

May 13, 2026



Veru Reports Fiscal 2026 Second Quarter Financial Results and Phase 2b PLATEAU Clinical Trial Progress

--Phase 2b PLATEAU clinical study evaluating enobosarm + semaglutide is actively enrolling and on track for interim analysis first quarter calendar year 2027—

--Company to host conference call and webcast today at 8:00 a.m. ET—

MIAMI, FL, May 13, 2026 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), a late clinical stage biopharmaceutical company focused on developing innovative medicines for the treatment of cardiometabolic and inflammatory diseases, today announced financial results for its fiscal 2026 second quarter ended March 31, 2026, and provided a corporate update.

"We are extremely pleased with the progress of the enrollment of the Phase 2b PLATEAU clinical trial to evaluate the effect of enobosarm 3mg on total body weight, fat mass, lean mass, physical function, bone mineral density and safety in older patients who have obesity and receiving a semaglutide GLP-1 RA treatment for weight reduction. We are on track for presenting the results of the interim analysis which is expected in Q1 calendar year 2027," said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru Inc.

Veru Obesity Program – Study of Enobosarm in combination with GLP-1 RA for higher quality weight reduction

Phase 2b PLATEAU Clinical Study – Actively enrolling

Phase 2b PLATEAU clinical trial is a double-blind, placebo-controlled study to evaluate the effect of enobosarm 3mg on total body weight, fat mass, lean mass, physical function, bone mineral density and safety in approximately 200 older patients (age ≥ 65 years) who have obesity (BMI ≥ 35) and are initiating semaglutide treatment for weight reduction. The Phase 2b PLATEAU study is designed to assess the ability of enobosarm treatment to break through the weight loss plateau observed in patients with obesity receiving GLP-1 RA treatment by preserving muscle mass and physical function to achieve clinically meaningful incremental weight reduction by 68 weeks. The primary efficacy endpoint of the study is the percent change from baseline in total body weight at 68 weeks. An interim analysis will be conducted at 36 weeks to assess the percent change from baseline in lean body mass and fat mass, as measured by DXA scan. The key secondary endpoints are total fat mass, total lean mass, physical function (stair climb test), mobility disability assessment, bone mineral density, and patient reported outcome questionnaires for physical function, HbA1c, and

insulin resistance.

Semaglutide was selected as the GLP-1 RA for the Phase 2b PLATEAU study to build on Veru's previous clinical experience using enobosarm in combination with semaglutide in the positive Phase 2 QUALITY clinical study. Further, the clinical data from the Phase 2b PLATEAU clinical trial using injectable semaglutide may support the use of oral semaglutide in combination with oral enobosarm in future Phase 3 clinical studies. In contrast, there is no approved oral formulation for tirzepatide. The Principal Investigator for the Phase 2b PLATEAU clinical trial is Steven Heymsfield, MD, a Professor and the Director of the Body Composition-Metabolism Laboratory at the Pennington Biomedical Research Center in Baton Rouge, Louisiana. Dr. Heymsfield was also the Principal Investigator of Veru's Phase 2 QUALITY clinical study.

An interim analysis to assess change in lean body mass and fat mass as measured by DXA will be conducted at 36 weeks with data expected in the first quarter of calendar year 2027. Final topline clinical data is expected in the fourth quarter of calendar year 2027.

Phase 2b QUALITY Clinical Study – Completed

The Phase 2b QUALITY clinical study was a positive multicenter, double-blind, placebo-controlled, randomized, dose-finding clinical trial designed to evaluate the safety and efficacy of enobosarm 3 mg, enobosarm 6 mg, or placebo as a treatment to augment fat loss and to prevent muscle loss in 168 older patients (≥ 60 years of age) receiving semaglutide (Wegovy®) for weight reduction. After the efficacy dose-finding portion of the Phase 2b QUALITY clinical trial was completed at 16 weeks, participants continued into a Phase 2b maintenance extension study where all patients discontinued semaglutide treatment, but continued receiving placebo, enobosarm 3 mg, or enobosarm 6 mg as monotherapy in a double-blind fashion for 12 weeks. The Phase 2b QUALITY and Maintenance Extension clinical trial was a positive study that demonstrated that preserving lean mass and physical function with enobosarm plus semaglutide led to greater fat loss during the 16 week active weight loss period. While weight loss was similar across treatment groups in this short 16 week study, we anticipate that preservation of lean mass and function will lead to increased energy expenditure, and this effect coupled with the direct effects of enobosarm on the additional selective reduction in fat mass will result in incremental weight reduction in a longer 68 week clinical study in patients who have obesity.

Second Quarter Financial Summary: Fiscal 2026 vs Fiscal 2025

- Research and development expenses decreased to \$3.1 million from \$3.9 million
- General and administrative expenses decreased to \$4.1 million from \$5.2 million
- Operating loss from continuing operations decreased to \$7.2 million from \$8.1 million
- Net loss decreased to \$2.7 million, or \$0.12 per share, compared to \$7.9 million, or \$0.54 per share

Year-to-Date Financial Summary: Fiscal 2026 vs Fiscal 2025

- Research and development expenses decreased to \$4.5 million from \$9.6 million
- General and administrative expenses decreased to \$8.2 million from \$10.4 million
- Operating loss from continuing operations decreased to \$12.6 million from \$18.4 million
- Net loss decreased to \$8.1 million, or \$0.37 per share, compared to \$16.8 million, or \$1.15 per share

Balance Sheet Information

- Cash, cash equivalents and restricted cash were \$27.6 million as of March 31, 2026 versus \$15.8 million as of September 30, 2025

Event Details

The audio webcast will be accessible under the Home page and Investors page of the Company's website at www.verupharma.com. To join the conference call via telephone, please dial 1-800-341-1602 (domestic) or 1-412-902-6706 (international) and ask to join the Veru Inc. call. An archived version of the audio webcast will be available for replay on the Company's website for approximately three months. A telephonic replay will be available at approximately 12:00 p.m. ET by dialing 1-855-669-9658 (domestic) or 1-412-317-0088 (international), passcode 8826955, for one week.

About Veru Inc.

Veru is a late clinical stage biopharmaceutical company focused on developing innovative medicines for the treatment of cardiometabolic and inflammatory diseases. The Company's drug development program includes two late-stage novel small molecules, enobosarm and sabizabulin. Enobosarm, an oral selective androgen receptor modulator (SARM), is being developed as a next generation drug that makes weight reduction by GLP-1 RA drugs more tissue selective for loss of fat and preservation of lean mass to improve body composition and physical function which is expected to result in clinically meaningful incremental weight reduction versus GLP-1 RA therapy alone. Sabizabulin, a microtubule disruptor, is being developed for the treatment of chronic inflammation related to atherosclerotic cardiovascular disease.

Forward-Looking Statements

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995, including, without limitation, express or implied statements related to the planned design, enrollment, timing, commencement, interim, topline and full data readout timing, scope and regulatory pathways for the continued development of enobosarm in patients with obesity, including the PLATEAU Phase 2b study; the planned design, number of sites, timing, endpoints, patient population and patient size of such trial and whether the PLATEAU trial will successfully meet any of its primary or secondary endpoints; whether the results of the Phase 2b QUALITY study and the extension maintenance study of enobosarm, including weight loss, preservation of lean mass and physical function and loss of fat mass, will be replicated to the same or any degree in the PLATEAU Phase 2b study or in any future Phase 3 studies; whether and when the PLATEAU Phase 2b study of enobosarm will produce an interim analysis and/or topline data; whether enobosarm in combination with a GLP-1 RA drug will provide a higher quality and/or greater quantity weight loss in patients and whether this combination therapy will be the next generation drug that makes weight reduction more tissue selective for loss of fat, preservation of lean mass and physical function, improved body composition and maintaining or increasing bone mineral density; whether patients treated with enobosarm in the PLATEAU Phase 2B study will preserve lean mass and physical function leading to an increased use of energy and whether such effects will result in incremental weight reduction; whether patients treated with enobosarm in the PLATEAU Phase 2B study will break through the weight loss plateau and achieve clinically meaningful incremental weight reduction by preserving muscle mass and physical function; and whether the oral form of semaglutide

may be used in combination with enobosarm in future Phase 3 clinical studies and whether the injectable semaglutide used in the PLATEAU Phase 2B study data of enobosarm will support the use of oral semaglutide formulation in combination with oral enobosarm in future Phase 3 clinical studies; The words "anticipate," "believe," "could," "expect," "intend," "may," "opportunity," "plan," "predict," "potential," "estimate," "should," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based upon current plans and strategies of the Company and reflect the Company's current assessment of the risks and uncertainties related to its business and are made as of the date of this press release. The Company assumes no obligation to update any forward-looking statements contained in this press release because of new information or future events, developments, or circumstances. Such forward-looking statements are subject to known and unknown risks, uncertainties and assumptions, and if any such risks or uncertainties materialize or if any of the assumptions prove incorrect, our actual results could differ materially from those expressed or implied by such statements. Factors that may cause actual results to differ materially from those contemplated by such forward-looking statements include, but are not limited to: the development of the Company's product portfolio and the results of clinical studies, including any interim or topline analysis, possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; although the Company has sought and received feedback from the FDA on the designs of its clinical trials and intends to continue to do so, the FDA may ultimately disagree that the Company's clinical trials support approval; the Company's ability to reach agreement with FDA on study design requirements for the Company's planned clinical studies, including for the Phase 2b program for enobosarm as a weight loss or body composition drug and the number of future Phase 3 studies to be required and the cost thereof; potential delays in the timing of and results from clinical trials and studies, including as a result of an inability to enroll sufficient numbers of subjects in clinical studies or an inability to enroll subjects in accordance with planned schedules; the ability to fund planned clinical development as well as other operations of the Company; the Company plans to prioritize the use of its current internal cash to the development of enobosarm, with a primary near-term focus on funding its PLATEAU Phase 2b clinical trial, and as a result advancement of sabizabulin as a treatment for slowing progression of or promoting regression of atherosclerosis disease will depend upon the Company securing additional funding; whether the Company will be able to partner with another company in the development of enobosarm or sabizabulin; the timing of any submission to the FDA or any other regulatory authority and any determinations made by the FDA or any other regulatory authority; the potential for disruptions at the FDA or other government agencies to negatively affect our business, including as a result of a future shutdown of the U.S. government; any products of the Company, if approved, possibly not being commercially successful; the ability of the Company to obtain sufficient financing, including any partnership or collaboration agreements, on acceptable terms when needed to fund development and operations and to enable us to continue as a going concern; the effect of the SEC's "baby shelf" rules on the Company's ability to raise sufficient capital when needed; demand for, market acceptance of, and competition against any of the Company's products or product candidates; new or existing competitors with greater resources and capabilities and new competitive product approvals and/or introductions; changes in regulatory practices or policies or government-driven healthcare reform efforts, including pricing pressures and insurance coverage and reimbursement changes; the Company's ability to protect and enforce its intellectual property; costs and other effects of litigation, including regulatory challenges, product liability

claims, intellectual property, securities litigation and litigation with the purchaser of the Company's FC2 business; the Company's ability to identify, successfully negotiate and complete suitable acquisitions or other strategic initiatives; the Company's ability to successfully integrate acquired businesses, technologies or products; and other risks detailed from time to time in the Company's press releases, shareholder communications and Securities and Exchange Commission filings, including the Company's Form 10-K for the year ended September 30, 2025, and subsequent quarterly reports on Form 10-Q. These documents are available on the "SEC Filings" section of our website at www.verupharma.com/investors.

Wegovy® is a registered trademark of Novo Nordisk A/S.

FINANCIAL SCHEDULES FOLLOW

Veru Inc. Condensed Consolidated Balance Sheets (unaudited)

	March 31, 2026	September 30, 2025
Cash, cash equivalents, and restricted cash	\$ 27,596,820	\$ 15,794,562
Investments in equity securities	3,167,733	2,525,305
Prepaid expenses and other current assets	2,590,923	595,251
Total current assets	33,355,476	18,915,118
Property and equipment, net	308,421	364,808
Operating lease right-of-use assets	2,479,348	2,746,014
Goodwill	6,878,932	6,878,932
Other assets	60,549	930,847
Total assets	\$ 43,082,726	\$ 29,835,719
Accounts payable	\$ 2,071,710	\$ 3,121,448
Accrued compensation	2,164,000	3,510,237
Accrued expenses and other current liabilities	382,876	394,529
Operating lease liability, short-term portion	770,257	758,946
Total current liabilities	5,388,843	7,785,160
Operating lease liability, long-term portion	2,063,089	2,358,018
Other liabilities	845,173	1,359,871
Total liabilities	8,297,105	11,503,049

Total stockholders' equity	34,785,621	18,332,670
Total liabilities and stockholders' equity	<u>\$ 43,082,726</u>	<u>\$ 29,835,719</u>

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended		Six Months Ended	
	March 31,		March 31,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	\$ 3,145,783	\$ 3,932,102	\$ 4,489,965	\$ 9,648,932
General and administrative	4,073,185	5,164,433	8,153,018	10,391,546
Total operating expenses	<u>7,218,968</u>	<u>9,096,535</u>	<u>12,642,983</u>	<u>20,040,478</u>
Gain on sale of ENTADFI® assets	—	974,303	—	1,669,519
Operating loss	(7,218,968)	(8,122,232)	(12,642,983)	(18,370,959)
Non-operating income:				
Gain on extinguishment of debt	—	—	—	8,624,778
Other non-operating income, net	4,126,418	269,839	4,217,854	83,885
Total non-operating income	<u>4,126,418</u>	<u>269,839</u>	<u>4,217,854</u>	<u>8,708,663</u>
Net loss from continuing operations	(3,092,550)	(7,852,393)	(8,425,129)	(9,662,296)
Net income (loss) from discontinued operations, net of taxes	351,418	(49,226)	351,418	(7,184,670)
Net loss	<u>\$ (2,741,132)</u>	<u>\$ (7,901,619)</u>	<u>\$ (8,073,711)</u>	<u>\$ (16,846,966)</u>
Net loss from continuing operations per basic and diluted common shares and pre-funded warrants outstanding	\$ (0.13)	\$ (0.54)	\$ (0.39)	\$ (0.66)

Net income (loss) from discontinued operations per basic and diluted common shares and pre-funded warrants outstanding	\$	0.02	\$	(0.00)	\$	0.02	\$	(0.49)
Net loss per basic and diluted common shares and pre-funded warrants outstanding	\$	(0.12)	\$	(0.54)	\$	(0.37)	\$	(1.15)
Basic and diluted weighted average common shares outstanding		23,050,320		14,638,614		21,655,705		14,638,502

Veru Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)

	Six Months Ended	
	March 31,	
	2026	2025
Net loss	\$ (8,073,711)	\$ (16,846,966)
Adjustments to reconcile net loss to net cash used in operating activities	(2,679,386)	2,525,640
Changes in operating assets and liabilities	(4,331,318)	(4,748,124)
Net cash used in operating activities	(15,084,415)	(19,069,450)
Net cash provided by investing activities	3,520,328	18,393,168
Net cash provided by (used in) financing activities	23,366,345	(4,221,611)
Net increase (decrease) in cash, cash equivalents, and restricted cash	11,802,258	(4,897,893)
Cash, cash equivalents and restricted cash at beginning of period	15,794,562	24,916,285
Cash, cash equivalents and restricted cash at end of period	<u>\$ 27,596,820</u>	<u>\$ 20,018,392</u>

Investor and Media Contact:

Samuel Fisch

Executive Director, Investor Relations and Corporate Communications

Email: veruinvestor@verupharma.com



Source: Veru Inc.