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 9, 2023

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 9, 2023, Veru Inc. issued a press release (the "Press Release") announcing results for the quarter ended December 31, 2022. 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 9, 2023.
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 9, 2023

VERU INC.

By: /s/ Michele Greco
Michele Greco
Chief Financial Officer and Chief Administrative Officer

Exhibit 99.1

Investor Contact:
Samuel Fisch
Executive Director, Investor Relations and Corporate Communications
Email: veruinvestor@verupharma.com

Media Contact:
Hannah Gendel
Manager, Corporate Communications
Email: media@verupharma.com

Veru Reports Fiscal 2023 First Quarter Financial Results

Sabizabulin for moderate to severe COVID-19 under review for potential emergency authorization by multiple global regulatory agencies

Presented late-breaker oral presentation at IDWeek; sabizabulin treatment resulted in 81.2% relative reduction in deaths compared to the placebo in the WHO 4 subset group

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

MIAMI, FL – February 9, 2023 – Veru Inc. (NASDAQ: VERU), a biopharmaceutical company focused on developing novel medicines for COVID-19 and other viral ARDS-related diseases and for oncology, today announced financial results for its fiscal 2023 first quarter and provided a business update.

"We have been busy seeking emergency authorization for sabizabulin for the treatment of hospitalized moderate to severe COVID-19 patients at high risk for ARDS with major global regulatory bodies," said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru. "Our U.S. and international commercial teams are on standby. We are actively enrolling subjects in our advanced breast and prostate cancer Phase 3 clinical studies. Further, we have put in place a multi-pronged strategy to increase revenues from our sexual health program which appears to be successful as Q2 FY 2023 sales are significantly improving. As we await regulatory decisions, we have implemented measures to prudently conserve our cash, and we will provide an update once we are able to determine our path forward."

Infectious Disease Program Updates

Sabizabulin, a Novel Oral Microtubule Disruptor, for the Treatment of Hospitalized Moderate to Severe COVID-19 Patients at High Risk for Acute Respiratory Distress Syndrome (ARDS)

Sabizabulin for the treatment of COVID-19 is currently under regulatory review for potential emergency authorization by U.S. Food and Drug Administration (FDA), European Union's European Medicines Agency (EMA), United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA), Australia's Therapeutic Goods Administration (TGA), Canada's Health Canada, South Korea's Ministry of Food and Drug Safety (MFDS), and Switzerland's Swissmedic. With respect to Europe, if the EMA authorizes sabizabulin for emergency use under Article 18, then individual EU nations may decide to authorize sabizabulin in their respective countries.

In October 2022, Phase 3 data of sabizabulin for the treatment ofCOVID-19 was presented as a late-breaker at IDWeek (Infectious Disease Week) 2022. Clinical highlights from the presentation include statistically and clinically significant reductions in mortality with sabizabulin treatment resulting in a 22.4 absolute percentage point and 81.2% relative reduction in deaths compared to the placebo (p=0.0090) in a subset analysis of hospitalized moderate to severe WHO-4 COVID-19 patients at high risk for ARDS.

Oncology Program Updates

Enobosarm, a Novel Oral Selective Androgen Receptor Targeting Agonist, and Abemaciclib, a CDK 4/6 Inhibitor, Combination Therapy for the 2nd Line Treatment of AR+ER+HER2- Metastatic Breast Cancer

Enrollment has been ongoing in the Phase 3 multicenter, open label, randomized (1:1), active controlENABLAR-2 trial to evaluate the combination of enobosarm and abemaciclib for the treatment of AR+ER+HER2- metastatic breast cancer. We have a collaboration and supply agreement with Eli Lilly and Company for this trial.

Enobosarm for the 3rd Line Treatment of AR+ER+HER2- Metastatic Breast Cancer

Enrollment has been ongoing in the Phase 3 multicenter, international, open label, randomized (1:1) ARTEST trial to evaluate enobosarm for the treatment of AR+ER+HER2- metastatic breast cancer.

Sabizabulin for the Treatment of Metastatic Castration and Androgen Receptor Targeting Agent Resistant Prostate Cancer

Enrollment has been ongoing in the Phase 3 VERACITY open label, randomized (2:1), multicenter trial to evaluate sabizabulin 32mg for the treatment of chemotherapy naïve men with metastatic castration resistant prostate cancer who have tumor progression after previously receiving at least one androgen receptor targeting agent.

VERU-100, a Novel Proprietary Long-Acting Gonadotropin-Releasing Hormone (GnRH) Antagonist Peptide 3-Month Subcutaneous Depot Formulation, for Androgen Deprivation Therapy of Advanced Prostate Cancer

Enrollment has been ongoing in the Phase 2 clinical dose finding trial to evaluateVERU-100 for the treatment of androgen deprivation therapy in patients with advanced prostate cancer.

Urev - Sexual Health Program Updates

FC2 Female Condom/Internal Condom®

The Company markets and sells the FC2 Female Condom®, an FDA-approved product for dual protection against unplanned pregnancy and the transmission of sexually transmitted infections.

ENTADFI™ (finasteride and tadalafil) capsules for oral use, a New Treatment for Benign Prostatic Hyperplasia (BPH)

The Company markets ENTADFI™, an FDA-approved oral, once daily product for benign prostatic hyperplasia (BPH) for men with an enlarged prostate experiencing the signs and symptoms of BPH for up to 26 weeks.

First Quarter Financial Summary: Fiscal 2023 vs Fiscal 2022

- Net revenues decreased to $2.5 million from $14.1 million
- Gross profit decreased to $0.7 million from $11.8 million

- Research and development expenses increased to $18.7 million from $10.1 million
- Selling, general and administrative expenses increased to $17.5 million from $6.7 million
- Operating loss was $35.6 million versus $5.0 million
- Net loss was $36.8 million, or $0.46 per share, compared to $6.4 million, or $0.08 per share

Balance Sheet Information

- Cash and cash equivalents were $46.9 million as of December 31, 2022 versus $80.2 million as of September 30, 2022
- Net accounts receivable were $3.9 million as of December 31, 2022 versus $3.6 million as of September 30, 2022

Event Details

The audio webcast will be accessible under "Investor Kit" in the Investors page of the Company's website atwww.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 9, 2023 at approximately 12:00 p.m. ET by dialing 1-877-344-7529 (domestic) or 1-412-317-0088 (international) passcode 9127050 for one week.

About Veru Inc.

Veru is a biopharmaceutical company focused on developing novel medicines for COVID-19 and other viral ARDS-related diseases and for oncology. The Company's infectious disease development program includes sabizabulin, an oral microtubule disruptor, for the treatment of hospitalized moderate to severe COVID-19 patients at high risk for acute respiratory distress syndrome (ARDS). In the final analysis of the Phase 3 trial, treatment with sabizabulin 9 mg once daily resulted in a clinically meaningful and statistically significant 51.6% relative reduction in deaths compared to placebo. Sabizabulin for COVID-19 is currently under regulatory review for potential emergency or conditional authorization by U.S. FDA, European Union's EMA, United Kingdom's MHRA, Australia's TGA, Canada's Health Canada, South Korea's MFDS, and Switzerland's Swissmedic.

The Company's breast cancer development portfolio comprises enobosarm, a selective androgen receptor targeting agonist, and sabizabulin. Veru's oncology program also includes product candidates in development for the treatment of prostate cancer: sabizabulin, VERU-100, a long-acting GnRH antagonist and zuclomiphene citrate, an oral nonsteroidal estrogen receptor agonist.

The Company's commercial sexual health program, Urev, has 2FDA-approved products, including FC2 Female Condom® (internal condom), for the dual protection against unplanned pregnancy and the transmission of sexually transmitted infections, which is sold in the U.S. and globally and ENTADFI™ (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia.

Forward-Looking Statements

The statements in this release that are not historical facts are "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this release include statements regarding: whether the Company will successfully develop or commercialize any drug in the infectious disease area and whether any such drug will serve a potentially life-saving unmet need; whether the Company's infections disease franchise will generate any commercially available product and whether it will expand sabizabulin or any other compound beyond the potential

treatment of certain COVID-19 patients; whether and when the Company will receive an emergency use authorization or any approval from FDA or from any regulatory authority outside the U.S. for sabizabulin for certain COVID-19 patients; whether and when sabizabulin will become an available treatment option for certain COVID-19 patients in the U.S. or anywhere outside the U.S.; whether any additional efficacy or safety clinical studies of sabizabulin for certain COVID-19 patients will be required by the FDA or any other regulatory authority as a condition to any authorization or as a post-authorization requirement; whether the Company will have sufficient supply of sabizabulin or sufficient commercial resources to meet demand, if an emergency use authorization or other approval is granted in the U.S. or in any other country; whether the Company will secure any advance purchase agreement with any government; whether the current and future clinical development and results will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of any of the Company's other drug candidates; whether the drug candidates will be approved for the targeted line of therapy; the anticipated design and scope of clinical studies and FDA acceptance of such design and scope; whether any regulatory pathways, including the accelerated Fast Track designations, to seek FDA approval for sabizabulin, enobosarm or any of the Company's drug candidates are or will continue to be available; whether the expected commencement and timing of the Company's clinical studies, including the Phase 3 ENABLAR-2 study, the sabizabulin monotherapy Phase 2b clinical study for 3rd line treatment of metastatic breast cancer, and the Phase 2 registration clinical study forVERU-100 will be met; when clinical results from the ongoing clinical studies will be available, whether sabizabulin, enobosarm, VERU-100, or zuclomiphene will serve any unmet need or, what dosage, if any, might be approved for use in the U.S. or elsewhere, and also statements about the potential, timing and efficacy of the rest of the Company's development pipeline, and the timing of the Company's submissions to FDA and FDA's review of all such submissions; whether ENTADFI will be commercialized successfully, the Company will grow sales of ENTADFI or the Company will be able to successful partner with any other entity to grow sales of ENTADFI; whether the telemedicine customers for FC2 will return to historical ordering patterns or increase their purchases of FC2 at all; whether the Company's current cash will be sufficient to fund its planned or expected operations, especially if any authorizations for sabizabulin for certain COVID-19 patients are not obtained and whether the Company may need to raise capital; and whether any of the specified clinical trials will be suspended, modified or terminated as the Company seeks to conserve cash. These forward-looking statements are based on the Company's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related 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; 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 possibility that as vaccines become widely distributed the need for new COVID-19 treatment candidates may be reduced or eliminated; government entities possibly taking actions that directly or indirectly have the effect of limiting opportunities for sabizabulin as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments; the Company's existing products, including FC2 and ENTADFI and, if authorized, sabizabulin, and any future products, if approved, possibly not being commercially successful; the effects of the COVID-19 pandemic and measures to address the pandemic on the Company's clinical studies, supply chain and other third-party providers, commercial efforts, and business development operations; 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 successfully commercialize any of its products, if approved; risks relating to the Company's development of its own dedicated direct to patient telemedicine and telepharmacy services platform, including the Company's lack of experience in developing such a platform, potential regulatory complexity, and development costs; 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, COVID-19 (including the impact of COVID-19 on suppliers of key raw materials), product testing, transportation delays or regulatory actions; costs and other effects of litigation, including product liability claims; 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 fiscal year ended September 30, 2022 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. The Company disclaims any intent or obligation to update these forward-looking statements.

FINANCIAL SCHEDULES FOLLOW

Veru Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	December 31, 2022	September 30, 2022
Cash and cash equivalents	$ 46,927,187	$ 80,190,675
Accounts receivable, net	3,864,310	3,550,895
Inventories, net	8,732,627	8,618,944
Prepaid expenses and other current assets	13,484,521	12,408,960
Total current assets	73,008,645	104,769,474
Plant and equipment, net	1,425,970	1,185,766
Operating lease right-of-use assets	4,600,783	4,786,915
Deferred income taxes	13,052,163	12,965,985
Intangible assets, net	3,959,524	3,977,381
Goodwill	6,878,932	6,878,932
Other assets	856,435	1,561,564
Total assets	$103,782,452	$136,126,017
Accounts payable	$ 10,566,962	$ 22,003,394
Accrued research and development costs	12,678,176	9,071,503
Accrued expenses and other current liabilities	15,146,618	9,193,637
Residual royalty agreement liability, short-term portion	1,688,691	1,169,095
Total current liabilities	40,080,447	41,437,629
Residual royalty agreement liability, long-term portion	10,550,764	9,656,441
Operating lease liability, long-term portion	3,963,202	4,093,667
Other liabilities	89,181	99,644
Total liabilities	54,683,594	55,287,381
Total stockholders' equity	49,098,858	80,838,636
Total liabilities and stockholders' equity	$103,782,452	$136,126,017

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended December 31,	
	2022	**2021**
Net revenues	$ 2,507,794	$14,135,132
Cost of sales	1,805,739	2,293,050
Gross profit	702,055	11,842,082
Operating expenses:		
Research and development	18,744,349	10,081,161
Selling, general and administrative	17,545,865	6,723,206
Total operating expenses	36,290,214	16,804,367
Operating loss	(35,588,159)	(4,962,285)
Non-operating expenses	(1,322,298)	(1,303,066)
Loss before income taxes	(36,910,457)	(6,265,351)
Income tax (benefit) expense	(68,278)	114,655
Net loss	$(36,842,179)	$ (6,380,006)
Net loss per basic and diluted common shares outstanding	$ (0.46)	$ (0.08)
Basic and diluted weighted average common shares outstanding	80,558,670	80,023,168

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

	Three Months Ended December 31,	
	2022	2021
Net loss	$(36,842,179)	$ (6,380,006)
Adjustments to reconcile net loss to net cash used in operating activities	6,407,640	2,650,481
Changes in operating assets and liabilities	(4,099,489)	(4,928,267)
Net cash used in operating activities	(34,534,028)	(8,657,792)
Net cash (used in) provided by investing activities	(285,565)	2,197,791
Net cash provided by financing activities	1,556,105	204,427
Net decrease in cash	(33,263,488)	(6,255,574)
Cash at beginning of period	80,190,675	122,359,535
Cash at end of period	$ 46,927,187	$116,103,961