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 8, 2024

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 February 8, 2024, Veru Inc. issued a press release (the "Press Release") announcing certain financial highlights for the quarter ended December 31, 2023. 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 February 8, 2024.
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 8, 2024

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 2024 First Quarter Financial Highlights

—Company receives FDA IND clearance for the development of enobosarm in combination with GLP-1 drugs for potentially higher quality weight loss than has been shown with GLP-1 drug alone—

—Company to initiate Phase 2b obesity study by April 2024—

—Company completed public offering for net proceeds of $35.2 million, bringing total cash to $40.6 million at December 31, 2023—

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

MIAMI, FL – February 8, 2024 – Veru Inc. (NASDAQ: VERU), a late clinical stage biopharmaceutical company focused on developing innovative medicines for potentially higher quality weight loss, oncology, and viral induced acute respiratory distress syndrome (ARDS), today announced financial highlights for its fiscal 2024 first quarter and provided a business update.

“FDA’s clearance of the Investigational New Drug application (IND) for the planned enobosarm clinical trial to further increase fat loss and weight loss while preventing the significant muscle loss that occurs with weight-loss drugs, is a significant milestone for Veru,” said Mitchell Steiner, M.D., Chairman, President, and CEO of Veru Inc. “There’s a critical unmet medical need for orally administered therapeutics today that produce higher quality weight loss for patients by preserving muscle and augmenting fat loss with minimal to no additional side effects. Based on the promising results of past enobosarm clinical muscle studies, we think that enobosarm could effectively meet this critical unmet medical need. We plan to commence the Phase 2b clinical study in April 2024 and expect top line data by the end of the calendar year.”

Dr. Steiner added: “Supported by the solid institutional investment of our recent financing, including many highly regarded biotech institutional investors who were excited about the potential of enobosarm for the avoidance of muscle loss—weight loss indication, we believe our current funds are sufficient to complete and report topline results for the Phase 2b enobosarm study for potentially higher quality weight loss as well as the Phase 2b open label extension study.”

Metabolic Disease Program Update:

The Company's metabolic disease drug pipeline is focused on the clinical development of enobosarm, a novel oral selective androgen receptor modulator, to preserve muscle while augmenting fat loss in patients receiving a GLP-1 RA for weight loss.

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 simulates a "starvation state" where there is significant unintentional loss or wasting of both muscle and fat mass similar to what is observed with GLP-1 RA treatment. The totality of the clinical data from these 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 that were generated from these five enobosarm clinical trials in both elderly patients and in patients with a cancer induced starvation-like state 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 avoiding muscle loss.

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

Initially, enobosarm will be developed in a Phase 2b clinical study to address the large subpopulation of sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness leading to physical function mobility disability and frailty.

Phase 2b multicenter, double-blind, placebo-controlled, randomized, dose-finding clinical trial to evaluate enobosarm as a treatment to augment fat loss and to prevent muscle loss in receiving GLP-1 drug for weight loss.

We submitted an Investigational New Drug (IND) application for enobosarm in January 2024. In February 2024, the Company received FDA clearance to initiate the Phase 2b, 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 90 sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness. The primary endpoint is lean body mass (muscle), and the key secondary endpoint is total body fat mass at 16 weeks. The clinical study is expected to begin in April 2024 with the topline clinical results from the trial expected in the end of the fourth calendar quarter of 2024.

After completing the efficacy dose-finding portion of the Phase 2b clinical trial, it is expected that participants will then continue into an open label extension trial where all patients will receive 6 mg of enobosarm monotherapy for 12 weeks to determine the ability of enobosarm to rescue, or reverse muscle loss and prevent fat and weight rebound after stopping a GLP-1 RA. The results of the separate Phase 2b open label extension clinical study are expected in calendar Q2 2025.

Other Program Updates:

The Company's oncology drug pipeline is focused on the clinical development of enobosarm, an oral selective androgen receptor agonist, for the 2nd line treatment of metastatic breast cancer.

Enobosarm is a new kind of endocrine therapy for advanced breast cancer. Enobosarm is an oral, new chemical entity, selective androgen receptor agonist that activates the androgen receptor (AR) in AR+ ER+ HER2- metastatic breast cancer, which suppresses tumor growth without the unwanted masculinizing side effects and increases in hematocrit seen with androgens. Enobosarm was being developed in a Phase 3 clinical trial for treatment of androgen receptor positive (AR+), estrogen receptor positive (ER+) and human epidermal growth factor receptor 2 negative (HER2-) metastatic breast cancer in the 2nd line setting. As we have prioritized our clinical programs to focus on enobosarm for obesity, the continued clinical development of enobosarm for the treatment of metastatic breast cancer is subject to the availability of sufficient funding.

The Company's infectious disease pipeline is focused on the clinical development of sabizabulin, an oral, microtubule disruptor for hospitalized adult COVID-19 patients at high risk for ARDS.

The Company is developing sabizabulin 9mg, a novel oral microtubule disruptor, which has both host targeted antiviral and broad anti-inflammatory properties, as a two-pronged approach to the treatment of hospitalized patients with viral lung infection at high risk for ARDS and death. The Company has completed positive Phase 2 and positive Phase 3 COVID-19 clinical studies that have demonstrated that sabizabulin treatment resulted in a mortality benefit in hospitalized moderate to severe patients with COVID-19 viral lung infection at high risk for ARDS and death. The Company met with the FDA and reached agreement on the design of the Phase 3 confirmatory COVID-19 clinical trial to evaluate sabizabulin treatment of hospitalized moderate to severe COVID-19 patients who are at high risk for ARDS and the path forward to submit a new EUA application and/or NDA. Although we received agreement from the FDA on the design of a Phase 3 clinical trial broadly evaluating sabizabulin in any viral-induced ARDS, we will continue to seek external funding through government grants, pharmaceutical partnerships, and similar sources to fund the clinical development program. Without such external funding, we do not plan to advance the Phase 3 development of sabizabulin as a treatment for viral-induced ARDS.

FC2 Female Condom® (internal condom)

The Company sells FC2 in both the U.S. commercial sector and in the public health sector both in the U.S. and globally. FC2 is the only FDA approved female (internal) condom in the US. FC2 is a well-established business that has sold over 750 million female condoms worldwide. Since 2017, FC2 has generated over $213 million of net revenue.

Telehealth is an important commercial strategy in the U.S. for access to birth control products especially FC2 as a nonhormonal and latex free option to prevent pregnancy and transmission of sexually transmitted infections. In order to maximize its reach and to have more direct control of the promotion, distribution, and sales of FC2, the Company made the decision last year to launch its own independent, FC2-dedicated telehealth digital portal. The Company continues to invest in and grow its direct to patient telehealth portal as well as adding new telehealth and internet fulfillment pharmacy partners to provide coverage in all 50 states in the U.S.

In the global public health sector, the Company markets FC2 to entities, including ministries of health, government health agencies, U.N. agencies, nonprofit organizations and commercial partners, that work to support and improve the lives, health and well-being of women around the world. We are currently supplying a large multi-year South African tender for female condoms, which is expected to continue until 2025 and have seen sales grow in the current year as the current tender launched. We also expect a formal Brazil tender process to commence this year.

First Quarter Financial Summary: Fiscal 2024 vs Fiscal 2023

- Net revenues decreased to $2.1 million from $2.5 million
- Gross profit increased to $1.2 million from $0.7 million

Balance Sheet Information

- Cash and cash equivalents were $40.6 million as of December 31, 2023 versus $9.6 million as of September 30, 2023

Event Details

The audio webcast will be accessible under the 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 on February 8, 2024 at approximately 12:00 p.m. ET by dialing 1-877-344-7529 (domestic) or 1-412-317-0088 (international), passcode 8260066, for one week.

About Sarcopenic Obesity

According to the CDC, 41.5% of older adults have obesity in the United States and could benefit from a weight loss medication. Up to 34.4% of these obese patients over the age of 60 have sarcopenic obesity. This large subpopulation of sarcopenic obese patients is especially at risk for taking GLP-1 drugs for weight loss as they already have critically low amount of muscle due to age-related muscle loss. Further loss of muscle mass when taking a GLP-1 RA medication may lead to muscle weakness leading to poor balance, decreased gait speed, mobility disability, loss of independence, falls, bone fractures and increased mortality which is a condition like age-related frailty. Because of the magnitude and speed of muscle loss while on GLP-1 RA therapy for weight loss, GLP-1 RA drugs may accelerate the development of frailty in older obese or overweight elderly patients.

About Veru Inc.

Veru is a late clinical stage biopharmaceutical company focused on developing novel medicines for the treatment of metabolic diseases, oncology, and ARDS. The Company's drug development program includes two late-stage novel small molecules, enobosarm and sabizabulin.

Metabolic pipeline: Enobosarm (aka ostarine, MK-2866, GTx-024, and VERU-024), an oral daily novel selective androgen receptor modulator (SARM), is being developed as a treatment in combination with weight loss drugs to augment fat loss and avoid muscle loss in overweight or obese patients for chronic weight management. Initially, enobosarm will be developed in a Phase 2b clinical study to address the large subpopulation of sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness leading to physical function mobility disability and frailty.

Oncology pipeline: Phase 3 clinical development of enobosarm for treatment of androgen receptor positive (AR+), estrogen receptor positive (ER+) and human epidermal growth factor receptor 2 negative (HER2-) metastatic breast cancer in the 2nd line setting.

Infectious disease pipeline: sabizabulin, a microtubule disruptor, is being developed as a Phase 3 clinical trial for the treatment of hospitalized patients with viral-induced ARDS. The Company does not intend to undertake further development of sabizabulin for the treatment of viral-induced ARDS until we obtain funding from government grants, pharmaceutical company partnerships, or other similar third-party external sources.

The Company also has an FDA-approved commercial product, the FC2 Female Condom® (Internal Condom), for the dual protection against unplanned pregnancy and sexually transmitted infections.

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 Veru's expectations regarding whether and when the planned phase 2b trial of enobosarm discussed above will commence by April 2024, the planned design, timing, endpoints, patient population and patient size of such Phase 2b trial and whether such trial will successfully meet any of its endpoints; whether enobosarm will be shown to preserve muscle and physical function while augmenting fat loss in the specified patient populations; whether the Phase 2b data will be available by the end of 2024; whether the data will warrant continued study and whether and when the clinical trial participants will continue into an open-label extension study and when those results will be available; whether enobosarm will meet any unmet need for obesity patients; the planned timing, design, endpoints, patient population and expected funding of the Company's breast cancer and infectious disease pipeline; and whether the Company will be successful in its transformation into a late stage biopharmaceutical company focused on obesity and oncology; and whether the Company has sufficient cash to complete the planned enobosarm Phase 2b trial in specified obesity patients. 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 Veru Inc. (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, uncertainties related to market conditions and the satisfaction of customary closing conditions related to the proposed public offering and the Company's expectations regarding the completion, timing and size of the proposed public offering and the use of proceeds therefrom. This list is not exhaustive and other risks are detailed in the Company's periodic reports filed with the SEC, including the Company's Form 10-K for the year ended September 30, 2023.