
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): August 10, 2026

VERU INC.

(Exact name of registrant as specified in its charter)

Wisconsin
(State or other jurisdiction
of incorporation)

1-13602
(Commission
File Number)

39-1144397
(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 August 10, 2026, Veru Inc. issued a press release (the “Press Release”) announcing results for the quarter and nine months ended June 30, 2026. 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.

<u>Exhibit No.</u>	<u>Document</u>
99.1	Press Release of Veru Inc., issued August 10, 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: August 10, 2026

VERU INC

By: /s/ Michele Greco

Michele Greco
Chief Financial Officer and
Chief Administrative Officer



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

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

— Phase 2b PLATEAU clinical trial of enobosarm and semaglutide combination for high quality weight loss is fully enrolled with 239 patients —

— Phase 2b PLATEAU clinical trial interim analysis and results on track for calendar Q1 2027 —

— In June 2026 Company announced a clinical supply agreement with Novo Nordisk for its Phase 2b PLATEAU clinical trial —

— In August 2026 Company announced USPTO notice of allowance for key U.S. patent for enobosarm and semaglutide; when issued, U.S. patent protection until at least October 2044 —

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

MIAMI, FL – August 10, 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 third quarter ended June 30, 2026, and provided an update on progress of its clinical development programs.

“We are extremely pleased with the continued enobosarm progress during this past quarter,” said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru Inc. “We reached full enrollment of the Phase 2b PLATEAU clinical trial and entered into a clinical supply agreement with Novo Nordisk for the Phase 2b PLATEAU clinical trial.* In addition, we received from the USPTO a notice of allowance for a key U.S. patent for enobosarm with semaglutide for high quality weight loss which when issued, will provide U.S. patent protection until at least October 2044.”

Dr. Steiner added: “We believe these accomplishments mark important milestones in advancing enobosarm as a potential important combination therapy with GLP-1 receptor agonists. There is a significant unmet medical need to make weight reduction more tissue selective by maximizing fat loss while preserving lean mass, physical function, and bone mineral density for the highest quality weight reduction especially in older patients who have low muscle reserves and obesity. I want to thank both the patients and the investigators for their enthusiasm to expeditiously reach full enrollment for this very important study. We remain on track to achieve the near-term milestone of reporting the interim analysis results from the Phase 2b PLATEAU clinical trial in the first quarter of calendar year 2027.”

Obesity Program

Evaluating enobosarm in combination with GLP-1 RA for higher quality weight reduction in older patients with obesity

Fully Enrolled Phase 2b PLATEAU Clinical Study

The 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 older patients (age ≥ 65 years) who have obesity (BMI ≥ 35) and are initiating semaglutide treatment for weight reduction. During the past quarter, the Company exceeded its Phase 2b PLATEAU clinical trial targeted full enrollment of 200 patients by enrolling 239 patients. 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. 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. Results of an interim analysis assessing lean body mass and fat mass as measured by DXA after patients have completed 32 weeks is expected in the first quarter of calendar year 2027. Final topline clinical data is expected in the fourth quarter of calendar year 2027. 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.

Completed Positive Phase 2b QUALITY Clinical Study

The Phase 2b QUALITY clinical study was a positive multicenter, double-blind, placebo-controlled, randomized, dose-finding clinical trial that evaluated 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 enobosarm plus semaglutide preserved lean mass and physical function and led to greater fat loss during the 16 week active weight loss period and enobosarm monotherapy prevented the regain of weight lost when the GLP-1 RA was discontinued.

Recent Developments Regarding Enobosarm Intellectual Property

Recently the Company received from the United States Patent and Trademark Office (USPTO) a Notice of Allowance for U.S. Patent Application titled "Compositions Comprising Selective Androgen Receptor Modulator Compounds in Combination with Weight Loss Drugs and Uses Thereof for Quality Weight Loss." The Notice of Allowance indicates that the USPTO has determined that the patent application meets the requirements for patentability and is expected to issue as a U.S. patent.

The Notice of Allowance encompasses treatment regimens where: (i) enobosarm is concurrently given with semaglutide; (ii) enobosarm is added to initial semaglutide monotherapy with said co-therapy continuing; and (iii) enobosarm continues or is initiated as monotherapy after semaglutide therapy is discontinued.

The allowed claims are directed to the: (i) preservation, restoration, or gaining of lean body mass; (ii) preservation, restoration, or gaining of muscle mass; (iii) enhancement of fat mass loss, including reducing abdominal, subcutaneous, or intramuscular fat accumulation, improving body composition, lowering body fat content, and lowering fat mass; (iv) preservation, restoration, or improvement of physical function and the corresponding prevention or treatment of a number of conditions that can result from decreased physical function such as reducing or treating muscle weakness, poor balance, decreased gait speed, mobility disability, loss of independence, increased risk of falls, loss of physical function, physical disability, poor quality of life, high hospitalization rates, and/or increased mortality; (v) preservation, restoration, or gaining of bone, and the corresponding prevention or treatment of bone fractures; (vi) overcoming or improving of insulin resistance; (vii) improving of HbA1c; (viii) reduction of or treatment to prevent total body weight gain rebound after discontinuing semaglutide; (ix) reduction of or treatment to prevent fat mass gain rebound after discontinuing semaglutide; and (x) treatment to prevent or restore lean mass loss during rebound after discontinuing semaglutide.

When issued, this U.S. patent will have a patent expiry of at least October 3, 2044, prior to the potential application of any patent term adjustment or patent term extension.

These allowed claims add to the Company's growing intellectual property portfolio for enobosarm for quality weight loss, including already issued enobosarm specific polymorph composition of matter patents, as well as a number of other pending uses of selective androgen receptor modulator compounds alone or in combination with weight loss drugs for quality weight loss and chronic weight management patent applications. In addition, the patent portfolio of Veru includes patent applications directed to a novel, oral, modified-release enobosarm formulation, which if such patent were to issue, would provide patent protection until at least May 2046.

The Company owns a worldwide portfolio of patent applications directed to the methods of use of enobosarm in combination with weight loss drugs for higher quality weight loss and incremental weight loss. These claims encompass weight loss drugs including incretin containing drugs such as GLP-1 RA drugs. The Company continues to prosecute a number of pending patent applications worldwide covering a number of different weight loss drugs beyond semaglutide.

Third Quarter Financial Summary: Fiscal 2026 vs Fiscal 2025

- Research and development expenses increased to \$4.4 million from \$3.0 million
- General and administrative expenses decreased to \$3.4 million from \$5.0 million
- Operating loss from continuing operations increased to \$7.7 million from \$7.5 million
- Net loss decreased to \$7.0 million, or \$0.30 per share, compared to \$7.3 million, or \$0.50 per share

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

- Research and development expenses decreased to \$8.8 million from \$12.7 million
- General and administrative expenses decreased to \$11.5 million from \$15.4 million
- Operating loss from continuing operations decreased to \$20.4 million from \$25.9 million
- Net loss decreased to \$15.1 million, or \$0.68 per share, compared to \$24.2 million, or \$1.65 per share

Balance Sheet Information

- Cash, cash equivalents and restricted cash were \$23.9 million as of June 30, 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 2565519, 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; express or implied statements related to the issuance and scope of coverage, including allowed claims and treatment regimens, of a method of use patent from the Notice of Allowance for US Patent Application titled "Compositions Comprising Selective Androgen Receptor Modulator Compounds in Combination with Weight Loss Drugs and Uses Thereof for Quality Weight Loss", as well as other pending methods of use and formulation patents; whether the patent application meets requirements of patentability and, if and when the patent is issued, will provide patent protection until at least October 2044; whether new indications will be discovered or granted and whether the allowed claims under said Notice of Allowance, if and when issued, will add additional coverage and protection to new indications and the Company's growing intellectual property portfolio for enobosarm for quality weight loss, and other pending uses of selective androgen receptor modulator compounds alone or in combination with weight loss drugs; whether the pending patent applications will be approved for claims that encompass a novel, oral, modified-release enobosarm formulation and if issued, will provide patent protection until at least May 2046; 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 and the prevention of the regain of fat mass and total body weight loss, 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 enobosarm will be the next generation combination therapy with GLP-1 receptor agonists for older patients with obesity that makes weight reduction more tissue selective for loss of fat, preservation of lean mass, physical function, improved body composition and maintaining or increasing bone mineral density, and demonstrating favorable HbA1c and insulin resistance results, all while maintaining a favorable safety profile; 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 whether enobosarm will enhance or achieve a higher quality weight loss or the preservation of muscle in, or meet any unmet need for, obesity patients, including whether it will provide important insights into quality weight loss therapy and the design of a Phase 3 clinical development program; and whether the Company will be successful in its transformation into a late stage biopharmaceutical company focused on obesity and inflammatory disease. 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 patients in clinical studies or an inability to enroll patients 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 risk that the Supply Agreement with Novo Nordisk could be terminated prior to the completion of the Company's PLATEAU Phase 2b clinical trial, including pursuant to a provision that permits Novo Nordisk to terminate for convenience upon 60 days' prior notice; 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 obtain, protect and enforce its data, intellectual property and other proprietary rights; costs and other effects of litigation, including regulatory challenges, product liability claims, intellectual property claims and challenges, 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.

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- * During the past quarter the Company announced a clinical supply agreement with Novo Nordisk for its Phase 2b PLATEAU clinical study. Please see the Company's SEC Form 8-K dated June 2, 2026 for further details.
- ** Wegovy® is a registered trademark of Novo Nordisk A/S.

FINANCIAL SCHEDULES FOLLOW

Veru Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	June 30, 2026	September 30, 2025
Cash, cash equivalents, and restricted cash	\$23,880,142	\$15,794,562
Investments in equity securities	1,911,386	2,525,305
Prepaid expenses and other current assets	1,436,799	595,251
Total current assets	27,228,327	18,915,118
Property and equipment, net	280,227	364,808
Operating lease right-of-use assets	2,342,186	2,746,014
Goodwill	6,878,932	6,878,932
Other assets	297,998	930,847
Total assets	<u>\$37,027,670</u>	<u>\$29,835,719</u>
Accounts payable	\$ 1,709,689	\$ 3,121,448
Accrued compensation	2,721,934	3,510,237
Accrued expenses and other current liabilities	949,092	394,529
Operating lease liability, short-term portion	775,157	758,946
Total current liabilities	6,155,872	7,785,160
Operating lease liability, long-term portion	1,907,735	2,358,018
Other liabilities	587,823	1,359,871
Total liabilities	8,651,430	11,503,049
Total stockholders' equity	28,376,240	18,332,670
Total liabilities and stockholders' equity	<u>\$37,027,670</u>	<u>\$29,835,719</u>

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	\$ 4,352,668	\$ 3,020,563	\$ 8,842,633	\$ 12,669,495
General and administrative	3,361,013	5,010,528	11,514,031	15,402,074
Total operating expenses	7,713,681	8,031,091	20,356,664	28,071,569
Gain on sale of ENTADFI® assets	—	484,615	—	2,154,134
Operating loss	(7,713,681)	(7,546,476)	(20,356,664)	(25,917,435)
Non-operating income:				
Gain on extinguishment of debt	—	—	—	8,624,778
Other non-operating income, net	725,331	223,375	4,943,185	307,260
Total non-operating income	725,331	223,375	4,943,185	8,932,038
Net loss from continuing operations	(6,988,350)	(7,323,101)	(15,413,479)	(16,985,397)
Net (loss) income from discontinued operations, net of taxes	—	(9,719)	351,418	(7,194,389)
Net loss	<u>\$ (6,988,350)</u>	<u>\$ (7,332,820)</u>	<u>\$ (15,062,061)</u>	<u>\$ (24,179,786)</u>
Net loss from continuing operations per basic and diluted common shares and pre-funded warrants outstanding	\$ (0.30)	\$ (0.50)	\$ (0.70)	\$ (1.16)
Net income (loss) from discontinued operations per basic and diluted common shares and pre-funded warrants outstanding	\$ 0.00	\$ (0.00)	\$ 0.02	\$ (0.49)
Net loss per basic and diluted common shares and pre-funded warrants outstanding	\$ (0.30)	\$ (0.50)	\$ (0.68)	\$ (1.65)
Basic and diluted weighted average common shares outstanding	23,050,320	14,657,777	22,127,243	14,644,927

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

	Nine Months Ended June 30,	
	2026	2025
Net loss	\$(15,062,061)	\$(24,179,786)
Adjustments to reconcile net loss to net cash used in operating activities	(2,482,190)	3,920,100
Changes in operating assets and liabilities	(3,007,404)	(4,292,066)
Net cash used in operating activities	(20,551,655)	(24,551,752)
Net cash provided by investing activities	5,322,804	18,867,232
Net cash provided by (used in) financing activities	23,314,431	(4,221,611)
Net increase (decrease) in cash, cash equivalents, and restricted cash	8,085,580	(9,906,131)
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>\$ 23,880,142</u>	<u>\$ 15,010,154</u>