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 12, 2025

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 August 12, 2025, Veru Inc. issued a press release (the "Press Release") announcing results for the quarter and nine months ended June 30, 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 August 12, 2025.
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: August 12, 2025

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 2025 Third Quarter Financial Results and Clinical Program Progress

—Company reported positive efficacy and safety data from Phase 2b QUALITY study showing enobosarm added to semaglutide led to preservation of muscle, greater fat loss, and fewer gastrointestinal side effects compared to semaglutide alone—

—Company reported positive efficacy and safety data from Phase 2b QUALITY Maintenance Extension study showing enobosarm significantly reduced body weight regain, prevented fat regain, and preserved lean mass after semaglutide discontinuation—

—Company has selected a novel modified release oral enobosarm formulation following pharmacokinetic clinical study—

—Company anticipates FDA feedback to clarify the regulatory pathway for enobosarm to preserve lean mass during chronic weight loss management —

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

MIAMI, FL – August 12, 2025 – 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 2025 third quarter and provided an update on progress of its clinical development programs.

“We have now reported all the positive efficacy and safety topline results from our Phase 2b QUALITY and Maintenance Extension study, and are looking forward to FDA feedback on the regulatory pathway for enobosarm to be used as an adjunctive therapy with GLP-1 RA to preserve lean mass while burning more fat for chronic weight loss management,” said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru. “The efficacy and safety of Veru’s oral agent enobosarm looks better than any of the injectable myostatin inhibitors now under development by our competitors. Unlike our competitors, enobosarm has positive physical function data measured by stair climb power. Furthermore, we have strengthened our intellectual property position with the selection of a novel modified release oral enobosarm formulation confirmed in a clinical pharmacokinetic study.”

Enobosarm for Chronic Weight Loss Management Program

Phase 2b QUALITY study- enobosarm is a next generation drug that makes GLP-1 RA weight loss more selective for fat loss while preserving lean mass and physical function

In January 2025, the Company announced positive topline efficacy results from the Phase 2b QUALITY clinical study, which is a multicenter, double-blind, placebo-controlled, randomized, dose-finding clinical trial designed to evaluate the safety and efficacy of enobosarm 3mg, enobosarm 6mg, or placebo as a treatment to augment fat loss and to prevent muscle loss in 168 older patients (≥60 years of age) receiving semaglutide for chronic weight management. The 3mg enobosarm dose had the best profile to advance into Phase 3 program.

- Enobosarm 3mg + semaglutide group met the primary endpoint of study with a statistically significant 100% average preservation of total lean mass compared to placebo + semaglutide at 16 weeks ($p<0.001$).
- Enobosarm + semaglutide treatment resulted in dose dependent greater loss of fat mass compared to placebo + semaglutide with the enobosarm 6mg dose having a 42% greater relative loss of fat mass compared to placebo + semaglutide group at 16 weeks ($p=0.017$) and the enobosarm 3mg having a 12% greater fat loss.
- Even with having preserved lean mass, enobosarm + semaglutide treatment resulted in a similar mean body weight loss as semaglutide alone at 16 weeks.
- The tissue composition of the total body weight lost was 34% lean mass and 66% fat mass for the placebo + semaglutide group whereas it was 0% lean mass and 100% fat mass for the enobosarm 3mg + semaglutide group.
- Physical function was measured by the Stair Climb Test. A responder analysis was conducted using a greater than 10% decline in stair climb power as the cut off at 16 weeks which represents an approximate 7 to 8 year loss of stair climb power that naturally occurs with aging.
    - Phase 2b QUALITY clinical trial is the first human study to demonstrate that older patients who are overweight or have obesity receiving semaglutide are at higher risk for accelerated loss of physical function as 44.8% of the placebo + semaglutide group had at least a 10% decline in stair climb power physical function at 16 weeks.
    - Enobosarm treatment preserved lean mass which translated into a reduction in the proportion of patients that had a clinically significant stair climb physical function decline with 17% of the enobosarm 3mg + semaglutide group having at least a 10% decline in stair climb power physical function at 16 weeks which is a 59.8% relative reduction in the proportion of subjects that lost at least 10% stair climb power compared to placebo + semaglutide group ($p=0.006$).
    - **In May 2025, the Company announced that the enobosarm and semaglutide GLP-1 RA combination had a positive safety profile in the Phase 2b QUALITY clinical trial**

After trial participants completed the efficacy dose-finding portion of the Phase 2b QUALITY clinical trial, 148 participants continued to the Phase 2b Maintenance Extension study, a double-blind study, where all patients discontinued semaglutide treatment, but continued receiving placebo, enobosarm 3mg, or enobosarm 6mg as monotherapy for 12 weeks.

- In June 2025, the Company announced positive topline efficacy and safety results from the maintenance extension portion of the Phase 2b QUALITY clinical study that showed that enobosarm significantly reduced body weight regain, prevented fat regain, and preserved Lean mass after semaglutide discontinuation

- The 3mg enobosarm monotherapy significantly reduced the body weight regained by 46% after discontinuation of semaglutide.
    - At the end of the Phase 2b QUALITY study active weight loss period of 16 weeks, body weight loss was similar across treatment groups with the semaglutide plus placebo group losing an average of 11.88 lbs.
    - After the 12-week Maintenance Extension study period (Day 112 to Day 196) where all treatment groups discontinued semaglutide, the placebo monotherapy group regained 43% of body weight that was previously lost during the Phase 2b QUALITY for a mean percent change of 2.57% (5.06 lbs) in body weight, compared to 1.41% (2.73 lbs) for the 3mg enobosarm group (p=0.038) and 2.87% (5.29lbs) for the 6mg enobosarm group.
    - The mean tissue composition of body weight regained was 28% fat and 72% lean mass in the placebo group, versus 0% fat and 100% lean mass in both the 3mg and the 6mg enobosarm groups.
- *Enobosarm plus semaglutide followed by enobosarm monotherapy regimen was more effective in preserving lean mass and causing and maintaining greater loss of fat by the end of the study.*
    - Placebo plus semaglutide followed by placebo monotherapy group experienced a loss of lean mass, while both enobosarm plus semaglutide followed by enobosarm monotherapy groups (3 mg and 6 mg doses) significantly preserved more than 100% of lean mass (enobosarm 3mg p<0.001 and enobosarm 6mg p=0.004).
    - The enobosarm plus semaglutide followed by enobosarm monotherapy patients had a 58% greater loss of fat with enobosarm 3mg (p=0.085) and a 93% greater loss of fat with enobosarm 6mg (p=0.008) compared to placebo plus semaglutide followed by placebo monotherapy.
- *Adverse events (AEs) and adverse events of special Interest* In the double-blind Phase 2b QUALITY Maintenance Extension clinical trial (Day 112-196), enobosarm monotherapy had a positive safety profile. After discontinuation of semaglutide, there were essentially no gastrointestinal side effects, no evidence of drug induced liver injury (by Hy's law), and no increases in obstructive sleep apnea observed at any dose of enobosarm compared to placebo monotherapy. There were no AEs of increases in prostate specific antigen in men. There were no AEs related to masculinization in women. There were no reports of suicidal ideation observed (Columbia-Suicide Severity Rating Scale).

The Phase 2b QUALITY and Maintenance Extension clinical trial confirms 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 during the maintenance period such that by end of study there was greater loss of fat mass while preserving lean mass for a higher quality weight reduction compared to the placebo group.

Novel Modified Release Oral Enobosarm Formulation

On August 11, 2025, the Company announced the selection of a novel modified release oral enobosarm formulation following a pharmacokinetic clinical study for chronic weight loss management. The single-dose, open label pilot study evaluated the plasma concentration versus time profile of a proprietary, patentable modified release formulation of enobosarm 3mg. The new formulation demonstrated the intended distinct target product release profile, which includes a reduction in maximum plasma concentration (Cmax), a delayed time to maximum plasma concentration (Tmax), a distinct secondary peak concentration, and similar extent of absorption (AUC) compared to historical values for enobosarm immediate-release capsules. The novel modified release oral enobosarm formulation is planned to be available for further clinical studies and for commercialization. The novel enobosarm oral formulation's unique manufacturing process is protected by issued global patents with protection through 2037 and the new patents on the novel modified release oral enobosarm formulation have been filed and if issued, expiry is expected to be 2046.

Third Quarter Financial Summary: Fiscal 2025 vs Fiscal 2024

- Research and development expenses decreased to $3.0 million from $4.8 million
- Selling, general and administrative expenses decreased to $5.0 million from $5.8 million
- Operating loss from continuing operations decreased to $7.5 million from $10.5 million
- Net loss from continuing operations decreased to $7.3 million, or $0.50 per share, compared to $10.3 million, or $0.71 per share
- Net loss decreased to $7.3 million, or $0.50 per share, compared to $11.0 million, or $0.75 per share

Year-to-Date Financial Summary: Fiscal 2025 vs Fiscal 2024

- Research and development expenses increased to $12.7 million from $9.5 million
- Selling, general and administrative expenses decreased to $15.4 million from $18.4 million
- Operating loss from continuing operations decreased to $25.9 million from $26.8 million
- Net loss from continuing operations decreased to $17.0 million, or $1.16 per share, compared to $26.7 million, or $2.04 per share
- Net loss decreased to $24.2 million, or $1.65 per share, compared to $29.3 million, or $2.23 per share

Balance Sheet Information

Cash, cash equivalents, and restricted cash were $15.0 million as of June 30, 2025 versus $24.9 million as of September 30, 2024

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 1-877-344-7529 (domestic) or 1-412-317-0088 (international), passcode 2184944, 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, a 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 thereby improving body composition and physical function. Sabizabulin, a microtubule disruptor, is being developed for the treatment of inflammation in 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 whether and when the full data set, including safety data, from the Phase 2b QUALITY study and Maintenance Extension study of enobosarm discussed above will be made available and whether that data will align with disclosed topline results or change any of the conclusions drawn from the topline data; whether and when the Company will present the full data from the Phase 2b QUALITY study and Maintenance Extension study and in what forum; whether and when the Company will have an end-of-Phase-2 meeting with FDA and the results of any such meeting; whether the results of the Phase 2b QUALITY study and Maintenance Extension study of enobosarm will be replicated to the same or any degree in any future Phase 3 studies; the expected costs, timing, patient population, design, endpoints and results of the planned Phase 3 studies of enobosarm as a body composition drug or any other Phase 3 studies; whether the Company and FDA will align on the Phase 3 program for enobosarm as a body composition drug and whether any such program will be able to be funded by the Company; whether the modified-released formation of enobosarm will be developed successfully and whether such formulation will have the same effectiveness as the current formulation, and whether and when such modified-release formulation will be available for any planned or future clinical studies; whether and when any patents will actually issue regarding such modified-release formulation and what any expiration dates of any such patents might be; whether the Company will be able to obtain sufficient GLP-1 RA drugs in a timely or cost-effective manner in the planned Phase 3 study or other Phase 3 studies; whether FDA will require more than one Phase 3 study for enobosarm as a body composition drug; whether enobosarm will enhance weight loss or preserve muscle in, or meet any unmet need for, obesity patients and whether it will enhance weight loss in any planned or other Phase 3 studies or if approved, in clinical practice; whether patients treated with enobosarm for a longer period of time than in the Phase 2b QUALITY study and Maintenance Extension study will have a greater loss of adiposity or greater weight loss than with semaglutide alone; and whether and when enobosarm will be approved by the FDA as a body composition drug. 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 possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the Company's ability to reach agreement with FDA on study design requirements for the Company's planned clinical studies, including for the Phase 3 program for enobosarm as a body composition drug and the number of 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 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; any products of the Company, if approved, possibly not being commercially successful; the ability of the Company to obtain sufficient financing 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 product liability claims, securities litigation, and litigation and other disputes with the purchaser of the Company's FC2 business; our ability to maintain compliance with the continued listing requirements of the Nasdaq Stock Market, including our ability to regain and subsequently maintain compliance with the Nasdaq minimum bid price requirement after our recently completed reverse stock split; 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, 2024, 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.

FINANCIAL SCHEDULES FOLLOW

Veru Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	June 30, 2025	September 30, 2024
Cash, cash equivalents, and restricted cash	$15,010,154	$24,916,285
Prepaid expenses and other current assets	1,183,023	1,547,928
Current assets of discontinued operations	—	8,759,011
Total current assets	16,193,177	35,223,224
Property and equipment, net	393,381	481,372
Operating lease right-of-use assets	2,875,672	3,250,623
Goodwill	6,878,932	6,878,932
Other assets	989,596	989,596
Long-term assets of discontinued operations	—	13,595,025
Total assets	$27,330,758	$60,418,772
Accounts payable	$ 2,538,724	$ 2,259,668
Accrued compensation	2,780,570	4,494,278
Accrued expenses and other current liabilities	1,362,721	1,406,655
Residual royalty agreement liability, short-term portion	—	1,025,837
Current liabilities of discontinued operations	—	2,681,530
Total current liabilities	6,682,015	11,867,968
Residual royalty agreement liability, long-term portion	—	8,850,792
Operating lease liability, long-term portion	2,500,736	2,905,309
Other liabilities	2,803,374	4,477,991
Total liabilities	11,986,125	28,102,060
Total stockholders' equity	15,344,633	32,316,712
Total liabilities and stockholders' equity	$27,330,758	$60,418,772

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 3,020,563	$ 4,846,156	$ 12,669,495	$ 9,489,848
Selling, general and administrative	5,010,528	5,809,325	15,402,074	18,364,622
Total operating expenses	8,031,091	10,655,481	28,071,569	27,854,470
Gain on sale of ENTADFI® assets	484,615	110,000	2,154,134	1,028,372
Operating loss	(7,546,476)	(10,545,481)	(25,917,435)	(26,826,098)
Non-operating income:				
Gain on extinguishment of debt	—	—	8,624,778	—
Other non-operating income, net	223,375	205,425	307,260	115,561
Total non-operating income	223,375	205,425	8,932,038	115,561
Net loss from continuing operations	(7,323,101)	(10,340,056)	(16,985,397)	(26,710,537)
Net loss from discontinued operations, net of taxes	(9,719)	(628,818)	(7,194,389)	(2,560,266)
Net loss	$ (7,332,820)	$(10,968,874)	$(24,179,786)	$(29,270,803)
Net loss from continuing operations per basic and diluted common shares outstanding	$ (0.50)	$ (0.71)	$ (1.16)	$ (2.04)
Net loss from discontinued operations per basic and diluted common shares outstanding	$ (0.00)	$ (0.04)	$ (0.49)	$ (0.20)
Net loss per basic and diluted common shares outstanding	$ (0.50)	$ (0.75)	$ (1.65)	$ (2.23)
Basic and diluted weighted average common shares outstanding	14,657,777	14,638,317	14,644,927	13,101,071

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

	Nine Months Ended June 30,	
	2025	2024
Net loss	$(24,179,786)	$(29,270,803)
Adjustments to reconcile net loss to net cash used in operating activities	3,920,100	12,177,598
Changes in operating assets and liabilities	(4,292,066)	(223,034)
Net cash used in operating activities	(24,551,752)	(17,316,239)
Net cash provided by investing activities	18,867,232	14,714
Net cash (used in) provided by financing activities	(4,221,611)	36,826,910
Net (decrease) increase in cash, cash equivalents, and restricted cash	(9,906,131)	19,525,385
Cash, cash equivalents and restricted cash at beginning of period	24,916,285	9,625,494
Cash, cash equivalents and restricted cash at end of period	$ 15,010,154	$ 29,150,879