patients, exceeding the enrollment target of 159 patients due to patient demand, and is on track for topline readout of the 15-week primary efficacy analysis in December.
- Veligrotug BLA on Track for Second Half 2025: Viridian anticipates submitting a Biologics License Application (BLA) in the second half of 2025, pending data, and expects that its data package will support a marketing authorization application in Europe.

VRDN-003 is a potential best-in-class, subcutaneous, half-life extended anti-IGF-1R antibody with the same binding domain as veligrotug.

- REVEAL-1 and REVEAL-2 Initiated in August 2024: REVEAL-1 and REVEAL-2 are designed to evaluate VRDN-003 in patients with active and chronic TED, respectively, via a subcutaneous administration every four weeks or every eight weeks. Viridian believes the THRIVE topline results provide strong evidence to support the profile of VRDN-003 as a potential best-in-class subcutaneous anti-IGF-1R antibody in a low-volume, infrequent, self-administered, subcutaneous injection designed for patients to use at home.

- Topline Data and BLA in 2026: Viridian anticipates topline data from both REVEAL-1 and REVEAL-2 in the first half of 2026, with a BLA submission planned by year-end 2026. The company plans to launch VRDN-003 with a commercially available low-volume autoinjector for at-home administration.

FCRN PORTFOLIO UPDATE WITH NEW VRDN-008 NHP DATA

VRDN-006 is a highly selective Fc fragment which inhibits FcRn, and is designed to be a convenient subcutaneous and self-administered option for patients.

- IND on Track for Year-End 2024: Viridian is on track to submit an IND application for VRDN-006 by year-end 2024. Viridian anticipates starting a phase 1 clinical trial for VRDN-006 in healthy volunteers in early 2025 and proof-of-concept IgG reductions from that study in the second half of 2025.

VRDN-008 is a half-life extended bispecific FcRn inhibitor comprising an Fc fragment and an albumin-binding domain designed to prolong IgG suppression and provide a potentially best-in-class subcutaneous option for patients.

- Positive New NHP Data Confirms Half-Life Extension: In a head-to-head study, single doses of VRDN-008 demonstrated 3x the half-life of efgartigimod and showed a deeper and more sustained IgG reduction in NHPs with peak IgG reductions that were 20% deeper than efgartigimod. IgG levels returned to baseline 35 days after VRDN-008 dosing, more than twice as long as efgartigimod, which returned to baseline 14 days after dosing. VRDN-008 spared albumin and low-density lipoprotein (LDL), consistent with efgartigimod. Given that NHP data for FcRn inhibitors have been highly translatable to humans, Viridian believes this data shows the potential for VRDN-008 to be a best-in-class, extended half-life FcRn inhibitor for patients.
- IND Submission Expected Year-End 2025: With these positive proof-of-concept data for VRDN-008, Viridian plans to further advance IND-enabling activities and submit an IND by year-end 2025. Viridian anticipates proof-of-concept IgG reduction data in healthy volunteers in the second half of 2026.

FINANCIAL RESULTS

- Cash Position : Cash, cash equivalents, and short-term investments were $753.2 million as of September 30, 2024, compared with $571.4 million as of June 30, 2024. The company completed a public offering in September 2024 with net proceeds of $243.2 million and believes that its current cash, cash equivalents, and short-term investments will be sufficient to fund its operations into the second half of 2027.
- R&D Expenses : Research and development expenses were $69.2 million during the quarter ended September 30, 2024, compared to $30.4 million during the quarter ended September 30, 2023. The increase in research and development expenses was driven by increased clinical trials costs associated with our ongoing THRIVE

and THRIVE-2 pivotal clinical trials, as well as increased personnel costs to support our pipeline development.

- G&A Expenses : General and administrative expenses were $14.4 million during the quarter ended September 30, 2024, compared to $20.9 million during the quarter ended September 30, 2023. The decrease in general and administrative expenses was driven by a decrease in personnel-related costs, including share-based compensation expenses.
- Net Loss : The company's net loss was $76.7 million for the third quarter ended September 30, 2024, compared with $47.7 million for the same period last year.
- Shares Outstanding: As of September 30, 2024, Viridian had 97,850,645 shares of common stock outstanding on an as-converted basis, which included 79,181,445 shares of common stock and an aggregate 18,669,200 shares of common stock issuable upon the conversion of 134,864 and 145,160 shares of Series A and Series B preferred stock, respectively.

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 protein engineering enables the development of 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 a pivotal program for veligrotug (VRDN-001), including two global phase 3 clinical trials (THRIVE and THRIVE-2), to evaluate its efficacy and safety in patients with active and chronic TED. Viridian is also advancing VRDN-003 as a potential best-in-class subcutaneous therapy for the treatment of TED, including two ongoing global phase 3 pivotal clinical trials, REVEAL-1 and REVEAL-2, to evaluate the efficacy and safety of VRDN-003 in patients with active and chronic TED.

In addition to its TED portfolio, Viridian is advancing a novel portfolio of neonatal Fc receptor (FcRn) inhibitors, including VRDN-006 and VRDN-008, which has the potential to be developed in multiple autoimmune 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,” “on track,” “plan,” “potential,” “predict,” “project,” “design,” “should,” “target,” “will,” or “would” or other similar terms or expressions that concern our expectations, 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. Forward-looking statements include, without limitation, statements regarding: preclinical and clinical development of Viridian’s product candidates veligrotug (formerly VRDN-001), VRDN-003, VRDN-006 and VRDN-008; anticipated start dates of studies, including the initiation date of the phase 1 clinical trial for VRDN-006; milestones; timelines; anticipated data results and timing of their disclosure, including topline results; regulatory interactions and anticipated timing of regulatory submissions, including the anticipated IND submissions for VRDN-006 and VRDN-008 and the anticipated BLA submissions for veligrotug and VRDN-003; Viridian’s expectation that its data package will support a BLA submission for veligrotug in the second half of 2025, pending data; Viridian’s expectation that its data package will support a marketing authorization application in Europe for veligrotug; clinical trial designs, including the REVEAL-1 and REVEAL-2, global phase 3 clinical trials for VRDN-003; Viridian’s plans to launch VRDN-003 with a commercially available auto-injector pen, if approved; the potential utility, efficacy, potency, safety, clinical benefits, clinical response, convenience and number of indications of veligrotug, VRDN-003, VRDN-006 and VRDN-008; potential dosing regimen for VRDN-008; Viridian’s product candidates potentially being best-in-class; and that Viridian’s cash, cash equivalents and short-term investments will be sufficient to fund its operations into the second half of 2027.

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: potential utility, efficacy, potency, safety, clinical benefits, clinical response and convenience of Viridian’s product candidates; that results or data from completed or ongoing clinical trials may not be representative of the results of ongoing or future clinical trials; that preliminary data may not be representative of final data; the timing, progress and plans for our ongoing or future research, preclinical and clinical development programs; changes to trial protocols for ongoing or new clinical trials; expectations and changes regarding the timing for regulatory filings; regulatory interactions expectations and changes 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; manufacturing risks; 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 projected cash runway; our future operating results and financial performance; Viridian’s intellectual property position; the timing of preclinical and clinical trial activities and reporting results from same; and those risks set forth under the caption “Risk Factors” in our most recent quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August

8, 2024 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,	
	2024	2023	2024	2023
Revenue:				
Collaboration Revenue - related party	$ 86	$ 72	$ 230	$ 242
Total revenue	86	72	230	242
Operating Expenses:				
Research and development	69,158	30,385	166,294	121,208
General and administrative	14,408	20,911	45,499	62,006
Total operating expenses	83,566	51,296	211,793	183,214
Loss from operations	(83,480)	(51,224)	(211,563)	(182,972)
Other income (expense)				
Interest and other income	7,795	4,164	23,527	13,029
Interest and other expense	(1,004)	(600)	(2,188)	(931)
Net loss	(76,689)	(47,660)	(190,224)	(170,874)
Change in unrealized gain on investments	1,475	109	594	326
Comprehensive loss	$ (75,214)	$ (47,551)	$ (189,630)	$ (170,548)
Net loss	$ (76,689)	$ (47,660)	$ (190,224)	$ (170,874)
Net loss per share, basic and diluted	$ (1.15)	$ (1.09)	$ (2.98)	$ (3.97)
Weighted-average shares used to compute basic and diluted loss per share	66,420,063	43,654,577	63,800,798	43,057,658

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

	September 30, 2024	December 31, 2023
Cash, cash equivalents and short-term investments	$ 753,240	$ 477,370
Other assets	18,660	13,054
Total assets	$ 771,900	$ 490,424
Total liabilities	64,404	48,402
Total stockholders' equity	707,496	442,022

Total liabilities and stockholders' equity	$ 771,900	$ 490,424

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