UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 11, 2026

VERU INC.
(Exact name of registrant as specified in its charter)

Wisconsin	**1-13602**	**39-1144397**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2916 N. Miami Avenue, Suite 1000, Miami, Florida 33127
Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (305) 509-6897

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value per share	VERU	NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition

On February 11, 2026, Veru Inc. issued a press release (the "Press Release") announcing results for the quarter ended December 31, 2025. A copy of the Press Release is attached as Exhibit 99.1 to this report. The attached Exhibit 99.1 is furnished pursuant to Item 2.02 of Form 8-K.

The information in this Form 8-K, including Exhibit 99.1 furnished herewith, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Document
99.1	Press Release of Veru Inc., issued February 11, 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: February 11, 2026

VERU INC.

By: /s/ Michele Greco

Michele Greco
Chief Financial Officer and
Chief Administrative Officer

Exhibit 99.1

Investor and Media Contact:
Samuel Fisch
Executive Director, Investor Relations and Corporate Communications
Email: veruinvestor@verupharma.com

Veru Reports Fiscal 2026 First Quarter Financial Results and Clinical Program Progress

—Phase 2b PLATEAU clinical trial evaluating enobosarm in combination with semaglutide in older patients with obesity on track to initiate this quarter—

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

MIAMI, FL – February 11, 2026 – 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 first quarter ended December 31, 2025, and provided a corporate update.

"The strategy for the next generation of obesity drugs should be a combination therapy with GLP-1 receptor agonists for patients to ONLY lose fat, while preserving lean mass and physical function and increasing bone mineral density for the highest quality weight reduction," said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru. "Veru's completed positive Phase 2b QUALITY clinical trial provided the proof of concept that enobosarm could be that next generation drug in combination with a GLP-1 RA to make the weight loss journey more selective for only fat while preserving lean mass and physical function in older patients who have obesity lessening the potential risk of loss of balance, and fractures."

Dr. Steiner added: "An emerging, common, and serious clinical and therapeutic challenge with GLP-1 RA monotherapy is that 88% of patients with obesity after one year on drug hit a weight loss plateau where they stop losing additional weight while on a GLP-1 RA based on the SURMOUNT-1 study conducted by Eli Lilly and Company. Unfortunately, 62.6% of these patients still had clinical obesity at the time they reached the weight loss plateau. Loss of muscle may stimulate these patients to consume more calories and may be an important reason why patients hit the weight loss plateau. Enobosarm has been shown to directly burn fat and to preserve muscle to increase physical function and burn more calories which could help to break through the weight loss plateau leading to incremental weight reduction. Veru's Phase 2b PLATEAU clinical trial is designed to address this problem by testing a novel combination of enobosarm and a GLP-1 RA, especially in older patients who are also at risk for decline in physical function and loss of bone. The Phase 2b PLATEAU clinical trial is expected to initiate this calendar quarter with interim analysis results anticipated Q1 calendar year 2027."

"After serving as the Principal Investigator of the positive data Phase 2 QUALITY clinical trial, I am pleased to serve as the Principal Investigator for this important Phase 2b PLATEAU enobosarm clinical trial," said 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 added: "Older patients with obesity receiving a GLP-1 RA are at risk for loss of muscle and physical function and could benefit from enobosarm to preserve muscle mass and physical function to improve the quality of weight loss."

Enobosarm for chronic weight reduction program

Veru's Phase 2b QUALITY clinical trial in 168 older patients with obesity results confirmed that preserving lean mass with enobosarm plus semaglutide led to greater fat loss during the active weight loss period, and after semaglutide was discontinued, enobosarm monotherapy significantly prevented the regain of both weight and fat mass such that by the end of the 28 week study there was greater loss of fat mass while preserving lean mass for a higher quality weight reduction compared to the placebo group. During Q1 FY2026, Veru had scientific presentations of two abstracts at ObesityWeek 2025 November 4-7, 2025, in Atlanta, Georgia and multiple presentations at The Society on Sarcopenia, Cachexia, and Wasting Disorders (SCWD) International Conference, and the SCWD's Regulatory and Clinical Trials Update Regulatory Workshop, December 12-13 in Rome, Italy.

FDA regulatory feedback

In September 2025, the Company announced a successful FDA meeting providing regulatory clarity for enobosarm in combination with GLP-1 RA for greater weight loss in the treatment of obesity**.** According to FDA feedback on Veru's clinical development program for enobosarm, FDA has guided us that there are at least 2 possible regulatory pathways forward for the development of enobosarm in combination with a GLP-1 RA and are based on incremental weight loss. First, incremental weight loss with at least a 5% placebo-corrected weight loss difference at 52 weeks of maintenance treatment with enobosarm in combination with a GLP-1 RA treatment compared to the GLP-1 RA treatment alone is an acceptable primary endpoint to support efficacy for approval. Second, if incremental weight loss difference of <5% (including similar weight loss) is observed at 52 weeks of maintenance treatment with a clinically significant positive benefit, such as clinically beneficial preservation in physical function, enobosarm in combination with GLP-1 RA may also be acceptable to support efficacy for approval. FDA confirmed that enobosarm 3 mg is an acceptable dosage for future Veru clinical development.

Enobosarm has been shown in published preclinical studies to have anabolic and antiresorptive activity to increase bone mineral density in rat models of postmenopausal women and male osteoporosis. On December 19, 2025, the FDA announced that total hip bone mineral density (BMD) assessed by DXA qualifies as a validated surrogate endpoint for drug development in postmenopausal women with osteoporosis at risk for fracture providing an alternative to fracture endpoints. It has been reported in the scientific literature that GLP-1 RA therapy reduces hip BMD, and recently, the Wegovy® FDA label has been updated to include the safety concern of increased risk of hip and pelvic fractures based on the SELECT cardiovascular trial, a completed clinical trial sponsored by Novo Nordisk A/S that evaluated semaglutide in over 17,000 subjects. In the SELECT trial, 4-5 times more fractures of the hip and pelvis were reported on semaglutide than on placebo in female patients and patients ages 75 and older. Consequently, this means that distinct from incremental weight loss or muscle preservation and physical function as primary endpoints, improving BMD in postmenopausal women with obesity receiving GLP-1 RA at risk for bone fractures could be another primary endpoint with a clear regulatory pathway forward for enobosarm to improve body composition.

Planned Phase 2b PLATEAU clinical study

Veru's planned Phase 2b PLATEAU clinical trial design is a double-blind, placebo-controlled study to evaluate the effect of enobosarm 3mg on total body weight, fat mass, lean mass and physical function, bone mineral density and safety in approximately 200 older patients (age ≥ 65 yo) who have obesity (BMI ≥ 35) and are initiating semaglutide treatment for weight reduction. 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 34 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), BMD, and patient reported outcome questionnaires for physical function (SF-36 PF-10, and IWQOL-lite CT physical function), HbA1c, and insulin resistance. The Principal Investigator for the Phase 2b PLATEAU clinical trial will be Steven Heymsfield, MD, a Professor and the Director of the Body Composition-Metabolism Laboratory at the Pennington Biomedical Research Center in Baton Rouge, Louisiana.

The Phase 2b PLATEAU clinical study is designed to assess the ability of enobosarm treatment to break through the weight loss plateau observed in patients with obesity receiving semaglutide treatment to achieve clinically meaningful incremental weight reduction and preserve muscle mass and physical function by 68 weeks. Semaglutide was selected as the GLP-1 RA for the Phase 2b PLATEAU study to build on Veru's previous clinical experience in using enobosarm in combination with semaglutide in the Phase 2 QUALITY clinical study. Further, there is an oral form of semaglutide which may be used in combination with oral enobosarm in future Phase 3 clinical studies making potential bridging of the future Phase 3 clinical studies data to the Phase 2b PLATEAU enobosarm plus injectable semaglutide data possible. In contrast, tirzepatide injectable does not have an oral formulation.

The Phase 2b PLATEAU clinical study is expected to begin in the first quarter of calendar 2026 and an interim analysis is planned for the first quarter of calendar 2027.

First Quarter Financial Summary: Fiscal 2026 vs Fiscal 2025

- Research and development expenses decreased to $1.3 million from $5.7 million
- General and administrative expenses decreased to $4.1 million from $5.2 million
- Operating loss from continuing operations decreased to $5.4 million from $10.2 million
- Net loss decreased to $5.3 million, or $0.26 per share, compared to $8.9 million, or $0.61 per share

Balance Sheet Information

- Cash, cash equivalents and restricted cash were $33.0 million as of December 31, 2025 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 7414536, 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 new chemical entities, 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.

Enobosarm Obesity Program - Enobosarm is a next generation drug that in combination with GLP-1 RA results in higher quality weight reduction

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 completing the efficacy dose-finding portion of the Phase 2b QUALITY clinical trial ended 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 clinical study in patients who have obesity.

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 and full data readout timing, scope and regulatory pathways for the continued development of enobosarm in patients with obesity, including the planned PLATEAU Phase 2b study; 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 planned PLATEAU Phase 2b study or in any future Phase 3 studies; whether the use of the oral form of semaglutide in combination with oral enobosarm will or may be used in any future Phase 3 clinical study(ies) and whether the data from any such Phase 3 clinical study(ies) may successfully be bridged to the Phase 2b PLATEAU enobosarm plus injectable semaglutide data to support regulatory approval; whether the next generation of obesity drugs will be a combination therapy with a GLP-1 RA and whether enobosarm will be that next generation drug in combination with a GLP-1 RA; and the anticipated timing for beginning the planned PLATEAU Phase 2b study and for the interim analysis for such study. 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 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 the 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; whether the Company will be able to partner with another company in the development of enobosarm; 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; 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)

	December 31, 2025	September 30, 2025
Cash, cash equivalents, and restricted cash	$32,991,417	$15,794,562
Investments in equity securities	2,405,227	2,525,305
Prepaid expenses and other current assets	1,410,072	595,251
Total current assets	36,806,716	18,915,118
Property and equipment, net	336,615	364,808
Operating lease right-of-use assets	2,613,920	2,746,014
Goodwill	6,878,932	6,878,932
Other assets	930,847	930,847
Total assets	$47,567,030	$29,835,719
Accounts payable	$ 1,516,138	$ 3,121,448
Accrued compensation	4,546,621	3,510,237
Accrued expenses and other current liabilities	300,351	394,529
Operating lease liability, short-term portion	764,590	758,946
Total current liabilities	7,127,700	7,785,160
Operating lease liability, long-term portion	2,212,767	2,358,018
Other liabilities	1,102,522	1,359,871
Total liabilities	10,442,989	11,503,049
Total stockholders' equity	37,124,041	18,332,670
Total liabilities and stockholders' equity	$47,567,030	$29,835,719

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended December 31,	
	2025	2024
Operating expenses:		
Research and development	$ 1,344,182	$ 5,716,830
General and administrative	4,079,833	5,227,113
Total operating expenses	5,424,015	10,943,943
Gain on sale of ENTADFI® assets	—	695,216
Operating loss	(5,424,015)	(10,248,727)
Non-operating income:		
Gain on extinguishment of debt	—	8,624,778
Other non-operating income (expense), net	91,436	(185,954)
Total non-operating income	91,436	8,438,824
Net loss from continuing operations	(5,332,579)	(1,809,903)
Net loss from discontinued operations, net of taxes	—	(7,135,444)
Net loss	$ (5,332,579)	$ (8,945,347)
Net loss from continuing operations per basic and diluted common shares and pre-funded warrants outstanding	$ (0.26)	$ (0.12)
Net loss from discontinued operations per basic and diluted common shares and pre-funded warrants outstanding	$ 0.00	$ (0.49)
Net loss per basic and diluted common shares and pre-funded warrants outstanding	$ (0.26)	$ (0.61)
Basic and diluted weighted average common shares and pre-funded warrants outstanding	20,311,190	14,638,392

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

	Three Months Ended December 31,	
	2025	2024
Net loss	$ (5,332,579)	$ (8,945,347)
Adjustments to reconcile net loss to net cash used in operating activities	1,037,970	1,067,088
Changes in operating assets and liabilities	(1,874,881)	(3,454,728)
Net cash used in operating activities	(6,169,490)	(11,332,987)
Net cash provided by investing activities	—	17,245,315
Net cash provided by (used in) financing activities	23,366,345	(4,221,611)
Net increase in cash, cash equivalents, and restricted cash	17,196,855	1,690,717
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	$32,991,417	$ 26,607,002