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 2, 2021

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.)**

48 NW 25th 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.)

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 2, 2021, Veru Inc. issued a press release (the "Press Release") announcing results for the year ended September 30, 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.

Exhibit No.	Document
99.1	Press Release of Veru Inc., issued December 2, 2021.
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 2, 2021

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
Phone: 800-972-0538

Veru Reports Record Fiscal 2021 Full-Year Financial Results

—FY21 Net Revenues Increase 44% to $61 Million and Gross Profit Increases 56% to $48 Million, Achieving New Historical Highs—

—Phase 3 Sabizabulin COVID-19 Clinical Study for Treatment of Hospitalized Moderate to SevereCOVID-19 Patients at High Risk for Acute Respiratory Distress Syndrome Being Conducted in US, Mexico, South America, and Europe; Clinical Results Expected 1H 2022—

—Expansive Breast Cancer Program Continues Its Rapid Advance; Four Late-Stage Clinical Studies Enrolling or Planned in Metastatic Breast Cancer—

—Phase 3 VERACITY Clinical Study of Oral, Targeted, Cytoskeleton Disruptor Sabizabulin for Metastatic Castration Resistant Prostate Cancer Enrolling—

—Phase 2 Dose Finding Clinical Study of VERU-100 Long-Acting GnRH Antagonist Peptide, SubQ, 3-Month, Depot Injection for Advanced Hormone Sensitive Prostate Cancer Enrolling—

—ENTADFI, a New Treatment for Benign Prostatic Hyperplasia, PDUFA Date is On Track for this Month—

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

MIAMI – December 2, 2021 – 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 that fiscal 2021 full-year net revenues increased 44% to $61 million and gross profit increased 56% to $48 million, achieving new historical highs.

Fourth-Quarter Financial Highlights: Fiscal 2021 vs Fiscal 2020

- Net revenues increased 33% to $15.6 million from $11.7 million
- FC2 prescription net revenues climbed 55% to $13.6 million from $8.7 million
- Gross profit rose 29% to $12.3 million from $9.6 million
- Gross margin was 79% of net revenues compared with 81% of net revenues
- Operating loss was $1.9 million versus $11.3 million. Operating loss in the fiscal 2020 period included a $14.1 millionnon-cash impairment charge.
- Net loss was $4.3 million, or $0.05 per share, compared with $11.8 million, which included anon-cash impairment charge of $14.1 million related to intangible assets, or $0.17 per share.

Full-Year Financial Highlights: Fiscal 2021 vs Fiscal 2020

- Net revenues increased 44% to $61.3 million from $42.6 million, a record high when compared to any prior fiscal year
- FC2 prescription net revenues climbed 71% to $46.5 million from $27.1 million
- Gross profit rose 56% to $47.9 million from $30.8 million
- Gross margin increased to 78% of net revenues from 72% of net revenues
- Operating income was $13.0 million, which included an $18.4 million gain on the December 2020 sale of the PREBOOST business, compared with operating loss of $14.7 million, which included the $14.1 million non-cash impairment charge.
- Net income, which included the gain on the sale of the PREBOOST business, was $7.4 million and diluted EPS was $0.09 compared with net loss of $19.0 million and diluted loss per share of $0.28, which included the non-cash impairment charge.

Balance Sheet Information

- Cash and cash equivalents were $122.4 million as of September 30, 2021 versus $13.6 million as of September 30, 2020
- Net accounts receivable were $8.8 million as of September 30, 2021 versus $5.2 million as of September 30, 2020

“Once again we’ve reported new historical highs for full fiscal year net revenues and gross profit based on the robust growth of our US FC2 prescription business,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru Inc. “On a sobering note, US and global COVID-19 hospitalizations and deaths are on the rise again. The identification of the omicron variant and the possibility that the current vaccines and antibody drugs may not be as effective against this variant means that drugs to treat severe COVID-19 are desperately needed. The mechanism of drug action of sabizabulin is that it disrupts microtubule intracellular transport of the coronavirus, a process that will still be required by new variants or strains of COVID-19, including omicron, to cause infection. While there have been recent developments evaluating molnupiravir and PAXLOVID™ (PF-07321332; ritonavir) for the treatment of unhospitalized patients with mild to moderate COVID-19 at a relatively lower risk of dying, sabizabulin is being developed for hospitalized patients with a high risk of death. In our positive Phase 2 clinical study in hospitalized COVID-19 patients at risk for acute respiratory distress syndrome, sabizabulin treatment resulted in an 82% relative reduction in death compared to placebo. If our Phase 2 clinical results are replicated to any significant degree in our global Phase 3 clinical study, we believe sabizabulin would fill a significant current unmet medical need for hospitalized patients. In our global Phase 3 clinical study of sabizabulin we are enrolling 300 hospitalized patients with moderate to severe COVID-19 who are at high risk for Acute Respiratory Distress Syndrome. We expect to have clinical results in the first half of calendar 2022.

These strong financial results have also enabled us to continue to advance our deep late clinical stage drug pipeline portfolio. We are heavily committed to developing our drug candidate assets in breast and prostate cancer. In our breast cancer program, we are addressing 3rd line treatment of ER+ metastatic breast cancer through two separate studies with patient populations depending on the AR expression in the breast cancer tissue. Targeting patients whose AR expression in breast cancer is ³ 40% AR, we are enrolling the Phase 3 ARTEST clinical study to evaluate enobosarm monotherapy. Targeting patients whose AR breast cancer expression is <40%, we plan to conduct a Phase 2b clinical study of sabizabulin monotherapy. We are also moving enobosarm earlier in the treatment sequence to the 2nd line treatment of AR+ER+ metastatic breast cancer by targeting patients with AR breast cancer expression³ 40% in the Phase 3 ENABLAR-2 study. The Phase 3 ENABLAR-2 study will evaluate the efficacy and safety of enobosarm and CDK 4/6 inhibitor combination. Finally, for AR+ metastatic triple negative breast cancer, we plan to conduct a single arm Phase 2 clinical study evaluating the combination of enobosarm and sabizabulin treatment in patients who have progressed after receiving at least 2 systemic chemotherapies. Because of the importance of determining the patient’s AR status and based on the recommendation of FDA, we will develop a companion diagnostic AR test. We are pleased to be partnering with Roche/Ventana Diagnostics, a global oncology diagnostics company, who will develop and, if approved, commercialize a companion diagnostic AR test.

In our prostate cancer program, we are enrolling our Phase 3 VERACITY clinical study of sabizabulin for metastatic castration and androgen receptor targeting agent resistant prostate cancer, but prior to IV chemotherapy. We are also enrolling our Phase 2 dose-finding clinical study of VERU-100, a novel long-acting GnRH antagonist 3-month depot injection formulation for androgen deprivation therapy for hormone sensitive advanced prostate cancer. Once completed, we will start the Phase 3 registration study.

Finally, our Sexual Health division, led by robust FC2 sales, and if approved this month, the addition of ENTADFI sales expected in the first half of calendar year 2022, we will continue to have substantial resources to invest in our premium oncology drug pipeline line which is dedicated to addressing significant unmet medical needs for two of the most prevalent cancers, prostate and breast cancer. I am pleased and excited with Veru's transformation into a premium oncology biopharmaceutical company seeking large market opportunities. The Company remains duty-bound during this persistent global pandemic to pursue this COVID-19 indication even though it is not the primary focus of the Company."

Pharmaceutical Pipeline Highlights:

Breast Cancer Program

Enobosarm, a Novel Oral Selective Androgen Receptor Targeted Agonist, for the 3rd Line Treatment of Androgen Receptor Positive (AR+), Estrogen Receptor Positive (ER+) and Human Epidermal Growth Factor Receptor 2 Negative (HER2-) Metastatic Breast Cancer with AR ³ 40% - Phase 3 ARTEST Clinical Study- Enrolling.

Enobosarm is the first new class of targeted endocrine therapy in advanced breast cancer in decades. Enobosarm is an oral, new chemical entity, selective androgen receptor agonist that targets the androgen receptor, a tumor suppressor, in AR+ER+HER2- metastatic breast cancer without the unwanted masculinizing side effects. Enobosarm has extensive nonclinical and clinical experience having been evaluated in 25 separate clinical studies in over 2,000 patients including three Phase 2 clinical studies in advanced 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 targeting 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 the efficacy and safety of enobosarm monotherapy versus physician's choice of either exemestane ± everolimus or a SERM as the active comparator for the treatment of AR+ ER+ HER2- metastatic breast cancer in approximately 210 patients with AR nuclei staining ³40% in their breast cancer tissue who had tumor progression on a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor.

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

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

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

CDK 4/6 inhibitor and estrogen blocking agent combination has become first line therapy for patients with ER+HER2- advanced breast cancer. Unfortunately, almost all patients will develop resistance to CDK 4/6 inhibitors, and will eventually, have breast cancer progression. 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 efficacy and safety of enobosarm plus abemaciclib combination therapy 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 have an AR nuclei staining ³ 40% in their breast cancer tissue. We plan to enroll approximately 186 subjects in this Phase 3 clinical study which is expected to commence during the first quarter of calendar year 2022.

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

Sabizabulin is an oral, first-in-class, new chemical entity that targets and inhibits microtubules to disrupt the cytoskeleton. Sabizabulin is not a substrate for P-glycoprotein drug resistance protein. Over expression of P-glycoprotein is a common mechanism that results in taxane and chemotherapy resistance in metastatic triple negative breast cancer. Preclinical studies in human triple negative breast cancer grown in animal models demonstrate that sabizabulin significantly inhibits cancer proliferation, migration, metastases, and invasion of triple negative breast cancer tumors that have become resistant to paclitaxel (taxane). Furthermore, an enobosarm + pembrolizumab combination Phase 2 study in 18 heavily pretreated women with AR+ metastatic triple negative breast cancer demonstrated that enobosarm was well tolerated and resulted in promising preliminary efficacy of 25% clinical benefit rate (CR+PR+SD) at 16 weeks and objective tumor responses (1 CR and 1 PR). Thus, the combination of two oral agents, sabizabulin + enobosarm, may provide a new treatment option for women who have AR+ metastatic triple negative breast cancer. We intend to conduct a single arm, sabizabulin plus enobosarm combination therapy Phase 2 clinical study in approximately 111 women in calendar Q1 2022.

Companion Diagnostic AR Test

We have identified that patients who have greater than 40% androgen receptor nuclei staining in their breast cancer tissue are most likely to respond to enobosarm. Based on the recommendation of FDA to have a companion diagnostic test to determine the patient's AR status, we are partnering with Roche/Ventana Diagnostics, a global oncology diagnostics company, who will develop and, if approved, commercialize a companion diagnostic AR test. The companion diagnostic test will be developed in parallel with the Phase 3 ARTEST clinical study.

Prostate Cancer Program

Sabizabulin, a Novel Oral Androgen Receptor Transport Disruptor, for the Treatment of Metastatic Castration and Androgen Receptor Targeting Agent Resistant Prostate Cancer – Phase 3 VERACITY Clinical Study - Enrolling.

Sabizabulin is a novel oral new chemical entity that targets microtubules in the cytoskeleton to disrupt androgen receptor transport. 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 failed 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 formulation 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, 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. The Phase 3 clinical study is anticipated to begin in 1H calendar 2022.

COVID-19 Program

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

Sabizabulin has both broad anti-viral and anti-inflammatory activities which may serve atwo-pronged approach to the treatment of COVID-19 virus infection and the subsequent debilitating inflammatory effects that lead to ARDS and death. In May, we initiated the Phase 3 clinical study which is a double-blind, multicenter, multinational, randomized (2:1), placebo-controlled study evaluating daily oral doses of 9mg sabizabulin for up to 21 days versus placebo in 300 hospitalized COVID-19 patients (200 subjects will be treated with sabizabulin and 100 subjects will receive standard of care) who are at high risk for ARDS. The primary efficacy endpoint will be 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 ventilations, days in the hospital, and viral load. The study is being conducted in the US, Brazil, Argentina, Mexico, Colombia and Bulgaria.

Sexual Health Division

ENTADFI™ (Tadalafil 5mg and Finasteride 5mg Capsule) for the Treatment of Benign Prostatic Hyperplasia (BPH) - PDUFA Date December 2021.

ENTADFI™ (tadalafil 5mg and finasteride 5mg combination capsule) was developed to treat urinary tract symptoms caused by BPH without adverse sexual side effects. The co-administration of tadalafil and finasteride has been shown to be more effective for the treatment of BPH than finasteride alone without causing erectile dysfunction. The PDUFA date is scheduled for December 2021. If approved, ENTADFI™ is expected to be marketed and distributed by our own "direct to patient" telemedicine and telepharmacy 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, and offer a unique cash price to ensure our treatment is more affordable and accessible. We will augment our marketing and sales efforts by seeking partners in the US and ex-US. We expect to begin commercialization in the first half of calendar year 2022.

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. 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 10161217, 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 is comprised of enobosarm, a selective androgen receptor targeting agonist, and sabizabulin, a cytoskeleton disruptor, and includes: the ongoing Phase 3 ARTEST study of enobosarm in AR+ ER+ HER2- metastatic breast cancer with AR ³ 40% (3rd line metastatic setting); the planned Phase 2b study of sabizabulin in AR+ ER+ HER2- metastatic breast cancer with AR < 40% (3rd line metastatic setting); the planned Phase 3 ENABLAR-2 study of enobosarm + abemaciclib (a CDK 4/6 inhibitor) in AR+ ER+ HER2- metastatic breast cancer with AR ³ 40% (2nd line metastatic setting); and the planned Phase 2 study of sabizabulin + enobosarm combination therapy in metastatic triple negative breast cancer after two systemic chemotherapies.

The Company's late-stage prostate cancer development portfolio is comprised of sabizabulin,VERU-100, a long-acting GnRH antagonist, and zuclomiphene citrate, an oral nonsteroidal estrogen receptor agonist and includes: the ongoing Phase 3 VERACITY and Phase 2 studies of sabizabulin in metastatic castration and androgen receptor targeting agent resistant prostate cancer prior to IV chemotherapy; the ongoing Phase 2 dose finding study of VERU-100 in advanced hormone sensitive prostate cancer; and the planned Phase 2b study of zuclomiphene citrate in men with advanced prostate cancer on androgen deprivation therapy who suffer from hot flashes.

One of the Company's anticancer drugs, sabizabulin, also has dual antiviral and anti-inflammatory effects and is currently enrolling in a Phase 3 study for the potential treatment of hospitalized COVID-19 patients at high risk for acute respiratory distress syndrome (ARDS).

Veru also has a commercial Sexual Health Division which includes a drug candidate, ENTADFI™ (tadalafil 5mg and finasteride 5mg capsule), for the treatment of benign prostatic hyperplasia with a December 2021 PDUFA date, and a commercial product, the FC2 Female Condom® (Internal Condom), an FDA-approved product 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 the Company will generate record revenue again in 2022 or grow revenue in 2022; whether the Company's current and planned clinical trials in its breast cancer and prostate cancer programs or any future clinical development and their respective results will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of the Company's drug candidates;, whether the Phase 3 study of sabizabulin for certain COVID patients will produce results similar to the results of the previous Phase 2 study, whether such data will be sufficient for approval by the FDA and whether this would satisfy any unmet need or achieve acceptance by physicians; whether the companion diagnostic for enobosarm will be developed successfully or be approved by the FDA for use; the anticipated design and scope for clinical studies and FDA acceptance of such design and scope, whether sabizabulin, enobosarm, VERU-100, zuclomiphene citrate or ENTADFI will serve any unmet need, what dosage, if any, might be approved for use in the US or elsewhere for any of the Company's drug candidates; whether any enrollment or data timelines for any of the Company's clinical studies will be met; the potential, timing and efficacy of the rest of the Company's development pipeline; whether ENTADFI will be approved by the FDA in December 2021 or ever; and whether the Company will successfully launch ENTADFI, if approved or will be successful in partnering with any other company for commercialization in or outside the U.S. 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 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 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; 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, 2020 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.

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FINANCIAL SCHEDULES FOLLOW

Veru Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	September 30, 2021	September 30, 2020
Cash and cash equivalents	$122,359,535	$ 13,588,778
Accounts receivable, net	8,794,224	5,227,237
Inventory, net	5,574,253	6,704,134
Prepaid expenses and other current assets	15,025,475	1,494,541
Total current assets	151,753,487	27,014,690
Deferred income taxes	13,024,550	9,466,800
Intangible assets, net	4,048,810	5,752,127
Goodwill	6,878,932	6,878,932
Other assets	2,440,944	2,431,126
Total assets	$178,146,723	$ 51,543,675
Accounts payable	$ 3,409,771	$ 2,812,673
Accrued expenses and other current liabilities	9,120,328	4,972,401
Credit agreement liability	—	5,841,874
Residual royalty agreement liability, short-term portion	3,237,211	1,100,193
Total current liabilities	15,767,310	14,727,141
Residual royalty agreement liability, long-term portion	9,397,136	5,617,494
Other liabilities	688,333	1,087,724
Total liabilities	25,852,779	21,432,359
Total stockholders' equity	152,293,944	30,111,316
Total liabilities and stockholders' equity	$178,146,723	$ 51,543,675

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended September 30,		Year Ended September 30,	
	2021	2020	2021	2020
Net revenues	$ 15,646,460	$ 11,749,186	$ 61,259,528	$ 42,592,060
Cost of sales	3,337,282	2,187,039	13,332,305	11,805,202
Gross profit	12,309,178	9,562,147	47,927,223	30,786,858
Operating expenses	(14,180,404)	(6,731,918)	(53,364,724)	(31,433,552)
Gain on sale of PREBOOST®	—	—	18,410,158	—
Impairment of intangible assets	—	(14,100,000)	—	(14,100,000)
Operating (loss) income	(1,871,226)	(11,269,771)	12,972,657	(14,746,694)
Non-operating expenses	(2,779,321)	(1,671,834)	(8,707,421)	(5,305,282)
(Loss) income before income taxes	(4,650,547)	(12,941,605)	4,265,236	(20,051,976)
Income tax benefit	(356,067)	(1,109,060)	(3,129,138)	(1,078,441)
Net (loss) income	$ (4,294,480)	$(11,832,545)	$ 7,394,374	$(18,973,535)
Net (loss) income per basic common share outstanding	$ (0.05)	$ (0.17)	$ 0.10	$ (0.28)
Basic weighted average common shares outstanding	79,887,081	69,863,681	76,272,853	66,753,450
Net (loss) income per diluted common share outstanding	$ (0.05)	$ (0.17)	$ 0.09	$ (0.28)
Diluted weighted average common shares outstanding	79,887,081	69,863,681	83,802,420	66,753,450

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

	Year Ended September 30,	
	2021	2020
Net income (loss)	$ 7,394,374	$(18,973,535)
Adjustments to reconcile net income (loss) to net cash used in operating activities	(15,682,840)	21,389,716
Changes in operating assets and liabilities	(7,282,558)	(4,346,276)
Net cash used in operating activities	(15,571,024)	(1,930,095)
Net cash provided by (used in) investing activities	14,623,351	(105,760)
Net cash provided by financing activities	109,718,430	9,329,481
Net increase in cash	108,770,757	7,293,626
Cash at beginning of period	13,588,778	6,295,152
Cash at end of period	$122,359,535	$ 13,588,778

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

	Three Months Ended September 30, 2021			
	Sexual Health Business	Research & Development	Corporate	Total
Net revenues				
FC2	$15,646,460	$ —	$ —	$ 15,646,460
PREBOOST®	—	—	—	—
Total net revenues	15,646,460	—	—	15,646,460
Cost of sales	3,337,282	—	—	3,337,282
Gross profit	12,309,178	—	—	12,309,178
Operating expenses	(1,097,968)	(8,427,774)	(4,654,662)	(14,180,404)
Operating income (loss)	$11,211,210	$(8,427,774)	$ (4,654,662)	$ (1,871,226)

	Three Months Ended September 30, 2020			
	Sexual Health Business	Research & Development	Corporate	Total
Net revenues				
FC2	$10,963,903	$ —	$ —	$ 10,963,903
PREBOOST®	785,283	—	—	785,283
Total net revenues	11,749,186	—	—	11,749,186
Cost of sales	2,187,039	—	—	2,187,039
Gross profit	9,562,147	—	—	9,562,147
Operating expenses	(1,119,483)	(3,264,429)	(2,348,006)	(6,731,918)
Impairment of intangible assets	—	—	(14,100,000)	(14,100,000)
Operating income (loss)	$ 8,442,664	$(3,264,429)	$(16,448,006)	$(11,269,771)

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

	Year Ended September 30, 2021			
	Sexual Health Business	Research & Development	Corporate	Total
Net revenues				
FC2	$60,396,697	$ —	$ —	$ 60,396,697
PREBOOST	862,831	—	—	862,831
Total net revenues	61,259,528	—	—	61,259,528
Cost of sales	13,332,305	—	—	13,332,305
Gross profit	47,927,223	—	—	47,927,223
Operating expenses	(3,911,302)	(33,390,115)	(16,063,307)	(53,364,724)
Gain on sale of PREBOOST®	—	—	18,410,158	18,410,158
Operating income (loss)	$44,015,921	$(33,390,115)	$ 2,346,851	$ 12,972,657

	Year Ended September 30, 2020			
	Sexual Health Business	Research & Development	Corporate	Total
Net revenues				
FC2	$40,556,818	$ —	$ —	$ 40,556,818
PREBOOST	2,035,242	—	—	2,035,242
Total net revenues	42,592,060	—	—	42,592,060
Cost of sales	11,805,202	—	—	11,805,202
Gross profit	30,786,858	—	—	30,786,858
Operating expenses	(4,291,732)	(16,871,057)	(10,270,763)	(31,433,552)
Impairment of intangible assets	—	—	(14,100,000)	(14,100,000)
Operating income (loss)	$26,495,126	$(16,871,057)	$(24,370,763)	$(14,746,694)