December 17, 2025

Veru Reports Fiscal Year 2025 Financial Results and Clinical Program Progress

-- Following positive efficacy and safety results from Phase 2b QUALITY study, company received FDA regulatory clarity for enobosarm in combination with GLP-1 RA --

-- Incremental weight loss is an acceptable approvable primary endpoint with key secondary endpoints on physical function and body composition improvements --

-- Company plans to initiate Phase 2 PLATEAU clinical study in calendar Q1 2026 --

-- Post fiscal year end, company completed public offering for net proceeds of approximately $23.4 million --

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

MIAMI, FL, Dec. 17, 2025 (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 year 2025 ended September 30, 2025 and provided an update on the clinical progress of its obesity program.

“The current FDA regulatory guidance for muscle preservation drugs in combination with GLP-1 RA drugs in the treatment of obesity seems particularly well aligned for enobosarm,” said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru. “The FDA defines obesity as a disease of excess body fat, and as such, the medical objective to treat obesity should be to reduce excess body fat, NOT to reduce lean mass. Although GLP-1 RAs have demonstrated profound weight loss results, the strategy for the next generation of obesity drugs should be a combination therapy with GLP-1 RAs for patients to ONLY lose fat, while preserving lean mass and physical function for a quality weight reduction. The 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 receptor agonist 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. Unfortunately, 62.6% of these patients still had clinical obesity at the time they reached the

weight loss plateau based on the SURMOUNT-1 study. Loss of muscle may stimulate these patients to consume more calories and may be an important reason why patients hit the weight loss plateau. The Phase 2b PLATEAU clinical trial is designed to address this problem, especially in older patients, by testing a novel combination of enobosarm and a GLP-1 RA. Enobosarm has been shown to directly burn fat and 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. With our public offering now completed, the Phase 2b PLATEAU clinical trial is expected to start Q1 calendar year 2026 with interim analysis results anticipated Q1 calendar year 2027."

Enobosarm for chronic weight reduction 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 was a 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 increase fat loss and to prevent the loss of muscle in 168 older patients (≥60 years of age) receiving a GLP-1 RA (semaglutide) for chronic weight loss.

Highlights from the Phase 2b QUALITY clinical trialfocusing on 3 mg enobosarm dose that has been selected by the Company and agreed upon by FDA for the PLATEAU clinical trial

Efficacy

The results for the 16 week active weight loss period of treatment with enobosarm 3 mg or placebo in combination with semaglutide:

- The enobosarm 3 mg + semaglutide group met the primary endpoint of study, preservation of total lean mass, with a statistically significant 100% average preservation of total lean mass compared to placebo + semaglutide at 16 weeks.

- Enobosarm + semaglutide treatment resulted in dose dependent greater loss of fat mass compared to placebo + semaglutide with the enobosarm 3 mg group having a 12% greater fat loss at 16 weeks.

- Even with having preserved lean mass, enobosarm 3 mg + semaglutide treatment resulted in a similar mean body weight loss as semaglutide alone at 16 weeks. However, it should be noted, in a subset analysis of the subjects receiving enobosarm 3 mg and had a baseline BMI ≥ 35, incremental weight loss was observed at 16 weeks:
    - There was weight loss of -4.7% for semaglutide versus -5.58% for enobosarm 3 mg + semaglutide treatment group.
    - Proportion of patients that lost at least 5% of body weight at 16 weeks was 47.4% for semaglutide vs 65.4% for enobosarm 3 mg + semaglutide treatment group.
    - This weight loss occurred even with 84% preservation of lean mass in this subset of patients receiving semaglutide on enobosarm 3 mg.

- The tissue composition of the total body weight lost on average was 34% lean mass and 66% fat mass in the placebo and semaglutide group, whereas for the enobosarm 3 mg + semaglutide group, the weight loss was 0% lean mass and 100% fat mass.

- Physical function was measured by the Stair Climb Test. A prespecified responder analysis was conducted using a greater than 10% decline in stair climb power as the cut off at 16 weeks which is a decline that represents an approximate 7 to 8 years of loss of stair climb power function that naturally occurs with aging, but it occurred in 16 weeks.

    - Semaglutide alone resulted in a 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. The Phase 2b QUALITY study is the first to confirm that older patients with obesity receiving a GLP-1 RA had a significant and relevant physical function decline as early as 16 weeks on treatment.

    - In contrast, enobosarm 3 mg treatment reduced the proportion of patients receiving semaglutide to 17.6% who experienced ≥10% decline in stair climb power. This represents a 59.8% relative reduction in proportion of patients receiving enobosarm who experienced ≥10% decline in stair climb power.

Results for the Maintenance Extension portion of the study, where all patients discontinued semaglutide treatment, but continued receiving placebo, enobosarm 3 mg as monotherapy for 12 weeks:

- The placebo monotherapy group regained 43% of body weight that was previously lost during the Phase 2b QUALITY study for a mean percent change of 2.57% (5.06 lbs) in body weight, compared to 1.41% (2.73 lbs) for the 3 mg enobosarm group. This means that the 3 mg enobosarm monotherapy significantly reduced the body weight regained by 46% after discontinuation of semaglutide.

- By the way, the mean tissue composition of body weight regained was 100% lean mass, not fat for the enobosarm 3 mg compared to 28% fat and 72% lean mass in the placebo group.

- In fact, by end of the 28 week study, enobosarm 3 mg plus semaglutide followed by enobosarm 3 mg monotherapy regimen was more effective in preserving 100% lean mass and in losing 58% more fat compared to placebo plus semaglutide followed by placebo monotherapy.

Safety

At the end of the 16 week active weight loss period, enobosarm and semaglutide combination had a positive safety profile and enobosarm did not have any added gastrointestinal (GI) adverse events compared to semaglutide alone. For the Maintenance Extension clinical trial, where semaglutide was stopped for 12 weeks, enobosarm monotherapy also had a positive safety profile. After discontinuation of semaglutide, there

were essentially no GI side effects, no evidence of drug induced liver injury, and no increases in obstructive sleep apnea observed at any dose of enobosarm compared to placebo monotherapy. There were no AEs related to masculinization in women. There were no AEs of increases in prostate specific antigen in men.

Summary

The Phase 2b QUALITY 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 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.

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

Highlights from September 2025 FDA meeting

Incremental weight loss: 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.

Enobosarm dose - FDA confirmed that enobosarm 3 mg is an acceptable dosage for future Veru clinical development.

Planned Phase 2b PLATEAU clinical study
The planned Phase 2b PLATEAU clinical trial will measure incremental weight loss in this enriched patient population that has more weight to lose (BMI ≥ 35) and more at risk for physical decline and functional limitations (age ≥ 65) to better inform the design of the Phase 3 development program. For the planned Phase 2b PLATEAU clinical trial, we will evaluate the effect of enobosarm 3 mg on total body weight, physical function, and safety in approximately 200 patients who have obesity (BMI ≥ 35) and are older (age ≥ 65) and are initiating GLP-1 RA treatment for weight reduction. The primary efficacy endpoint of the study will be the percent change from baseline in total body weight at 72 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 DEXA scan. Since we want to continue to evaluate enobosarm as a muscle preserving and body composition drug, the key secondary endpoints will be function endpoints, physical function (stair climb test), mobility disability

status (functional limitations), and patient reported outcome questionnaires for physical function (SF-36 PF-10, and IWQOL-lite CT physical function) as well as body composition endpoints, total fat mass, total lean mass, and bone mineral density.

Building on the Phase 2 QUALITY study and with greater FDA regulatory clarity, we have designed the Phase 2b PLATEAU clinical study to assess the ability of enobosarm treatment to break through the weight loss plateau in older patients (age ≥ 65) with obesity (BMI ≥ 35) receiving GLP-1 RA treatment with the expectation that patients will achieve clinically meaningful incremental weight reduction and preserve muscle mass and physical function at 52 weeks of GLP-1 weight reduction maintenance dose.

Full Year Financial Summary: Fiscal 2025 vs Fiscal 2024

- Research and development expenses increased to $15.6 million from $12.8 million
- General and administrative expenses decreased to $19.9 million from $24.6 million
- Operating loss from continuing operations decreased to $24.8 million from $36.2 million
- Net loss from continuing operations decreased to $15.7 million, or $1.07 per share, compared to $35.3 million, or $2.61 per share
- Net loss decreased to $22.7 million, or $1.55 per share, compared to $37.8 million, or $2.80 per share

Balance Sheet Information

- Cash, cash equivalents and restricted cash were $15.8 million as of September 30, 2025 versus $24.9 million as of September 30, 2024
- Post fiscal 2025 year end, company completed public offering for additional net cash proceeds of approximately $23.4 million

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 2225332, 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 leading to improved body composition and physical function with expected clinically meaningful incremental weight reduction versus GLP-1 RA monotherapy. Sabizabulin, a microtubule disruptor, is being developed for the treatment of inflammation in 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 clinically meaningful incremental weight loss in the PLATEAU Phase 2b study will continue to be seen as an acceptable primary endpoint by the FDA to support potential approval; whether the FDA will continue to accept 3 mg as an acceptable dosage for enobosarm in the planned PLATEAU Phase 2b study or in any other studies; whether the FDA will further evolve its position on the acceptable patient population for the PLATEAU Phase 2b study or any other future studies; whether the Company will be able to partner with any other company in the development of enobosarm; 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 patients treated with enobosarm in the planned PLATEAU Phase 2B study will exhibit increased energy and whether such effects will result in incremental weight reduction; whether enobosarm will reduce body weight regain for patients discontinuing GLP-1 RA or reaching weight loss plateau; whether outcome questionnaires for evaluating physical function can be developed that will be accepted by the FDA or support drug approval; whether the Company will be able to raise sufficient capital, dilutive or otherwise, to fund the PLATEAU Phase 2b study of enobosarm in patients with obesity or any other studies; whether the Company will be able to recruit a sufficient number of patients in a timely manner for the PLATEAU Phase 2b study; whether the Company will be able to obtain sufficient GLP-1 RA drugs in a timely or cost-effective manner in the planned PLATEAU Phase 2b study; whether the Company will be able to engage clinical research organizations and recruit patients for the PLATEAU Phase 2b program and in a timely or cost-effective manner; whether enobosarm will cause weight loss or preserve muscle in, or meet any unmet need for, obesity patients and whether it will cause weight loss in the planned PLATEAU Phase 2b study or any future Phase 3 studies or, if approved and commercialized, in clinical practice; whether patients treated with enobosarm for a longer

period of time than in the Phase 2b QUALITY study will experience weight loss or have a greater loss of body fat or greater weight loss than with GLP-1 RA drug alone; whether and when enobosarm will be approved by the FDA as a weight loss drug or a body composition drug or any other type of drug; and whether and when the Company will be able to further advance the development of sabizabulin in atherosclerotic 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 analysis, possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; although the Company has sought and received feedback from FDA on the designs of its clinical trials and intends to continue to do so, 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 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, 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.
Wegovy® is a registered trademark of Novo Nordisk A/S.

FINANCIAL SCHEDULES FOLLOW

Veru Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	September 30, 2025	September 30, 2024
Cash, cash equivalents and restricted cash	$ 15,794,562	$ 24,916,285
Investment in equity securities	2,525,305	742,295
Prepaid expenses and other current assets	595,251	805,633
Current assets of discontinued operations	—	8,759,011
Total current assets	18,915,118	35,223,224
Property and equipment, net	364,808	481,372
Operating lease right-of-use asset	2,746,014	3,250,623
Goodwill	6,878,932	6,878,932
Other assets	930,847	989,596
Long-term assets of discontinued operations	—	13,595,025
Total assets	$ 29,835,719	$ 60,418,772
Accounts payable	$ 3,121,448	$ 2,259,668
Accrued compensation	3,510,237	4,494,278
Accrued expenses and other current liabilities	1,153,475	1,406,655
Residual royalty agreement, short-term portion	—	1,025,837
Current liabilities of discontinued operations	—	2,681,530
Total current liabilities	7,785,160	11,867,968
Residual royalty agreement, long-term portion	—	8,850,792
Operating lease liability, long-term portion	2,358,018	2,905,309
Other liabilities	1,359,871	4,477,991
Total liabilities	11,503,049	28,102,060
Total stockholders' equity	18,332,670	32,316,712
Total liabilities and stockholders' equity	$ 29,835,719	$ 60,418,772

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Year Ended	
	2025	**2024**
Operating expenses:		
Research and development	$ 15,588,185	$ 12,782,167
General and administrative	19,942,747	24,609,801
Total operating expenses	35,530,932	37,391,968
Gain on sale of ENTADFI® assets	10,780,290	1,222,908
Operating loss	(24,750,642)	(36,169,060)
Total non-operating income	9,069,385	909,122
Net loss from continuing operations	(15,681,257)	(35,259,938)
Net loss from discontinued operations, net of taxes	(7,045,022)	(2,541,488)
Net loss	$(22,726,279)	$(37,801,426)
Net loss from continuing operations per basic and diluted common shares outstanding	$ (1.07)	$ (2.61)
Net loss from discontinued operations per basic and diluted common shares outstanding	$ (0.48)	$ (0.19)
Net loss per basic and diluted common shares outstanding	$ (1.55)	$ (2.80)
Basic and diluted weighted average common shares outstanding	14,646,294	13,487,502

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

	Year Ended	
	2025	**2024**

Net loss	$(22,726,279)	$(37,801,426)
Adjustments to reconcile net loss to net cash used in operating activities	(3,187,918)	15,896,600
Changes in operating assets and liabilities	(4,128,891)	222,493
Net cash used in operating activities	(30,043,088)	(21,682,333)
Net cash provided by investing activities	25,142,976	146,214
Net cash (used in) provided by financing activities	(4,221,611)	36,826,910
Net (decrease) increase in cash, cash equivalents, and restricted cash	(9,121,723)	15,290,791
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT BEGINNING OF YEAR	24,916,285	9,625,494
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT END OF YEAR	$ 15,794,562	$ 24,916,285

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Source: Veru Inc.