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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 12, 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 May 12, 2021, Veru Inc. issued a press release (the "Press Release") announcing results for the quarter and six months ended March 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 Press Release contains non-GAAP financial measures. For additional information, see "Non-GAAP Financial Information" in the Press Release.

The information in this Form 8-K and the Exhibit attached hereto 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.

The following exhibit is furnished herewith:

Exhibit No.	Document
99.1	Press Release of Veru Inc., issued May 12, 2021.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 12, 2021

VERU INC.

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

Exhibit 99.1

Contact:
Sam Fisch 800-972-0538
Director of Investor Relations

Veru Reports Strong Second-Quarter Financial Results Based on Record High FC2 Prescription Revenues

— First Patient to Be Enrolled this Week in Phase 3 Clinical Trial of Sabizabulin (VERU-111) in High Risk Hospitalized COVID-19 Patients—

--New Drug Application Accepted for Review by FDA for Proprietary TADFIN Daily Oral Dosing Combination for BPH; PDUFA Date December 2021—

—Company Poised to Enroll First Patient in Phase 3 VERACITY Clinical Trial of Sabizabulin for Metastatic Castration and AR Targeting Agent Resistant Prostate Cancer Later this Month—

—Company Anticipates Enrolling First Patient in Phase 2 Clinical Trial of VERU-100 Novel Long-Acting GnRH Antagonist Depot as Androgen Deprivation Therapy for Advanced Prostate Cancer Later this Month—

—Company to Host Investor Conference Call Today at 8 a.m.ET--

MIAMI – May 12, 2021 – Veru Inc. (NASDAQ: VERU), an oncology biopharmaceutical company with a focus on developing novel medicines for the management of prostate and breast cancer, today announced that net revenues increased 34% and gross profit rose 47% for its fiscal 2021 second quarter ended March 31, 2021, attributable to record high quarterly FC2 US prescription net revenues.

Second Quarter Financial Highlights: Fiscal 2021 vs Fiscal 2020

- Net revenues increased 34% to $13.3 million from $9.9 million
- FC2 prescription net revenues climbed 48% to $10.3 million from $7.0 million
- Gross profit rose 47% to $10.9 million from $7.4 million
- Gross margin increased to 82% of net revenues from 75% of net revenues
- Operating loss was $1.5 million versus $0.3 million
- Net loss was $2.8 million, or $0.04 per share, compared with $0.8 million, or $0.01 per share.

Year-to-Date Financial Highlights: Fiscal 2021 vs Fiscal 2020

- Net revenues increased 36% to $28.0 million from $20.5 million, a record high for thesix-month period ended March 31, 2021
- FC2 prescription net revenues climbed 49% to $19.4 million from $13.0 million
- Gross profit rose 48% to $21.7 million from $14.7 million
- Gross margin increased to 78% of net revenues from 72% of net revenues
- Operating income was $17.7 million, which includes an $18.4 million gain on the December 2020 sale of the PREBOOST business. Adjusted operating loss, which excludes the gain on the sale of the PREBOOST business, was $0.7 million versus $2.1 million

- Net income, which includes the gain on the sale of the PREBOOST business, was $14.4 million and diluted EPS was $0.18. Adjusted net loss, which excludes the gain on the sale of the PREBOOST business, was $4.0 million compared with $4.1 million and adjusted diluted loss per share was $0.06, which remained consistent with fiscal 2020.

Balance Sheet Information

- Cash and cash equivalents were $136.7 million as of March 31, 2021 versus $13.6 million as of September 30, 2020
- Net accounts receivable were $5.1 million as of March 31, 2021 versus $5.2 million as of September 30, 2020.

"We reported another great quarter largely based on all-time record high quarterly FC2 net revenues from the U.S. prescription channel," said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru Inc. "We also will be enrolling our first patient in our Phase 3 clinical trial of sabizabulin in high risk hospitalized COVID-19 patients this week. Because of sabizabulin's anti-inflammatory and anti-viral properties and its favorable safety profile, we think sabizabulin could be that desperately needed oral therapeutic to prevent deaths in hospitalized patients with moderate to severe COVID-19 disease who are at risk for Acute Respiratory Distress Syndrome (ARDS).COVID-19 remains a serious threat worldwide and effective treatments are desperately needed."

Dr. Steiner noted: "We are advancing our novel oral drug candidates for the treatment of prostate and breast advanced cancers. We plan this month to enroll our first patient in the Phase 3 VERACITY clinical trial of sabizabulin for metastatic castration and androgen receptor targeting agent resistant prostate cancer. We plan to also enroll this month our first patient in the Phase 2 clinical trial of VERU-100, a novel long-acting GnRH antagonist injection formulation for androgen deprivation therapy. Next month, the Phase 3 ARTEST enobosarm for 3rd line AR+ER+ metastatic breast cancer is also expected to start enrolling. We are now a solid late clinical stage oncology biopharmaceutical company with novel drug candidates in development."

Pharmaceutical Pipeline Highlights:

Sabizabulin (VERU-111) a Novel Oral Agent for the Treatment of Hospitalized COVID-19 Patients at High Risk for Acute Respiratory Distress Syndrome (ARDS)- Phase 3 Clinical Study.

We expect to enroll our first patient within a few days in our Phase 3 clinical trial of sabizabulin, a novel once a day orally dosed small molecule that 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 high risk hospitalized COVID-19 patients. The Phase 3 clinical trial is a double-blind, multicenter, multinational, randomized (2:1), placebo-controlled trial evaluating daily oral doses of 9 mg sabizabulin for up to 21 days versus placebo in 300 hospitalized patients (200 subjects will be treated with sabizabulin and 100 subjects will receive placebo/standard of care) who tested positive for the SARS-CoV-2 virus and who are at high risk for ARDS. Because of better oral bioavailability, the systemic blood levels from the 9 mg sabizabulin dosage are similar to the 18 mg sabizabulin formulation used in the Phase 2 clinical study. Subjects in the sabizabulin and placebo arms will also be allowed to receive standard of care. 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 will be conducted in the United States, Brazil, Argentina, Mexico, and Colombia. Enrollment is targeted to be completed by calendar year-end.

In February of this year, the Company announced positive clinical results from the Phase 2 trial evaluating sabizabulin for the treatment of hospitalized patients with COVID-19 who were at high risk for ARDS. We conducted a double-blind, randomized, placebo-controlled Phase 2 clinical trial evaluating daily oral once a day dosing of sabizabulin 18 mg versus placebo in approximately 40 hospitalized COVID-19 patients who were at high risk for ARDS. This trial was conducted in 5 sites across the United States. Patients that were hospitalized with documented evidence of COVID-19 infection with symptoms and who were at high risk for ARDS were enrolled. Subjects received either sabizabulin 18 mg or placebo as well as standard of care for 21 days or until released from hospital. The primary efficacy endpoint was the proportion of patients that were alive without respiratory failure at Day 29. For the primary endpoint in the modified intent to treat population, sabizabulin compared to placebo had a statistically significant and clinically meaningful 81% relative reduction in death or respiratory failure at Day 29. With respect to secondary endpoints, sabizabulin had a statistically significant 82% relative reduction in patient mortality and statistically significant reduction in days in ICU; there was also a decrease in days on mechanical ventilation versus placebo. Sabizabulin was well tolerated with a good safety profile.

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.

Sabizabulin is a novel, oral, new chemical entity that targets microtubules in the cytoskeleton to disrupt androgen receptor transport. We anticipate enrolling patients this month into the open label, randomized (2:1), multicenter Phase 3 VERACITY clinical trial of sabizabulin 32 mg 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. Based on the recently conducted Phase 2 PK study, the blood levels of the Phase 3 clinical trial sabizabulin 32 mg drug dose formulation are similar to the Phase 1b/2 VERU-111 63 mg dosage formulation. The primary endpoint is median radiographic progression free survival. The Phase 3 VERACITY clinical trial is expected to enroll approximately 245 patients.

In the Phase 1b /Phase 2 clinical trial in metastatic castration and androgen receptor targeting agent resistant prostate cancer, chronic daily administration of sabizabulin was well tolerated with a good safety profile. There was also evidence of efficacy including PSA declines and objective and durable tumor responses (partial and complete responses).

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.

We anticipate initiation of the Phase 2 clinical trial of VERU-100 androgen deprivation therapy for hormone sensitive advanced prostate cancer this month. The Phase 2 VERU-100 clinical trial is expected to enroll approximately 35 patients.VERU-100 formulation is designed to address the current limitations of commercially available ADT. 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 (LHRH) agonists used for ADT. There are no GnRH antagonist depot injectable formulations commercially approved beyond a one-month injection. A Phase 3 registration clinical trial in approximately 100 men is anticipated to begin in the second half of calendar year 2021.

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

We expect to commence our pivotal enobosarm Phase 3 ARTEST clinical study in the second quarter of calendar year 2021. Enobosarm is the first new class of targeting endocrine therapy in advanced breast cancer in decades. Enobosarm is an oral, new chemical entity, selective androgen receptor agonist that targets and activates the androgen receptor (AR), 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 approximately 1,450 treated subjects, 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. In the fourth quarter of calendar 2020, the FDA agreed to 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 or a SERM as an active comparator for the treatment of metastatic AR+ER+HER2- breast cancer in approximately 210 patients who have failed a nonsteroidal aromatase inhibitor, fulvestrant and a CDK4/6 inhibitor (3rd line treatment in a metastatic setting) The primary endpoint is median radiographic progression-free survival. In a separate clinical development program, enobosarm in combination with abemaciclib, CDK4/6 inhibitor, will be evaluated in a 2nd line metastatic setting in AR+ER+ metastatic breast cancer. A Phase 2 study to evaluate the efficacy and safety of enobosarm in combination with CDK 4/6 inhibitor (abemaciclib) compared to estrogen receptor blocking agent (Active Control) for the treatment of AR+/ER+/HER2- metastatic breast cancer in patients that have failed an estrogen receptor blocking agent plus a CDK 4/6 inhibitor (palbociclib) is expected to commence in calendar Q3 2021.

Sabizabulin a Novel, Oral, Cytoskeleton Disruptor Agent for the Treatment of Systemic Chemotherapy including Taxane Resistant Metastatic Triple Negative Breast Cancer – Phase 2b Clinical Study.

Sabizabulin is also being evaluated for the treatment of taxane chemotherapy resistant metastatic triple negative breast cancer in a planned Phase 2b clinical study in approximately 200 women expected to begin in calendar Q3 2021. Metastatic triple negative breast cancer is an aggressive form of breast cancer that occurs in approximately 15% of all breast cancers. This form of breast cancer does not express ER, progesterone receptor (PR), or HER2 and is resistant to endocrine therapies. The first line of treatment usually includes combination chemotherapy which includes IV taxane chemotherapy. Almost all women will eventually develop taxane resistance. 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 resistance in 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 cells and tumors that have become resistant to paclitaxel (taxane). Using the safety information from the Phase 1b and Phase 2 sabizabulin prostate cancer clinical studies, the Company plans to meet with the FDA and to commence a three cohort Phase 2b clinical study in calendar Q3 2021 to evaluate oral daily dosing of sabizabulin monotherapy, TRODELVY® monotherapy, and sabizabulin + TRODELVY combination therapy in approximately 200 women with metastatic triple negative breast cancer that have become resistant to at least 2 systemic chemotherapies including a taxane.

TADFIN™ (Tadalafil 5mg and Finasteride 5mg Combination Capsule) for the Treatment of Lower Urinary Tract Symptoms Caused by Benign Prostatic Hyperplasia (BPH) – NDA Filed by FDA; PDUFA Date December 2021.

TADFIN (tadalafil 5mg and finasteride 5mg combination capsule) was developed to treat urinary tract symptoms caused by BPH. Tadalafil (CIALIS®) is currently approved for treatment of BPH and erectile dysfunction and finasteride is currently approved for treatment of BPH (finasteride 5mg PROSCAR®) and male pattern hair loss (finasteride 1mg PROPECIA®). The co-administration of tadalafil and finasteride has been shown to be more effective for the treatment of BPH than finasteride alone with the additional benefit of ameliorating erectile dysfunction. An NDA for TADFIN has been accepted for review by FDA with a PDUFA date in December 2021. If approved, TADFIN is expected to be marketed and distributed by telemedicine and telepharmacy groups.

Legacy Female Health Business

As previously announced, the Company continues to explore the full range of strategic alternatives for its legacy Female Health Company Business, which markets the FC2 Female Condom® (Internal Condom), including continuing to operate the business.

Non-GAAP Financial Information

Certain financial results for fiscal years 2021 and 2020 are presented on both a reported and a non-GAAP, adjusted basis. Reported results were prepared in accordance with U.S. GAAP and include all revenue and expenses recognized during the period. The non-GAAP results are adjusted to exclude the one-time gain on sale of PREBOOST in the first quarter of fiscal year 2021. Management believes non-GAAP financial measures provide useful information to investors regarding the Company's results of operations and assist management, analysts, and investors in evaluating the performance of the Company's business. Non-GAAP financial measures should be considered in addition to, and not as a substitute for, measures of financial performance prepared in accordance with GAAP. The Company has reconciled these non-GAAP financial measures to the nearest reported GAAP measures in the reconciliation table below.

Event Details

Interested parties may access the call by dialing 800-341-1602 from the U.S. or 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 877-344-7529 for U.S. callers, or 412-317-0088 from outside the U.S., passcode 10154431, for one week.

About Veru Inc.

Veru Inc. is an oncology biopharmaceutical company with a focus on developing novel medicines for the management of prostate cancer and breast cancer. Veru's prostate cancer pipeline includes: sabizabulin, an oral, first-in-class, new chemical entity that targets the cytoskeleton disruptor which in prostate cancer also disrupts androgen receptor transport, is expected to commence this month a Phase 3 VERACITY clinical trial in approximately 245 men for the treatment of metastatic castration and androgen receptor targeting agent resistant prostate cancer. VERU-100, a novel, proprietary GnRH antagonist peptide long acting 3-month subcutaneous injection formulation for androgen deprivation therapy, is expected to start the planned Phase 2 clinical study this month and the Phase 3 clinical study is planned to initiate in Q4 2021 to treat hormone sensitive metastatic prostate cancer. Veru's breast cancer pipeline includes: enobosarm, an oral, first-in-class, new chemical entity, selective androgen receptor agonist that targets and activates the androgen receptor, a tumor suppressor, to treat AR+ER+HER2- metastatic breast

cancer without unwanted masculinizing side effects; Phase 3 ARTEST clinical trial to evaluate enobosarm in a 3rd line metastatic setting in approximately 210 subjects with AR+ER+HER2- advanced breast cancer who have failed nonsteroidal aromatase inhibitor, fulvestrant, and a CDK 4/6 inhibitor is anticipated to commence Q2 2021. In a separate clinical development program, a Phase 2 study to evaluate the efficacy and safety of enobosarm in combination with CDK 4/6 inhibitor(abemaciclib) compared to estrogen receptor blocking agent (Active Control) for the treatment of AR+/ER+/HER2- metastatic breast cancer in patients that have failed an estrogen receptor blocking agent plus a CDK 4/6 inhibitor (palbociclib) is expected to commence in calendar Q3 2021. Sabizabulin is also being evaluated for the treatment of systemic chemotherapy including taxane resistant metastatic triple negative breast cancer in a planned Phase 2b clinical study in approximately 200 subjects expected to begin Q3 2021. Based on positive Phase 2 results on the reduction of mortality, sabizabulin will also be evaluated in a Phase 3 trial in approximately 300 subjects for the treatment of hospitalized patients with COVID-19 who are at high risk for acute respiratory distress syndrome with enrollment starting in May 2021.

The Company's Sexual Health Business commercial product is the FC2 Female Condom® (internal condom) ("FC2"), an FDA-approved product for dual protection against unintended pregnancy and the transmission of sexually transmitted infections. The Company's Female Health Company Division markets and sells FC2 commercially and in the public health sector both in the U.S. and globally. In the U.S., FC2 is available by prescription through multiple third-party telemedicine and internet pharmacy providers and retail pharmacies. In the global public health sector, 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. The second potential product, if approved, expected for the Sexual Health Business is TADFIN™ (tadalafil 5mg and finasteride 5mg) capsule for the administration of tadalafil 5mg and finasteride 5mg combination formulation dosed daily for benign prostatic hyperplasia (BPH). An NDA was filed by FDA in April 2021 with a PDUFA date in December 2021. To learn more about Veru products, please visit www.verupharma.com.

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 potential of sabizabulin to combat COVID-19 and prevent deaths in patients with moderate to severe COVID-19 disease who are at risk for ARDS, treat metastatic castration and androgen receptor targeting agent resistant prostate cancer, and taxane resistant metastatic triple negative breast cancer, the potential for enobosarm to treat AR+ ER+HER2- metastatic breast cancer, the potential for VERU-100 as an androgen deprivation therapy for advanced prostate cancer, and the potential for TADFIN to treat BPH, whether past, current and future clinical development and results and the Company's NDA for TADFIN will demonstrate sufficient efficacy and safety to secure FDA approval of the Company's drug candidates, whether the drug candidates will serve any unmet need, whether the enrollment or commencement timelines of any of our studies will be met, statements about the potential, timing and efficacy of the rest of the Company's development pipeline, including the ability of the Company to successfully launch TADFIN, and what strategic alternatives the Company may pursue regarding its Female Health Company business.

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 take 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; 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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Veru Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	March 31, 2021	September 30, 2020
Cash and cash equivalents	$136,675,153	$ 13,588,778
Accounts receivable, net	5,149,154	5,227,237
Inventory, net	7,794,523	6,704,134
Prepaid expenses and other current assets	6,432,823	1,494,541
Total current assets	156,051,653	27,014,690
Deferred income taxes	9,435,877	9,466,800
Intangible assets, net	4,084,524	5,752,127
Goodwill	6,878,932	6,878,932
Other assets	4,700,263	2,431,126
Total assets	$181,151,249	$ 51,543,675
Accounts payable	$ 5,722,391	$ 2,812,673
Accrued research and development costs	1,100,410	934,110
Accrued expenses and other current liabilities	4,770,892	4,038,291
Credit agreement liability	4,467,766	5,841,874
Residual royalty agreement liability, short-term portion	2,805,741	1,100,193
Total current liabilities	18,867,200	14,727,141
Residual royalty agreement liability, long-term portion	5,911,983	5,617,494
Other liabilities	876,060	1,087,724
Total liabilities	25,655,243	21,432,359
Total stockholders' equity	155,496,006	30,111,316
Total liabilities and stockholders' equity	$181,151,249	$ 51,543,675

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended March 31,		Six Months Ended March 31,	
	2021	2020	2021	2020
Net revenues	$ 13,340,487	$ 9,943,104	$ 27,957,476	$ 20,521,120
Cost of sales	2,432,187	2,506,606	6,212,543	5,815,527
Gross profit	10,908,300	7,436,498	21,744,933	14,705,593
Operating expenses	(12,379,710)	(7,736,176)	(22,439,344)	(16,789,664)
Gain on sale of PREBOOST®	—	—	18,410,158	—
Operating (loss) income	(1,471,410)	(299,678)	17,715,747	(2,084,071)
Non-operating expenses	(1,352,881)	(643,971)	(3,234,035)	(2,241,422)
(Loss) income before income taxes	(2,824,291)	(943,649)	14,481,712	(4,325,493)
Income tax expense (benefit)	21,690	(133,140)	99,992	(209,883)
Net (loss) income	$ (2,845,981)	$ (810,509)	$ 14,381,720	$ (4,115,610)
Net (loss) income per basic common share outstanding	$ (0.04)	$ (0.01)	$ 0.20	$ (0.06)
Basic weighted average common shares outstanding	75,175,077	65,367,493	72,717,621	65,202,103
Net (loss) income per diluted common share outstanding	$ (0.04)	$ (0.01)	$ 0.18	$ (0.06)
Diluted weighted average common shares outstanding	75,175,077	65,367,493	80,654,070	65,202,103

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

	Six Months Ended March 31,	
	2021	**2020**
Net income (loss)	$ 14,381,720	$(4,115,610)
Adjustments to reconcile net income (loss) to net cash used in operating activities	(15,606,848)	3,951,890
Changes in operating assets and liabilities	(705,137)	(4,763,771)
Net cash used in operating activities	(1,930,265)	(4,927,491)
Net cash provided by (used in) investing activities	14,987,882	(54,680)
Net cash provided by financing activities	110,028,758	1,244,533
Net increase (decrease) in cash	123,086,375	(3,737,638)
Cash at beginning of period	13,588,778	6,295,152
Cash at end of period	$136,675,153	$ 2,557,514

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

	Three Months Ended March 31, 2021			
	Sexual Health Business	Research & Development	Corporate	Total
Net revenues				
FC2	$13,340,487	$ —	$ —	$ 13,340,487
PREBOOST®	—	—	—	—
Total net revenues	13,340,487	—	—	13,340,487
Cost of sales	2,432,187	—	—	2,432,187
Gross profit	10,908,300	—	—	10,908,300
Operating expenses	(979,295)	(7,741,348)	(3,659,067)	(12,379,710)
Operating income (loss)	$ 9,929,005	$(7,741,348)	$(3,659,067)	$ (1,471,410)

	Three Months Ended March 31, 2020			
	Sexual Health Business	Research & Development	Corporate	Total
Net revenues				
FC2	$ 9,522,271	$ —	$ —	$ 9,522,271
PREBOOST®	420,833	—	—	420,833
Total net revenues	9,943,104	—	—	9,943,104
Cost of sales	2,506,606	—	—	2,506,606
Gross profit	7,436,498	—	—	7,436,498
Operating expenses	(1,102,612)	(3,884,272)	(2,749,292)	(7,736,176)
Operating income (loss)	$ 6,333,886	$(3,884,272)	$(2,749,292)	$ (299,678)

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

	Six Months Ended March 31, 2021			
	Sexual Health Business	Research & Development	Corporate	Total
Net revenues				
FC2	$27,094,645	$ —	$ —	$ 27,094,645
PREBOOST	862,831	—	—	862,831
Total net revenues	27,957,476	—	—	27,957,476
Cost of sales	6,212,543	—	—	6,212,543
Gross profit	21,744,933	—	—	21,744,933
Operating expenses	(1,900,992)	(13,600,185)	(6,938,167)	(22,439,344)
Gain on sale of PREBOOST®	—	—	18,410,158	18,410,158
Operating income (loss)	$19,843,941	$(13,600,185)	$11,471,991	$ 17,715,747

	Six Months Ended March 31, 2020			
	Sexual Health Business	Research & Development	Corporate	Total
Net revenues				
FC2	$19,947,195	$ —	$ —	$ 19,947,195
PREBOOST	573,925	—	—	573,925
Total net revenues	20,521,120	—	—	20,521,120
Cost of sales	5,815,527	—	—	5,815,527
Gross profit	14,705,593	—	—	14,705,593
Operating expenses	(2,402,644)	(9,174,131)	(5,212,889)	(16,789,664)
Gain on sale of PREBOOST®	—	—	—	—
Operating income (loss)	$12,302,949	$ (9,174,131)	$ (5,212,889)	$ (2,084,071)

Veru Inc.
Reconciliation of GAAP Reported to Non-GAAP Adjusted Information
(unaudited)

	Three Months Ended March 31,		Six Months Ended March 31,	
	2021	2020	2021	2020
Operating (loss) income reconciliation:				
GAAP operating (loss) income	$ (1,471,410)	$ (299,678)	$ 17,715,747	$ (2,084,071)
Gain on sale of PREBOOST®	—	—	(18,410,158)	—
Non-GAAP adjusted operating loss	$ (1,471,410)	$ (299,678)	$ (694,411)	$ (2,084,071)
Net (loss) income reconciliation:				
GAAP net (loss) income	$ (2,845,981)	$ (810,509)	$ 14,381,720	$ (4,115,610)
Gain on sale of PREBOOST®	—	—	(18,410,158)	—
Non-GAAP adjusted net loss	$ (2,845,981)	$ (810,509)	$ (4,028,438)	$ (4,115,610)
Net (loss) income per diluted common share outstanding reconciliation:				
GAAP net (loss) income per diluted common share outstanding	$ (0.04)	$ (0.01)	$ 0.18	$ (0.06)
Gain on sale of PREBOOST®	—	—	(0.23)	—
Effect of antidilutive shares	—	—	(0.01)	—
Non-GAAP adjusted net loss per diluted common share outstanding	$ (0.04)	$ (0.01)	$ (0.06)	$ (0.06)
GAAP diluted weighted average common shares outstanding	75,175,077	65,367,493	80,654,070	65,202,103
Potentially dilutive shares that are antidilutive due to net loss	—	—	(7,936,449)	—
Non-GAAP diluted weighted average common shares outstanding	75,175,077	65,367,493	72,717,621	65,202,103