May 8, 2025

Veru Reports Fiscal 2025 Second Quarter Financial Results and Clinical Program Progress

--Unblinded safety data from Phase 2b QUALITY study expected in the second quarter of calendar 2025 --

--Topline efficacy and safety data for Phase 2b extension maintenance study expected in the second quarter of calendar 2025 --

--With positive Phase 2b QUALITY study, Veru plans for end of Phase 2 meeting with FDA to discuss Phase 3 clinical program --

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

MIAMI, FL, May 08, 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 2025 second quarter and provided an update on progress of its clinical development programs.

“In addition to our previously disclosed robust and exciting topline efficacy data from the enobosarm Phase 2b QUALITY study, we are now looking forward to the near-term Company catalysts this calendar quarter including the unblinded safety data from the enobosarm Phase 2b QUALITY study as well as the topline efficacy and safety data from the Phase 2b extension maintenance study. The Phase 2b extension study should show us what happens to patients when they stop GLP-1 receptor agonist treatment but remain on enobosarm. The treatment objective is for patients to have a healthier option for choosing to stop GLP-1s without the fear of fat regain,” said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru. “We also expect to submit our End of Phase 2 meeting request to FDA. We anticipate that the End of Phase 2 FDA meeting will provide regulatory clarity for the Phase 3 clinical program and should occur in the third quarter of calendar 2025.”

Positive Phase 2b QUALITY clinical study: Enobosarm in combination with GLP-1 RA drugs makes weight reduction more tissue selective for fat loss while preserving lean mass and physical function.

In January 2025, the Company announced positive topline 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 older (≥60 years of age) patients receiving semaglutide (Wegovy®) for chronic weight management.

Topline Results
In the topline efficacy analysis, the trial met its prespecified primary endpoint with a statistically significant and a clinically meaningful benefit in all patients receiving enobosarm + semaglutide versus placebo + semaglutide at 16 weeks in total lean mass (71% relative reduction in lean mass loss, p=0.002). Notably, the enobosarm 3mg + semaglutide was the best dose with a >99% mean relative reduction in loss of lean mass (p <0.001). Enobosarm 6mg + semaglutide dose was not better than the Enobosarm 3mg + semaglutide dose on lean mass.

Topline Secondary Endpoints
Enobosarm + semaglutide treatment resulted in dose dependent greater loss of fat mass compared to placebo + semaglutide with the enobosarm 6mg dose having a 46% greater relative loss of fat mass compared to placebo + semaglutide group at 16 weeks (p=0.014). Although enobosarm + semaglutide significantly preserved lean mass, the additional loss of fat mass caused by enobosarm treatment was able to replace the lean mass preserved to allow a similar net mean weight loss with semaglutide at 16 weeks. Accordingly, the tissue composition of the total weight loss shifted to greater and selective loss of fat with enobosarm treatment. The median percentage of total body weight loss in the placebo + semaglutide group that was due to lean mass was 32% and estimated fat loss was 68%. In contrast, in the all enobosarm + semaglutide group, the total weight loss due to lean mass was 9.4% vs estimated fat loss of 90.6%, and for the enobosarm 3mg + semaglutide group, it was 0.9% lean mass vs 99.1% estimated fat loss. Therefore, enobosarm + semaglutide improved changes in body composition resulting in more selective and greater loss of adiposity than in subjects receiving placebo + semaglutide.

Physical Function
Physical function was measured by the Stair Climb Test. Climbing stairs is an activity of daily living, and the Stair Climb Test measures functional muscle strength, balance and agility. Declines in performance measured by Stair Climb Test predicts in older patients a higher risk for mobility disabilities, gait difficulties, falls and bone fractures, hospitalizations, and mortality. As a point of reference, stair climb power declines by -1.38% annually with aging according to Van Roie E. PLOS ONE 14:e0210653, 2019.

- **Phase 2b QUALITY clinical trial is the first human study to demonstrate that older patients who are overweight or have obesity receiving semaglutide GLP-1 RA are at higher risk for accelerated loss of lean mass with physical function decline.** A responders 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. In our study, the loss of lean mass mattered as 42.6% of patients on placebo + semaglutide group had at least a 10% decline in stair climb power physical function at 16 weeks.

- **Enobosarm treatment preserved lean mass (muscle) which translated into a reduction in the proportion of patients that had a clinically significant stair climb**

physical function decline versus subjects receiving semaglutide alone. The all enobosarm + semaglutide group had a statistically significant and clinically meaningfully 54.4% mean relative reduction in the proportion of subjects that lost at least 10% stair climb power compared to placebo + semaglutide group (p=0.0049). In enobosarm 3mg + semaglutide, there was a 62.4% relative reduction in the proportion of patients with at least a 10% decline in stair climb power from baseline vs. placebo + semaglutide group (p=0.0066). In enobosarm 6mg + semaglutide, there was a 46.2% relative reduction in the proportion of patients with at least a 10% decline in stair climb power from baseline vs. placebo + semaglutide group (p=0.0505).

Topline Results Conclusion
Enobosarm represents a novel drug that improves GLP-1 RA therapy resulting in tissue SELECTIVE quality weight reduction, that is, enobosarm + semaglutide improved changes in body composition which resulted in more selective and greater loss of adiposity (fat mass) than in subjects receiving placebo + semaglutide alone.

Phase 2b QUALITY Clinical Trial Safety
Safety data for the Phase 2b QUALITY study remains blinded as the Phase 2b extension clinical study portion is ongoing. The unblinded Phase 2b QUALITY clinical trial safety will be available this quarter. However, to the Company's knowledge, the aggregate, blinded safety data have to date not shown any significant differences compared to what is expected based on previous studies of enobosarm or GLP-1 RAs.

Phase 2b Extension Maintenance Study
After completing the efficacy dose-finding portion of the Phase 2b QUALITY clinical trial, the participants continued into a Phase 2b extension trial where all patients have stopped treatment with semaglutide, but continued taking placebo, enobosarm 3mg, or enobosarm 6mg in a blinded fashion for 12 weeks. The Phase 2b extension clinical trial is evaluating whether enobosarm can maintain muscle and prevent the fat regain that generally occurs after discontinuing a GLP-1 RA. The topline efficacy and safety results for the Phase 2b extension clinical study are expected this quarter.

Regulatory Next Steps
As the Phase 2b QUALITY clinical trial is a positive study, we plan to request an End of Phase 2 meeting with the FDA. During the preIND FDA meeting, FDA provided general comments about a regulatory path forward for enobosarm as a drug that improves body composition during weight loss including input on Phase 3 clinical program design.

As a path forward, we plan to propose a Phase 3 clinical program that is similar to the positive Phase 2b QUALITY clinical trial. The proposed Phase 3 clinical trial design is a double-blind, placebo-controlled study in older patients, greater than or equal to 60 years of age, who have obesity or who are overweight and who are eligible for treatment with GLP-1 RA. The GLP-1 RA may be either WEGOVY (semaglutide) and/or Zepbound® (tirzepatide). Patients will be randomized to oral daily enobosarm or matching placebo. All subjects will start and receive GLP-1 RA during the study. The proposed primary objective will be the effect of enobosarm on physical function measured by the Stair Climb Test at 24 weeks. Proposed key secondary objectives will be to assess the effect of enobosarm on total lean mass, total fat mass, HOMA-IR, and hemoglobin A1c at 24 weeks.

After the Phase 3 clinical trial ends at 24 weeks of treatment, the plan is to continue to

measure total lean mass, total body weight, stair climb, total fat mass, bone mineral density, HOMA-IR, and hemoglobin A1c up to 68 weeks to capture the longer-term benefits of enobosarm improvements on body composition for greater loss of adiposity or fat, weight reduction, and preservation of both lean mass and bone.

Novel Modified Release Oral Enobosarm Formulation is on Track to be Available for Phase 3 Clinical Studies and Commercialization

Veru is currently developing a novel, patentable, modified release oral formulation for enobosarm. The actual formulation, pharmacokinetic release profile(s), and method of manufacturing will be the subjects of future patent applications. If issued, the expiry for the new modified release oral enobosarm formulation patent is expected to be 2045. The new enobosarm formulation has completed animal trials and is anticipated to be in Phase 1 bioavailability clinical trials during the first half of calendar 2025. The expectation is that this novel modified release oral enobosarm formulation will be available for the Phase 3 clinical studies and for commercialization.

Atherosclerosis Inflammation Program
Veru has evolved its drug development strategy for sabizabulin, a novel oral broad anti-inflammatory agent, and is exploring the possibility of its clinical development for the treatment of inflammation in atherosclerotic cardiovascular disease.

About Atherosclerotic Coronary Artery Disease
Atherosclerotic coronary artery disease (CAD) remains the leading cause of mortality worldwide. Inflammation and high cholesterol jointly contribute to atherosclerotic cardiovascular disease. It appears that the pathogenesis and progression of coronary artery disease, however, is largely driven by inflammation in response to atheromatous plaques containing cholesterol in the arterial wall. Even with maximum cholesterol reduction therapies, there remains a major and largely untreated residual inflammatory risk. The realization that the combined use of aggressive lipid-lowering and inflammation-inhibiting therapies might be needed to further reduce atherosclerotic risk has sparked the search for anti-inflammatory medications that could lower the risk of atherosclerotic events in patients with CAD.

An old drug, colchicine, inhibits tubulin polymerization to disrupt microtubules resulting in broad anti-inflammatory activity. Recent randomized controlled trials assessing the role of low-dose colchicine to treat inflammation to reduce major adverse cardiovascular events had promising results demonstrating significant cardiovascular risk reduction. Colchicine lowered major adverse cardiovascular events by 31% among those with stable CAD and by 23% in patients following a recent myocardial infarction. This magnitude of benefit is greater than what has been observed in contemporary trials of lipid lowering medications including those with proprotein convertase subtilisin/kexin type 9 (PCSK-9) inhibitors. Data from these trials led the FDA in June 2023 to approve colchicine as the first anti-inflammatory drug for reducing cardiovascular events in adults with established atherosclerotic cardiovascular disease.

However, while colchicine may be the first FDA approved drug to treat atherosclerotic inflammation, unfortunately colchicine has significant safety concerns that may limit its expected widespread use. Colchicine has high potential for drug-drug interactions with commonly used cardiovascular drugs including almost all statins (HMG-CoA reductase

inhibitors). In contrast, Veru's sabizabulin is a new molecular entity, small molecule that targets the colchicine binding site on β-tubulin. Like colchicine, sabizabulin inhibits microtubule polymerization and has demonstrated the ability to reduce the most important inflammatory mediators that play a role in the initiation and progression of atherosclerotic CAD. In contrast to colchicine, sabizabulin has stable pharmacokinetics and low potential for drug-drug interactions; thus, sabizabulin may be administered potentially more safely as a secondary therapy in combination with statin therapy for the reduction of inflammation to slow the progression or promote regression of atherosclerotic cardiovascular disease. Overall preclinical data from in vitro and in vivo inflammation studies show that sabizabulin treatment suppressed all cytokines and chemokines tested. In Phase 2 and 3 pulmonary inflammation COVID-19 clinical studies, sabizabulin has demonstrated broad anti-inflammatory activity. The safety database consists of 266 dosed patients from the previous sabizabulin clinical development programs.

The Company's decision to explore this major cardiometabolic indication was based on the significant unmet medical need to treat inflammation in atherosclerotic cardiovascular disease, the large global market opportunity, current clinical and safety sabizabulin database of 266 patients, high probability of success given that sabizabulin drug's mechanism of action is similar to colchicine, strong intellectual property position, and is consistent with Company's focus on cardiometabolic diseases. Furthermore, the Company believes sabizabulin may be evaluated in a small Phase 2 dose finding proof of concept study to assess the progression of coronary atherosclerosis in patients using as the primary endpoint coronary plaque volume and composition measured by coronary CT angiography imaging. If the Company decides to pursue the Phase 2 clinical study, the Company plans to partner with the Colorado Prevention Center, Aurora, Colorado and Lundquist Institute, Torrence, California.

Veru had a pre-IND meeting with the FDA Division of Cardiology and Nephrology Center for Drug Evaluation and Research on December 26, 2024. The indication for discussion was the use of sabizabulin to slow progression or promote regression of atherosclerotic disease in patients with a history of coronary artery disease. The FDA agreed that there remains an unmet medical need based on disease pathophysiology and concurred with the general design of the small Phase 2 study using coronary CT angiography imaging as primary endpoint. The FDA also requested that the Company conduct chronic nonclinical toxicology animal studies to support the chronic use of sabizabulin for this indication. The chronic nonclinical toxicology studies are expected to be completed and a new IND for the proposed indication is planned to be submitted by the first half calendar 2026. Veru currently has sufficient drug substance to supply the proposed Phase 2 clinical study.

Second Quarter Financial Summary: Fiscal 2025 vs Fiscal 2024

- Research and development expenses increased to $3.9 million from $3.0 million
- Selling, general and administrative expenses decreased to $5.2 million from $5.9 million
- Operating loss from continuing operations decreased to $8.1 million from $8.9 million
- Net loss from continuing operations decreased to $7.9 million, or $0.05 per share, compared to $8.7 million, or $0.06 per share
- Net loss decreased to $7.9 million, or $0.05 per share, compared to $10.0 million, or $0.07 per share

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

- Research and development expenses increased to $9.6 million from $4.6 million
- Selling, general and administrative expenses decreased to $10.4 million from $12.6 million
- Operating loss from continuing operations increased to $18.4 million from $16.3 million
- Net loss from continuing operations decreased to $9.7 million, or $0.07 per share, compared to $16.4 million, or $0.13 per share
- Net loss decreased to $16.8 million, or $0.12 per share, compared to $18.3 million, or $0.15 per share

Balance Sheet Information

- Cash, cash equivalents, and restricted cash were $20.0 million as of March 31, 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 7682749, for one week.

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 unblinded safety data from the Phase 2b QUALITY study of enobosarm and the topline efficacy and safety data from the Phase 2b extension maintenance study will be made available and whether that data will align with previously disclosed topline results or change any of the conclusions drawn from previously disclosed topline data; whether and when the Company will present the full data from the Phase 2b QUALITY study or the Phase 2b extension maintenance study and in what forum; whether the Phase 2b extension study will successfully meet any of its endpoints, including whether such study will show that enobosarm may help prevent fat regain; 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 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, whether and when the Phase 1 study of formulation will begin, 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, including any Phase 3 program for enobosarm; 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 will have a greater loss of adiposity or greater weight loss than with semaglutide alone; whether and when enobosarm will be approved by the FDA as a body composition drug; whether and when sabizabulin will be developed for an atherosclerotic coronary artery disease indication ("CAD"), and whether sabizabulin would provide a safer, effective alternative to colchicine; whether prior data regarding sabizabulin's anti-inflammatory effects would be repeated in any such future CAD indication; the timing of the completion of tox studies and the submission of an IND for sabizabulin in a CAD indication; 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; 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 and securities litigation; 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.
Zepbound® is a registered trademark of Eli Lilly and Company.

FINANCIAL SCHEDULES FOLLOW

Veru Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	March 31, 2025	September 30, 2024
Cash, cash equivalents, and restricted cash	$20,018,392	$24,916,285
Prepaid expenses and other current assets	1,359,372	1,547,928
Current assets of discontinued operations	—	8,759,011
Total current assets	21,377,764	35,223,224
Property and equipment, net	422,712	481,372
Operating lease right-of-use assets	3,002,939	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	$32,671,943	$60,418,772
Accounts payable	$ 2,205,474	$ 2,259,668
Accrued research and development costs	196,918	120,448
Accrued compensation	1,986,800	4,494,278
Accrued expenses and other current liabilities	1,230,128	1,286,207
Residual royalty agreement liability, short-term portion	—	1,025,837
Current liabilities of discontinued operations	—	2,681,530
Total current liabilities	5,619,320	11,867,968
Residual royalty agreement liability, long-term portion	—	8,850,792
Operating lease liability, long-term portion	2,640,965	2,905,309
Other liabilities	3,364,425	4,477,991
Total liabilities	11,624,710	28,102,060
Total stockholders' equity	21,047,233	32,316,712
Total liabilities and stockholders' equity	$32,671,943	$60,418,772

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended March 31,		Six Months Ended March 31,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 3,932,102	$ 2,985,118	$ 9,648,932	$ 4,643,693
Selling, general and administrative	5,164,433	5,903,673	10,391,546	12,555,296
Total operating expenses	9,096,535	8,888,791	20,040,478	17,198,989
Gain on sale of ENTADFI® assets	974,303	—	1,669,519	918,372
Operating loss	(8,122,232)	(8,888,791)	(18,370,959)	(16,280,617)
Non-operating income (expenses):				
Gain on extinguishment of debt	—	—	8,624,778	—
Other non-operating income (expenses), net	269,839	185,692	83,885	(89,864)
Total non-operating income (expenses)	269,839	185,692	8,708,663	(89,864)
Net loss from continuing operations	(7,852,393)	(8,703,099)	(9,662,296)	(16,370,481)
Net loss from discontinued operations, net of taxes	(49,226)	(1,322,849)	(7,184,670)	(1,931,448)
Net loss	$ (7,901,619)	$ (10,025,948)	$ (16,846,966)	$ (18,301,929)
Net loss from continuing operations per basic and diluted common shares outstanding	$ (0.05)	$ (0.06)	$ (0.07)	$ (0.13)

Net loss from discontinued operations per basic and diluted common shares outstanding	$ (0.00)	$ (0.01)	$ (0.05)	$ (0.02)
Net loss per basic and diluted common shares outstanding	$ (0.05)	$ (0.07)	$ (0.12)	$ (0.15)
Basic and diluted weighted average common shares outstanding	146,386,142	146,381,186	146,385,019	123,366,486

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

	Six Months Ended March 31,	
	2025	**2024**
Net loss	$(16,846,966)	$(18,301,929)
Adjustments to reconcile net loss to net cash used in operating activities	2,525,640	8,086,492
Changes in operating assets and liabilities	(4,748,124)	(1,454,993)
Net cash used in operating activities	(19,069,450)	(11,670,430)
Net cash provided by (used in) investing activities	18,393,168	(40,656)
Net cash (used in) provided by financing activities	(4,221,611)	36,823,630
Net (decrease) increase in cash, cash equivalents, and restricted cash	(4,897,893)	25,112,544
Cash at beginning of period	24,916,285	9,625,494
Cash at end of period	$ 20,018,392	$ 34,738,038

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Source: Veru Inc.