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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**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, 2022**

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**VERU INC.**

(Exact name of registrant as specified in its charter)

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**Wisconsin**  
(State or other jurisdiction  
of incorporation)

**1-13602**  
(Commission  
File Number)

**39-1144397**  
(IRS Employer  
Identification No.)

**48 NW 25<sup>th</sup> Street, Suite 102, 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.)

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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.

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**Item 2.02 Results of Operations and Financial Condition**

On February 9, 2022, Veru Inc. issued a press release (the “Press Release”) announcing results for the quarter ended December 31, 2021. 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.

<u>Exhibit No.</u>	<u>Document</u>
99.1	<a href="#">Press Release of Veru Inc., issued February 9, 2022.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).





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

**Veru Reports First Quarter Fiscal 2022 Results as US FC2 Prescription Net Revenues Climb 27%**

*--FC2 Prescription Business Entering 6<sup>th</sup> Year of Growth --*

*--FDA Approves Company's ENTADFI™, New Treatment for Benign Prostatic Hyperplasia with Commercialization Plans Underway--*

*—Company Enters into Clinical Trial Collaboration and Supply Agreement with Lilly to Evaluate Enobosarm and Abemaciclib Combination in Phase 3 ENABLAR-2 Trial—*

*— International Phase 3 ARTEST Clinical Trial of Enobosarm Monotherapy in Metastatic Breast Cancer is Enrolling and Receives FDA Fast Track Designation—*

*—Phase 3 COVID-19 Registration Program Receives FDA Fast Track Designation, Clinical Results Expected in the First Half of Calendar 2022—*

*—Company to Host Investor Conference Call Today at 8 AM ET—*

**MIAMI – February 9, 2022** – Veru Inc. (NASDAQ: VERU), an oncology biopharmaceutical company with a focus on developing novel medicines for the management of breast and prostate cancer, today announced financial results for its fiscal 2022 first quarter ended December 31, 2021.

**First Quarter Financial Summary: Fiscal 2022 vs Fiscal 2021**

- Total net revenues decreased 3% to \$14.1 million from \$14.6 million
- FC2 net revenues increased 3% to \$14.1 million from \$13.8 million
- US FC2 prescription net revenues climbed 27% to \$11.6 million from \$9.1 million
- Gross profit rose 9% to \$11.8 million from \$10.8 million
- Gross margin increased to 84% of net revenues from 74% of net revenues, a record high compared to any prior quarter
- Operating loss was \$5.0 million compared with operating income of \$19.2 million, which included an \$18.4 million gain on the December 2020 sale of the PREBOOST® business
- Net loss was \$6.4 million or \$0.08 per diluted share compared with net income, which included the gain on the sale of the PREBOOST business, of \$17.2 million or \$0.23 per diluted share

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## Balance Sheet Information

- Cash and cash equivalents were \$116.1 million as of December 31, 2021 versus \$122.4 million at September 30, 2021
- Net accounts receivable of \$8.1 million as of December 31, 2021 versus \$8.8 million as of September 30, 2021

“The 27% increase in year-over-year US FC2 prescription net revenues as well as achieving an all-time high in gross margin percentage underscore the continued robust US demand for our best-in-class FC2 product,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru Inc. “In addition to securing additional telemedicine and internet pharmacy partners, we are actively constructing our own direct to patient telemedicine and internet pharmacy services platform to further increase the US prescription business. This quarter also marked FDA’s approval of Veru’s ENTADFI™, (finasteride and tadalafil) capsule, a new treatment for BPH with low potential for sexual side effects, including impotence. ENTADFI will also be marketed and distributed by our own direct to patient telemedicine and internet pharmacy services platform. Veru has also partnered with GoodRx®, a US based digital resource for healthcare, to reach their almost 20 million monthly visitors. GoodRx will drive awareness and be integrated with our direct to patient telemedicine platform. ENTADFI’s approval is a significant execution milestone for Veru and an important step in expanding revenues from our Sexual Health Division called Urev. Urev is comprised of the ENTADFI and FC2 FDA approved products.”

“These strong financial results enable us to continue to fund and advance our late clinical stage oncology drug development pipeline. During the quarter we began enrolling patients in our Phase 3 ARTEST clinical trial evaluating enobosarm monotherapy in a third-line setting for AR+ER+HER2- metastatic breast cancer patients whose AR expression in breast cancer is  $\geq 40\%$ . We were very pleased that FDA granted Fast Track designation to the enobosarm ARTEST Phase 3 registration program, a distinction that underscores the urgent need for new, novel, targeted therapies for this important patient population suffering from this aggressive disease. FDA Fast Track designation is intended to expedite the development and review of new drugs to treat serious medical conditions that fill unmet medical needs. We also recently announced a clinical trial collaboration and supply agreement with Eli Lilly and Company for our Phase 3 ENABLAR-2 trial to evaluate enobosarm in combination with Verzenio® (abemaciclib), Lilly’s CDK4/6 inhibitor, as a second line therapy in the treatment of AR+ER+HER2- metastatic breast cancer.”

“Also, we received good news that FDA had granted Fast Track designation to our Phase 3 COVID-19 registration program for the investigation of sabizabulin, a novel, proprietary, oral cytoskeleton disruptor with both anti-inflammatory and anti-viral properties, to combat COVID-19 infection and the cytokine storm that is responsible for acute respiratory distress syndrome and death. We expect to have Phase 3 clinical results in the first half of calendar 2022.”

“This marks the receipt of two fast track designations from FDA on two of the Company’s major drug development programs, all within the span of just a few weeks. We look forward to ongoing, productive regulatory interactions with the FDA on both drug development programs, which are further enabled with this designation.”

## Pharmaceutical Pipeline Highlights:

### *COVID-19 Program*

#### **Sabizabulin for the Treatment of Hospitalized COVID-19 Patients at High Risk for Acute Respiratory Distress Syndrome (ARDS) Phase 3 COVID-19 Clinical Study - Enrolling.**

Sabizabulin has both broad anti-viral and anti-inflammatory activities which may serve a two-pronged approach to the treatment of COVID-19 virus infection and the subsequent debilitating inflammatory effects that lead to ARDS and death. In May 2021, we initiated the Phase 3 COVID-19 clinical study which is a double-blind, multicenter, multinational, randomized (2:1), placebo-controlled study evaluating daily oral 9mg dose of sabizabulin for up to 21 days versus placebo in 300 hospitalized COVID-19 patients

who are at high risk for ARDS. The primary efficacy endpoint will be the proportion of patients that die on study up to Day 60. Secondary endpoints will include the proportion of patients without respiratory failure, days in ICU, WHO Ordinal Scale for Clinical Improvement change from baseline, days on mechanical ventilation, days in the hospital, and viral load. The study is being conducted in the US, Brazil, Argentina, Mexico, Colombia and Bulgaria. In January 2022, FDA granted Fast Track designation to our Phase 3 COVID-19 registration program. We expect to have Phase 3 clinical results in the first half of calendar 2022.

### ***Breast Cancer Program***

#### **Enobosarm, a Novel Oral Selective Androgen Receptor Targeting Agonist, for the 3<sup>rd</sup> Line Treatment of AR+ER+HER2 Metastatic Breast Cancer with AR $\geq$ 40% Expression - Phase 3 ARTEST Clinical Study- Enrolling.**

Enobosarm is an oral, new chemical entity, selective androgen receptor targeting agonist that activates the androgen receptor (AR), a tumor suppressor, in AR+ER+HER2- metastatic breast cancer without causing unwanted masculinizing side effects. Enobosarm has extensive nonclinical and clinical experience having been evaluated in 25 separate clinical studies in approximately 1,450 subjects dosed, including three Phase 2 clinical studies in advanced AR+ ER+ HER2- metastatic breast cancer involving more than 250 patients. In the two Phase 2 clinical studies conducted in women with AR+ER+HER2- metastatic breast cancer, enobosarm demonstrated significant antitumor efficacy in heavily pretreated cohorts that failed estrogen receptor blocking agents, chemotherapy, and/or CDK 4/6 inhibitors and was well tolerated with a favorable safety profile.

We are enrolling the Phase 3 multicenter, international, open label, and randomized (1:1) ARTEST registration clinical trial design to evaluate enobosarm monotherapy versus physician's choice of either exemestane  $\pm$  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 AR expression  $\geq$ 40% 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 registration program, a distinction that underscores the urgent need for novel, targeted therapies for this important unmet medical need.

#### **Sabizabulin, Novel Oral Cytoskeleton Disruptor Agent, for the 3<sup>rd</sup> Line Treatment of AR+ER+HER2- Metastatic Breast Cancer with AR < 40% Expression - Phase 2b Clinical Study.**

We intend to conduct a Phase 2b clinical study which will be an open label, multicenter, and randomized (1:1) study evaluating sabizabulin 32mg monotherapy versus active comparator (exemestane  $\pm$  everolimus or a SERM, physician's choice) for the treatment of AR+ER+ HER2- metastatic breast cancer in approximately 200 patients with AR <40% expression in their breast cancer tissue who have previously received a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor. The Phase 2b study is expected to commence in calendar Q1 2022.

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**Enobosarm and Abemaciclib, CDK 4/6 Inhibitor, Combination Therapy for the 2<sup>nd</sup> Line Treatment of AR+ER+HER2- Metastatic Breast Cancer with AR  $\geq$  40% Expression - Phase 3 ENABLAR-2 Clinical Study.**

Based on positive Phase 2 clinical data and the preclinical data supporting the use of enobosarm in combination with a CDK 4/6 inhibitor in patients that are CDK 4/6 inhibitor and estrogen blocking agent resistant, we plan to conduct a Phase 3 multicenter, open label, randomized (1:1), active control clinical study, named ENABLAR-2 to evaluate the treatment of the 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 an AR  $\geq$  40% expression in their breast cancer tissue. We plan to enroll approximately 186 subjects which is expected to commence during the first quarter of calendar year 2022. We recently announced a clinical trial collaboration and supply agreement with Lilly for our Phase 3 ENABLAR-2 trial.

**Sabizabulin and Enobosarm Combination Therapy for AR+ Metastatic Triple Negative Breast Cancer Patients who have Progressed After Receiving at Least Two Systemic Chemotherapies –Planned Phase 2 Study.**

We intend to conduct a single arm, sabizabulin plus enobosarm combination therapy Phase 2 clinical study in approximately 111 women. However, due to prioritizing several other late stage Phase 3 studies, the Company has made the strategic decision to suspend further work on this metastatic triple negative breast cancer Phase 2 trial at this time.

***Prostate Cancer Program***

**Sabizabulin for the Treatment of Metastatic Castration and Androgen Receptor Targeting Agent Resistant Prostate Cancer – Phase 3 VERACITY Clinical Study—Enrolling.**

In June, the Company initiated the open label, randomized (2:1), multicenter Phase 3 VERACITY clinical study 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. The Phase 3 VERACITY clinical study is expected to enroll approximately 245 patients from 45 clinical centers.

**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 – Phase 2 Clinical Study - Enrolling.**

VERU-100 is designed to address the current limitations of commercially available androgen deprivation therapy. Androgen deprivation therapy is currently the mainstay of advanced prostate cancer treatment and is used as a foundation of treatment throughout the course of the disease even as other endocrine, chemotherapy, or radiation treatments are added or stopped. Specifically, VERU-100 is a chronic, long-acting GnRH antagonist peptide administered as a small volume, three-month depot subcutaneous injection without a loading dose. VERU-100 immediately suppresses testosterone with no testosterone surge upon initial or repeated administration, a problem that occurs with currently approved luteinizing hormone-releasing hormone agonists used for androgen deprivation therapy. There are no GnRH antagonist depot injectable formulations commercially approved beyond a one-month injection. In June 2021, the Company initiated the Phase 2 dose finding clinical study of VERU-100 androgen deprivation therapy for hormone sensitive advanced prostate cancer. The Phase 2 VERU-100 clinical study is expected to enroll approximately 35 patients. A Phase 3 registration clinical study has been agreed upon with FDA and will enroll approximately 100 men.

**ENTADFI™ (tadalafil and finasteride) capsule, a new Treatment for Benign Prostatic Hyperplasia (BPH) – Received FDA Approval in December 2021.**

We plan to market and distribute ENTADFI™ by our own “direct to patient” telemedicine and internet pharmacy services platform. We have also partnered with GoodRx, America’s digital resource for healthcare, to reach their almost 20 million monthly visitors, which include both consumers and healthcare providers to increase awareness and to drive patients to our telemedicine platform. Commercialization launch plans are underway.

**Event Details**

Interested parties may access the call by dialing 1-800-341-1602 from the U.S. or 1-412-902-6706 from outside the U.S. and asking to be joined into the Veru Inc. call. The call will also be available through a live, listen-only audio broadcast via the Internet at [www.verupharma.com](http://www.verupharma.com). Listeners are encouraged to visit the website at least 10 minutes prior to the start of the scheduled presentation to register, download and install any necessary software. A playback of the call will be archived and accessible on the same website for at least three months. A telephonic replay of the conference call will be available, beginning the same day at approximately 12 p.m. (noon) ET by dialing 1-877-344-7529 for U.S. callers, or 1-412-317-0088 from outside the U.S., passcode 3664461, for one week.

**About Veru Inc.**

Veru is an oncology biopharmaceutical company with a principal focus on developing novel medicines for the management of breast and prostate cancers.

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

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 AR <sup>3</sup> 40% expression (third-line metastatic setting), and which has been granted Fast Track designation by the FDA.
- Planned Q1 2022 Phase 3 ENABLAR-2 study of enobosarm + abemaciclib (a CDK 4/6 inhibitor) combination in AR+ ER+ HER2- metastatic breast cancer with AR <sup>3</sup> 40% expression (second-line metastatic setting). The Company has entered into a clinical trial collaboration and supply agreement with Lilly regarding Lilly’s supply of Verzenio® (abemaciclib) for the ENABLAR-2 trial.
- Planned Q1 2022 Phase 2b study of sabizabulin in AR+ ER+ HER2- metastatic breast cancer with AR < 40% expression (third-line metastatic setting).

The Company has determined that patients who have<sup>3</sup> 40% androgen receptor nuclei staining by immunohistochemistry in their breast cancer tissue, a measure of AR expression, are most likely to respond to enobosarm. Consequently, Veru is developing a companion diagnostic to determine a patient’s androgen receptor expression status, and has partnered with Roche/Ventana Diagnostics, a world leader in oncology companion diagnostics, which will develop and, if it is approved, commercialize the companion AR diagnostic.



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 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 in men with advanced prostate cancer undergoing androgen deprivation therapy who suffer from hot flashes.

In addition, sabizabulin, which has dual antiviral and anti-inflammatory effects, is currently enrolling in a Phase 3 COVID-19 study for the treatment of hospitalized COVID-19 patients at high risk for acute respiratory distress syndrome, and which has been granted Fast Track designation by the FDA.

Veru also has a commercial sexual health division - Urev, the proceeds of which help fund its drug development programs, comprised of 2 FDA approved products:

- ENTADFI™ (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia, commercialization launch plans are underway.
- 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 current and future clinical development and results, including whether sabizabulin will be an effective therapy for hospitalized COVID-19 patients, 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 for clinical trials 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; the expected commencement and timing of 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, including the delayed Phase 2 study of sabizabulin and enobosarm combination therapy for metastatic triple negative breast cancer, the Phase 3 VERU-100 clinical study and the sabizabulin clinical study for the treatment of hospitalized COVID-19 patients at high risk of ARDS; when clinical results from the ongoing clinical trials will be available, whether sabizabulin, enobosarm, VERU-100, zuclomiphene, and ENTADFI will serve any unmet need or, what dosage, if any, might be approved for use in the US 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; when commercial launch of ENTADFI will occur and the Company's ability to develop its own direct to patient telemedicine and telepharmacy services platform to market and distribute ENTADFI; the magnitude of any potential revenues generated by ENTADFI; whether the

companion diagnostic for enobosarm will be developed successfully or be approved by the FDA for use; that demand for the FC2 in the US prescription business and the Company's commercial products, including FC2 and ENTADFI, will continue and further financially support the Company's clinical oncology development pipeline; and whether and when the Company will launch its own telemedicine and internet pharmacy services platforms to market either FC2 or ENTADFI and whether either such platform will increase awareness or drive sales of such products. 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 trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials 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 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 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 trials, 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, 2021 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](http://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

GoodRx® is a registered trademark of GoodRx, Inc.

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**FINANCIAL SCHEDULES FOLLOW**  
**Veru Inc.**  
**Condensed Consolidated Balance Sheets**  
**(unaudited)**

	December 31, 2021	September 30, 2021
Cash and cash equivalents	\$116,103,961	\$122,359,535
Accounts receivable, net	8,071,541	8,794,224
Inventory, net	4,899,868	5,574,253
Prepaid expenses and other current assets	16,631,298	15,025,475
<b>Total current assets</b>	<b>145,706,668</b>	<b>151,753,487</b>
Deferred income taxes	12,931,129	13,024,550
Intangible assets, net	4,030,952	4,048,810
Goodwill	6,878,932	6,878,932
Other assets	2,616,876	2,440,944
<b>Total assets</b>	<b>\$172,164,557</b>	<b>\$178,146,723</b>
Accounts payable	\$ 4,087,708	\$ 3,409,771
Accrued expenses and other current liabilities	6,251,788	9,120,328
Residual royalty agreement liability, short-term portion	3,601,007	3,237,211
<b>Total current liabilities</b>	<b>13,940,503</b>	<b>15,767,310</b>
Residual royalty agreement liability, long-term portion	9,618,698	9,397,136
Other liabilities	601,121	688,333
<b>Total liabilities</b>	<b>24,160,322</b>	<b>25,852,779</b>
<b>Total stockholders' equity</b>	<b>148,004,235</b>	<b>152,293,944</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$172,164,557</b>	<b>\$178,146,723</b>

**Veru Inc.**  
**Condensed Consolidated Statements of Operations**  
**(unaudited)**

	<b>Three Months Ended</b>	
	<b>December 31,</b>	
	<b>2021</b>	<b>2020</b>
Net revenues	\$14,135,132	\$14,616,989
Cost of sales	<u>2,293,050</u>	<u>3,780,356</u>
Gross profit	11,842,082	10,836,633
Operating expenses:		
Research and development	10,081,161	5,677,754
Selling, general and administrative	<u>6,723,206</u>	<u>4,381,880</u>
Total operating expenses	16,804,367	10,059,634
Gain on sale of PREBOOST®	<u>—</u>	<u>18,410,158</u>
Operating (loss) income	(4,962,285)	19,187,157
Non-operating expenses	<u>(1,303,066)</u>	<u>(1,881,154)</u>
(Loss) income before income taxes	(6,265,351)	17,306,003
Income tax expense	<u>114,655</u>	<u>78,302</u>
Net (loss) income	<u><u>\$ (6,380,006)</u></u>	<u><u>\$ 17,227,701</u></u>
Net (loss) income per basic common share outstanding	\$ (0.08)	\$ 0.25
Basic weighted average common shares outstanding	80,023,168	70,313,589
Net (loss) income per diluted common share outstanding	\$ (0.08)	\$ 0.23
Diluted weighted average common shares outstanding	80,023,168	75,799,037

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

	<b>Three Months Ended</b>	
	<b>December 31,</b>	
	<b>2021</b>	<b>2020</b>
Net (loss) income	\$ (6,380,006)	\$ 17,227,701
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities	2,650,481	(16,697,883)
Changes in operating assets and liabilities	(4,928,267)	129,423
Net cash (used in) provided by operating activities	(8,657,792)	659,241
Net cash provided by investing activities	2,197,791	14,992,814
Net cash provided by financing activities	204,427	1,680,663
Net (decrease) increase in cash	(6,255,574)	17,332,718
Cash at beginning of period	122,359,535	13,588,778
Cash at end of period	<u>\$116,103,961</u>	<u>\$ 30,921,496</u>

**Veru Inc.**  
**Operating Income (Loss) by Segment**  
**(unaudited)**

	<b>Three Months Ended December 31, 2021</b>			
	<b>FC2</b>	<b>Pharmaceuticals</b>	<b>Corporate</b>	<b>Total</b>
Net revenues				
FC2	\$14,135,132	\$ —	\$ —	\$ 14,135,132
PREBOOST®	—	—	—	—
Total net revenues	14,135,132	—	—	14,135,132
Cost of sales	2,293,050	—	—	2,293,050
Gross profit	11,842,082	—	—	11,842,082
Operating expenses	(983,331)	(11,648,249)	(4,172,787)	(16,804,367)
Operating income (loss)	<u>\$10,858,751</u>	<u>\$ (11,648,249)</u>	<u>\$ (4,172,787)</u>	<u>\$ (4,962,285)</u>
	<b>Three Months Ended December 31, 2020</b>			
	<b>FC2*</b>	<b>Pharmaceuticals</b>	<b>Corporate</b>	<b>Total</b>
Net revenues				
FC2	\$13,754,158	\$ —	\$ —	\$ 13,754,158
PREBOOST®	862,831	—	—	862,831
Total net revenues	14,616,989	—	—	14,616,989
Cost of sales	3,780,356	—	—	3,780,356
Gross profit	10,836,633	—	—	10,836,633
Operating expenses	(921,697)	(5,858,837)	(3,279,100)	(10,059,634)
Gain on sale of PREBOOST®	—	—	18,410,158	18,410,158
Operating income (loss)	<u>\$ 9,914,936</u>	<u>\$ (5,858,837)</u>	<u>\$ 15,131,058</u>	<u>\$ 19,187,157</u>

\* Operating income from the FC2 segment, previously referred to as the Sexual Health Business segment, for the three months ended December 31, 2020 included \$415,000 related to the PREBOOST® business before the sale in December 2020