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): August 10, 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 August 10, 2023, Veru Inc. issued a press release (the "Press Release") announcing results for the quarter and nine months ended June 30, 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 August 10, 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: August 10, 2023

VERU INC.

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

Exhibit 99.1

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

Veru Reports Fiscal 2023 Third Quarter Financial Results

Company receives further regulatory clarity from FDA on Phase 3 ENABLAR-2 study. Potential for enobosarm +/- abemaciclib accelerated approval pathway in metastatic breast cancer, if successful based on new FDA Guidance

Company plans to expand sabizabulin Phase 3 confirmatory study to include all types of viral induced lung infections (influenza, RSV andCOVID-19) in hospitalized patients requiring supplemental oxygen who are at risk for ARDS

Company reported positive separate preclinical data for sabizabulin against both influenza and against poxvirus; FDA preIND meeting for sabizabulin against poxvirus set for August 2023

Company-owned telehealth digital platform making good progress; FC2 prescriptions growing

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

Company's cash burn during this quarter was $7.3 million - a $16.1 million reduction compared to the prior quarter

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

MIAMI, FL – August 10, 2023 – Veru Inc. (NASDAQ: VERU), a late clinical stage biopharmaceutical company focused on developing novel medicines for metastatic breast cancer and for viral induced acute respiratory distress syndrome (ARDS), today announced financial results for its fiscal 2023 third quarter and provided a business update.

"This quarter was marked by important Company efforts to seek additional regulatory clarity from FDA regarding our two lead development programs, enobosarm and sabizabulin and to secure funding sources," said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru. "We recently received further FDA regulatory clarity on the first stage of the Phase 3 ENABLAR-2 clinical trial design in order to add enobosarm alone as well as enobosarm in combination with abemaciclib as a 2nd line treatment for metastatic breast cancer with objective tumor response rates (ORR) as the primary endpoint. If ORR improvement is significant, we plan to pursue the accelerated approval pathway. As for sabizabulin, although there is a new summer and expected fall/winter COVID-19 surge, we believe that sabizabulin, as a broad antiviral and anti-inflammatory agent, may address viral lung infections and ARDS caused by other common viruses as well. Accordingly, we plan to discuss with FDA expanding the sabizabulin Phase 3 confirmatory study to include all hospitalized adult patients who have any kind of viral induced lung infection (influenza and RSV in addition to COVID)

requiring supplemental oxygen and who are at risk for ARDS. FDA has granted this meeting for September 2023. Viral induced pneumonia and lung infection is a leading cause of hospitalization in the U.S. according to the American Thoracic Society. In the U.S. alone, it is common to see well over 2 million hospitalizations annually from viral induced lung infections."

Dr. Steiner added: "During the quarter, we continued to make great progress on reducing our cash burn as we focus on our prioritized Phase 3 clinical programs. The Company's cash burn during the quarter was $7.3 million, a $16.1 million reduction compared to the prior quarter. We also increased available capital through the completed $20 million ENTADFI sale and the $100 million Lincoln Park Capital Fund common stock purchase agreement. I am also excited to report that our sexual health business is making great progress with the FC2 Female Condom® telehealth platform prescription business in the U.S. which has turned around and is growing to provide additional cash that we can invest, as we have done historically, in our two Phase 3 clinical development programs for large market opportunities."

Oncology Program Update:

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

Enobosarm is a new kind of endocrine therapy for advanced breast cancer. Enobosarm is an oral, new chemical entity, selective androgen receptor agonist that activates the androgen receptor (AR) in AR+ ER+ HER2- metastatic breast cancer, which suppresses tumor growth without the unwanted masculinizing side effects and increases in hematocrit seen with androgens.

Phase 3 clinical ENABLAR-2 study – Enobosarm +/- abemaciclib (CDK 4/6 inhibitor) combination versus estrogen blocking agent (active control) as a 2nd line treatment for AR+ ER+ HER2- metastatic breast cancer.

On March 30, 2023, the Company met with the FDA to gain further agreement on Phase 3 clinical trial design and program. The Phase 3 study has been amended to accommodate the FDA's latest recommendations to support registration as a second line treatment for patients with AR+ ER+ HER2- metastatic breast cancer who have tumor progression while receiving a CDK 4/6 inhibitor plus an estrogen blocking agent (nonsteroidal aromatase inhibitor or selective estrogen receptor degrader). The Phase 3 ENABLAR-2 study has 2 distinct study stages:

In Stage 1 of the Phase 3 study which will enroll 160 patients, the objectives are to optimize the dose of enobosarm in the abemaciclib combination and to assess the efficacy of enobosarm as a monotherapy compared to an estrogen blocking agent active control. The primary endpoint for Stage 1 is ORR. The Stage 1 initial run-in enrolled 3 patients to assess the safety and pharmacokinetics of the abemaciclib + enobosarm 9mg combination. In thisrun-in portion, there were no drug-to-drug interactions between abemaciclib and enobosarm, and there were no new safety findings. Further, the early preliminary clinical results showed 2 partial responses and 1 stable disease in the first 3 patients based on local assessments, and all patients have been on study for over 9 months. Our current plan is to have Phase 3 Stage 1 clinical results by late 2024 or early 2025. If enobosarm monotherapy or abemaciclib + enobosarm combination therapy compared to estrogen blocking agent (active control) demonstrates significant improvement in ORR, which is considered a surrogate endpoint for clinical benefit, then the Company plans to meet with the FDA to consider an accelerated approval regulatory pathway based on the clinical data from the Stage 1 portion of the Phase 3 study.

In Stage 2 of the Phase 3 study, we plan to enroll approximately 200 subjects in a multicenter, open label, randomized (1:1), active control clinical study, to evaluate the efficacy and safety of enobosarm with or without abemaciclib therapy (depending on the outcome of Stage 1) versus an alternative estrogen blocking agent (selective estrogen receptor degrader or an aromatase inhibitor) in subjects with AR+ ER+ HER2- metastatic breast cancer who have failed a CDK 4/6 inhibitor plus an estrogen blocking agent (nonsteroidal aromatase inhibitor or selective estrogen receptor degrader). The primary endpoint for Stage 2 of the Phase 3 study is progression-free survival.

In January 2022, Veru entered into a clinical trial collaboration and supply agreement through which Eli Lilly supplies abemaciclib for the ENABLAR-2 trial.

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

We have agreement with FDA on the design of the Phase 3 confirmatory COVID-19 study, but given the current COVID-19 landscape and unmet need for other types of viral induced ARDS in general, the Company now plans to meet with the FDA to reach agreement on the design of a proposed expanded Phase 3 confirmatory study evaluating sabizabulin 9mg for the treatment of hospitalized adult patients who have any viral lung infection, including SARS-CoV-2, Influenza A and B, Respiratory Syncytial Virus (RSV) and other viruses, and who require oxygen support and are at high risk for ARDS. The FDA has granted this meeting with Veru for September 2023.

The Company is developing sabizabulin 9mg, a novel oral microtubule disruptor, which has both host targeted antiviral and broad anti-inflammatory properties, as a two-pronged approach to the treatment of hospitalized patients with viral lung infection at high risk for ARDS and death. The Company has completed positive Phase 2 and positive Phase 3 COVID-19 clinical studies that have demonstrated that sabizabulin treatment resulted in a mortality benefit in hospitalized moderate to severe patients with COVID-19 viral lung infection at high risk for ARDS and death. On April 27, 2023, the Company met with the FDA and reached agreement on the design of the Phase 3 confirmatory COVID-19 clinical trial to evaluate sabizabulin treatment of hospitalized moderate to severe COVID-19 patients who are at high risk for ARDS and the path forward to submit a new EUA application and/or NDA.

On April 4, 2023, Veru announced positive results from a sabizabulin animal study conducted by a team of researchers at Labcorp Early Development Laboratories, Ltd, United Kingdom. The purpose of the study was to evaluate the efficacy of sabizabulin in the influenza H1N1 pulmonary inflammation mouse ARDS model. In the final study report, sabizabulin significantly reduced key cytokines involved in ARDS in H1N1 influenza pulmonary inflammation murine ARDS model. This positive preclinical influenza animal study further supports the potential use of sabizabulin as a broad antiviral and anti-inflammatory agent for viral induced ARDS.

As viruses that cause viral lung infection and ARDS do so in a similar way, the Company believes sabizabulin has the potential to be a treatment for all types of viral lung infections in hospitalized adult patients on oxygen who are at high risk for ARDS and death - not only SARS-CoV-2, but also influenza A or B, RSV, and other viruses. Although we have reached agreement with the FDA for the design of Phase 3 confirmatory COVID-19 clinical trial, the Company now plans to meet with the FDA again to reach agreement on the design of a proposed expanded Phase 3 confirmatory study evaluating sabizabulin 9mg for the treatment of hospitalized adult patients who have any kind of viral lung infection and on oxygen support who are at high risk for ARDS. The FDA has granted a meeting with Veru for September 2023. If we reach agreement with the FDA on the proposed ARDS sabizabulin study, we would not pursue the Phase 3 confirmatory COVID-19 only study or the influenza A or B only study.

Sabizabulin, as a host directed therapeutic, has been selected as a finalist drug candidate for consideration by The Influenza & Emerging Infectious Diseases Division of BARDA (The Biomedical Advanced Research and Development Authority of the U.S. Department of Health

and Human Services) for a planned large multicenter, placebo-controlled clinical trial in hospitalized adult patients with ARDS. A decision by BARDA for final selection is expected during calendar Q4 2023. This clinical trial sponsored by BARDA plans to evaluate the safety and efficacy of up to 3 novel threat-agnostic and host-directed therapeutics representing different mechanisms of action that could address ARDS caused by known and unknown health security threats such as pandemic influenza, COVID-19, other emerging infectious diseases, and chemical, biological, radiological, and nuclear incidents.

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

On April 11, 2023, Veru announced positive results from a preclinical in vitro study conducted by a team of researchers led by Brian M. Ward, Ph.D., Associate Professor of Microbiology and Immunology, University of Rochester School of Medicine and Dentistry, Rochester, New York. The preclinical study evaluated the effects of sabizabulin against the prototypical poxvirus, vaccinia virus, which demonstrated that sabizabulin prevented both the release of poxvirus from infected cells and the spread of poxvirus to healthy cells. The Company plans to have preIND meetings with the FDA to discuss Animal Rule regulatory requirements for assessing the efficacy of sabizabulin for smallpox virus as well as Ebola virus. The smallpox virus pre-IND meeting has been granted and will take place in August 2023. Clinical human efficacy trials of drugs for preventing or treating viral infections, such as smallpox are not feasible and challenge studies in healthy subjects are unethical. Therefore, drugs for these indications are generally developed and approved under a regulatory pathway commonly referred to as the *Animal Rule* (21 CFR part 314, subpart I, for drugs and 21 CFR part 601, subpart H, for biologics). The FDA may grant marketing approval based on adequate and well-controlled animal efficacy studies when the results of those studies establish that the drug is reasonably likely to produce clinical benefit in humans.

Urev - Sexual Health Program Updates

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.

FC2 Female Condom® (internal condom)

The Company sells FC2 in both the U.S. commercial sector and in the public health sector both in the U.S. and globally. FC2 is the only FDA approved female (internal) condom in the US. FC2 is a well-established business that has sold over 750 million female condoms worldwide. Since 2017, FC2 has generated over $213 million of net revenue. We have and plan to continue to invest the profits from the FC2 business to help fund the clinical development of our drug candidates, enobosarm and sabizabulin.

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

Having taken the time to refine our marketing, drive operational improvements, and enhance the patient experience during the initial launch phase over the last nine months, there are increasing new prescriptions being written and filled through our FC2 telehealth portal. During the third quarter of fiscal 2023, we saw our acquisition costs remain stable with new prescriptions growing over 115%, providing prescriptions to approximately 4,400 patients in total. We believe these results support our strategy and demonstrate high demand for FC2. We plan to continue to grow and deepen our investment in a profitable way by further expanding our presence both in social media channels and online search.

In the U.S. public sector, the company has seen an 115% increase in volume for the third quarter fiscal 2023 versus the third quarter fiscal 2022. This growth is attributable to key US public sector partnerships including the Company's recent announcement in April 2023 that it has entered into a Purchasing Agreement with Afaxys Group Services, LLC (AGS), the #1 provider of oral and emergency contraceptives in US clinics.

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

Corporate Updates

In June 2023, the Company announced that The University of Tennessee Health Science Center (UTHSC), oncology drug discovery research partner to Veru Inc., secured two additional grants to develop oncology therapeutics for indications of high unmet need. UTHSC was awarded $924,000 from the U.S. Department of Defense (DoD) and $3,074,470 from the National Cancer Institute's Research Project Grant (NCI R01). These two new grants awarded to UTHSC bring the university's aggregate oncology funding related to this project to over $10 million.

In May 2023, the Company entered into a common stock purchase agreement for the purchase of up to $100 million with Lincoln Park Capital Fund. In May 2023, the Company also entered into a common stock open market sale agreement (At-the-Market facility) with Jefferies LLC for the sale of up to $75 million.

Third Quarter Financial Summary: Fiscal 2023 vs Fiscal 2022

- Net revenues decreased to $3.3 million from $9.6 million
- Gross profit decreased to $1.2 million from $7.1 million
- Research and development expenses decreased to $2.9 million from $18.1 million
- Selling, general and administrative expenses increased to $10.9 million from $10.8 million
- Operating income, which included a gain on the sale of the Company's ENTADFI assets of $17.5 million, was $4.9 million versus operating loss of $21.8 million
- Net income was $6.3 million, or $0.07 per share, compared to net loss of $22.2 million, or $0.28 per share

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

- Net revenues decreased to $12.4 million from $36.8 million
- Gross profit decreased to $6.0 million from $30.1 million
- Research and development expenses increased to $44.5 million from $43.8 million
- Selling, general and administrative expenses increased to $41.3 million from $24.9 million
- Operating loss, which included an impairment charge of $3.9 million, a provision for credit losses of $3.9 million, and a gain on the sale of the Company's ENTADFI assets of $17.5 million, was $70.1 million versus $38.6 million
- Net loss was $69.3 million, or $0.83 per share, compared to $42.8 million, or $0.53 per share

Balance Sheet Information

- Cash and cash equivalents were $16.2 million as of June 30, 2023 versus $80.2 million as of September 30, 2022
- Net accounts receivable were $5.1 million as of June 30, 2023 versus $3.6 million as of September 30, 2022
- Notes receivable, gross of imputed interest, from the sale of the Company's ENTADFI assets are $14.0 million as of June 30, 2023

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 August 10, 2023 at approximately 12:00 p.m. ET by dialing 1-877-344-7529 (domestic) or 1-412-317-0088 (international) passcode 1699199 for one week.

About Veru Inc.

Veru is a late clinical stage biopharmaceutical company focused on developing novel medicines for breast cancer and for viral ARDS.

Oncology program: advanced breast cancer

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

- Enrolling Phase 3 clinical ENABLAR-2 study – enobosarm +/- abemaciclib combination versus estrogen blocking agent (active control) as a 2nd line treatment in AR+ ER+ HER2- metastatic breast cancer. The Company and Eli Lilly and Company have entered into a clinical study collaboration and supply agreement for the ENABLAR-2 study. Lilly supplies Verzenio® (abemaciclib).

Infectious disease program focuses on viruses that pose serious worldwide global threat

- **COVID-19:** Sabizabulin is an oral, first-in-class, new chemical entity, microtubule disruptor that has dual anti-inflammatory and host mediated antiviral properties. Veru has conducted a positive double-blind, randomized, placebo-controlled Phase 3 COVID-19 clinical trial in 204 hospitalized moderate to severe COVID-19 patients at high risk for ARDS and death. The primary endpoint was the proportion of deaths by Day 60. Treatment with sabizabulin resulted in a clinically meaningful and statistically significant 51.6% relative reduction in deaths (p=0.0046) and was well tolerated. FDA granted Fast Track designation to the Company's COVID-19 program in January 2022. In April 2023, the Company reached agreement with FDA on design of the Phase 3 confirmatory COVID-19 clinical trial to evaluate sabizabulin in hospitalized moderate to severe COVID-19 patients at high risk for ARDS. Although the Company has reached agreement with FDA for the design of Phase 3 confirmatory COVID-19 clinical trial, the Company now plans to meet with FDA to reach agreement on the design of a proposed expanded Phase 3 confirmatory study evaluating sabizabulin 9mg for the treatment of hospitalized adult patients who have and type of viral lung infection and on oxygen support who are at high risk for ARDS and death. The FDA has granted a meeting with Veru for September 2023.
- **Smallpox and Ebola viruses:** The Company is planning a pre-IND meeting with FDA to discuss the development of sabizabulin for smallpox virus and Ebola virus under the Animal Rule FDA regulatory approval pathway. A preIND meeting has been granted for smallpox virus in August 2023.

Sexual health program – Urev

Veru has a commercial sexual health division called Urev that is comprised of 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. The Company made the decision last year to launch its own independent, FC2-dedicated direct to patient telehealth and pharmacy services portal. The Company continues to invest in and grow its direct to patient telemedicine 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.

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 3 study of enobosarm in combination with abemaciclib for the 2nd line treatment of AR+ ER+ HER2 metastatic breast cancer, the Phase 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 the Company will expand the study of sabizabulin into other ARDS indications; whether and when the Company will receive the future installment payments of the ENTADFI purchase price or sales milestone payments; and the outlook for growth in the Company's FC2 business through telehealth customers, our direct to patient telehealth portal and the global public health sector. 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 or other ARDS 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 or other ARDS treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 or other ARDS treatments; the Company's existing products, including FC2 and, if authorized, sabizabulin, 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 telemedicine and telepharmacy services 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 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)

	June 30, 2023	September 30, 2022
Cash and cash equivalents	$ 16,213,136	$ 80,190,675
Accounts receivable, net	5,082,878	3,550,895
Notes receivable, short-term portion	8,536,535	—
Inventories, net	6,489,968	8,618,944
Prepaid expenses and other current assets	6,898,647	12,408,960
Total current assets	43,221,164	104,769,474
Plant and equipment, net	1,492,183	1,185,766
Operating lease right-of-use assets	4,495,336	4,786,915
Deferred income taxes	13,098,090	12,965,985
Intangible assets, net	23,810	3,977,381
Goodwill	6,878,932	6,878,932
Notes receivable, long-term portion	4,437,850	—
Other assets	1,548,049	1,561,564
Total assets	$ 75,195,414	$ 136,126,017
Accounts payable	$ 18,118,594	$ 22,003,394
Accrued research and development costs	1,112,788	9,071,503
Accrued expenses and other current liabilities	7,392,905	9,193,637
Residual royalty agreement liability, short-term portion	1,061,893	1,169,095
Total current liabilities	27,686,180	41,437,629
Residual royalty agreement liability, long-term portion	9,276,735	9,656,441
Operating lease liability, long-term portion	3,805,137	4,093,667
Other liabilities	40,111	99,644
Total liabilities	40,808,163	55,287,381
Total stockholders' equity	34,387,251	80,838,636
Total liabilities and stockholders' equity	$ 75,195,414	$ 136,126,017

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2023	2022	2023	2022
Net revenues	$ 3,341,185	$ 9,602,195	$ 12,434,946	$ 36,765,721
Cost of sales	2,110,567	2,533,572	6,410,198	6,679,738
Gross profit	1,230,618	7,068,623	6,024,748	30,085,983
Operating expenses:				
Research and development	2,925,171	18,133,412	44,534,153	43,755,677
Selling, general and administrative	10,902,916	10,761,486	41,283,275	24,887,830
Provision for (recovery of) credit losses	—	(2,500)	3,911,714	(6,500)
Impairment of intangible assets	—	—	3,900,000	—
Total operating expenses	13,828,087	28,892,398	93,629,142	68,637,007
Gain on sale of ENTADFI® assets	17,456,814	—	17,456,814	—
Operating income (loss)	4,859,345	(21,823,775)	(70,147,580)	(38,551,024)
Non-operating income (expenses)	1,512,410	(234,198)	749,413	(3,977,580)
Income (loss) before income taxes	6,371,755	(22,057,973)	(69,398,167)	(42,528,604)
Income tax expense (benefit)	57,551	137,603	(77,286)	224,808
Net income (loss)	$ 6,314,204	$(22,195,576)	$(69,320,881)	$(42,753,412)
Net income (loss) per basic common shares outstanding	$ 0.07	$ (0.28)	$ (0.83)	$ (0.53)
Basic weighted average common shares outstanding	88,266,152	80,088,431	83,218,748	80,054,594
Net income (loss) per diluted common shares outstanding	$ 0.07	$ (0.28)	$ (0.83)	$ (0.53)
Diluted weighted average common shares outstanding	88,301,516	80,088,431	83,218,748	80,054,594

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

	Nine Months Ended June 30,	
	2023	**2022**
Net loss	$ (69,320,881)	$ (42,753,412)
Adjustments to reconcile net loss to net cash used in operating activities	3,599,367	9,529,631
Changes in operating assets and liabilities	(12,799,840)	6,597,275
Net cash used in operating activities	(78,521,354)	(26,626,506)
Net cash provided by investing activities	5,547,174	4,415,755
Net cash provided by financing activities	8,996,641	401,826
Net decrease in cash	(63,977,539)	(21,808,925)
Cash at beginning of period	80,190,675	122,359,535
Cash at end of period	$ 16,213,136	$ 100,550,610