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): May 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 May 8, 2024, Veru Inc. issued a press release (the "Press Release") announcing results for the quarter and six months ended March 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.

Exhibit No.	Document
99.1	Press Release of Veru Inc., issued May 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: May 8, 2024

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 2024 Second Quarter Financial Results and Progress of its Enobosarm High Quality Weight Loss Clinical Program

—Phase 2b clinical study of enobosarm in combination with semaglutide (Wegovy®*) for high quality weight loss is actively enrolling—

—Company assembles esteemed high quality weight loss Scientific Advisory Board – five MDs with significant relevant medical, clinical and scientific expertise—

—Company to present this month at upcoming American Association of Clinical Endocrinology annual meeting and GLP-1 Based Therapeutics Summit—

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

MIAMI, FL – May 8, 2024 – Veru Inc. (NASDAQ: VERU), a late clinical stage biopharmaceutical company focused on developing innovative medicines for preserving muscle for high quality weight loss, oncology, and viral induced acute respiratory distress syndrome, today announced financial results for its fiscal 2024 second quarter and provided a business update.

"We are pleased to have initiated the Phase 2b enobosarm clinical trial," said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru Inc. "There is a significant unmet medical need to have a drug that may effectively preserve muscle and augment fat loss in patients receiving GLP-1 drugs for weight loss. Dr. Steiner also added: "We are also very pleased to have assembled such an esteemed group of five medical experts for our high quality weight loss Scientific Advisory Board. All of these experts in obesity and muscle share our vision and goal to develop enobosarm as a drug candidate that may potentially enhance quality weight loss for obese or overweight patients by preferentially increasing fat loss while preserving muscle. We know that all of them will make valuable contributions to guide the enobosarm development program."

High Quality Weight Loss Program Update:

The Company's high quality weight loss program 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.

About the Enobosarm Phase 2b clinical trial

The Phase 2b, multicenter, double-blind, placebo-controlled, randomized, dose-finding clinical trial was designed to evaluate the safety and efficacy of enobosarm 3mg, enobosarm 6mg, or placebo as a treatment to preserve muscle and augment fat loss in approximately 90 patients with sarcopenic obesity or overweight elderly (>60 years of age) patients receiving semaglutide (Wegovy®).The primary

endpoint is difference in total lean body mass measured by DEXA, and the key secondary endpoints are differences in total body fat mass measured by DEXA and physical function as measured by stair climb test at 16 weeks. The Phase 2b clinical trial is actively enrolling patients from up to 15 clinical sites in the United States. Topline clinical results from the trial are expected by the end of calendar year 2024.

After completing the efficacy dose-finding portion of the Phase 2b clinical trial, it is expected that participants will then continue in blinded fashion into a Phase 2b extension clinical trial where all patients will stop receiving a GLP-1 RA, but will continue taking placebo, enobosarm 3mg, or enobosarm 6mg for an additional 12 weeks. The Phase 2b extension clinical trial will evaluate whether enobosarm can maintain muscle and prevent the fat and weight gain that occurs after discontinuing a GLP-1 RA. The topline results of the separate blinded Phase 2b extension clinical study are expected in calendar Q2 2025.

Second Quarter Financial Summary: Fiscal 2024 vs Fiscal 2023

- Net revenues decreased to $4.1 million from $6.6 million
- Gross profit decreased to $0.7 million from $4.1 million
- Research and development expenses decreased to $3.0 million from $17.9 million, as restated
- Selling, general and administrative expenses decreased to $7.6 million from $12.8 million
- Operating loss decreased to $9.9 million versus $34.4 million, as restated
- Net loss was $10.0 million, or $0.07 per share, compared to $33.8 million, or $0.42 per share, as restated

Year-to-Date Financial Summary: Fiscal 2024 vs Fiscal 2023

- Net revenues decreased to $6.3 million from $9.1 million
- Gross profit decreased to $1.8 million from $4.8 million
- Research and development expenses decreased to $4.6 million from $38.5 million, as restated
- Selling, general and administrative expenses decreased to $15.9 million from $30.4 million
- Operating loss was $17.8 million versus $71.9 million, as restated
- Net loss was $18.3 million, or $0.15 per share, compared to $72.5 million, or $0.90 per share, as restated

Balance Sheet Information

- Cash and cash equivalents were $34.7 million as of March 31, 2024 versus $9.6 million as of September 30, 2023
- Net accounts receivable were $2.8 million as of March 31, 2024 versus $4.5 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 at approximately 12:00 p.m. ET by dialing 1-877-344-7529 (domestic) or 1-412-317-0088 (international), passcode 8861692, 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 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 simulates a "starvation state" 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 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 preserving muscle mass.

Importantly, 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.

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.

Enobosarm, a selective androgen receptor modulator (SARM), is being developed for two indications: (i) Phase 2b clinical study of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness and (ii) subject to the availability of sufficient funding, Phase 3 ENABLAR-2 clinical trial of enobosarm and abemaciclib for the 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.

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 whether and when the phase 2b trial of enobosarm discussed above will produce topline data or patients will progress into the extension study, the planned design, number of sites, timing, endpoints, patient population and patient size of such trial and whether such trial will successfully meet any of its endpoints, 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, whether the Company's scientific advisors will make valuable contributions to the Company's enobosarm program and whether

the Company will be successful in its transformation into a late stage biopharmaceutical company focused on obesity and oncology. 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 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; the Company's existing product, FC2, and any future products, 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; risks relating to the Company's development of its own dedicated direct to patient telehealth platform, including the Company's lack of experience in developing such a platform, potential regulatory complexity, development costs, and market awareness and acceptance of any telehealth platform we develop; risks relating to our ability to increase sales of FC2 after significant declines in recent periods due to telehealth industry consolidation and the bankruptcy of a large telehealth customer; the Company's ability to protect and enforce its intellectual property; the potential that delays in orders or shipments under government tenders or the Company's U.S. prescription business could cause significant quarter-to-quarter variations in the Company's operating results and adversely affect its net revenues and gross profit; the Company's reliance on its international partners and on the level of spending by country governments, global donors and other public health organizations in the global public sector; the concentration of accounts receivable with our largest customers and the collection of those receivables; the Company's production capacity, efficiency and supply constraints and interruptions, including potential disruption of production at the Company's and third party manufacturing facilities and/or of the Company's ability to timely supply product due to labor unrest or strikes, labor shortages, raw material shortages, physical damage to the Company's and third party facilities, product testing, transportation delays or regulatory actions; 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, 2023, as amended by the Form 10-K/A, 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.

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FINANCIAL SCHEDULES FOLLOW

Veru Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	March 31, 2024	September 30, 2023 (Restated)
Cash and cash equivalents	$34,738,038	$ 9,625,494
Accounts receivable, net	2,785,331	4,506,508
Inventories, net	4,804,665	6,697,117
Prepaid expenses and other current assets	2,809,267	2,104,103
Total current assets	45,137,301	22,933,222
Plant and equipment, net	1,534,196	1,652,732
Operating lease right-of-use assets	3,947,417	4,332,473
Deferred income taxes	12,635,927	12,707,419
Goodwill	6,878,932	6,878,932
Other assets	1,666,586	1,518,313
Total assets	$71,800,359	$ 50,023,091
Accounts payable	$ 2,464,135	$ 12,931,172
Accrued compensation	2,683,214	990,609
Accrued expenses and other current liabilities	3,468,414	3,024,328
Residual royalty agreement liability, short-term portion	950,600	864,623
Total current liabilities	9,566,363	17,810,732
Residual royalty agreement liability, long-term portion	8,775,284	8,870,136
Operating lease liability, long-term portion	3,262,818	3,634,114
Other liabilities	4,986,250	29,948
Total liabilities	26,590,715	30,344,930
Total stockholders' equity	45,209,644	19,678,161
Total liabilities and stockholders' equity	$71,800,359	$ 50,023,091

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended March 31,		Six Months Ended March 31,	
	2024	2023 (Restated)	2024	2023 (Restated)
Net revenues	$ 4,135,301	$ 6,585,967	$ 6,276,027	$ 9,093,761
Cost of sales	3,457,002	2,493,892	4,447,276	4,299,631
Gross profit	678,299	4,092,075	1,828,751	4,794,130
Operating expenses:				
Research and development	2,986,791	17,860,701	4,636,841	38,471,828
Selling, general and administrative	7,580,340	12,834,494	15,881,771	30,380,359
Provision for credit losses	—	3,911,714	—	3,911,714
Impairment of intangible assets	—	3,900,000	—	3,900,000
Total operating expenses	10,567,131	38,506,909	20,518,612	76,663,901
Gain on sale of ENTADFI® assets	—	—	918,372	—
Operating loss	(9,888,832)	(34,414,834)	(17,771,489)	(71,869,771)
Non-operating income (expenses)	44,886	559,301	(420,877)	(762,997)
Loss before income taxes	(9,843,946)	(33,855,533)	(18,192,366)	(72,632,768)
Income tax expense (benefit)	182,002	(66,559)	109,563	(134,837)
Net loss	$ (10,025,948)	$(33,788,974)	$ (18,301,929)	$(72,497,931)
Net loss per basic and diluted common shares outstanding	$ (0.07)	$ (0.42)	$ (0.15)	$ (0.90)
Basic and diluted weighted average common shares outstanding	146,381,186	80,834,453	123,366,486	80,695,046

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

	Six Months Ended March 31,	
	2024	2023 (Restated)
Net loss	$(18,301,929)	$(72,497,931)
Adjustments to reconcile net loss to net cash used in operating activities	8,086,492	17,792,692
Changes in operating assets and liabilities	(1,454,993)	(5,384,460)
Net cash used in operating activities	(11,670,430)	(60,089,699)
Net cash used in investing activities	(40,656)	(427,152)
Net cash provided by financing activities	36,823,630	3,824,547
Net increase (decrease) in cash	25,112,544	(56,692,304)
Cash at beginning of period	9,625,494	80,190,675
Cash at end of period	$ 34,738,038	$ 23,498,371