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 11, 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 May 11, 2023, Veru Inc. issued a press release (the "Press Release") announcing results for the quarter and six months ended March 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 May 11, 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: May 11, 2023

VERU INC.

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

Exhibit 99.1

Investor Contact:
Samuel Fisch
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Hannah Gendel
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Veru Reports Fiscal 2023 Second Quarter Financial Results

Agreement reached with FDA on confirmatory Phase 3 clinical trial design for sabizabulin treatment of hospitalizedCOVID-19 adult patients at high risk for acute respiratory distress syndrome (ARDS), including two planned interim efficacy analyses

ENTADFI® product sold for $20 million, plus up to an additional potential $80 million from sales milestones

Common stock purchase agreement with Lincoln Park Capital for up to $100 million provides financial flexibility

Company reported positive preclinical data for sabizabulin for influenza induced ARDS and for poxvirus

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

MIAMI, FL – May 11, 2023 – Veru Inc. (NASDAQ: VERU), a late clinical stage biopharmaceutical company focused on developing novel medicines for the treatment of breast cancer and for SARS-CoV-2 and other viral ARDS-related diseases, today announced financial results for its fiscal 2023 second quarter and provided a business update.

"This past quarter, we prioritized our clinical development program to focus on those indications with the largest market opportunities and with the potential for meaningful Phase 3 clinical data results in 2024 for both enobosarm for 2nd line AR+ ER+ HER2- metastatic breast cancer and sabizabulin for SARS-CoV-2 viral ARDS," said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru. "As part of this prioritization, we are planning to also expand enobosarm into bone-only, metastatic breast cancer and sabizabulin into influenza-induced ARDS."

Dr. Steiner added, "On the regulatory front, we received FDA clarity to continue advancing ourENABLAR-2 Phase 2b/3 clinical trial for metastatic breast cancer and agreement to pursue our confirmatory Phase 3 clinical trial for hospitalized COVID-19 adult patients at high risk for ARDS. We also reduced our cash burn rate, and in parallel, we increased available capital through the completed ENTADFI sale and the Lincoln Park Capital transaction. We are also seeking partnerships for both our clinical drug candidates. In addition, we continue to invest in Veru's FC2 Female Condom® telemedicine portal and establish partnerships to grow our FC2 prescription business in the U.S."

Breast Cancer Program Updates

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

In March 2023, the Company made the strategic decision to focus on theENABLAR-2 Phase 2b/3 trial (combination of enobosarm + abemaciclib). The decision to focus on an earlier line of treatment is supported by the larger target patient population in a second line metastatic setting for AR+ ER+ HER2- breast cancer patients. On March 30, 2023, the Company met with the FDA to gain further regulatory clarity for the ongoing Phase 2b/3 clinical trial design and program. The Phase 2b/3 study has been amended to accommodate the FDA's latest recommendations to support a potential registration. In the first stage of the trial, the dose of enobosarm in the abemaciclib combination is being optimized and the efficacy and safety of the combination therapy is being assessed compared to an estrogen blocking agent. The primary endpoint for stage 1 of the study is objective response rate (ORR), an endpoint that the FDA recognizes as an appropriate surrogate endpoint for clinical benefit for a possible accelerated approval. In Stage 2 of the Phase 2b/3 study, we plan to enroll approximately 210 subjects in a multicenter, open label, randomized (1:1), active control clinical study, to evaluate the efficacy and safety of enobosarm plus abemaciclib combination therapy versus an alternative estrogen blocking agent (SERD or an aromatase inhibitor) in subjects with AR+ ER+ HER2- metastatic breast cancer who have failed a CDK4/6 inhibitor plus an estrogen blocking agent (non-steroidal aromatase inhibitor or SERD). The primary endpoint is progression free survival. The regulatory strategy and clinical design for the Phase 2b/3 ENABLAR-2 clinical study could yield an accelerated approval from stage 1 and full approval from stage 2 for the 2nd line abemaciclib and enobosarm combination treatment of AR+ ER+ HER2- metastatic breast cancer. We anticipate having clinical data for the Phase 2b/3 ENABLAR-2 study in 2024. We have a collaboration and supply agreement with Eli Lilly and Company.

Enobosarm, a Novel Oral Selective Androgen Receptor Agonist, for the Treatment of Bone-only Nonmeasurable ER+ HER2- Metastatic Breast Cancer

The Company is planning a Phase 2b/3 study in bone-only nonmeasurable hormone receptor and HER2- metastatic breast cancer with enobosarm. Enobosarm has the ability to build both cortical and trabecular bone and muscle in clinical and/or nonclinical models, which may reduce the incidence of skeletal related events caused by bone metastases and positively impact quality of life for patients.

Infectious Disease: Viral Induced*Acute Respiratory Distress Syndrome (*ARDS) Program Updates

Sabizabulin, a Novel Oral Microtubule Disruptor, for the Treatment of Hospitalized Moderate to SevereCOVID-19 Patients at High Risk for ARDS

In February 2023, the FDA declined to grant at this time an Emergency Use Authorization (EUA) for sabizabulin for hospitalizedCOVID-19 patients at high risk for ARDS because of the possibility of unknown influences or uncertainties in the study. Nonetheless, in communicating its decision, the FDA remains committed to working with the Company for the future development of sabizabulin.

In April 2023, the Company met with the FDA and reached an agreement on the trial design and path forward for a confirmatory Phase 3 study, which will include 408 subjects with a primary endpoint of all-cause mortality at Day 60. In addition, the study's treatment population is expanded to include all hospitalized patients that require oxygen (WHO-4, WHO-5 and WHO-6) with no requirement to have a comorbidity. In order to get a potentially efficacious drug to patients in an efficient time frame, two planned interim efficacy analyses will be conducted: As requested by FDA, the first planned interim analysis will occur when 204 patients (50%) have completed the Day 60 primary efficacy endpoint, and

the second planned interim analysis is expected to occur when 290 patients (71%) have completed the Day 60 primary efficacy endpoint. If either of the interim efficacy analyses meets the statistical significance criteria, the trial could be stopped for efficacy. Should the pre-specified primary efficacy endpoint analysis demonstrate a statistically significant effect on all-cause mortality favoring sabizabulin, the Company may consider a new request for an EUA and/or a submission of an NDA, "as the Company would potentially have two adequate and well controlled trials for review." The confirmatory Phase 3 clinical trial is expected to enroll in the second half of 2023, and the first planned interim analysis is expected to be conducted in 2024.

Sabizabulin, a Novel Oral Microtubule Disruptor, for the Treatment of Hospitalized Moderate to Severe Influenza Patients at High Risk for ARDS

In April 2023, the Company announced preclinical results of sabizabulin demonstrating robust anti-inflammatory activity with improved outcomes in an Influenza-Induced Pulmonary Inflammation Mouse ARDS model. As a result, Veru is planning a Phase 3 study of sabizabulin in hospitalized influenza patients at high risk for ARDS.

Sabizabulin, a Novel Oral Microtubule Disruptor, for the Treatment of Viruses that Pose Serious Worldwide Global Threats

In April 2023, the Company announced preclinical *in vitro* study results that demonstrate sabizabulin prevented both the release of Vaccinia poxvirus from infected cells and the spread of Vaccinia poxvirus to healthy cells. As a result, Veru is planning a pre-Investigational New Drug (IND) meeting with the FDA to discuss the development of sabizabulin for smallpox virus and Ebola virus under the Animal Rules FDA regulatory approval pathway.

Urev - Sexual Health Program Updates

FC2 Female Condom® (internal condom)

In April 2023, the Company entered into a supply agreement with Afaxys Group Services, LLC (AGS), a healthcare company, to offer FC2 Female Condom® through the AGS Group Purchasing Organization (GPO) for up to 31 million individuals that depend on public health centers for essential healthcare.

The Company continues to invest in and grow its direct to patienttelemedicine portal and is focused on executing new contracts with additional telemedicine and internet fulfillment pharmacy partners to provide coverage in all 50 states in the U.S.

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

In April 2023, the Company sold ENTADFI®, an FDA-approved oral, once daily product for BPH for men with an enlarged prostate experiencing the signs and symptoms of BPH for up to 26 weeks, to Blue Water Biotech for $20 million ($6 million upfront and the remaining $14 million in installments through Fiscal Year 2024), with the potential for up to an additional $80 million from sales milestones.

Corporate Updates

In May 2023, the Company entered into a common stock purchase agreement (Agreement) with Lincoln Park Capital Fund (LPC). Under the terms of the Agreement, LPC has committed to purchase up to $100 million of Veru's common stock at Veru's sole discretion from time to time over a 36-month period.

Second Quarter Financial Summary: Fiscal 2023 vs Fiscal 2022

- Net revenues decreased to $6.6 million from $13.0 million
- Gross profit decreased to $4.1 million from $11.2 million
- Research and development expenses increased to $22.9 million from $15.5 million
- Selling, general and administrative expenses increased to $12.8 million from $7.4 million
- Operating loss, which included an impairment charge of $3.9 million and a provision for credit losses of $3.9 million, was $39.4 million versus $11.8 million
- Net loss was $38.8 million, or $0.48 per share, compared to $14.2 million, or $0.18 per share

Year-to-Date Financial Summary: Fiscal 2023 vs Fiscal 2022

- Net revenues decreased to $9.1 million from $27.2 million
- Gross profit decreased to $4.8 million from $23.0 million
- Research and development expenses increased to $41.6 million from $25.6 million
- Selling, general and administrative expenses increased to $30.4 million from $14.1 million
- Operating loss, which included an impairment charge of $3.9 million and a provision for credit losses of $3.9 million, was $75.0 million versus $16.7 million
- Net loss was $75.6 million, or $0.94 per share, compared to $20.6 million, or $0.26 per share.
- The net loss for the Company increased by $55 million for the current period. The main reason for the increase in the net loss relates to the Company preparing for the potential launch of sabizabulin for COVID-19 in the U.S. and outside the U.S. This required building a commercial team, engaging vendors to assist with the commercial launch, and manufacturing drug product for the launch upon EUA approval as required by the FDA. Since the declination, the majority of the employees hired for the commercial team have been terminated and the commercial launch sales and marketing related vendor contracts have been cancelled.

Balance Sheet Information

- Cash and cash equivalents were $23.5 million as of March 31, 2023 versus $80.2 million as of September 30, 2022. Subsequent to the Company's Fiscal Year 2023 second quarter, and as previously disclosed, Frost Gamma Investments Trust acquired $5 million of Company common stock in a private placement, and the Company sold its ENTADFI product to Blue Water Biotech for $6 million upfront, $14 million in notes receivable, and up to an additional $80 million if certain ENTADFI sales milestones are achieved.
- Net accounts receivable were $4.2 million as of March 31, 2023 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 May 11, 2023 at approximately 12:00 p.m. ET by dialing 1-877-344-7529 (domestic) or 1-412-317-0088 (international) passcode 1592419 for one week.

About Veru Inc.

Veru is a late clinical stage biopharmaceutical company focused on developing novel medicines for the treatment of breast cancer and forSARS-CoV-2 and other viral ARDS-related diseases. Veru also has a commercial sexual health division called Urev that is comprised of the FC2 Female Condom® (internal condom), for the dual protection against unplanned pregnancy and sexually transmitted infections which is sold in the U.S. and globally.

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: the planned design, enrollment, timing, commencement, interim and full data readout timing, scope, regulatory pathways, and results of the Company's current and planned clinical trials, including the confirmatory Phase 3 study of sabizabulin for certain COVID-19 patients, the Phase 2b/3 study of enobosarm in combination with abemaciclib for the 2nd line treatment of AR+ ER+ HER2 metastatic breast cancer, the Phase 2b/3 study of enobosarm in bone-only non-measurable hormone receptor and HER2- metastatic breast cancer, the Phase 3 study of sabizabulin in hospitalized influenza patients at high risk of ARDS, and studies of sabizabulin in smallpox virus and Ebola virus, and whether any of such studies will meet any of its primary or secondary endpoint; whether and when any of the planned interim analyses in the planned Phase 3 confirmatory study of sabizabulin for certain COVID patients will occur and what the results of any such interim analyses will be; whether the results of such interim analyses or the completed confirmatory Phase 3 study or any other interim data will be sufficient to support a new EUA application or an NDA; whether and when any potential EUA or NDA would be grated; whether and when the Company will meet with BARDA regarding any potential partnering opportunities and whether those efforts will be successful; whether and how the Company will fund the planned Phase 3 studies of sabizabulin in influenza, pox virus and COVID-19; whether and when the Company will expand the study of sabizabulin into other ARDS indications; whether the current and future clinical development efforts of the Company, including all studies of sabizabulin in infectious disease indications and enobosarm in oncology indications, and any of their results will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of any of the Company's drug candidates; whether the drug candidates will be approved for the targeted line of therapy; whether sabizabulin will become a treatment for broad ARDS; whether the Company's FC2 telemedicine portal sales will grow or replace prior revenue from the U.S. prescription sales of FC2; whether the Company will recover any of the monies owed it by The Pill Club; whether and when the Company will receive the remaining installments from Blue Water in connection with the sale of ENTADFI or will receive any of the potential sales milestones related thereto; whether, when and how many shares may be sold under the Lincoln Park Capital Fund equity line; and whether the Company's current cash will be sufficient to fund its planned or expected operations. 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 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 possibility that as vaccines, anti-virals and other treatments 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; 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 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 fiscal year ended September 30, 2022 and subsequent quarterly reports on Form10-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)

	March 31, 2023	September 30, 2022
Cash and cash equivalents	$23,498,371	$ 80,190,675
Accounts receivable, net	4,205,967	3,550,895
Inventories, net	7,665,194	8,618,944
Prepaid expenses and other current assets	7,918,745	12,408,960
Total current assets	43,288,277	104,769,474
Plant and equipment, net	1,519,789	1,185,766
Operating lease right-of-use assets	4,675,739	4,786,915
Deferred income taxes	13,070,469	12,965,985
Intangible assets, net	41,667	3,977,381
Goodwill	6,878,932	6,878,932
Other assets	778,697	1,561,564
Total assets	$70,253,570	$136,126,017
Accounts payable	$17,237,474	$ 22,003,394
Accrued research and development costs	13,786,241	9,071,503
Accrued expenses and other current liabilities	6,881,260	9,193,637
Residual royalty agreement liability, short-term portion	1,354,823	1,169,095
Total current liabilities	39,259,798	41,437,629
Residual royalty agreement liability, long-term portion	10,257,325	9,656,441
Operating lease liability, long-term portion	3,987,612	4,093,667
Other liabilities	32,933	99,644
Total liabilities	53,537,668	55,287,381
Total stockholders' equity	16,715,902	80,838,636
Total liabilities and stockholders' equity	$70,253,570	$136,126,017

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended March 31,		Six Months Ended March 31,	
	2023	2022	2023	2022
Net revenues	$ 6,585,967	$ 13,028,394	$ 9,093,761	$ 27,163,526
Cost of sales	2,493,892	1,853,116	4,299,631	4,146,166
Gross profit	4,092,075	11,175,278	4,794,130	23,017,360
Operating expenses:				
Research and development	22,864,633	15,541,104	41,608,982	25,622,265
Selling, general and administrative	12,834,494	7,401,138	30,380,359	14,126,344
Provision for (recovery of) credit losses	3,911,714	(2,000)	3,911,714	(4,000)
Impairment of intangible assets	3,900,000	—	3,900,000	—
Total operating expenses	43,510,841	22,940,242	79,801,055	39,744,609
Operating loss	(39,418,766)	(11,764,964)	(75,006,925)	(16,727,249)
Non-operating income (expenses)	559,301	(2,440,316)	(762,997)	(3,743,382)
Loss before income taxes	(38,859,465)	(14,205,280)	(75,769,922)	(20,470,631)
Income tax (benefit) expense	(66,559)	(27,450)	(134,837)	87,205
Net loss	$(38,792,906)	$(14,177,830)	$(75,635,085)	$(20,557,836)
Net loss per basic and diluted common shares outstanding	$ (0.48)	$ (0.18)	$ (0.94)	$ (0.26)
Basic and diluted weighted average common shares outstanding	80,834,453	80,052,504	80,695,046	80,037,675

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

	Six Months Ended March 31,	
	2023	**2022**
Net loss	$(75,635,085)	$ (20,557,836)
Adjustments to reconcile net loss to net cash used in operating activities	17,792,692	6,659,447
Changes in operating assets and liabilities	(2,247,306)	1,293,920
Net cash used in operating activities	(60,089,699)	(12,604,469)
Net cash (used in) provided by investing activities	(427,152)	2,012,566
Net cash provided by financing activities	3,824,547	247,873
Net decrease in cash	(56,692,304)	(10,344,030)
Cash at beginning of period	80,190,675	122,359,535
Cash at end of period	$ 23,498,371	$112,015,505