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): February 10, 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 February 10, 2021, Veru Inc. issued a press release (the "Press Release") announcing results for the three months ended December 31, 2020. 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 February 10, 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: February 10, 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 First Quarter

—Q1 FY21 Net Revenues and Gross Profit of $15M and $11M, Respectively, Achieve New Historical Highs for Second Consecutive Quarter—

—Late Clinical Stage Oncology Drug Pipeline Focused on Prostate and Breast Cancers Continues to Advance to Registration Phase 3 Clinical Studies—

—Company Reports Positive Results from Phase 2 Clinical Trial Evaluating VERU-111 for the Treatment of Hospitalized COVID-19 Patients at High Risk for ARDS—

—Company Anticipates Submitting TADFIN New Drug Application with FDA Next Week—

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

MIAMI – February 10, 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 38% and gross profit rose 49% for its fiscal 2021 first quarter ended December 31, 2020, setting new quarterly records for its second consecutive quarter and entering its fourth year of revenue growth.

First-Quarter Financial Highlights: Fiscal 2021 vs Fiscal 2020

- Net revenues increased 38% to $14.6 million from $10.6 million
- FC2 prescription net revenues climbed 50% to $9.1 million from $6.1 million
- Gross profit rose 49% to $10.8 million from $7.3 million
- Gross margin increased to 74% of net revenues from 69% of net revenues
- Operating income was $19.2 million, which includes an $18.4 million gain on sale of the PREBOOST® business. Adjusted operating income, which excludes the gain on sale of PREBOOST, was $0.8 million versus an operating loss of $1.8 million
- Net income, which includes the gain on sale of PREBOOST, was $17.2 million and diluted EPS was $0.23. Adjusted net loss, which excludes the gain on sale of PREBOOST, was $1.2 million compared with $3.3 million and adjusted diluted loss per share was $0.02, compared with $0.05 per share.

Balance Sheet Information

- Cash and cash equivalents were $30.9 million as of December 31, 2020 versus $13.6 million as of September 30, 2020
- Net accounts receivable were $4.2 million as of December 31, 2020 versus $5.2 million as of September 30, 2020

“During this quarter we reported another consecutive quarterly record both in net revenues and in gross profit driven primarily by the 50% growth in prescription sales of FC2,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru. “We plan to submit the TADFIN NDA next week which, if approved by the FDA, will add to the already significant cash being generated by the FC2 business to invest in the clinical development of our late-stage prostate and breast cancer drug pipeline. We are off to a great start for fiscal 2021.”

“Furthermore, I could not be more pleased with Veru’s progress in developing new and novel oral therapies to treat both prostate and breast advanced cancers that have become resistant to current endocrine therapies, but prior to proceeding to IV chemotherapy. We are excited to be driving our prostate cancer drug candidates, VERU-111 and VERU-100, as well as our breast cancer drug candidates, Enobosarm andVERU-111 for triple negative breast cancer, into registration clinical studies. Now with the positive clinical efficacy and safety results from the Phase 2 clinical study that evaluated VERU-111 treatment in hospitalized patients with COVID-19 and at high risk for ARDS, Veru anticipates the potential for five registration clinical trials for one COVID-19 and four oncology indications to commence in calendar year 2021.”

Pharmaceutical Pipeline Highlights:

TADFIN™ (Tadalafil 5mg and Finasteride 5mg Combination Capsule) for the Treatment of Lower Urinary Tract Symptoms Caused by Benign Prostatic Hyperplasia (BPH)

We expect to submit the NDA for TADFIN next week. We received a waiver of the FDA NDA PDUFA filing fees as a first-time filer worth approximately $2.4 million in cost savings. We plan to launch TADFIN, which contains finasteride (approved for BPH) and tadalafil (approved for BPH and erectile dysfunction), for the indication to treat BPH, if approved by FDA. We intend to launch TADFIN through third-party telemedicine sales channels and not have to invest in our own TADFIN sales organization. This is the same sales model that has been successful for FC2, and previously, for PREBOOST.

VERU-111, a Novel, Oral, Targeted Cytoskeleton Disruptor, for the Treatment of Metastatic Castration and Androgen Receptor Targeting Agent Resistant Prostate Cancer

The Phase 2 clinical trial ofVERU-111 for the treatment of metastatic castration and androgen receptor targeting agent resistant prostate cancer is fully enrolled. Although the study is still ongoing, daily chronic drug administration continues to appear feasible and safe. At 63mg daily continuous oral once-a-day dosing, there were no reports of neutropenia, a single report of minor neurotoxicity, and manageable and fewer cases oflow-grade diarrhea. Like the Phase 1b, we have observed efficacy results including PSA declines as well as objective and durable tumor responses including complete and partial responses. We will be presenting updated clinical results for the Phase 1b and as well as an update on the Phase 2 clinical trials at the ASCO Genitourinary Cancers Symposium: “Abstract 325053: Clinical study of VERU-111, an oral cytoskeletal disruptor, in metastatic castration-resistant prostate cancer who failed an androgen receptor targeting agent” by Dr. Mark Markowski, Assistant Professor of Oncology, Johns Hopkins Kimmel Comprehensive Cancer Center, taking place February 11th-13th, 2021.

The Company has submitted its Phase 3 clinical registration protocol to evaluateVERU-111 for the treatment of men with metastatic castration resistant prostate cancer who have failed one androgen receptor targeting agent, but prior to IV chemotherapy. The Company anticipates starting the VERACITY Phase 3 study in the first quarter of calendar year 2021.

VERU-100, a Novel, Proprietary Long-Acting Gonadotropin-Releasing Hormone (GnRH) Antagonist Peptide, 3-Month Subcutaneous Depot Formulation, for Androgen Deprivation Therapy (ADT) for Advanced Prostate Cancer

VERU-100 is designed to address the current limitations of commercially available androgen deprivation therapies. ADT is currently the mainstay of advanced prostate cancer treatment and used as a foundation of treatment throughout the course of the disease. Furthermore, ADT is continued even as other endocrine, chemotherapy, and/or radiation treatments are added or stopped. The specific target product profile for 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 is expected to immediately suppress testosterone with no testosterone surge upon initial or repeated administration, a concern that occurs with currently approved luteinizing hormone-releasing hormone agonists used for ADT. There are no GnRH antagonist depot injectable formulations commercially approved for treatment beyond a one-month duration. A Phase 2 study to evaluate VERU-100 dosing is anticipated to begin the first half of calendar year 2021 and the Phase 3 registration study in approximately 100 men is anticipated to start in the second half of calendar year 2021.

Enobosarm, Selective AR Targeted Agent, to Treat Estrogen Receptor Targeted Agent and CDK4/6 Inhibitor Resistant AR+/ ER+/HER2- Metastatic Breast Cancer

Enobosarm, our oral, first-in-class, new chemical entity, is a selective androgen receptor targeted activating agent that is being developed for the treatment of AR+/ER+/HER2- metastatic breast cancer, that has become resistant to estrogen endocrine therapy and CDK 4/6 inhibitors, but prior to IV chemotherapy. Enobosarm, by targeting and activating the AR which is present in up to 85% of advanced ER+ positive breast cancers, represents the first new class of targeting endocrine therapy in advanced breast cancer in decades. The androgen receptor acts as a tumor suppressor in ER+ breast cancer. Enobosarm activates the AR in breast cancer to inhibit AR+ ER+ breast cancer cell proliferation and tumor growth including when ER+ breast cancer has become resistant to estrogen receptor targeting agents and CDK 4/6 inhibitors. Enobosarm could have additional beneficial clinical properties. For example, preclinical studies have shown that enobosarm builds and heals cortical and trabecular bone with the potential to treat osteoporosis and skeletal related cancer events. Enobosarm has also been shown to build muscle, to reduce fat, and to improve physical function in clinical studies involving elderly subjects and patients with cancer cachexia, including breast cancer. Furthermore, the tissue selectivity of enobosarm also results in a favorable side effect profile with no masculinization (facial hair and acne), no increase in hematocrit, and no liver toxicity. Two positive Phase 2 studies involving approximately 150 women with AR+/ER+ metastatic breast cancer have been conducted. Enobosarm AR targeted treatment demonstrated favorable clinical benefit rates, objective and durable tumor responses in women with heavily pretreated estrogen receptor targeted resistant AR+ ER+ metastatic breast cancer. Quality of life measurements demonstrated overall improvement including mobility, anxiety/depression and pain. Enobosarm appears safe and well tolerated without virilizing effects, increase in hematocrit, or liver toxicity.

FDA agreed to our enobosarm Phase 3 registration clinical trial to evaluate the efficacy and safety of enobosarm 9mg versus an active control (either exemestane or tamoxifen) 2:1 randomization for the treatment of metastatic AR+/ER+/HER2- breast cancer in approximately 240 patients who have failed a nonsteroidal aromatase inhibitor (anastrozole or letrozole), fulvestrant, and a CDK4/6 inhibitor. The Phase 3 study will be called the ARTEST study. The primary endpoint is radiographic progression-free survival. Our enobosarm key opinion leaders have been particularly intrigued by the preclinical data that showed that the combination of enobosarm and a CDK4/6 inhibitor restored CDK4/6 sensitivity in AR+/ER+ metastatic breast cancer that was resistant to both estrogen receptor targeted agents and CDK4/6 inhibitors, which is the target patient population in our planned Phase 3 ARTEST clinical study. Consequently, we plan to add a third arm to our Phase 3 trial which would be a combination of

enobosarm plus a CDK 4/6 inhibitor. The Phase 3 ARTEST trial will now have three treatment arms: enobosarm alone, enobosarm in combination with a CDK4/6 inhibitor, and active control of either exemestane or tamoxifen. The trial sample size will remain the same at approximately 240 women but randomized 1:1:1 instead of the 2:1 in the previous Phase 2 clinical trial design. The pivotal Phase 3, open label, randomized, active control ARTEST study is anticipated to commence next quarter.

VERU-111 for Taxane Resistant Metastatic Triple Negative Breast Cancer

Metastatic triple negative breast cancer (TNBC) is an aggressive form of breast cancer that is present in approximately 15% of all breast cancers. This form of breast cancer does not express ER, PR or HER2 and is resistant to endocrine therapies. The first line of treatment usually includes IV taxane chemotherapy. Almost all these women will develop taxane resistance and could be a candidate for VERU-111. Preclinical studies in human triple negative breast cancer grown in animal models demonstrate that VERU-111 significantly inhibits cancer proliferation, migration, metastases, and invasion of triple negative breast cancer cells and tumors that have become resistant to paclitaxel, which is a taxane.

Using the safety information from the Phase 1b and Phase 2VERU-111 prostate cancer clinical studies in a total of approximately 80 men, we will meet with FDA in the first half of calendar year 2021 to discuss Phase 2b clinical trial design for possible accelerated approval for VERU-111 versus active control Trodelvy for patients with taxane resistant triple negative breast cancer, making the proposed trial a potential registration trial. The Phase 2b clinical study is planned to commence in the second half of calendar year 2021.

VERU-111 for COVID-19

This past Monday we announced positive results from the Phase 2 clinical trial evaluatingVERU-111 for the treatment of hospitalized patients with COVID-19 who were at high risk for acute respiratory distress syndrome (ARDS).VERU-111 is a novel once a day orally dosed small molecule that has both broad antiviral 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. We conducted a double-blind, randomized, placebo-controlled Phase 2 clinical trial evaluating daily oral once a day dosing of VERU-111 18mg versus placebo in approximately 40 hospitalizedCOVID-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 VERU-111 18mg 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 hospitalized patients that had >1 dose of study drug,VERU-111 for COVID-19 treatment 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, VERU-111 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. Furthermore, VERU-111 was well tolerated with a good safety profile.

The Company has been granted an expedited End of Phase 2 meeting with the FDA to discuss next steps including a Phase 3 clinical registration trial design for the VERU-111 COVID-19 program. The Company expects that this confirmatory study will have a similar trial design as the Phase 2 study to evaluate daily oral doses of VERU-111 versus placebo with the primary efficacy endpoint of proportion of patients that are alive without respiratory failure at Day 29. We expect the Phase 3 clinical trial will be conducted in approximately 200 hospitalized patients who have COVID-19 and are at high risk for

ARDS. The Biomedical Advanced Research and Development Authority of the US Department of Health and Human Services (BARDA) has granted Veru a meeting to discuss possible grant funding for the Phase 3 study and manufacturing scale up. We plan to commence the VERU-111 for COVID-19 Phase 3 study in April 2021.

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

Veru Inc. will host a conference call today at 8 a.m. ET to review the Company's performance. Interested investors 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. 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 10151507, 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. The Veru prostate cancer pipeline includes VERU-111, VERU-100, and Zuclomiphene citrate. VERU-111 is an oral, first-in-class, new chemical entity that targets, crosslinks, and disrupts alpha and beta tubulin subunits of microtubules for the treatment of metastatic castration and androgen receptor resistant prostate cancer. VERU-100 is a novel, proprietary peptide formulation designed to address the current limitations of commercially available androgen deprivation therapies (ADT) for advanced prostate cancer. Zuclomiphene citrate is an oral nonsteroidal estrogen receptor agonist being developed to treat hot flashes, a common side effect caused by ADT in men with advanced prostate cancer. The Veru breast cancer pipeline includes enobosarm for AR+/ER+/HER2- metastatic breast cancer and VERU-111 for taxane resistant metastatic triple negative breast cancer. Enobosarm is an oral, first-in-class, new chemical entity, selective androgen receptor agonist that targets the androgen receptor in AR+/ER+/HER2- metastatic breast cancer without unwanted virilizing side effects. VERU-111 is also being advanced into Phase 3 for the treatment of hospitalized patients with COVID-19 who are at high risk for acute respiratory distress syndrome.

Veru is advancing a new drug formulation in its specialty pharmaceutical pipeline addressing unmet medical needs in urology such as the Tadalafil and Finasteride Combination (TADFIN™) for the administration of tadalafil 5mg and finasteride 5mg combination formulation dosed daily for benign prostatic hyperplasia (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 by finasteride alone. The Company expects to submit the NDA for TADFIN™ next week. The Company's Sexual Health Business

commercial product is the FC2 Female Condom®/ FC2 Internal Condom ("FC2"), an FDA-approved product for the 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. To learn more about Veru products, please visit www.verupharma.com.

"Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995:*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 regulatory pathway to secure FDA approval of the Company's drug candidates, the anticipated timeframe for clinical studies and FDA submissions, preclinical and clinical study results including potential benefits and the absence of adverse events and anticipated results of future clinical trials, the anticipated design and scope for clinical trials and FDA acceptance of such design and scope, and the ability of the Company to successfully launch TADFIN and implement the Company's sales plans for TADFIN. Any forward-looking statements in this release are based upon the Company's current plans and strategies and reflect the Company's current assessment of the risks and uncertainties related to its business and are made as of the date of this release. The Company assumes no obligation to update any forward-looking statements contained in this release because of new information or future events, developments or circumstances. Such forward-looking statements are subject to known and unknown risks, uncertainties and assumptions. If any such risks or uncertainties materialize or if any of the assumptions prove incorrect, our actual results could differ materially from those expressed or implied by such statements. Factors that may cause actual results to differ materially from those contemplated by such forward-looking statements include, but are not limited to, the following: risks related to the development of the Company's product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market; potential delays in the timing of and results from clinical trials and studies, including potential delays in the recruitment of patients and their ability to effectively participate in such trials and studies due to COVID-19, and the risk that such results will not support marketing approval and commercialization; potential delays in the timing of any submission to the FDA and regulatory approval of products under development and the risk that disruptions at the FDA caused by the COVID-19 pandemic may delay the review of submissions or approvals for new drugs; the risk of a delay or failure in reaching agreement with the FDA on the design of a clinical trial or in obtaining authorization to commence a clinical trial; preclinical or clinical results or early data from clinical trials may not be replicated or continue to occur in additional trials or may not otherwise support further development in the specified product candidate or at all; our pursuit of a COVID-19 treatment candidate is at an early stage and we may be unable to develop a drug that successfully treats the virus in a timely manner, if at all; risks related to our commitment of financial resources and personnel to the development of a COVID-19 treatment which may cause delays in or otherwise negatively impact our other development programs, despite uncertainties about the longevity and extent of COVID-19 as a global health concern and the possibility that as vaccines become widely distributed the need for new COVID-19 treatment candidates may be reduced or eliminated; government entities may take actions that directly or indirectly have the effect of limiting opportunities for VERU-111 as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments; the risk that the Company's products may not be commercially successful; risks related to the impact of the COVID-19 pandemic on our business, the nature and extent of which is highly uncertain and unpredictable; risks relating to the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations, including our ability to secure timely grant or other funding to develop VERU-111 as a potential COVID-19 treatment; product demand and market acceptance; competition in the Company's markets and therapeutic areas and the risk of new or existing competitors with greater resources and capabilities*

and new competitive product approvals and/or introductions; the risk that the Company will be affected by regulatory developments, including a reclassification of products; price erosion, both from competing products and increased government pricing pressures; manufacturing and quality control problems; compliance and regulatory matters, including costs and delays resulting from extensive governmental regulation, and effects of healthcare insurance and regulation, including reductions in reimbursement and coverage or reclassification of products; some of the Company's products are in development and the Company may fail to successfully commercialize such products; risks related to intellectual property, including the uncertainty of obtaining patents, the effectiveness of the patents or other intellectual property protections and ability to enforce them against third parties, the uncertainty regarding patent coverages, the possibility of infringing a third party's patents or other intellectual property rights, and licensing risks; government contracting risks, including the appropriations process and funding priorities, potential bureaucratic delays in awarding contracts, process errors, politics or other pressures, and the risk that government tenders and contracts may be subject to cancellation, delay, restructuring or substantial delayed payments; the risk 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; a governmental tender award indicates acceptance of the bidder's price rather than an order or guarantee of the purchase of any minimum number of units, and as a result government ministries or other public sector customers may order and purchase fewer units than the full maximum tender amount or award; penalties and/or debarment for failure to satisfy tender awards; 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; risks related to concentration of accounts receivable with our largest customers and the collection of those receivables; the economic and business environment and the impact of government pressures; risks involved in doing business on an international level, including currency risks, regulatory requirements, political risks, export restrictions and other trade barriers; 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; risks related to the 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 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.

# # #

FINANCIAL SCHEDULES FOLLOW

Veru Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	December 31, 2020	September 30, 2020
Cash and cash equivalents	$30,921,496	$ 13,588,778
Accounts receivable, net	4,155,792	5,227,237
Inventory, net	6,665,908	6,704,134
Prepaid expenses and other current assets	5,824,110	1,494,541
Total current assets	47,567,306	27,014,690
Deferred income taxes	9,429,298	9,466,800
Intangible assets, net	4,102,381	5,752,127
Goodwill	6,878,932	6,878,932
Other assets	4,810,560	2,431,126
Total assets	$72,788,477	$ 51,543,675
Accounts payable	$ 3,274,856	$ 2,812,673
Accrued research and development costs	1,862,366	934,110
Accrued expenses and other current liabilities	4,654,684	4,038,291
Credit agreement liability	5,331,809	5,841,874
Residual royalty agreement liability, short-term portion	1,938,817	1,100,193
Total current liabilities	17,062,532	14,727,141
Residual royalty agreement liability, long-term portion	5,985,728	5,617,494
Other liabilities	992,084	1,087,724
Total liabilities	24,040,344	21,432,359
Total stockholders' equity	48,748,133	30,111,316
Total liabilities and stockholders' equity	$72,788,477	$ 51,543,675

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended December 31,	
	2020	**2019**
Net revenues	$ 14,616,989	$10,578,016
Cost of sales	3,780,356	3,308,921
Gross profit	10,836,633	7,269,095
Operating expenses	(10,059,634)	(9,053,488)
Gain on sale of PREBOOST	18,410,158	—
Operating income (loss)	19,187,157	(1,784,393)
Non-operating expenses	(1,881,154)	(1,597,451)
Income (loss) before income taxes	17,306,003	(3,381,844)
Income tax expense (benefit)	78,302	(76,743)
Net income (loss)	$ 17,227,701	$ (3,305,101)
Net income (loss) per basic common share outstanding	$ 0.25	$ (0.05)
Basic weighted average common shares outstanding	70,313,589	65,038,511
Net income (loss) per diluted common share outstanding	$ 0.23	$ (0.05)
Diluted weighted average common shares outstanding	75,799,037	65,038,511

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

	Three Months Ended December 31,	
	2020	2019
Net income (loss)	$ 17,227,701	$(3,305,101)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities	(16,697,883)	2,342,005
Changes in operating assets and liabilities	129,423	(1,547,406)
Net cash provided by (used in) operating activities	659,241	(2,510,502)
Net cash provided by (used in) investing activities	14,992,814	(21,807)
Net cash provided by financing activities	1,680,663	412,114
Net increase (decrease) in cash	17,332,718	(2,120,195)
Cash at beginning of period	13,588,778	6,295,152
Cash at end of period	$ 30,921,496	$ 4,174,957

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

	Three Months Ended December 31, 2020			
	Sexual Health Business	Research & Development	Corporate	Total
Net revenues				
FC2	$13,754,158	$ —	$ —	$ 13,754,158
PREBOOST	862,831	—	—	862,831
Total net revenues	14,616,989	—	—	14,616,989
Cost of sales	3,780,356	—	—	3,780,356
Gross profit	10,836,633	—	—	10,836,633
Operating expenses	(925,854)	(5,858,837)	(3,274,943)	(10,059,634)
Gain on sale of PREBOOST	—	—	18,410,158	18,410,158
Operating income (loss)	$ 9,910,779	$(5,858,837)	$15,135,215	$ 19,187,157

	Three Months Ended December 31, 2019			
	Sexual Health Business	Research & Development	Corporate	Total
Net revenues				
FC2	$10,424,924	$ —	$ —	$ 10,424,924
PREBOOST	153,092	—	—	153,092
Total net revenues	10,578,016	—	—	10,578,016
Cost of sales	3,308,921	—	—	3,308,921
Gross profit	7,269,095	—	—	7,269,095
Operating expenses	(1,300,032)	(5,289,859)	(2,463,597)	(9,053,488)
Gain on sale of PREBOOST	—	—	—	—
Operating income (loss)	$ 5,969,063	$(5,289,859)	$ (2,463,597)	$ (1,784,393)

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

	Three Months Ended December 31,	
	2020	**2019**
Operating income (loss) reconciliation:		
GAAP operating income (loss)	$ 19,187,157	$ (1,784,393)
Gain on sale of PREBOOST	(18,410,158)	—
Non-GAAP adjusted operating income (loss)	$ 776,999	$ (1,784,393)
Net income (loss) reconciliation:		
GAAP net income (loss)	$ 17,227,701	$ (3,305,101)
Gain on sale of PREBOOST	(18,410,158)	—
Non-GAAP adjusted net loss	$ (1,182,457)	$ (3,305,101)
Net income (loss) per diluted common share outstanding reconciliation:		
GAAP net income (loss) per diluted common share outstanding	$ 0.23	$ (0.05)
Gain on sale of PREBOOST	(0.24)	—
Effect of antidilutive shares	(0.01)	—
Non-GAAP adjusted net loss per diluted common share outstanding	$ (0.02)	$ (0.05)
GAAP diluted weighted average common shares outstanding	75,799,037	65,038,511
Potentially dilutive shares that are antidilutive due to net loss	(5,485,448)	—
Non-GAAP diluted weighted average common shares outstanding	70,313,589	65,038,511