
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): February 13, 2025

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 February 13, 2025, Veru Inc. issued a press release (the “Press Release”) announcing results for the quarter ended December 31, 2024. 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 February 13, 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: February 13, 2025

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 2025 First Quarter Financial Results
 and Clinical Program Progress**

- Company reported positive Phase 2b QUALITY study topline results for enobosarm + semaglutide (Wegovy®) with study meeting prespecified primary endpoint of preservation of lean mass as well as greater fat loss and improvement of physical function—**
- The Independent Data Monitoring Committee met this week on February 10, 2025 to evaluate the unblinded safety Phase 2b QUALITY data and recommended to continue the QUALITY extension study as designed—**
- Topline results of the Phase 2b extension maintenance study to reduce fat regain following discontinuation of GLP-1 RA are expected in the second quarter of calendar 2025—**
- Company announces new cardiometabolic indication for sabizabulin to treat inflammation in atherosclerotic coronary artery disease—**
- Company sold the FC2 Female Condom® (Internal Condom) Business for \$18 million —**
- Company to host conference call and webcast today at 8:00 a.m.ET--**

MIAMI, FL – February 13, 2025 – Veru Inc. (NASDAQ: VERU), a late clinical stage biopharmaceutical company focused on developing innovative medicines for the treatment of cardiometabolic and inflammatory disease, today announced financial results for its fiscal 2025 first quarter and provided an update on progress of its clinical development programs.

Enobosarm is a next generation drug that makes weight reduction by GLP-1 RA drugs more tissue selective for fat loss– Phase 2b QUALITY clinical study update:

On January 27, 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 QUALITY 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 sarcopenic obese or overweight older (>60 years of age) patients receiving semaglutide (Wegovy).

The Phase 2b QUALITY study is the first human study to report the effects of a muscle preservation drug candidate on body composition in older patients who have obesity or are overweight and receiving a GLP-1 receptor agonist. In the topline efficacy analysis, the trial met its prespecified primary endpoint

with a statistically significant and a clinically meaningful benefit in the preservation of total lean body mass in all patients receiving enobosarm + semaglutide versus placebo + semaglutide at 16 weeks (71% relative reduction in lean mass loss, $p=0.002$). 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.

As for secondary clinical 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 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 higher risk for mobility disabilities, gait difficulties, hospitalizations, falls, and bone fractures. 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.

- A responders analysis was conducted using a greater than 10% decline in stair climb power as the cut off at 16 weeks which represents 8 to 10 year loss of stair climb power function due to 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. **This 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.**
- The all enobosarm + semaglutide group had a statistically significant and clinically meaningful 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 ($p=0.0505$). **Therefore, 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.**

Enobosarm represents a next generation drug that improves GLP-1 RA therapy to result 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.

Safety data for the Phase 2b QUALITY study remains blinded as the Phase 2b extension clinical study portion is ongoing. The unblinded complete safety set will be available after the Phase 2b extension study is completed. However, the aggregate, blinded safety data have not shown any significant differences compared to previous studies of enobosarm and what is expected with GLP-1 RAs. The Independent Data Monitoring Committee met this week on February 10, 2025 to evaluate the unblinded safety data, and they made the recommendation to continue the study as designed.

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 continue taking placebo, enobosarm 3mg, or enobosarm 6mg in a blinded fashion for 12 weeks. The Phase 2b extension clinical trial will evaluate whether enobosarm can maintain muscle and prevent the fat regain that generally occurs after discontinuing a GLP-1 RA. The topline results of the separate blinded Phase 2b extension clinical study are expected in the second quarter of calendar 2025.

The Company plans to present the full clinical efficacy and safety data set for the Phase 2b QUALITY clinical study in future scientific conferences and publications after the Phase 2b extension portion of the study is completed and unblinded.

As the Phase 2b QUALITY study has positive topline clinical results, we plan to move forward to request an end of Phase 2 meeting with the FDA. We have previously met with the FDA to discuss our regulatory path forward as an improvement in body composition drug, and the FDA has provided general advice on Phase 3 design. Based on the successful Phase 2b QUALITY clinical trial, we plan to run a similar study as a Phase 3 study. The duration of treatment is expected to be 52 weeks which will allow us to also capture the longer-term benefits of enobosarm improvements on body composition for greater loss of adiposity and weight reduction.

Novel enobosarm modified release oral formulation

Veru is currently developing a novel, patentable, modified release formulation for enobosarm. We anticipate the actual formulation, pharmacokinetic release profile(s), and method of manufacturing will be the subjects of future patents. The drug product formulation is currently in animal trials and is anticipated to be available for a Phase 1 bioavailability clinical trial during the first half of calendar 2025. The expectation is that the oral enobosarm modified release drug formulation will be utilized for the Phase 3 clinical studies and for commercialization.

Atherosclerosis Inflammation Program

Given the recent positive topline results from the Phase 2b QUALITY study evaluating enobosarm as a cardiometabolic agent that has the potential to preserve muscle and augment fat loss in overweight and obese patients receiving GLP-1 RA therapy for weight reduction, Veru has evolved its drug development strategy for sabizabulin and is exploring the possibility of the clinical development of sabizabulin, a novel oral broad anti-inflammatory agent, for the treatment of inflammation in atherosclerotic cardiovascular disease. The Company believes there are compelling scientific evidence and rationale to evaluate sabizabulin as a treatment for the inflammation associated with atherosclerotic cardiovascular 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, Torrance, 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.

"We are very excited with the Phase 2b QUALITY topline results. The efficacy data from the study provides the proof of concept that you can retain lean mass and improve physical function and lose enough fat mass to make up for the lean mass retained to have the same weight loss as semaglutide alone at 16 weeks," said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru. "The Phase 2b QUALITY study is the first human study to demonstrate that older patients who

are overweight or have obesity and receiving only a semaglutide GLP-1 RA are at higher risk for accelerated loss of lean mass and physical function decline. The expectation is that all GLP-1 RA containing drugs could cause significant loss of lean mass in older patients raising concerns for potential declines in physical function, mobility disability, functional limitations, and loss of balance with a higher risk for falls and fractures. Further, our expectation is that when patients are treated longer with enobosarm + semaglutide, this tissue SELECTIVE and greater loss of adiposity (fat) should translate to a greater quality weight reduction than with semaglutide alone.” Dr. Steiner added: “Similarly, we are excited to explore advancing sabizabulin as a better option to colchicine to treat inflammation responsible for the progression of atherosclerotic coronary artery disease, a major cardiometabolic indication.”

FC2 Female Condom (Internal Condom) Sale

On December 30, 2024, The Female Health Company Limited entered into a Stock and Asset Purchase Agreement (the “Purchase Agreement”) with Clear Future, Inc. (the “Purchaser”). Pursuant to, and subject to the terms and conditions of, the Purchase Agreement, the Purchaser purchased substantially all of the assets (the “FC2 Business Sale”) related to the Company’s FC2 female condom business ® (internal condom), including the stock of the Company’s U.K. and Malaysian operating subsidiaries. The Purchaser assumed certain liabilities relating to the FC2 business that are specified in the Purchase Agreement. The transaction closed on December 30, 2024. The purchase price for the FC2 Business Sale was \$18.0 million in cash, subject to adjustment as set forth in the Purchase Agreement. The adjustments to the purchase price in the Purchase Agreement include a customary working capital adjustment based on the amount by which certain working capital items at closing are greater or less than a target set forth in the Purchase Agreement. Estimated proceeds to the Company after deducting a change of control payment due to SWK Funding LLC (“SWK”) pursuant to the residual royalty agreement, dated as of March 5, 2018 (the “Royalty Agreement”), between the Company and SWK, together with other customary transaction fees for a transaction of this type, is approximately \$12.3 million, subject to adjustment as set forth in the Purchase Agreement. In addition, due to the FC2 Business Sale, liabilities associated with the Residual Royalty Agreement which totaled \$9.9 million at September 30, 2024 were extinguished.

First Quarter Financial Summary: Fiscal 2025 vs Fiscal 2024

- Research and development expenses increased to \$5.7 million from \$1.7 million
- Selling, general and administrative expenses decreased to \$5.2 million from \$6.7 million
- Operating loss from continuing operations increased to \$10.2 million from \$7.4 million
- Net loss from continuing operations decreased to \$1.8 million, or \$0.01 per share, compared to \$7.7 million, or \$0.08 per share
- Net loss increased to \$8.9 million, or \$0.06 per share, compared to \$8.3 million, or \$0.08 per share

Balance Sheet Information

- Cash, cash equivalents, and restricted cash were \$26.6 million as of December 31, 2024 versus \$24.9 million as of September 30, 2024
- Estimated net proceeds from the sale of the FC2 business are \$12.3 million, after the change of control payment to terminate the Residual Royalty Agreement of \$4.2 million.
- Due to the sale of the FC2 business, liabilities associated with the Residual Royalty Agreement, which totaled \$9.9 million as of September 30, 2024 were extinguished.

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 3764668, 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 disease. 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 fat loss thereby improving body composition and physical function. Sabizabulin, a microtubule disruptor, is being developed for the treatment of inflammation in atherosclerotic cardiovascular disease.

About Sarcopenic Obesity

The clinical condition to improve body composition by preserving muscle and enhancing the loss of adiposity. We believe the market for this condition is quite large. Based on Medicare statistics, 22% of the US population is over 60 years of age, and according to the CDC, 42% of older adults have obesity in the United States and could benefit from a weight loss medication. Up to 34 % of obese patients over the age of 60 have sarcopenic obesity, sarcopenia being age-related loss of muscle. This large subpopulation of sarcopenic obese patients is especially at risk when taking GLP-1 drugs for weight reduction as they may already have critically low amounts of muscle due to age-related muscle loss. Because of the magnitude and the speed of muscle loss while on GLP-1 RA therapy for weight loss, GLP-1 RA drugs may accelerate the development of frailty and muscle weakness in obese or overweight elderly patients.

Muscle weakness may lead to poor balance, decreased gait speed, mobility disability, functional limitations, loss of independence, and higher risk for falls and fractures. In fact, the safety section of the package insert for Wegovy has been updated based on the recently reported SELECT cardiovascular outcomes clinical trial which now highlights a 400% increase in pelvic and hip fractures that was observed in patients greater than 75 years of age receiving Wegovy compared to placebo (2.4% versus 0.6%). Fractures of the hip and pelvis typically occur because of falls which increase with decreased muscle mass.

About Enobosarm

Enobosarm (aka ostarine, MK-2866, GTx-024, and VERU-024), a novel oral daily selective androgen receptor modulator (SARM), has been previously studied in 5 clinical studies involving 968 older normal men and postmenopausal women as well as older patients who have muscle wasting because of advanced cancer. Advanced cancer causes the loss of appetite where there is significant unintentional loss or wasting of both muscle and fat mass which is similar to what is observed with in patients taking GLP-1 RA drugs. We believe the totality of the clinical data from these previous five clinical trials demonstrates that enobosarm treatment leads to dose-dependent increases in muscle mass with improvements in physical function as well as significant dose-dependent reductions in fat mass. The patient data generated from these five enobosarm clinical trials in both elderly patients and in patients with a cancer induced appetite suppression provide strong clinical rationale for enobosarm. The expectation is that enobosarm in combination with a GLP-1 RA would potentially augment the fat reduction and total weight loss while preserving muscle mass.

Enobosarm has a large safety database, which includes 27 clinical trials involving 1581 men and women, some of which included patients dosed for up to 3 years. In this large safety database, enobosarm was generally well tolerated with no increases in gastrointestinal side effects. This is important as there are already significant and frequent gastrointestinal side effects with a GLP-1 RA treatment alone.

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 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 in what forum; whether and when patients will progress into the extension study; the planned design, number of sites, timing, endpoints, patient population and patient size of such extension study and whether such extension study will successfully meet any of its endpoints; 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 timed-released formulation of enobosarm will be developed successfully and whether such formulation will have the same effectiveness as the current formulation, and whether and when such timed-release formulation will be available for any planned or future clinical studies; 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; the ability to enroll sufficient numbers of subjects in clinical studies and the ability 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; 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; the Company's failure to timely file certain reports in February 2024 may impair its ability to raise capital under the Company's current effective shelf registration statement on Form S-3 or under a new registration statement; 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

FINANCIAL SCHEDULES FOLLOW



Veru Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	December 31, 2024	September 30, 2024
Cash, cash equivalents, and restricted cash	\$26,607,002	\$24,916,285
Prepaid expenses and other current assets	1,773,134	1,547,928
Current assets of discontinued operations	—	8,759,011
Total current assets	28,380,136	35,223,224
Property and equipment, net	452,043	481,372
Operating lease right-of-use assets	3,127,887	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	\$39,828,594	\$60,418,772
Accounts payable	\$ 1,994,645	\$ 2,259,668
Accrued research and development costs	1,572,429	120,448
Accrued compensation	1,503,233	4,494,278
Accrued expenses and other current liabilities	1,277,921	1,286,207
Residual royalty agreement liability, short-term portion	—	1,025,837
Current liabilities of discontinued operations	—	2,681,530
Total current liabilities	6,348,228	11,867,968
Residual royalty agreement liability, long-term portion	—	8,850,792
Operating lease liability, long-term portion	2,775,190	2,905,309
Other liabilities	4,078,187	4,477,991
Total liabilities	13,201,605	28,102,060
Total stockholders' equity	<u>26,626,989</u>	<u>32,316,712</u>
Total liabilities and stockholders' equity	<u>\$39,828,594</u>	<u>\$60,418,772</u>

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended	
	December 31,	
	2024	2023
Operating expenses:		
Research and development	\$ 5,716,830	\$ 1,658,574
Selling, general and administrative	5,227,113	6,651,624
Total operating expenses	10,943,943	8,310,198
Gain on sale of ENTADFI® assets	695,216	918,372
Operating loss from continuing operations	(10,248,727)	(7,391,826)
Non-operating income (expenses):		
Gain on extinguishment of debt	8,624,778	—
Other non-operating expenses, net	(185,954)	(275,557)
Total non-operating income (expenses)	8,438,824	(275,557)
Net loss from continuing operations	(1,809,903)	(7,667,383)
Net loss from discontinued operations, net of taxes	(7,135,444)	(608,598)
Net loss	\$ (8,945,347)	\$ (8,275,981)
Net loss from continuing operations per basic and diluted common shares outstanding	\$ (0.01)	\$ (0.08)
Net loss from discontinued operations per basic and diluted common shares outstanding	\$ (0.05)	\$ (0.01)
Net loss per basic and diluted common shares outstanding	\$ (0.06)	\$ (0.08)
Basic and diluted weighted average common shares outstanding	146,383,920	100,601,946

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

	Three Months Ended	
	December 31,	
	2024	2023
Net loss	\$ (8,945,347)	\$ (8,275,981)
Adjustments to reconcile net loss to net cash used in operating activities	1,067,088	3,044,876
Changes in operating assets and liabilities	(3,454,728)	(789,284)
Net cash used in operating activities	(11,332,987)	(6,020,389)
Net cash provided by investing activities	17,245,315	—
Net cash (used in) provided by financing activities	(4,221,611)	36,973,954
Net increase in cash, cash equivalents, and restricted cash	1,690,717	30,953,565
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	<u>\$ 26,607,002</u>	<u>\$40,579,059</u>