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): December 5, 2022

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 December 5, 2022, Veru Inc. issued a press release (the "Press Release") announcing results for the year ended September 30, 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 December 5, 2022.
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: December 5, 2022

VERU INC.

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

Investor Contact:
Samuel Fisch
Executive Director, Investor Relations and Corporate Communications
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Veru Reports Fiscal 2022 Fourth Quarter and Full Year Financial Results

U.S. FDA reviewing EUA application for sabizabulin to treat hospitalized COVID-19 patients at high risk for ARDS

European Medicines Agency's (EMA) Emergency Task Force reviewing sabizabulin for emergency use in EU member states

Sabizabulin also under review for potential emergency authorization by MHRA (UK), TGA (Australia), and Health Canada

Veru preparing for U.S. and international commercialization and distribution of sabizabulin, and manufacturing capacity for drug supply in place

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

MIAMI, FL – December 5, 2022 – 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 2022 fourth quarter and full year ended September 30, 2022 and provided a business update.

"This has been a transformational year for Veru. We reported positive Phase 3 results demonstrating that sabizabulin treatment resulted in a statistically and clinically significant reduction in death in hospitalized moderate to severe COVID-19 patients at high risk for ARDS and death, which was published in the NEJM Evidence®," said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru. "As sabizabulin is being reviewed in the U.S. and internationally for potential emergency use authorization, we are preparing for commercialization and will be ready to deliver this treatment to patients, if authorized."

Dr. Steiner added, "While FC2 revenue decreased this past year due to business challenges experienced by our largest telemedicine customers, we are working diligently to regenerate FC2 product sales, and our recently launched telemedicine platform has shown steady market uptake to date."

Infectious Disease Program Highlights

Sabizabulin: A Novel Oral, First-in-Class, Microtubule Disruptor for the Treatment of Hospitalized Moderate to SevereCOVID-19 Patients at High Risk for Acute Respiratory Distress Syndrome (ARDS)

In November 2022, the U.S. FDA's Pulmonary-Allergy Drugs Advisory Committee met with the Company to review its request for Emergency Use Authorization (EUA) of sabizabulin. The Advisory Committee voted 8-5 that the known and potential benefits of sabizabulin when used for the treatment of adult patients hospitalized with COVID-19 at high risk of ARDS do not outweigh the known and potential risks of sabizabulin. The FDA considers the Advisory Committee's input as part of their review, but the FDA makes the final decision on issuing an EUA.

In October 2022, the Company presented data from the Phase 3 trial of sabizabulin in a late-breaker oral presentation at IDWeek (Infectious Disease Week) 2022.

In August 2022, Australia's Therapeutic Goods Administration (TGA) granted the Company an expedited provisional registration regulatory pathway for sabizabulin treatment in hospitalized COVID-19 patients at high risk for ARDS.

In August 2022, the Company presented the Phase 3 trial results of sabizabulin at the 11th International Conference on Emerging Infectious Diseases (ICEID).

In July 2022, European Medicines Agency's (EMA) Emergency Task Force (ETF) initiated the review of sabizabulin for emergency use in the EU member states.

In July 2022, United Kingdom's (UK's) Medicines and Healthcare Products Regulatory Agency (MHRA) supported an expedited review of the marketing authorization application for sabizabulin treatment in hospitalized COVID-19 patients at high risk for ARDS.

On July 6, 2022, The *New England Journal of Medicine Evidence*® published results from the Phase 3 trial evaluating the efficacy and safety of oral sabizabulin in hospitalized COVID-19 patients.

Breast Cancer Program Highlights

Enobosarm, a Novel Oral Selective Androgen Receptor Targeting Agonist, for the 3rd Line Treatment of AR+ER+HER2- Metastatic Breast Cancer with sufficient AR Expression

We are enrolling patients in the Phase 3 multicenter, international, open label, randomized (1:1) ARTEST registrational trial to evaluate enobosarm versus either exemestane ± everolimus or a selective estrogen receptor modulator (SERM) as the active comparator for the treatment of AR+ER+HER2- metastatic breast cancer in approximately 210 patients with sufficient AR expression in their breast cancer tissue who had previously received a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor. In January 2022, the FDA granted Fast Track designation to the ARTEST Phase 3 registrational program.

Enobosarm and Abemaciclib, CDK 4/6 Inhibitor, Combination Therapy for the 2nd Line Treatment of AR+ER+HER2- Metastatic Breast Cancer with sufficient AR Expression

We are enrolling patients in the Phase 3 multicenter, open label, randomized (1:1), active controlENABLAR-2 trial to evaluate enobosarm and abemaciclib combination versus an alternative estrogen blocking agent (fulvestrant or an aromatase inhibitor) in subjects with AR+ER+HER2- metastatic breast cancer who have failed first line palbociclib (a CDK 4/6 inhibitor) plus an estrogen blocking agent (non-steroidal aromatase inhibitor or fulvestrant) and who have sufficient AR expression in their breast cancer tissue in approximately 186 subjects. We have a collaboration and supply agreement with Eli Lilly for this trial.

Sabizabulin for the 3rd Line Treatment of AR+ER+HER2- Metastatic Breast Cancer with sufficient AR Expression

We intend to conduct a Phase 2b open label, multicenter, randomized (1:1) trial evaluating sabizabulin 32mg versus active comparator (exemestane ± everolimus or a SERM, physician's choice) for the treatment of AR+ER+HER2- metastatic breast cancer in approximately 200 patients with sufficient AR expression in their breast cancer tissue who have previously received a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor.

Prostate Cancer Program Highlights

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

We are enrolling patients in the Phase 3 VERACITY open label, randomized (2:1), multicenter trial evaluating sabizabulin 32mg versus an alternative androgen receptor targeting agent 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. The primary endpoint is radiographic progression free survival in approximately 245 patients.

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

We are enrolling patients in the Phase 2 clinical dose finding trial ofVERU-100 for androgen deprivation therapy of advanced prostate cancer. The trial design for a future Phase 3 registrational trial of approximately 100 patients has been agreed upon by the FDA.

Urev - Sexual Health Program Highlights

ENTADFI™ (tadalafil and finasteride) capsule, a new Treatment for Benign Prostatic Hyperplasia (BPH)

The Company recently initiated the U.S. commercial launch and availability of ENTADFI™– an FDA-approved oral, once daily product for benign prostatic hyperplasia (BPH) that is approved for men with an enlarged prostate that are experiencing the signs and symptoms of BPH for up to 26 weeks.

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.

Full Year Financial Summary: Fiscal 2022 vs Fiscal 2021

- Total net revenues decreased to $39.4 million from $61.3 million
- Gross profit decreased to $30.6 million from $47.9 million
- Gross margin remained consistent at 78% of net revenues
- Research and development expenses increased to $70.6 million from $32.7 million
- Operating loss was $83.2 million compared with operating income of $13.0 million, which included an $18.4 million gain on the December 2020 sale of the PREBOOST® business

- Net loss was $83.8 million, or $1.05 per diluted share, compared with net income, which included the gain on sale of the PREBOOST business, of $7.4 million, or $0.09 per diluted share

Balance Sheet Information

- Cash and cash equivalents were $80.2 million as of September 30, 2022 versus $122.4 million as of September 30, 2021
- Net accounts receivable were $3.6 million as of September 30, 2022 versus $8.8 million as of September 30, 2021

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 December 5, 2022 at approximately 12:00 p.m. ET by dialing 1-877-344-7529 (domestic) or 1-412-317-0088 passcode 4646397 (international) 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.

Infectious disease program:

The Company has completed a positive Phase 3 COVID-19 study evaluating sabizabulin, an oral, first-in-class, new chemical entity, microtubule disruptor that has dual anti-inflammatory and antiviral properties, in hospitalized moderate to severe COVID-19 patients at high risk for ARDS.

A double-blind, randomized, placebo-controlled Phase 3 COVID-19 clinical trial was conducted in 204 hospitalized moderate to severeCOVID-19 patients at high risk for ARDS and death. The primary endpoint was the proportion of deaths by Day 60. Based on a planned interim analysis of the first 150 patients randomized, the Independent Data Monitoring Committee unanimously halted the study for clear clinical efficacy and no safety concerns were identified. Treatment with sabizabulin 9 mg once daily resulted in a clinically meaningful and statistically significant 55.2% relative reduction in deaths compared to placebo.

Oncology program:

The Company's late-stage breast cancer development portfolio comprises enobosarm, a selective androgen receptor targeting agonist, and sabizabulin.

Current studies on the two drugs include:

- Enrolling Phase 3 ARTEST study of enobosarm in androgen receptor positive, estrogen receptor positive, and human epidermal growth factor receptor two negative (AR+ ER+ HER2-) metastatic breast cancer with sufficient AR expression (third-line metastatic setting), and which has been granted Fast Track designation by the FDA.
- Enrolling Phase 3 ENABLAR-2 study of enobosarm + abemaciclib (a CDK 4/6 inhibitor) combination in AR+ ER+ HER2- metastatic breast cancer with sufficient AR expression (second-line metastatic setting). The Company and Eli Lilly and Company have entered into a clinical study collaboration and supply agreement for the ENABLAR-2 study. Lilly is supplying Verzenio® (abemaciclib).

- Planned Phase 2b study of sabizabulin in AR+ ER+ HER2- metastatic breast cancer with sufficient AR expression (third-line metastatic setting).

Veru's late-stage prostate cancer portfolio comprises sabizabulin, VERU-100, a long-acting GnRH antagonist, and zuclomiphene citrate, an oral nonsteroidal estrogen receptor agonist.

Current studies on these drugs include:

- Enrolling Phase 3 VERACITY study in metastatic castration and androgen receptor targeting agent resistant prostate cancer prior to IV chemotherapy.
- Enrolling Phase 2 dose-finding study of VERU-100 in advanced hormone sensitive prostate cancer.
- Planned Phase 2b study of zuclomiphene citrate to treat hot flashes in men with advanced prostate cancer undergoing androgen deprivation therapy.

Commercial sexual health program, Urev, has 2 FDA approved products:

- ENTADFI™ (tadalafil and finasteride) capsules for oral use, a new treatment for benign prostatic hyperplasia.
- 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.

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 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 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 the U.S. government or any foreign government; whether the current and future clinical development and results will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of the Company's drug candidates and companion diagnostic; 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 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, the Phase 2 registration clinical study for VERU-100, and the development of the companion diagnostic 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 any of the selective clinical properties previously observed in clinical studies of sabizabulin, enobosarm, VERU-100 or other drug candidates will be replicated in the current and planned clinical development program for such drug candidates and whether any such properties will be recognized by the FDA in any potential approvals and labeling; whether the companion diagnostic for enobosarm will be developed successfully or be approved by the FDA for use; 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; and 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. 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 onCOVID-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 ofCOVID-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, 2021 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.

Verzenio® is a registered trademark of Eli Lilly and Company

NEJM Evidence® is a registered trademark of the Massachusetts Medical Society

FINANCIAL SCHEDULES FOLLOW

Veru Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	September 30, 2022	September 30, 2021
Cash and cash equivalents	$ 80,190,675	$122,359,535
Accounts receivable, net	3,550,895	8,794,224
Inventories, net	8,618,944	5,574,253
Prepaid expenses and other current assets	12,408,960	15,025,475
Total current assets	104,769,474	151,753,487
Plant and equipment, net	1,185,766	592,603
Operating lease right-of-use assets	4,786,915	969,839
Deferred income taxes	12,965,985	13,024,550
Intangible assets, net	3,977,381	4,048,810
Goodwill	6,878,932	6,878,932
Other assets	1,561,564	878,502
Total assets	$136,126,017	$178,146,723
Accounts payable	$ 22,003,394	$ 3,409,771
Accrued research and development costs	9,071,503	2,020,445
Accrued expenses and other current liabilities	9,193,637	7,099,883
Residual royalty agreement liability, short-term portion	1,169,095	3,237,211
Total current liabilities	41,437,629	15,767,310
Residual royalty agreement liability, long-term portion	9,656,441	9,397,136
Operating lease liability, long-term portion	4,093,667	609,921
Other liabilities	99,644	78,412
Total liabilities	55,287,381	25,852,779
Total stockholders' equity	80,838,636	152,293,944
Total liabilities and stockholders' equity	$136,126,017	$178,146,723

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended September 30,		Year Ended September 30,	
	2022	2021	2022	2021
Net revenues	$ 2,588,631	$15,646,460	$ 39,354,352	$61,259,528
Cost of sales	2,083,226	3,337,282	8,762,964	13,332,305
Gross profit	505,405	12,309,178	30,591,388	47,927,223
Operating expenses:				
Research and development	26,890,426	8,255,592	70,646,103	32,694,405
Selling, general and administrative	18,287,515	5,924,812	43,168,845	20,670,319
Total operating expenses	45,177,941	14,180,404	113,814,948	53,364,724
Gain on sale of PREBOOST®	—	—	—	18,410,158
Operating (loss) income	(44,672,536)	(1,871,226)	(83,223,560)	12,972,657
Non-operating income (expenses)	3,661,517	(2,779,321)	(316,063)	(8,707,421)
(Loss) income before income taxes	(41,011,019)	(4,650,547)	(83,539,623)	4,265,236
Income tax expense (benefit)	11,589	(356,067)	236,397	(3,129,138)
Net (loss) income	$(41,022,608)	$ (4,294,480)	$ (83,776,020)	$ 7,394,374
Net (loss) income per basic common share outstanding	$ (0.51)	$ (0.05)	$ (1.05)	$ 0.10
Basic weighted average common shares outstanding	80,324,106	79,887,081	80,122,526	76,272,853
Net (loss) income per diluted common share outstanding	$ (0.51)	$ (0.05)	$ (1.05)	$ 0.09
Diluted weighted average common shares outstanding	80,324,106	79,887,081	80,122,526	83,802,420

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

	Year Ended September 30,	
	2022	2021
Net (loss) income	$ (83,776,020)	$ 7,394,374
Adjustments to reconcile net (loss) income to net cash used in operating activities	10,389,053	(15,682,840)
Changes in operating assets and liabilities	25,881,963	(7,282,558)
Net cash used in operating activities	(47,505,004)	(15,571,024)
Net cash provided by investing activities	4,266,948	14,623,351
Net cash provided by financing activities	1,069,196	109,718,430
Net (decrease) increase in cash	(42,168,860)	108,770,757
Cash at beginning of period	122,359,535	13,588,778
Cash at end of period	$ 80,190,675	$122,359,535