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

FORM 8-K

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

Date of Report (Date of earliest event reported): August 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 August 12, 2021, Veru Inc. issued a press release (the "Press Release") announcing results for the quarter and nine months ended June 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 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, including Exhibit 99.1 furnished herewith, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

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

VERU INC.

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

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

Veru Sets Another Quarterly Record in Both Net Revenues and in Gross Profit for Fiscal 2021 Third Quarter

—Q3 FY21 Net Revenues Increase 71% to $18M and Gross Profit Increases 113% to $14M, Achieving New Historical Highs—

—Nine-Month FY21 Year to Date Net Revenues Increased 48% to $46M, also a Record High, Even Exceeding Any Prior Full Fiscal Year Net Revenues—

—Late Clinical Stage Oncology Drug Pipeline Focused on Prostate and Breast Cancers Continues its Significant Advance—

—Phase 3 COVID-19 Clinical Trial to Treat Hospitalized Patients at Risk for Acute Respiratory Distress Syndrome on Track and Enrolling in the United States and South America—

—Company Initiated Phase 3 VERACITY Clinical Trial for Metastatic Castration Resistant Prostate Cancer and Phase 2VERU-100 Clinical Trial for Advanced Prostate Cancer During Past Quarter—

—Phase 3 ARTEST Clinical Trial for 3rd line AR+ ER+ Metastatic Breast Cancer, Phase 2b Combination Clinical Trial for 2nd Line AR+ ER+ Metastatic Breast Cancer, and Phase 2b Clinical Trial for Metastatic Triple Negative Breast Cancer Expected to Start 2H of Calendar Year—

—TADFIN for the Treatment of Benign Prostatic Hyperplasia PDUFA Date is On Track for December 2021—

—Cash and Cash Equivalents were $123M as of June 30, 2021—

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

MIAMI – August 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 71% and gross profit rose 113% for its fiscal 2021 third quarter ended June 30, 2021, setting new quarterly records for both net revenues and gross profit.

Third Quarter Financial Highlights: Fiscal 2021 vs Fiscal 2020

- Net revenues increased 71% to $17.7 million from $10.3 million
- FC2 prescription net revenues climbed 150% to $13.5 million from $5.4 million
- Gross profit rose 113% to $13.9 million from $6.5 million
- Gross margin increased to 79% of net revenues from 63% of net revenues
- Operating loss was $2.9 million versus $1.4 million
- Net loss was $2.7 million, or $0.03 per share, compared with $3.0 million, or $0.05 per share.

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

- Net revenues increased 48% to $45.6 million from $30.8 million, a record high not only for the nine-month period ended June 30, 2021, but also a record high when compared to any prior full fiscal year
- FC2 prescription net revenues climbed 79% to $32.9 million from $18.4 million
- Gross profit rose 68% to $35.6 million from $21.2 million
- Gross margin increased to 78% of net revenues from 69% of net revenues
- Operating income was $14.8 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 $3.6 million versus $3.5 million
- Net income, which includes the gain on the sale of the PREBOOST business, was $11.7 million and diluted EPS was $0.14. Adjusted net loss, which excludes the gain on the sale of the PREBOOST business, was $6.7 million compared with $7.1 million and adjusted diluted loss per share was $0.09, compared with $0.11 per share

Balance Sheet Information

- Cash and cash equivalents were $123.2 million as of June 30, 2021, versus $13.6 million as of September 30, 2020
- Net accounts receivable were $8.3 million as of June 30, 2021, versus $5.2 million as of September 30, 2020

“We reported another record quarter based on all-time high quarterly and year to date FC2 net revenues from the U.S. business,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru Inc. “We have enjoyed having this significant revenue stream to invest in our pharmaceutical programs. In fact, we have made great progress advancing our late-stage drug pipeline this past quarter, as we have initiated and are actively enrolling our: (i) Phase 3 VERACITY clinical trial of sabizabulin for metastatic castration and androgen receptor targeting agent resistant prostate cancer; (ii) Phase 2 clinical trial of VERU-100, a novel long-acting GnRH antagonist injection formulation for androgen deprivation therapy for advanced prostate cancer, and (iii) Phase 3 clinical trial of sabizabulin in hospitalized patients with COVID-19 at high risk for ARDS. Unfortunately, yet another COVID-19 viral infection wave has hit the United States and globally, making ourCOVID-19 drug development program highly relevant and timely as COVID-19 remains a severe threat with few effective therapies to complement theCOVID-19 vaccination strategy.”

Dr. Steiner further noted: “We are also making significant progress on our novel oral drug candidates for the treatment of advanced breast cancer. In the second half of the calendar year, we anticipate starting our: (i) Phase 3 ARTEST clinical trial of enobosarm monotherapy in a 3rd line metastatic setting in AR+ER+HER2- metastatic breast cancer; (ii) Phase 2b clinical trial of enobosarm in combination with abemaciclib, CDK 4/6 inhibitor, in a 2nd line metastatic setting in AR+ER+HER2- metastatic breast cancer; and (iii) Phase 2b clinical trial evaluating sabizabulin monotherapy and sabizabulin + Trodelvy® (sacituzumab govitecan-hziy) combination therapy versus Trodelvy® monotherapy in metastatic triple negative breast cancer. We have solidly transformed Veru into a premium oncology biopharmaceutical company seeking large market opportunities.”

Pharmaceutical Pipeline Highlights:

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 trial evaluating sabizabulin 32mg versus an alternative androgen receptor targeting agent for the treatment of chemotherapy naïve men with metastatic castration resistant prostate cancer who have failed at least one androgen receptor targeting agent. The primary endpoint is median radiographic progression free survival. The Phase 3 VERACITY clinical trial 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.

In June, the Company initiated the Phase 2 clinical trial of VERU-100 androgen deprivation therapy for hormone sensitive advanced prostate cancer. 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 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. A Phase 3 registration clinical trial has been agreed upon with FDA and will enroll approximately 100 men. The Phase 3 clinical study is anticipated to begin in Q4 calendar year 2021.

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 – Phase 3 ARTEST Clinical Study.

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 and activates 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. The Phase 3 multicenter, international, open label, and randomized (1:1) ARTEST registration clinical trial is designed to evaluate the efficacy and safety of enobosarm monotherapy versus physician's choice of either exemestane ± everolimus or a SERM as an active comparator for the 3rd line 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. The primary endpoint is median radiographic progression-free survival. We expect to commence our pivotal enobosarm Phase 3 ARTEST clinical study in the second half of calendar year 2021.

Enobosarm in Combination with Abemaciclib, CDK 4/6 Inhibitor, for the 2nd Line Treatment of AR+ER+HER2- Metastatic Breast Cancer- Phase 2b 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 evaluate as 2nd line treatment in the metastatic setting the addition of enobosarm in combination with a CDK 4/6 inhibitor (abemaciclib) in a Phase 2b clinical study in subjects with AR+ER+HER2 metastatic breast cancer that have experienced disease progression on 1st line palbociclib + estrogen blocking agent in approximately 186 patients. The Phase 2b clinical study is expected to commence in calendar 2H 2021.

Sabizabulin, Novel Oral Cytoskeleton Disruptor Agent, Versus Trodelvy® for the Treatment of Metastatic Triple Negative Breast Cancer- Phase 2b 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). A three cohort Phase 2b clinical study is planned to start in calendar Q3 2021 to evaluate sabizabulin monotherapy and sabizabulin + Trodelvy® combination therapy versus Trodelvy® monotherapy in approximately 216 women with metastatic triple negative breast cancer that have become resistant to at least 2 systemic chemotherapies.

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.

In May, we initiated our Phase 3 clinical trial of sabizabulin, which has both broad anti-viral and anti-inflammatory activities and 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 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 placebo/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 United States, Brazil, Argentina, Mexico, and Colombia.

Benign Prostatic Hyperplasia Program

TADFIN™ (Tadalafil 5mg and Finasteride 5mg Combination Capsule) for the Treatment of Benign Prostatic Hyperplasia (BPH)—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. The PDUFA date is scheduled for December 2021. If approved, we expect to market and distribute TADFIN by telemedicine and telepharmacy sales channels.

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 10157539, 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 which in prostate cancer also disrupts the transport of the androgen receptor. A Phase 3 VERACITY clinical trial evaluating the efficacy and safety of sabizabulin in approximately 245 men for the treatment of metastatic castration and androgen receptor targeting agent resistant prostate cancer is enrolling. VERU-100, a novel, proprietary gonadotropin releasing hormone antagonist peptide long acting 3-month subcutaneous injection formulation for androgen deprivation therapy to treat hormone sensitive advanced prostate cancer, is currently enrolling in a Phase 2 clinical trial, and the Phase 3 clinical trial is planned to initiate in calendar Q4 2021. Veru's breast cancer pipeline includes: enobosarm, an oral, first-in-class, new chemical entity, selective androgen receptor agonist that targets the androgen receptor, a tumor suppressor, to treat AR+ER+HER2- metastatic breast cancer without unwanted masculinizing side effects. The enobosarm clinical program is initially focusing on 2 indications: 1) Phase 3 ARTEST clinical trial to evaluate enobosarm monotherapy in a 3rd line metastatic setting in approximately 210 subjects with AR+ER+HER2- metastatic breast cancer (³ 40% AR positivity) who have failed nonsteroidal aromatase inhibitor, fulvestrant, and a CDK 4/6 inhibitor which is anticipated to commence calendar 2H 2021; 2) Phase 2b study to evaluate the efficacy and safety of enobosarm and CDK 4/6 inhibitor, abemaciclib, combination compared to estrogen blocking agent (Active Control) for the treatment of AR+ER+HER2- metastatic breast cancer in a 2nd line metastatic setting in approximately 186 patients who have failed 1st line treatment in a metastatic setting with CDK 4/6 inhibitor, palbociclib, in combination with either an aromatase inhibitor or fulvestrant which is expected

to commence in calendar 2H 2021. Sabizabulin will also be evaluated in a three arm Phase 2b clinical study planned to initiate in calendar Q3 2021 to evaluate oral daily dosing of sabizabulin monotherapy and sabizabulin + Trodelvy® (sacituzumab govitecan-hziy) combination therapy versus Trodelvy® monotherapy in approximately 216 women with metastatic triple negative breast cancer that have become resistant to at least two systemic chemotherapies. Based on positive Phase 2 results on the reduction of mortality, sabizabulin is also being evaluated in a Phase 3 clinical trial for the treatment of hospitalized patients with moderate to severe COVID-19 who are at high risk for acute respiratory distress syndrome in approximately 300 subjects and is currently enrolling in the United States and South America.

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 commercial product, if approved, expected for the Sexual Health Business is TADFIN™ (tadalafil 5mg and finasteride 5mg capsule) dosed daily for benign prostatic hyperplasia (BPH). PDUFA date for the NDA is in December 2021. The Company plans to initially launch through telemedicine and telepharmacy sales channels. 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 as either a monotherapy or a combination therapy 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, the expected timing of the PDUFA date for TADFIN, 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.

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 Form10-Q. These documents are available on the "SEC Filings" section of our website at www.verupharma.com/investors. The Company disclaims any intent or obligation to update these forward-looking statements.

Trodelvy® (sacituzumab govitecan-hziy) is a registered trademark of Gilead Sciences, Inc.

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FINANCIAL SCHEDULES FOLLOW

Veru Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	June 30, 2021	September 30, 2020
Cash and cash equivalents	$123,155,968	$ 13,588,778
Accounts receivable, net	8,313,543	5,227,237
Inventory, net	6,945,916	6,704,134
Prepaid expenses and other current assets	15,990,107	1,494,541
Total current assets	154,405,534	27,014,690
Deferred income taxes	12,379,578	9,466,800
Intangible assets, net	4,066,667	5,752,127
Goodwill	6,878,932	6,878,932
Other assets	2,342,372	2,431,126
Total assets	$180,073,083	$ 51,543,675
Accounts payable	$ 4,927,680	$ 2,812,673
Accrued expenses and other current liabilities	7,719,489	4,972,401
Credit agreement liability	884,917	5,841,874
Residual royalty agreement liability, short-term portion	3,679,871	1,100,193
Total current liabilities	17,211,957	14,727,141
Residual royalty agreement liability, long-term portion	7,100,145	5,617,494
Other liabilities	792,703	1,087,724
Total liabilities	25,104,805	21,432,359
Total stockholders' equity	154,968,278	30,111,316
Total liabilities and stockholders' equity	$180,073,083	$ 51,543,675

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2021	2020	2021	2020
Net revenues	$ 17,655,592	$10,321,754	$ 45,613,068	$ 30,842,874
Cost of sales	3,782,480	3,802,636	9,995,023	9,618,163
Gross profit	13,873,112	6,519,118	35,618,045	21,224,711
Operating expenses	(16,744,976)	(7,911,970)	(39,184,320)	(24,701,634)
Gain on sale of PREBOOST®	—	—	18,410,158	—
Operating (loss) income	(2,871,864)	(1,392,852)	14,843,883	(3,476,923)
Non-operating expenses	(2,694,065)	(1,392,026)	(5,928,100)	(3,633,448)
(Loss) income before income taxes	(5,565,929)	(2,784,878)	8,915,783	(7,110,371)
Income tax (benefit) expense	(2,873,063)	240,502	(2,773,071)	30,619
Net (loss) income	$ (2,692,866)	$ (3,025,380)	$ 11,688,854	$ (7,140,990)
Net (loss) income per basic common share outstanding	$ (0.03)	$ (0.05)	$ 0.16	$ (0.11)
Basic weighted average common shares outstanding	79,729,370	66,728,782	75,054,871	65,709,139
Net (loss) income per diluted common share outstanding	$ (0.03)	$ (0.05)	$ 0.14	$ (0.11)
Diluted weighted average common shares outstanding	79,729,370	66,728,782	82,807,156	65,709,139

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

	Nine Months Ended June 30,	
	2021	**2020**
Net income (loss)	$ 11,688,854	$ (7,140,990)
Adjustments to reconcile net income (loss) to net cash used in operating activities	(17,904,260)	6,176,292
Changes in operating assets and liabilities	(8,549,150)	(624,286)
Net cash used in operating activities	(14,764,556)	(1,588,984)
Net cash provided by (used in) investing activities	14,845,584	(73,444)
Net cash provided by financing activities	109,486,162	10,761,699
Net increase in cash	109,567,190	9,099,271
Cash at beginning of period	13,588,778	6,295,152
Cash at end of period	$123,155,968	$15,394,423

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

	Three Months Ended June 30, 2021			
	Sexual Health Business	Research & Development	Corporate	Total
Net revenues				
FC2	$17,655,592	$ —	$ —	$ 17,655,592
PREBOOST®	—	—	—	—
Total net revenues	17,655,592	—	—	17,655,592
Cost of sales	3,782,480	—	—	3,782,480
Gross profit	13,873,112	—	—	13,873,112
Operating expenses	(912,342)	(11,362,155)	(4,470,479)	(16,744,976)
Operating income (loss)	$12,960,770	$(11,362,155)	$(4,470,479)	$ (2,871,864)

	Three Months Ended June 30, 2020			
	Sexual Health Business	Research & Development	Corporate	Total
Net revenues				
FC2	$ 9,645,720	$ —	$ —	$ 9,645,720
PREBOOST®	676,034	—	—	676,034
Total net revenues	10,321,754	—	—	10,321,754
Cost of sales	3,802,636	—	—	3,802,636
Gross profit	6,519,118	—	—	6,519,118
Operating expenses	(769,605)	(4,432,497)	(2,709,868)	(7,911,970)
Operating income (loss)	$ 5,749,513	$ (4,432,497)	$(2,709,868)	$ (1,392,852)

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

	Nine Months Ended June 30, 2021			
	Sexual Health Business	Research & Development	Corporate	Total
Net revenues				
FC2	$44,750,237	$ —	$ —	$ 44,750,237
PREBOOST	862,831	—	—	862,831
Total net revenues	45,613,068	—	—	45,613,068
Cost of sales	9,995,023	—	—	9,995,023
Gross profit	35,618,045	—	—	35,618,045
Operating expenses	(2,813,334)	(24,962,340)	(11,408,646)	(39,184,320)
Gain on sale of PREBOOST®	—	—	18,410,158	18,410,158
Operating income (loss)	$32,804,711	$(24,962,340)	$ 7,001,512	$ 14,843,883

	Nine Months Ended June 30, 2020			
	Sexual Health Business	Research & Development	Corporate	Total
Net revenues				
FC2	$29,592,915	$ —	$ —	$ 29,592,915
PREBOOST	1,249,959	—	—	1,249,959
Total net revenues	30,842,874	—	—	30,842,874
Cost of sales	9,618,163	—	—	9,618,163
Gross profit	21,224,711	—	—	21,224,711
Operating expenses	(3,172,250)	(13,606,628)	(7,922,756)	(24,701,634)
Gain on sale of PREBOOST®	—	—	—	—
Operating income (loss)	$18,052,461	$(13,606,628)	$ (7,922,756)	$ (3,476,923)

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

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2021	2020	2021	2020
Operating (loss) income reconciliation:				
GAAP operating (loss) income	$ (2,871,864)	$ (1,392,852)	$ 14,843,883	$ (3,476,923)
Gain on sale of PREBOOST®	—	—	(18,410,158)	—
Non-GAAP adjusted operating loss	$ (2,871,864)	$ (1,392,852)	$ (3,566,275)	$ (3,476,923)
Net (loss) income reconciliation:				
GAAP net (loss) income	$ (2,692,866)	$ (3,025,380)	$ 11,688,854	$ (7,140,990)
Gain on sale of PREBOOST®	—	—	(18,410,158)	—
Non-GAAP adjusted net loss	$ (2,692,866)	$ (3,025,380)	$ (6,721,304)	$ (7,140,990)
Net (loss) income per diluted common share outstanding reconciliation:				
GAAP net (loss) income per diluted common share outstanding	$ (0.03)	$ (0.05)	$ 0.14	$ (0.11)
Gain on sale of PREBOOST®	—	—	(0.22)	—
Effect of antidilutive shares	—	—	(0.01)	—
Non-GAAP adjusted net loss per diluted common share outstanding	$ (0.03)	$ (0.05)	$ (0.09)	$ (0.11)
GAAP diluted weighted average common shares outstanding	79,729,370	66,728,782	82,807,156	65,709,139
Potentially dilutive shares that are antidilutive due to net loss	—	—	(7,752,285)	—
Non-GAAP diluted weighted average common shares outstanding	79,729,370	66,728,782	75,054,871	65,709,139