
**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 13, 2020

VERU INC.

(Exact name of registrant as specified in its charter)

Wisconsin
(State or other jurisdiction
of incorporation)

1-13602
(Commission
File Number)

39-1144397
(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 13, 2020, Veru Inc. issued a press release (the “Press Release”) announcing results for the quarter and nine months ended June 30, 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 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:

<u>Exhibit No.</u>	<u>Document</u>
99.1	<u>Press Release of Veru Inc., issued August 13, 2020.</u>

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 13, 2020

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 Reports Higher Net Revenues for Fiscal 2020 Third Quarter

—Received Agreement and Positive Input from FDA on Phase 3 Pivotal Clinical Trial Design for VERU-111; Phase 3 Trial Expected to Commence in Q1 2021—

—VERU-111 Phase 1b Clinical Trial Results Accepted for Presentation at European Society for Medical Oncology 2020 Congress —

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

MIAMI – August 13, 2020 – Veru Inc. (NASDAQ: VERU), an oncology and urology biopharmaceutical company with a focus on developing novel medicines for the management of prostate cancer, today announced that net revenues for its fiscal 2020 third quarter ended June 30, 2020 increased to \$10.3 million, based on sharply higher U.S. prescription sales of FC2®.

Third-Quarter Financial Highlights: Fiscal 2020 vs Fiscal 2019

- Net revenues increased 6% to \$10.3 million from \$9.7 million
- FC2 U.S. prescription sales climbed 23% to \$5.4 million from \$4.4 million
- Gross profit was \$6.5 million, or 63% of net revenues, compared with \$6.6 million, or 68% of net revenues
- Operating loss narrowed to \$1.4 million from \$1.8 million
- Net loss was \$3.0 million, or \$0.05 per share, compared with \$2.8 million, or \$0.04 per share

Year-to-Date Financial Highlights: Fiscal 2020 vs Fiscal 2019

- Net revenues rose 34% to \$30.8 million from \$23.1 million
- FC2 U.S. prescription sales increased 95% to \$18.4 million from \$9.4 million
- Gross profit of \$21.2 million, or 69% of net revenues, significantly improved from \$15.8 million, or 69% of net revenues

Balance Sheet Information

- Cash and cash equivalents were \$15.4 million as of June 30, 2020 versus \$2.6 million as of March 31, 2020
- Net accounts receivable were \$4.1 million as of June 30, 2020 versus \$5.8 million as of March 31, 2020

“Strong U.S. prescription sales of FC2, along with a solid contribution from PREBOOST® / Roman Swipes® and lower operating expenses, fueled our improved financial performance over last year’s fiscal third quarter and our substantial Year-to-Date growth in revenues and gross profit,” said Mitchell Steiner, MD, Chairman, President and Chief Executive Officer of Veru Inc. “Our continued robust

growth validates the strategic decision we made almost 3 years ago to utilize the growing telemedicine channel. We are pleased not only with our overall financial results, but also that our commercial sexual health business continues to generate significant funding to invest in the advancement of our clinical development programs.”

Pharmaceutical Pipeline Recent Highlights:

VERU-111 for Metastatic Castration Resistant Prostate Cancer

In July the Company announced that it had received input from the U.S. Food and Drug Administration (FDA) on its pivotal Phase 3 trial design for VERU-111, an oral, first-in-class, novel alpha and beta tubulin targeting drug candidate being evaluated for the treatment of metastatic castration and novel androgen receptor targeting agent resistant prostate cancer.

“We received positive FDA input, agreement, and regulatory guidance regarding the design of the pivotal Phase 3 registration clinical trial for VERU-111,” said Dr. Steiner. “We received clarity on a number of items including: the proposed indication of metastatic castration and novel androgen receptor targeting agent resistant prostate cancer, which is prior to IV chemotherapy population, being acceptable; an open label, randomized, active control study using an alternative novel androgen receptor targeting agent as the active control is reasonable; and a primary endpoint for the trial of radiographic progression-free survival. This last item is especially important because by allowing radiographic progression-free survival as an endpoint the sample size for the Phase 3 study could be potentially between 200 and 300 men. We plan to submit the final Phase 3 protocol to FDA in the fourth quarter of the current calendar year.”

Dr. Steiner added: “Patient enrollment of the Phase 2 trial is nearing completion and we are already observing some significant PSA declines. We anticipate commencing the global Phase 3 pivotal clinical study in the first quarter of calendar year 2021. As this study will be conducted in the U.S. and globally, we plan to get input from the European Medicines Agency (EMA) as well.”

In July the Company also announced that the clinical results from its Phase 1b/2 study of VERU-111 have been accepted for oral presentation at the prestigious European Society for Medical Oncology (ESMO) Virtual Congress 2020 to be held September 19-21, 2020.

VERU-100 for Hormone Sensitive Advanced Prostate Cancer Phase 2 Clinical Trial

VERU-100, a long acting gonadotropin antagonist peptide 3-month depot formulation, GMP manufacturing is progressing and an IND expected to be submitted next quarter. The Phase 2 dose finding clinical study should start late calendar year Q4 2020 and a Phase 3 pivotal registration clinical study is expected to commence in the second half of calendar year 2021.

VERU-111 COVID-19: Phase 2 Clinical Trial

As previously announced, the Company is developing VERU-111 which has potentially both antiviral and anti-inflammatory dual action to broadly treat the cytokine storm which is associated with high COVID-19 mortality rates. The Company received FDA permission to initiate a Phase 2 clinical trial to assess the efficacy of VERU-111 in combating COVID-19 in patients at high risk for acute respiratory distress syndrome (ARDS). We recently reported the results of an *in vitro* study conducted by a team of researchers at the University of Tennessee Health Science Center to determine if VERU-111 can suppress toxic shock levels of these key cytokines of the cytokine storm. At a concentration that represents the blood levels of VERU-111 observed in clinically dosed patients, VERU-111 (40 nM) highly significantly reduced the production of key cytokines known to be involved with COVID-19

cytokine storm: TNF α (-31%), IL-1 α (-123%), IL-1 β (-97%), IL-6 (-85%), and IL-8 homologue (-96%), all p values were (p<0.001). This reduction was similar to, or greater than, depending on the specific cytokine, to that observed with dexamethasone (10nM), a steroid and a known inhibitor of cytokine production during inflammation. Suppression of these key cytokines may be an effective way to prevent clinical deterioration of patients with COVID-19 to ARDS.

The Phase 2 clinical trial is a double-blind randomized (1:1) placebo-controlled trial evaluating daily oral doses of 18 mg VERU-111 for 21 days versus placebo in 40 hospitalized COVID-19 patients who are at high risk for ARDS. The primary efficacy endpoint is the proportion of subjects that are alive without respiratory distress at Day 29. Secondary endpoints include measures of improvements on the WHO Disease Severity Scale (8-point ordinal scale), which captures COVID-19 disease symptoms and signs, including hospitalization to progression of pulmonary symptoms to mechanical ventilation, as well as improving overall survival.

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 10146652, for one week.

About Veru Inc.

Veru Inc. is an oncology and urology biopharmaceutical company with a focus on developing novel medicines for the management of prostate 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. VERU-111 is being evaluated in an open label Phase 1b/Phase 2 clinical study in men with metastatic castration and androgen receptor targeting agent resistant prostate cancer. The Phase 1b clinical study completed enrollment of 39 men and is ongoing. The Phase 2 clinical study is enrolling approximately 40 men who have metastatic castration resistant prostate cancer and who have also become resistant to at least one novel androgen receptor targeting agent, such as abiraterone or enzalutamide, but prior to proceeding to IV chemotherapy. VERU-111 is also being evaluated in a Phase 2 clinical trial to assess the efficacy of VERU-111 in combating COVID-19. 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. VERU-100 is a long-acting gonadotropin-releasing hormone (GnRH) antagonist administered as a small volume, subcutaneous 3-month depot injection without a loading dose. VERU-100 immediately suppresses testosterone with no testosterone surge upon initial or repeated administration --- a problem which occurs with currently approved luteinizing hormone-releasing hormone (LHRH) agonists used for ADT. There are no GnRH antagonists commercially approved beyond a one-month injection. A Phase 2 study to evaluate VERU-100 dosing is anticipated to begin in the fourth quarter of calendar year 2020. 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. Following an End of Phase 2 meeting with the FDA, the Company plans to advance Zuclomiphene Citrate to a Phase 3 clinical trial in men with advanced prostate cancer who experience moderate to severe hot flashes.

Veru is also advancing new drug formulations 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 had a successful pre-NDA meeting with the FDA and the expected submission of the NDA for TADFIN is the fourth quarter of calendar year 2020 or early 2021. Veru is also developing Tamsulosin XR capsules which is a formulation of tamsulosin, the active ingredient in FLOMAX®, which Veru has designed to avoid the “food effect” inherent in currently marketed formulations of the drug, allowing for potentially safer administration and improved patient compliance.

The Company’s commercial products include the FC2 Female Condom / FC2 Internal Condom® (“FC2”), an FDA-approved product for the dual protection against unwanted pregnancy and the transmission of sexually transmitted infections, and the PREBOOST® 4% benzocaine medicated individual wipe for the treatment of premature ejaculation. 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. PREBOOST® is marketed through online sales in the U.S. under the Roman Swipes brand name by Roman Health Ventures Inc. Roman is a leading telemedicine company that discreetly sells men’s health products via the internet website www.getroman.com. 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, the anticipated design and scope for clinical trials and FDA acceptance of such design and scope, and clinical study results including potential benefits and the absence of adverse events. 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; 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; 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's 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 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 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, 2019 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.

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FINANCIAL SCHEDULES FOLLOW

Veru Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	June 30, 2020	September 30, 2019
Cash and cash equivalents	\$15,394,423	\$ 6,295,152
Accounts receivable, net	4,144,351	5,021,057
Inventory, net	5,194,442	3,647,406
Prepaid expenses and other current assets	2,125,730	1,843,297
Total current assets	26,858,946	16,806,912
Property and equipment, net	315,456	351,895
Operating lease right-of-use assets	1,012,951	—
Deferred income taxes	8,628,006	8,433,669
Intangible assets, net	19,931,219	20,168,495
Goodwill	6,878,932	6,878,932
Other assets	1,562,126	988,867
Total assets	\$65,187,636	\$53,628,770
Accounts payable	\$ 3,772,990	\$ 3,124,751
Accrued expenses and other current liabilities	6,219,345	5,509,575
Credit agreement, short-term portion	6,599,095	5,385,649
Residual royalty agreement, short-term portion	356,346	—
Operating lease liability, short-term portion	425,136	—
Total current liabilities	17,372,912	14,019,975
Credit agreement, long-term portion	—	2,886,382
Residual royalty agreement	5,407,007	3,845,518
Operating lease liability, long-term portion	808,401	—
Deferred income taxes	292,740	296,605
Other liabilities	27,469	247,154
Total liabilities	23,908,529	21,295,634
Total stockholders' equity	41,279,107	32,333,136
Total liabilities and stockholders' equity	\$65,187,636	\$53,628,770

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended		Nine Months Ended	
	June 30,		June 30,	
	2020	2019	2020	2019
Net revenues	\$10,321,754	\$ 9,727,060	\$30,842,874	\$23,074,984
Cost of sales	<u>3,802,636</u>	<u>3,155,902</u>	<u>9,618,163</u>	<u>7,250,895</u>
Gross profit	6,519,118	6,571,158	21,224,711	15,824,089
Operating expenses	<u>7,911,970</u>	<u>8,413,160</u>	<u>24,701,634</u>	<u>20,802,408</u>
Operating loss	(1,392,852)	(1,842,002)	(3,476,923)	(4,978,319)
Non-operating expenses	<u>(1,392,026)</u>	<u>(932,532)</u>	<u>(3,633,448)</u>	<u>(3,861,383)</u>
Loss before income taxes	(2,784,878)	(2,774,534)	(7,110,371)	(8,839,702)
Income tax expense (benefit)	<u>240,502</u>	<u>(458)</u>	<u>30,619</u>	<u>117,207</u>
Net loss	<u>\$ (3,025,380)</u>	<u>\$ (2,774,076)</u>	<u>\$ (7,140,990)</u>	<u>\$ (8,956,909)</u>
Net loss per basic and diluted common share outstanding	\$ (0.05)	\$ (0.04)	\$ (0.11)	\$ (0.14)
Basic and diluted weighted average common shares outstanding	66,728,782	62,917,362	65,709,139	62,745,355

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

	Nine Months Ended	
	June 30,	
	2020	2019
Net loss	\$ (7,140,990)	\$(8,956,909)
Adjustments to reconcile net loss to net cash used in operating activities	6,176,292	5,895,238
Changes in operating assets and liabilities	(624,286)	(1,468,534)
Net cash used in operating activities	(1,588,984)	(4,530,205)
Net cash used in investing activities	(73,444)	(74,948)
Net cash provided by financing activities	10,761,699	8,884,760
Net increase in cash	9,099,271	4,279,607
Cash at beginning of period	6,295,152	3,759,509
Cash at end of period	<u>\$15,394,423</u>	<u>\$ 8,039,116</u>

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

	Three Months Ended June 30, 2020			
	Commercial	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	899,950	4,436,496	2,575,524	7,911,970
Operating income (loss)	<u>\$ 5,619,168</u>	<u>\$(4,436,496)</u>	<u>\$(2,575,524)</u>	<u>\$ (1,392,852)</u>

	Three Months Ended June 30, 2019			
	Commercial	Research & Development	Corporate	Total
Net revenues				
FC2	\$ 9,283,736	\$ —	\$ —	\$ 9,283,736
PREBOOST	443,324	—	—	443,324
Total net revenues	9,727,060	—	—	9,727,060
Cost of sales	3,155,902	—	—	3,155,902
Gross profit	6,571,158	—	—	6,571,158
Operating expenses	1,307,362	4,853,344	2,252,454	8,413,160
Operating income (loss)	<u>\$ 5,263,796</u>	<u>\$(4,853,344)</u>	<u>\$(2,252,454)</u>	<u>\$ (1,842,002)</u>

(Continued)

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

	Nine Months Ended June 30, 2020			
	Commercial	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	3,615,739	13,549,652	7,536,243	24,701,634
Operating income (loss)	<u>\$17,608,972</u>	<u>\$(13,549,652)</u>	<u>\$(7,536,243)</u>	<u>\$ (3,476,923)</u>

	Nine Months Ended June 30, 2019			
	Commercial	Research & Development	Corporate	Total
Net revenues				
FC2	\$22,452,055	\$ —	\$ —	\$22,452,055
PREBOOST	622,929	—	—	622,929
Total net revenues	23,074,984	—	—	23,074,984
Cost of sales	7,250,895	—	—	7,250,895
Gross profit	15,824,089	—	—	15,824,089
Operating expenses	4,399,371	10,103,528	6,299,509	20,802,408
Operating income (loss)	<u>\$11,424,718</u>	<u>\$(10,103,528)</u>	<u>\$(6,299,509)</u>	<u>\$ (4,978,319)</u>

(Concluded)