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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended December 31, 2020

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from______ to______

Commission File Number 1-13602

Veru Inc.

(Exact Name of Registrant as Specified in its Charter)

Wisconsin	**39-1144397**
(State of Incorporation)	(I.R.S. Employer Identification No.)
48 NW 25th Street, Suite 102, Miami, FL	**33127**
(Address of Principal Executive Offices)	(Zip Code)

305-509-6897
(Registrant's Telephone Number, Including Area Code)

N/A
(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company☒
	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. ☐

Indicate by check mark whether the registrant is a shell company (as determined by Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of February 8, 2021, the registrant had 71,911,903 shares of $0.01 par value common stock outstanding.

VERU INC.
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FORWARD LOOKING STATEMENTS

Certain statements included in this quarterly report on Form 10-Q which are not statements of historical fact are intended to be, and are hereby identified as, "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about the anticipated or potential impact of COVID-19 and the global response thereto on our financial condition or business, future financial and operating results, plans, objectives, expectations and intentions, costs and expenses, debt repayments, outcome of contingencies, financial condition, results of operations, liquidity, cost savings, objectives of management, business strategies, clinical trial timing and plans, the achievement of clinical and commercial milestones, the advancement of our technologies and our products and drug candidates, and other statements that are not historical facts. Forward-looking statements can be identified by the use of forward-looking words or phrases such as "anticipate," "believe," "could," "expect," "intend," "may," "opportunity," "plan," "predict," "potential," "estimate," "should," "will," "would" or the negative of these terms or other words of similar meaning. These statements 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 report. These statements are inherently subject to known and unknown risks and uncertainties. You should read these statements carefully because they discuss our future expectations or state other “forward-looking” information. There may be events in the future that we are not able to accurately predict or control and our actual results may differ materially from the expectations we describe in our forward-looking statements. Factors that could cause actual results to differ materially from those currently anticipated include the following:

- 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 U.S. Food and Drug Administration (the “FDA”) and in regulatory approval of products under development, including 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;
- risks related to our ability to obtain sufficient financing on acceptable terms when needed to fund product development and our operations, including our ability to secure timely grant or other funding to develop VERU-111 as a potential COVID-19 treatment;
- risks related to the development of our product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market;
- risks related to the impact of the COVID-19 pandemic on our business, the nature and extent of which is highly uncertain and unpredictable;
- 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;
- product demand and market acceptance;
- some of our products are in development and we may fail to successfully commercialize such products;
- risks related to intellectual property, including the uncertainty of obtaining intellectual property protections and in enforcing them, the possibility of infringing a third party’s intellectual property, and licensing risks;
- competition from existing and new competitors including the potential for reduced sales, pressure on pricing and increased spending on marketing;
- risks related to compliance and regulatory matters, including costs and delays resulting from extensive government regulation and reimbursement and coverage under healthcare insurance and regulation;
- the risk that we will be affected by regulatory and legal developments, including a reclassification of products or repeal of the Patient Protection and Affordable Care Act (the “ACA”);

- risks inherent in doing business on an international level, including currency risks, regulatory requirements, political risks, export restrictions and other trade barriers;
- the disruption of production at our manufacturing facilities or facilities of third parties on which we rely and/or of our ability to supply product due to raw material shortages, labor shortages, physical damage to our or third parties' facilities, COVID-19 (including the impact of COVID-19 on suppliers of key raw materials), product testing, transportation delays or regulatory actions;
- our reliance on major customers and risks related to delays in payment of accounts receivable by major customers;
- risks related to our growth strategy;
- our continued ability to attract and retain highly skilled and qualified personnel;
- the costs and other effects of litigation, governmental investigations, legal and administrative cases and proceedings, settlements and investigations;
- 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;
- 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 health sector customers may order and purchase fewer units than the full maximum tender amount;
- our ability to identify, successfully negotiate and complete suitable acquisitions or other strategic initiatives; and
- our ability to successfully integrate acquired businesses, technologies or products.

All forward-looking statements in this report should be considered in the context of the risks and other factors described above and in Part I, Item 1A, "Risk Factors," in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2020. The Company undertakes no obligation to make any revisions to the forward-looking statements contained in this report or to update them to reflect events or circumstances occurring after the date of this report except as required by applicable law.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2020	September 30, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 30,921,496	$ 13,588,778
Accounts receivable, net	4,155,792	5,227,237
Notes receivable, short-term portion	2,500,000	—
Inventory, net	6,665,908	6,704,134
Prepaid expenses and other current assets	3,324,110	1,494,541
Total current assets	47,567,306	27,014,690
Plant and equipment, net	287,997	312,691
Operating lease right-of-use assets	1,260,553	1,352,315
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
Notes receivable, long-term portion	2,500,000	—
Other assets	762,010	766,120
Total assets	$ 72,788,477	$ 51,543,675
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,274,856	$ 2,812,673
Accrued research and development costs	1,862,366	934,110
Accrued compensation	1,930,387	2,274,396
Accrued expenses and other current liabilities	2,101,564	1,177,126
Credit agreement liability	5,331,809	5,841,874
Residual royalty agreement liability, short-term portion	1,938,817	1,100,193
Operating lease liability, short-term portion	622,733	586,769
Total current liabilities	17,062,532	14,727,141
Residual royalty agreement liability, long-term portion	5,985,728	5,617,494
Operating lease liability, long-term portion	899,121	990,020
Deferred income taxes	74,724	74,724
Other liabilities	18,239	22,980
Total liabilities	24,040,344	21,432,359
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock; no shares issued and outstanding at December 31, 2020 and September 30, 2020	—	—
Common stock, par value $0.01 per share; 154,000,000 shares authorized, 74,090,607 and 72,047,385 shares issued and 71,906,903 and 69,863,681 shares outstanding at December 31, 2020 and September 30, 2020, respectively	740,906	720,474
Additional paid-in-capital	128,360,202	126,971,518
Accumulated other comprehensive loss	(581,519)	(581,519)
Accumulated deficit	(71,964,851)	(89,192,552)
Treasury stock, 2,183,704 shares, at cost	(7,806,605)	(7,806,605)
Total stockholders' equity	48,748,133	30,111,316
Total liabilities and stockholders' equity	$ 72,788,477	$ 51,543,675

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended December 31, 2020	Three Months Ended December 31, 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:		
Research and development	5,677,754	5,299,974
Selling, general and administrative	4,381,880	3,753,514
Total operating expenses	10,059,634	9,053,488
Gain on sale of PREBOOST® business	18,410,158	—
Operating income (loss)	19,187,157	(1,784,393)
Non-operating expenses:		
Interest expense	(1,189,183)	(1,141,425)
Increase in fair value of derivative liabilities	(604,000)	(394,000)
Other expense, net	(87,971)	(62,026)
Total 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

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock			Additional Paid-in Capital		Accumulated Other Comprehensive Loss	Accumulated Deficit	Treasury Stock, at Cost	Total
	Shares		Amount						
Balance at September 30, 2020	72,047,385	$	720,474	$126,971,518	$	(581,519)	$(89,192,552)	$ (7,806,605)	$ 30,111,316
Share-based compensation	—		—	785,297		—	—	—	785,297
Issuance of shares pursuant to share-based awards	468,611		4,686	619,133		—	—	—	623,819
Issuance of shares pursuant to common stock purchase warrants	1,574,611		15,746	(15,746)		—	—	—	—
Net income	—		—	—		—	17,227,701	—	17,227,701
Balance at December 31, 2020	74,090,607	$	740,906	$128,360,202	$	(581,519)	$(71,964,851)	$ (7,806,605)	$ 48,748,133
Balance at September 30, 2019	67,221,951	$	672,220	$110,268,057	$	(581,519)	$(70,219,017)	$ (7,806,605)	$ 32,333,136
Share-based compensation	—		—	614,498		—	—	—	614,498
Issuance of shares pursuant to share-based awards	867		8	(8)		—	—	—	—
Net loss	—		—	—		—	(3,305,101)	—	(3,305,101)
Balance at December 31, 2019	67,222,818	$	672,228	$110,882,547	$	(581,519)	$(73,524,118)	$ (7,806,605)	$ 29,642,533

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Three Months Ended December 31,	
	2020	2019
OPERATING ACTIVITIES		
Net income (loss)	$ 17,227,701	$ (3,305,101)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	91,783	116,623
Noncash change in right-of-use assets	91,762	76,147
Noncash interest expense	92,793	1,141,425
Share-based compensation	785,297	614,498
Gain on sale of PREBOOST® business	(18,410,158)	—
Deferred income taxes	37,502	(152,610)
Provision for obsolete inventory	9,138	151,922
Change in fair value of derivative liabilities	604,000	394,000
Changes in current assets and liabilities:		
Decrease (increase) in accounts receivable	1,071,445	(642,764)
Decrease (increase) in inventory	29,088	(1,099,906)
Increase in prepaid expenses and other assets	(1,825,459)	(209,177)
Increase in accounts payable	462,183	703,123
Increase (decrease) in accrued expenses and other current liabilities	447,101	(245,398)
Decrease in operating lease liabilities	(54,935)	(53,284)
Net cash provided by (used in) operating activities	659,241	(2,510,502)
INVESTING ACTIVITIES		
Cash proceeds from sale of PREBOOST® business	15,000,000	—
Capital expenditures	(7,186)	(21,807)
Net cash provided by (used in) investing activities	14,992,814	(21,807)
FINANCING ACTIVITIES		
Installment payments on SWK credit agreement	—	(423,366)
Proceeds from stock option exercises	623,819	—
Proceeds from premium finance agreement	1,061,442	836,780
Cash paid for debt portion of finance lease	(4,598)	(1,300)
Net cash provided by financing activities	1,680,663	412,114
Net increase (decrease) in cash	17,332,718	(2,120,195)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	13,588,778	6,295,152
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 30,921,496	$ 4,174,957
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 1,096,390	$ —
Schedule of non-cash investing and financing activities:		
Right-of-use assets recorded in exchange for lease liabilities	$ —	$ 1,229,926
Notes receivable for sale of PREBOOST® business	$ 5,000,000	$ —

See notes to unaudited condensed consolidated financial statements.

VERU INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1 – Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements for Veru Inc. (“we,” “our,” “us,” “Veru” or the “Company”) have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) for reporting of interim financial information. Pursuant to these rules and regulations, certain information and footnote disclosures normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) have been condensed or omitted, although the Company believes that the disclosures made are adequate to make the information not misleading. Accordingly, these statements do not include all the disclosures normally required by U.S. GAAP for annual financial statements and should be read in conjunction with Management’s Discussion and Analysis of Financial Condition and Results of Operations contained in this report and the audited financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended September 30, 2020. The accompanying condensed consolidated balance sheet as of September 30, 2020 has been derived from our audited financial statements. The unaudited condensed consolidated statements of operations and cash flows for the three months ended December 31, 2020 are not necessarily indicative of the results to be expected for any future period or for the fiscal year ending September 30, 2021.

The preparation of our unaudited interim condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates.

In the opinion of management, the accompanying unaudited interim condensed consolidated financial statements contain all adjustments (consisting of only normally recurring adjustments) necessary to present fairly the financial position and results of operations as of the dates and for the periods presented.

Principles of consolidation and nature of operations: Veru Inc. is referred to in these notes collectively with its subsidiaries as “we,” “our,” “us,” “Veru” or the “Company.” The consolidated financial statements include the accounts of Veru and its wholly owned subsidiaries, Aspen Park Pharmaceuticals, Inc. (APP) and The Female Health Company Limited, and The Female Health Company Limited’s wholly owned subsidiary, The Female Health Company (UK) plc (The Female Health Company Limited and The Female Health Company (UK) plc, collectively, the “U.K. subsidiary”), and The Female Health Company (UK) plc’s wholly owned subsidiary, The Female Health Company (M) SDN.BHD (the “Malaysia subsidiary”). All significant intercompany transactions and accounts have been eliminated in consolidation. The Company is an oncology biopharmaceutical company with a focus on developing novel medicines for the management of prostate and breast cancers. The Company has multiple drug products under clinical development. During fiscal 2020, the Sexual Health Business segment also included PREBOOST® 4% benzocaine medicated individual wipe for the treatment of premature ejaculation. The PREBOOST® business was sold on December 8, 2020. See Note 3 for additional information. Most of the Company’s net revenues during the three months ended December 31, 2020 and 2019 were derived from sales of FC2.

Reclassifications: Certain prior period amounts on the accompanying unaudited interim condensed consolidated financial statements have been reclassified to conform with the current period presentation. These reclassifications had no effect on the results of operations or financial position for any period presented.

Other comprehensive income (loss): Accounting principles generally require that recognized revenue, expenses, gains and losses be included in net income (loss). Although certain changes in assets and liabilities, such as foreign currency translation adjustments, are reported as a separate component of the equity section of the accompanying unaudited condensed consolidated balance sheets, these items, along with net income (loss), are components of other comprehensive loss. For the three months ended December 31, 2020 and 2019, comprehensive income (loss) is equivalent to the reported net income (loss).

Recently adopted accounting pronouncements: In June 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-13, Financial Instruments—Credit Losses (Topic 326). This ASU introduces a new accounting model, the Current Expected Credit Losses model (CECL), which could result in earlier recognition of credit losses and additional disclosures related to credit risk. The CECL model requires the Company to use a forward-looking expected credit loss impairment methodology for the recognition of credit losses for financial instruments at the time the financial asset is originated or acquired. The expected credit losses are adjusted each period for changes in expected lifetime credit losses. This model replaces the multiple existing impairment models in current U.S. GAAP, which generally require that a loss be incurred before it is recognized. The new standard also applies to receivables arising from revenue transactions such as accounts receivable. The Company adopted ASU 2016-13 on a modified-retrospective basis effective October 1, 2020. The adoption of ASU 2016-13 did not impact our consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU 2017-04, Intangibles - Goodwill and Other Topics (Topic 350): Simplifying the Test for Goodwill Impairment. The purpose of ASU 2017-04 is to reduce the cost and complexity of evaluating goodwill for impairment. It eliminates the need for entities to calculate the implied fair value of goodwill by assigning the fair value of a reporting unit to all of its assets and liabilities as if that reporting unit had been acquired in a business combination. Under this amendment, an entity will perform its goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An impairment charge is recognized for the amount by which the carrying value exceeds the reporting unit's fair value. The Company adopted ASU 2017-04 on a prospective basis effective October 1, 2020. The adoption of ASU 2017-04 did not impact our consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework – Change to the Disclosure Requirements for Fair Value Measurement. ASU 2018-13 modifies the disclosure requirements by adding, removing, and modifying certain required disclosures for fair value measurements for assets and liabilities disclosed within the fair value hierarchy. The Company adopted ASU 2018-13 on a retrospective basis effective October 1, 2020. The adoption of ASU 2018-13 did not impact our financial position, results of operations, or cash flows as it modified disclosure requirements only.

Note 2 – Liquidity

The Company anticipates that it will continue to consume cash as it develops its drug candidates. Because of the numerous risks and uncertainties associated with the development of pharmaceutical products, the Company is unable to estimate the exact amounts of capital outlays and operating expenditures necessary to fund development of its drug candidates and obtain regulatory approvals. The Company's future capital requirements will depend on many factors.

The Company believes its current cash position and cash expected to be generated from sales of the Company's commercial product are adequate to fund planned operations of the Company for the next 12 months. To the extent the Company may need additional capital for its operations, it may access financing alternatives that may include debt financing, common stock offerings, or financing involving convertible debt or other equity-linked securities and may include financings under the Company's current effective shelf registration statement on Form S-3 (File No. 333-239493). The Company intends to be opportunistic when pursuing equity or debt financing which could include selling common stock under the 2020 Purchase Agreement with Aspire Capital (see Note 10).

Note 3 – Sale of PREBOOST® Business

On December 8, 2020, the Company entered into an Asset Purchase Agreement (the "Purchase Agreement"), pursuant to which the Company sold substantially all of the assets related to the Company's PREBOOST® business. PREBOOST® is a 4% benzocaine medicated individual wipe for the treatment of premature ejaculation and was a commercial product in the Company's Sexual Health Division until the date of the sale. The transaction closed on December 8, 2020. The purchase price for the transaction was $20.0 million, consisting of $15.0 million paid at closing, a $2.5 million note receivable due 12 months after closing and a $2.5 million note receivable due 18 months after closing. Total assets sold, consisting of intangible assets, had a net book value of approximately $1.6 million, resulting in a pre-tax gain on sale of approximately $18.4 million. The Company had income before income taxes of $327,000 and $48,000 during the three months ended December 31, 2020 and 2019, respectively, related to the PREBOOST® business.

Note 4 – Fair Value Measurements

FASB Accounting Standards Codification (ASC) Topic 820 specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

The three levels of the fair value hierarchy are as follows:

Level 1 – Quoted prices for identical instruments in active markets.

Level 2 – Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3 – Instruments with primarily unobservable value drivers.

As of December 31, 2020 and September 30, 2020, the Company's financial liabilities measured at fair value on a recurring basis, which consisted of embedded derivatives, were classified within Level 3 of the fair value hierarchy.

The following table provides a reconciliation of the beginning and ending liability balance associated with embedded derivatives measured at fair value using significant unobservable inputs (Level 3) as of December 31, 2020 and 2019:

	Three Months Ended December 31,	
	2020	2019
Beginning balance	$ 4,182,000	$ 3,625,000
Change in fair value of derivative liabilities	604,000	394,000
Ending balance	$ 4,786,000	$ 4,019,000

The expense associated with the change in fair value of the embedded derivatives is included as a separate line item on the accompanying unaudited condensed consolidated statements of operations.

The liabilities associated with embedded derivatives represent the fair value of the change of control provisions in the Credit Agreement and Residual Royalty Agreement. See Note 9 for additional information. There is no current observable market for these types of derivatives. The Company determined the fair value of the embedded derivatives usinga Monte Carlo simulation model to value the financial liabilities at inception and on subsequent valuation dates. This valuation model incorporates the contractual terms of the instruments and assumptions including projected FC2 revenues, expected cash outflows, expected repayment dates, probability and estimated dates of a change of control, expected volatility, and risk-free interest rates and applicable credit risk. A significant increase in projected FC2 revenues or a significant increase in the probability or acceleration of the timing of a change of control event, in isolation, would result in a significantly higher fair value measurement of the liabilities associated with the embedded derivatives.

The following table presents quantitative information about the inputs and valuation methodologies used to determine the fair value of the embedded derivatives classified in Level 3 of the fair value hierarchy as of December 31, 2020 and September 30, 2020:

		Weighted Average (range, if applicable)	
Valuation Methodology	Significant Unobservable Input	December 31, 2020	September 30, 2020
Monte Carlo Simulation	Estimated change of control dates	December 2021 to June 2022	December 2021 to June 2022
	Discount rate	9.9% to 10.8%	14.1% to 16.0%
	Probability of change of control	20% to 90%	20% to 90%

Note 5 – Revenue from Contracts with Customers

The Company generates nearly all its revenue from direct product sales. Revenue from direct product sales is generally recognized when the customer obtains control of the product, which occurs at a point in time, and may be upon shipment or upon delivery based on the contractual shipping terms of a contract. Sales taxes and other similar taxes that the Company collects concurrent with revenue-producing activities are excluded from revenue.

The amount of consideration the Company ultimately receives varies depending upon sales discounts, and other incentives that the Company may offer, which are accounted for as variable consideration when estimating the amount of revenue to recognize. The estimate of variable consideration requires significant judgment. The Company includes estimated amounts in the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved. The estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely upon an assessment of current contract sales terms and historical payment experience.

Product returns are typically not significant because returns are generally not allowed unless the product is damaged at time of receipt.

The Company's revenue is from sales of FC2 in theU.S. prescription channel and direct sales of FC2 in theglobal public health sector, and also included sales of PREBOOST® medicated wipes for prevention of premature ejaculationbefore the sale of the PREBOOST® business. The following table presents net revenues from these three categories:

	Three Months Ended December 31, 2020	Three Months Ended December 31, 2019
FC2		
U.S. prescription channel	$ 9,101,739	$ 6,051,130
Public health sector	4,652,419	4,373,794
Total FC2	13,754,158	10,424,924
PREBOOST®	862,831	153,092
Net revenues	$ 14,616,989	$ 10,578,016

The following table presents net revenue by geographic area:

	Three Months Ended December 31, 2020	Three Months Ended December 31, 2019
United States	$ 10,355,838	$ 6,491,154
United Arab Emirates	*	1,605,000
Other	4,261,151	2,481,862
Net revenues	$ 14,616,989	$ 10,578,016

*Less than 10% of total net revenues

The Company's performance obligations consist mainly of transferring control of products identified in the contracts which occurs either when: i) the product is made available to the customer for shipment; ii) the product is shipped via common carrier; or iii) the product is delivered to the customer or distributor, in accordance with the terms of the agreement. Some of the Company's contracts require the customer to make advanced payments prior to transferring control of the products. These advanced payments create a contract liability for the Company. The Company did not have significant contract liabilities at December 31, 2020 or September 30, 2020.

Note 6 – Accounts Receivable and Concentration of Credit Risk

The Company's standard credit terms vary from 30 to 120 days, depending on the class of trade and customary terms within a territory, so accounts receivable is affected by the mix of purchasers within the period. As is typical in the Company's business, extended credit terms may occasionally be offered as a sales promotion or for certain sales. For sales to the Company's distributor in Brazil, the Company has agreed to credit terms of up to 90 days subsequent to clearance of the product by the Ministry of Health in Brazil.

The components of accounts receivable consist of the following at December 31, 2020 and September 30, 2020:

	December 31, 2020	September 30, 2020
Trade receivables, gross	$ 4,253,681	$ 5,332,786
Less: allowance for doubtful accounts	(25,643)	(25,643)
Less: allowance for sales returns and payment term discounts	(72,246)	(79,906)
Accounts receivable, net	$ 4,155,792	$ 5,227,237

At December 31, 2020 and at September 30, 2020, no customers had a current accounts receivable balance that represented greater than 10% of current assets.

At December 31, 2020, four customers had an accounts receivable balance greater than 10% of net accounts receivable, representing 81% of net accounts receivable in the aggregate. At September 30, 2020, three customers had an accounts receivable balance greater than 10% of net accounts receivable, representing 89% of net accounts receivable in the aggregate.

For the three months ended December 31, 2020, there were two customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 61% of the Company's net revenues in the aggregate. For the three months ended December 31, 2019, there were three customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 86% of the Company's net revenues in the aggregate.

The Company maintains an allowance for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments on accounts receivable. Management determines the allowance for doubtful accounts by identifying troubled accounts and by using historical experience applied to an aging of accounts. Management also periodically evaluates individual customer receivables and considers a customer's financial condition, credit history, and the current economic conditions. Accounts receivable are charged-off when deemed uncollectible. There was no change in the allowance for doubtful accounts for the three months ended December 31, 2020 and 2019.

Recoveries of accounts receivable previously charged off are recorded when received. The Company's customers are primarily large global agencies, non-government organizations, ministries of health and other governmental agencies, which purchase and distribute FC2 for use in HIV/AIDS prevention and family planning programs. In the U.S., the Company's customers include telemedicine providers who sell into the prescription channel.

Note 7 – Balance Sheet Information

Inventory

Inventories are valued at the lower of cost or net realizable value. The cost is determined using the first-in, first-out (FIFO) method. Inventories are also written down for management's estimates of product which will not sell prior to its expiration date. Write-downs of inventories establish a new cost basis which is not increased for future increases in the net realizable value of inventories or changes in estimated obsolescence.

Inventory consisted of the following at December 31, 2020 and September 30, 2020:

	December 31, 2020	September 30, 2020
FC2:		
Raw material	$ 1,231,480	$ 962,860
Work in process	63,075	106,272
Finished goods	5,400,476	5,634,612
FC2, gross	6,695,031	6,703,744
Less: inventory reserves	(29,123)	(29,331)
FC2, net	6,665,908	6,674,413
PREBOOST®		
Finished goods	—	29,721
Inventory, net	$ 6,665,908	$ 6,704,134

Fixed Assets

We record equipment, furniture and fixtures, and leasehold improvements at historical cost. Expenditures for maintenance and repairs are recorded to expense. Depreciation and amortization are primarily computed using the straight-line method. Depreciation and amortization are computed over the estimated useful lives of the respective assets. Leasehold improvements are depreciated on a straight-line basis over the lesser of the remaining lease term or the estimated useful lives of the improvements.

Plant and equipment consisted of the following at December 31, 2020 and September 30, 2020:

	Estimated Useful Life	December 31, 2020	September 30, 2020
Plant and equipment:			
Manufacturing equipment	5 - 8 years	$ 2,734,637	$ 2,752,854
Office equipment, furniture and fixtures	3 - 10 years	826,688	803,484
Leasehold improvements	3 - 8 years	298,886	298,886
Total plant and equipment		3,860,211	3,855,224
Less: accumulated depreciation and amortization		(3,572,214)	(3,542,533)
Plant and equipment, net		$ 287,997	$ 312,691

Note 8 – Intangible Assets and Goodwill

Intangible Assets

The gross carrying amounts and net book value of intangible assets are as follows at December 31, 2020:

	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Intangible asset with finite life:			
Covenants not-to-compete	$ 500,000	$ 297,619	$ 202,381
Indefinite-lived intangible assets:			
Acquired in-process research and development assets	3,900,000	—	3,900,000
Total intangible assets	$ 4,400,000	$ 297,619	$ 4,102,381

The gross carrying amounts and net book value of intangible assets are as follows at September 30, 2020:

	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Intangible assets with finite lives:			
Developed technology - PREBOOST®	$ 2,400,000	$ 768,111	$ 1,631,889
Covenants not-to-compete	500,000	279,762	220,238
Total intangible assets with finite lives	2,900,000	1,047,873	1,852,127
Acquired in-process research and development assets	3,900,000	—	3,900,000
Total intangible assets	$ 6,800,000	$ 1,047,873	$ 5,752,127

As discussed in Note 3, the Company sold its intangible assets related to PREBOOST® as part of the sale of the PREBOOST® business on December 8, 2020. The remaining net book value of the PREBOOST® developed technology, acquired in the acquisition of APP, was $1.6 million on the date of the sale. For the three months ended December 31, 2020 and 2019, amortization expense was approximately $60,000 and $79,000, respectively.

Goodwill

The carrying amount of goodwill at December 31, 2020 and September 30, 2020 was $6.9 million. There was no change in the balance during the three months ended December 31, 2020 and 2019.

Note 9 – Debt

SWK Credit Agreement

On March 5, 2018, the Company entered into a Credit Agreement (as amended, the "Credit Agreement") with the financial institutions party thereto from time to time (the "Lenders") and SWK Funding LLC, as agent for the Lenders (the "Agent"), for a synthetic royalty financing transaction. On and subject to the terms of the Credit Agreement, the Lenders provided the Company with a term loan of $10.0 million, which was advanced to the Company on the date of the Credit Agreement. After payment by the Company of certain fees and expenses of the Agent and the Lenders as required in the Credit Agreement, the Company received net proceeds of approximately $9.9 million from the $10.0 million loan under the Credit Agreement.

The Lenders will be entitled to receive quarterly payments on the term loan based on the Company's product revenue from net sales of FC2 as provided in the Credit Agreement until the Company has paid 176.5% of the aggregate amount advanced to the Company under the Credit Agreement. If product revenue from net sales of FC2 for the 12-month period ended as of the last day of the respective quarterly payment period is less than $10.0 million, the quarterly payments will be 32.5% of product revenue from net sales of FC2 during the quarterly period. If product revenue from net sales of FC2 for the 12-month period ended as of the last day of the respective quarterly payment period is equal to or greater than $10.0 million, the quarterly payments are calculated as follows: (i) as it relates to each quarter during the 2019 calendar year, the sum of 12.5% of product revenue from net sales of FC2 up to and including $12.5 million in the Elapsed Period (as defined in the Credit Agreement), plus 5% of product revenue from net sales of FC2 greater than $12.5 million in the Elapsed Period, (ii) as it relates to each quarter during the 2020 calendar year, the sum of 25% of product revenue from net sales of FC2 up to and including $12.5 million in the Elapsed Period, plus 10% of product revenue from net sales of FC2 greater than $12.5 million in the Elapsed Period, and (iii) as it relates to each quarter during the 2021 calendar year and thereafter, the sum of 30% of product revenue from net sales of FC2 up to and including $12.5 million in the Elapsed Period, plus 20% of product revenue from net sales of FC2 greater than $12.5 million in the Elapsed Period. Upon the Credit Agreement's termination date of March 5, 2025, the Company must pay 176.5% of the aggregate amount advanced to the Company under the Credit Agreement less the amounts previously paid by the Company from product revenue. The payment requirements described above reflect an amendment to the Credit Agreement dated May 13, 2019 (the "Second Amendment") which included a reduction to the percentages to be used to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar year 2019, a return to the original percentages to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar year 2020 and an increase to the percentages to be used to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar year 2021 and thereafter until the loan has been repaid.

Upon a change of control of the Company or sale of the FC2 business, the Company must pay off the loan by making a payment to the Lenders equal to (i) 176.5% of the aggregate amount advanced to the Company under the Credit Agreement less the amounts previously paid by the Company from product revenue from net sales of FC2, plus (ii) the greater of (A) $2.0 million or (B) the product of (x) 5% of the product revenue from net sales of FC2 for the most recently completed 12-month period multiplied by (y) five. A "change of control" under the Credit Agreement includes (i) an acquisition by any person of direct or indirect ownership of more than 50% of the Company's issued and outstanding voting equity, (ii) a change of control or similar event in the Company's articles of incorporation or bylaws, (iii) certain Key Persons as defined in the Credit Agreement cease to serve in their current executive capacities unless replaced within 90 days by a person reasonably acceptable to the Agent, which acceptance not to be unreasonably withheld, or (iv) the sale of all or substantially all of the Company's assets.

The Credit Agreement contains customary representations and warranties in favor of the Agent and the Lenders and certaincovenants, including financial covenants addressing minimum quarterly marketing and distribution expenses for FC2 and a requirement to maintain minimum unencumbered liquid assets of $1.0 million. The Credit Agreement also restricts the payment of dividends and share repurchases. The recourse of the Lenders and the Agent for obligations under the Credit Agreement is limited to assets relating to FC2.

In connection with the Credit Agreement, the Company and the Agent also entered into a Residual Royalty Agreement, dated as of March 5, 2018 (as amended, the “Residual Royalty Agreement”), which provides for an ongoing royalty payment of 5% of product revenue from net sales of FC2 commencing after the Company would have paid 175% of the aggregate amount advanced to the Company under the Credit Agreement based on a calculation of revenue-based payments under the Credit Agreement without taking into account the amendments to the payment requirements under the Credit Agreement effected by the Second Amendment. The Residual Royalty Agreement will terminate upon (i) a change of control or sale of the FC2 business and the payment by the Company of the amount due in connection therewith pursuant to the Credit Agreement, or (ii) mutual agreement of the parties. If a change of control or sale of the FC2 business occurs prior to payment in full of the Credit Agreement, there will be no further payment due with respect to the Residual Royalty Agreement.If a change of control or sale of the FC2 business occurs after payment in full of the Credit Agreement, the Agent will receive a payment that is the greater of (A) $2.0 million or (B) the product of (x) 5% of the product revenue from net sales of FC2 for the most recently completed12-month period multiplied by (y) five.

Pursuant to a Guarantee and Collateral Agreement dated as of March 5, 2018 (the “Collateral Agreement”) and an Intellectual Property Security Agreement dated as of March 5, 2018 (the “IP Security Agreement”), the Company’s obligations under the Credit Agreement are secured by a lien against substantially all of the assets of the Company that relate to or arise from FC2. In addition, pursuant to a Pledge Agreement dated as of March 5, 2018 (the “Pledge Agreement”), the Company’s obligations under the Credit Agreement are secured by a pledge of up to 65% of the outstanding shares of The Female Health Company Limited, a wholly owned U.K. subsidiary.

For accounting purposes, the $10.0 million advance under the Credit Agreement was allocatedbetween the Credit Agreement and the Residual Royalty Agreement on a relative fair value basis. A portion of the amount allocated to the Credit Agreement and a portion of the amount allocated to the Residual Royalty Agreement, in both cases equal to the fair value of the respective change of control provisions, was allocated to the embedded derivative liabilities. The derivative liabilities are adjusted to fair market value at each reporting period. For financial statement presentation, the embedded derivative liabilities have been included with their respective host instruments as noted in the following tables. The debt discounts are being amortized to interest expense over the expected term of the loan using the effective interest method. Additionally, the Company recorded deferred loan issuance costs of approximately $267,000 for legal fees incurred in connection with the Credit Agreement. The deferred loan issuance costs are presented as a reduction of the Credit Agreement obligation and are being amortized to interest expense over the expected term of the loan using the effective interest method. The Second Amendment was accounted for as a debt modification, which resulted in prospective adjustment to the effective interest rate.

At December 31, 2020 and September 30, 2020, the Credit Agreement liability consisted of the following:

	December 31, 2020	**September 30, 2020**
Aggregate repayment obligation	$ 17,650,000	$ 17,650,000
Less: cumulative payments	(11,410,885)	(10,314,495)
Remaining repayment obligation	6,239,115	7,335,505
Less: unamortized discounts	(886,470)	(1,459,330)
Less: unamortized deferred issuance costs	(20,836)	(34,301)
Credit agreement liability	$ 5,331,809	$ 5,841,874

The Company repaid the original principal of$10.0 million during the quarter ended September 30, 2020. Remaining quarterly payments under the Credit Agreement will be classified as interest payments, consistent with the terms of the Credit Agreement. The Company currently estimates the remaining repayment obligation under the Credit Agreement will be paid during the 12-month period subsequent to December 31, 2020.

At December 31, 2020 and September 30, 2020, the Residual Royalty Agreement liability consisted of the following:

	December 31, 2020	September 30, 2020
Residual royalty agreement liability, fair value at inception	$ 346,000	$ 346,000
Add: accretion of liability using effective interest rate	2,792,545	2,189,687
Residual royalty agreement liability, excluding embedded derivative liability	3,138,545	2,535,687
Add: embedded derivative liability at fair value (see Note 4)	4,786,000	4,182,000
Total residual royalty agreement liability	7,924,545	6,717,687
Residual royalty agreement liability, short-term portion	(1,938,817)	(1,100,193)
Residual royalty agreement liability, long-term portion	$ 5,985,728	$ 5,617,494

The short-term portion of the Residual Royalty Agreement liability represents the aggregate of the estimated quarterly royalty payments payable during the 12-month period subsequent to the balance sheet date.

Interest expense related to the Credit Agreement and the Residual Royalty Agreement consisted of amortization of the discounts, accretion of the liability for the Residual Royalty Agreement and amortization of the deferred issuance costs. For the three months ended December 31, 2020 and 2019, interest expense related to the Credit Agreement and Residual Royalty Agreement was as follows:

	Three Months Ended December 31,	
	2020	2019
Amortization of discounts	$ 572,860	$ 861,986
Accretion of residual royalty agreement	602,858	259,178
Amortization of deferred issuance costs	13,465	20,261
Interest expense	$ 1,189,183	$ 1,141,425

Premium Finance Agreement

On November 1, 2020, the Company entered into a Premium Finance Agreement to finance $1.1 million of its directors and officers liability insurance premium at an annual percentage rate of 3.94%. The financing is payable in three quarterly installments of principal and interest, beginning on January 1, 2021. The insurance premium liability remains outstanding and is included in accrued expenses and other current liabilities on the accompanying unaudited condensed consolidated balance sheet as of December 31, 2020.

On November 1, 2019, the Company entered into a Premium Finance Agreement to finance$837,000 of its directors and officers liability insurance premium at an annual percentage rate of 4.18%. The financing was payable inthree quarterly installments of principal and interest, which began on January 1, 2020. The last payment was made on July 1, 2020 and there was no balance outstanding as of September 30, 2020.

Note 10 – Stockholders' Equity

Preferred Stock

The Company has 5,000,000 authorized shares designated as Class A Preferred Stock with a par value of$0.01 per share. There are 1,040,000 shares of Class A Preferred Stock – Series 1 authorized; 1,500,000 shares of Class A Preferred Stock – Series 2 authorized; 700,000 shares of Class A Preferred Stock – Series 3 authorized; and 548,000 shares of Class A Preferred Stock – Series 4 (the "Series 4 Preferred Stock") authorized. There were no shares of Class A Preferred Stock of any series issued and outstanding at December 31, 2020 and September 30, 2020. The Company has 15,000 authorized shares designated as Class B Preferred Stock with a par value of$0.50 per share. There were no shares of Class B Preferred Stock issued and outstanding at December 31, 2020 and September 30, 2020, and there was no activity during the three-month periods then ended.

Common Stock Purchase Warrants

In connection with the closing of the acquisition of APP (the “APP Acquisition”) on October 31, 2016, the Company issued warrants to purchase up to 2,585,379 shares of the Company's common stock to Torreya Capital, the Company's financial advisor (the “Financial Advisor Warrants”). The Financial Advisor Warrants had a five-year term expiring October 31, 2021, a cashless exercise feature and a strike price equal to $1.93 per share. The Financial Advisor Warrants vested upon issuance. As of September 30, 2020, an aggregate of 2,326,841 shares of common stock remained available for purchase under the Financial Advisor Warrants. During the three months ended December 31, 2020, the remaining Financial Advisor Warrants to purchase 2,326,841 shares of the Company’s common stock were exercised using the cashless exercise feature, resulting in the issuance of 1,574,611 shares of common stock. As of December 31, 2020, there were no outstanding common stock purchase warrants.

Aspire Capital Purchase Agreement

On June 26, 2020, the Company entered into a common stock purchase agreement (the “2020 Purchase Agreement”) with Aspire Capital Fund, LLC (Aspire Capital) which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right, from time to time in its sole discretion during the 36-month term of the 2020 Purchase Agreement, to direct Aspire Capital to purchase up to $23.9 million of the Company’s common stock in the aggregate. Concurrently with entering into the 2020 Purchase Agreement, the Company also entered into a registration rights agreement with Aspire Capital (the “Registration Rights Agreement”), in which the Company agreed to prepare and file under the Securities Act of 1933 one or more prospectus supplement for the sale or potential sale of the shares of the Company’s common stock that have been and may be issued to Aspire Capital under the 2020 Purchase Agreement.

Under the 2020 Purchase Agreement, on any trading day selected by the Company, the Company has the right, in its sole discretion, to present Aspire Capital with a purchase notice (each, a “Purchase Notice”), directing Aspire Capital (as principal) to purchase up to 200,000 shares of the Company’s common stock per business day at a per share price (the “Purchase Price”) equal to the lesser of the lowest sale price of the Company’s common stock on the purchase date or the average of the three lowest closing sale prices for the Company’s common stock during the ten consecutive trading days ending on the trading day immediately preceding the purchase date.

In addition, on any date on which the Company submits a Purchase Notice to Aspire Capital in an amount equal to200,000 shares and the closing sale price of our common stock is equal to or greater than $0.50 per share, the Company also has the right, in its sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice (each, a “VWAP Purchase Notice”) directing Aspire Capital to purchase an amount of common stock equal to up to 30% of the aggregate shares of the common stock traded on its principal market on the next trading day (the “VWAP Purchase Date”), subject to a maximum number of shares the Company may determine. The purchase price per share pursuant to such VWAP Purchase Notice is generally 97% of the volume-weighted average price for the Company’s common stock traded on its principal market on the VWAP Purchase Date.

Since inception of the 2020 Purchase Agreement, we have sold 1,644,737 shares of common stock to Aspire Capital resulting in proceeds to the Company of $5.0 million. As of December 31, 2020, the amount remaining under the 2020 Purchase Agreement was$18.9 million, which is registered under the Company’s 2020 shelf registration statement on Form S-3 (File No. 333-239493).

In consideration for entering into the 2020 Purchase Agreement, concurrently with the execution of the 2020 Purchase Agreement, the Company issued to Aspire Capital 212,130 shares of the Company’s common stock. The shares of common stock issued as consideration were valued at $681,000, based on the closing price per share of the Company’s common stock on the date the shares were issued. This amount and related expenses of $50,000, which total approximately $731,000, were recorded as deferred costs. The unamortized amount of deferred costs related to the 2020 Purchase Agreement of $578,000 at December 31, 2020 and September 30, 2020 is included in other assets on the accompanying unaudited condensed consolidated balance sheets.

Note 11 – Share-based Compensation

We allocate share-based compensation expense to cost of sales, selling, general and administrative expense, and research and development expense based on the award holder's employment function. For the three months ended December 31, 2020 and 2019, we recorded share-based compensation expenses as follows:

	Three Months Ended December 31,	
	2020	2019
Cost of sales	$ 16,212	$ 14,545
Selling, general and administrative	561,484	471,695
Research and development	207,601	128,258
Share-based compensation	$ 785,297	$ 614,498

We have issued share-based awards to employees and non-executive directors under the Company's approved equity plans. Upon the exercise of share-based awards, new shares are issued from authorized common stock.

Equity Plans

In March 2018, the Company's stockholders approved the Company's 2018 Equity Incentive Plan (as amended, the "2018 Plan"). A total of 11.0 million shares are authorized for issuance under the 2018 Plan. As of December 31, 2020, 3,659,905 shares remain available for issuance under the 2018 Plan.

In July 2017, the Company's stockholders approved the Company's 2017 Equity Incentive Plan (the "2017 Plan"). A total of 4.7 million shares are authorized for issuance under the 2017 Plan. As of December 31, 2020, 99 shares remain available for issuance under the 2017 Plan. The 2017 Plan replaced the Company's 2008 Stock Incentive Plan (the "2008 Plan"), and no further awards will be made under the 2008 Plan.

Stock Options

Each option grants the holder the right to purchase from us one share of our common stock at a specified price, which is generally the closing price per share of our common stock on the date the option is issued. Options generally vest on a pro-rata basis on each anniversary of the issuance date within three years of the date the option is issued. Options may be exercised after they have vested and prior to the specified expiry date provided applicable exercise conditions are met, if any. The expiry date can be for periods of up to ten years from the date the option is issued. The fair value of each option is estimated on the date of grant using the Black-Scholes option pricing model based on the assumptions established at that time. The Company accounts for forfeitures as they occur and does not estimate forfeitures as of the option grant date.

The following table outlines the weighted average assumptions for options granted during the three months ended December 31, 2020 and 2019:

	Three Months Ended December 31,	
	2020	2019
Weighted Average Assumptions:		
Expected volatility	65.81%	63.03%
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	0.51%	1.67%
Expected term (in years)	5.9	5.9
Fair value of options granted	$ 1.58	$ 1.11

During the three months ended December 31, 2020 and 2019, the Company used historical volatility of our common stock over a period equal to the expected life of the options to estimate their fair value. The dividend yield assumption is based on the Company's recent history and expectation of future dividend payouts on the common stock. The risk-free interest rate is based on the implied yield available on U.S. treasury zero-coupon issues with an equivalent remaining term.

The following table summarizes the stock options outstanding and exercisable at December 31, 2020:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2020	8,599,000	$ 1.67		
Granted	2,407,100	$ 2.75		
Exercised	(468,611)	$ 1.33		
Forfeited and expired	(62,535)	$ 1.79		
Outstanding at December 31, 2020	10,474,954	$ 1.94	8.24	$ 70,324,759
Exercisable at December 31, 2020	5,259,198	$ 1.61	7.45	$ 37,027,670

The aggregate intrinsic values in the table above are before income taxes andrepresent the number of in-the-money options outstanding or exercisable multiplied by the closing price per share of the Company's common stock on the last trading day of the quarter ended December 31, 2020 of $8.65, less the respective weighted average exercise price per share at period end

The total intrinsic value of options exercised during the three months ended December 31, 2020 and 2019 was approximately$2.4 million and $2,000, respectively. Cash received from options exercised during the three months ended December 31, 2020 was approximately $624,000. During the three months ended December 31, 2019, there was no cash received for option exercises as options to purchase1,666 shares of common stock were exercised using the cashless exercise feature available under the 2017 Plan, which resulted in the issuance of 867 shares of common stock. There were no options exercised using the cashless exercise feature during the three months ended December 31, 2020.

As of December 31, 2020, the Company had unrecognized compensation expense of approximately$5.7 million related to unvested stock options. This expense is expected to be recognized over a weighted average period of 1.8 years.

Stock Appreciation Rights

In connection with the closing of the APP Acquisition, the Company issued stock appreciation rights based on50,000 and 140,000 shares of the Company's common stock to an employee and an outside director, respectively, that vested on October 31, 2018. The stock appreciation rights have a ten-year term and an exercise price per share of$0.95, which was the closing price per share of the Company's common stock as quoted on NASDAQ on the trading day immediately preceding the date of the completion of the APP Acquisition. Upon exercise, the stock appreciation rights will be settled in common stock issued under the 2017 Plan. As of December 31, 2020, vested stock appreciation rights based on 50,000 shares of common stock remain outstanding.

Note 12 – Leases

The Company has operating leases for its office, manufacturing and warehouse space, and office equipment. The Company has a finance lease for office equipment, furniture, and fixtures. The Company's leases have remaining lease terms of less than one year to five years, which include the option to extend a lease when the Company is reasonably certain to exercise that option. The Company does not have any leases that have not yet commenced as of December 31, 2020. Certain of our lease agreements include variable lease payments for common area maintenance, real estate taxes, and insurance or based on usage for certain equipment leases. For one of our office space leases, the Company entered into a sublease, for which it receives sublease income. Sublease income is recognized as a reduction to operating lease costs as the sublease is outside of the Company's normal business operations. This is consistent with the Company's recognition of sublease income prior to the adoption of FASB ASC Topic 842.

The components of the Company's lease cost were as follows for the three months ended December 31, 2020 and 2019:

	Three Months Ended December 31,	
	2020	2019
Finance lease cost:		
Amortization of right-of-use assets	$ 2,178	$ 2,178
Interest on lease liabilities	939	1,480
Operating lease cost	135,326	132,574
Short-term lease cost	1,863	1,863
Variable lease cost	36,683	33,465
Sublease income	(44,845)	(44,844)
Total lease cost	$ 132,144	$ 126,716

The Company paid cash of $143,000 and $114,000 for amounts included in the measurement of operating lease liabilities during the three months ended December 31, 2020 and 2019, respectively.

The Company's operating lease ROU assets and the related lease liabilities are presented as separate line items on the accompanying unaudited condensed consolidated balance sheets as of December 31, 2020 and September 30, 2020.

Other information related to the Company's leases as of December 31, 2020 was as follows:

	December 31, 2020	September 30, 2020
Operating Leases		
Weighted-average remaining lease term	3.4	3.6
Weighted-average discount rate	11.5%	11.5%
Finance Leases		
Weighted-average remaining lease term	1.2	1.4
Weighted-average discount rate	13.9%	13.9%

The Company's lease agreements do not provide a readily determinable implicit rate. Therefore, the Company estimates its incremental borrowing rate based on information available at lease commencement in order to discount lease payments to present value.

Note 13 – Contingent Liabilities

The testing, manufacturing and marketing of consumer products by the Company and the clinical testing of our product candidates entail an inherent risk that product liability claims will be asserted against the Company. The Company maintains product liability insurance coverage for claims arising from the use of its products. The coverage amount is currently $10.0 million.

Litigation

From time to time we may be involved in litigation or other contingencies arising in the ordinary course of business. Based on the information presently available, management believes there are no contingencies, claims or actions, pending or threatened, the ultimate resolution of which will have a material adverse effect on our financial position, liquidity or results of operations.

In accordance with FASB ASC 450, Contingencies, we accrue loss contingencies including costs of settlement, damages and defense related to litigation to the extent they are probable and reasonably estimable. Otherwise, we expense these costs as incurred. If the estimate of a probable loss is a range and no amount within the range is more likely, we accrue the minimum amount of the range.

License and Purchase Agreements

From time to time, we license or purchase rights to technology or intellectual property from third parties. These licenses and purchase agreements require us to pay upfront payments as well as development or other payments upon successful completion of preclinical, clinical, regulatory or revenue milestones. In addition, these agreements may require us to pay royalties on sales of products arising from the licensed or acquired technology or intellectual property. Because the achievement of future milestones is not reasonably estimable, we have not recorded a liability on the accompanying unaudited condensed consolidated financial statements for any of these contingencies.

Note 14 – Income Taxes

The Company accounts for income taxes using the liability method, which requires the recognition of deferred tax assets or liabilities for the tax-effected temporary differences between the financial reporting and tax bases of its assets and liabilities, and for net operating loss (NOL) and tax credit carryforwards.

As of September 30, 2020, the Company had U.S. federal and state NOL carryforwards of$41.7 million and $25.7 million, respectively, for income tax purposes with $13.5 million and $19.8 million, respectively, expiring in years2022 to 2038 and $28.2 million and $5.9 million, respectively, which can be carried forward indefinitely. The Company's U.K. subsidiary has U.K. NOL carryforwards of $61.3 million as of September 30, 2020, which can be carried forward indefinitely to be used to offset future U.K. taxable income.

A reconciliation of income tax expense (benefit) and the amount computed by applying the U.S. statutory rate of 21% to income (loss) before income taxes is as follows:

	Three Months Ended December 31,	
	2020	2019
Income tax expense (benefit) at U.S. federal statutory rates	$ 3,634,260	$ (710,188)
State income tax expense (benefit), net of federal expense (benefits)	281,396	(55,000)
Effect of stock options exercised	(64,290)	—
Effect of common stock purchase warrants exercised	(2,038,919)	—
Effect of Paycheck Protection Program funds	(95,886)	—
Effect of foreign income tax rates	(32,570)	42,554
Effect of global intangible low taxed income	125,145	50,451
Change in valuation allowance	(1,732,786)	592,710
Other, net	1,952	2,730
Income tax expense (benefit)	$ 78,302	$ (76,743)

Significant components of the Company's deferred tax assets and liabilities are as follows:

	December 31, 2020	September 30, 2020
Deferred tax assets:		
Federal net operating loss carryforwards	$ 7,677,224	$ 8,759,589
State net operating loss carryforwards	1,606,045	1,682,104
Foreign net operating loss carryforwards – U.K.	11,618,351	11,655,853
Foreign capital allowance – U.K.	113,522	113,522
Share-based compensation	1,005,282	1,255,983
Interest expense	—	850,248
Other, net – U.K.	93,739	93,739
Other, net – U.S.	528,251	374,942
Gross deferred tax assets	22,642,414	24,785,980
Valuation allowance for deferred tax assets	(12,341,954)	(14,074,740)
Net deferred tax assets	10,300,460	10,711,240
Deferred tax liabilities:		
In-process research and development	(882,427)	(882,427)
Developed technology	—	(369,237)
Covenant not-to-compete	(45,791)	(49,832)
Other, net – Malaysia	(11,297)	(11,297)
Other, net – U.S.	(6,371)	(6,371)
Net deferred tax liabilities	(945,886)	(1,319,164)
Net deferred tax asset	$ 9,354,574	$ 9,392,076

The deferred tax amounts have been classified on the accompanying unaudited condensed consolidated balance sheets as follows:

	December 31, 2020	September 30, 2020
Deferred tax asset – U.K.	$ 9,429,298	$ 9,466,800
Total deferred tax asset	$ 9,429,298	$ 9,466,800
Deferred tax liability – U.S.	$ (63,427)	$ (63,427)
Deferred tax liability – Malaysia	(11,297)	(11,297)
Total deferred tax liability	$ (74,724)	$ (74,724)

Note 15 – Paycheck Protection Program

The CARES Act established the Paycheck Protection Program (PPP) administered by the U.S. Small Business Administration (SBA), which authorized forgivable loans to small businesses. Pursuant to the CARES Act, PPP loans will be fully forgiven if the funds are used for payroll costs, rent and utilities, subject to certain conditions, including maintaining employees and maintaining salary levels. In April 2020, the Company applied for a PPP loan and received funding of approximately $540,000. The Company expended the funds received under the PPP in full on qualifying expenses, and maintained the conditions set forth by the PPP. The Company submitted its application for forgiveness in September 2020 and the SBA approved the forgiveness of the full amount of the loan and the related interest on November 10, 2020.

Note 16 – Net Income (Loss) Per Share

Basic net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period. Diluted net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period after giving effect to all dilutive potential common shares that were outstanding during the period. Dilutive potential common shares consist of the incremental common shares issuable upon the exercise of stock options, stock appreciation rights and common stock purchase warrants as determined under the treasury stock method.

The following table provides a reconciliation of the net income (loss) per basic and diluted common share outstanding:

	Three Months Ended December 31,	
	2020	2019
Net income (loss)	$ 17,227,701	$ (3,305,101)
Basic weighted average common shares outstanding	70,313,589	65,038,511
Net effect of dilutive instruments:		
Stock options	4,421,341	—
Stock appreciation rights	38,527	—
Common stock purchase warrants	1,025,580	—
Total net effect of dilutive instruments	5,485,448	—
Diluted weighted average common shares outstanding	75,799,037	65,038,511
Net income (loss) per basic common share outstanding	$ 0.25	$ (0.05)
Net income (loss) per diluted common share outstanding	$ 0.23	$ (0.05)

For the three months ended December 31, 2020, 1.4 million potentially dilutive instruments were excluded from the computation of net income per diluted weighted average common share outstanding because their effect would have been antidilutive. Due to our net loss for the three months ended December 31, 2019, all potentially dilutive instruments were excluded because their inclusion would have been anti-dilutive. See Notes 10 and 11 for a discussion of our potentially dilutive instruments.

Note 17 – Industry Segments

The Company currently operates in two reporting segments: Sexual Health Business and Research and Development. The Sexual Health Business segment consists of the Company's commercial product, FC2. The Sexual Health Business also included PREBOOST® before the sale of the business in December 2020. The Research and Development segment consists of multiple drug products under clinical development. The Company's Sexual Health Business segment will include future revenues, cost of sales and selling expenses for TADFIN™. Costs associated with the development of TADFIN™ are currently included in the Research and Development segment. There are no significant inter-segment sales. We evaluate the performance of each segment based on operating profit or loss. There is no inter-segment allocation of non-operating expenses and income taxes. Our chief operating decision-maker (CODM) is Mitchell S. Steiner, M.D., our Chairman, President and Chief Executive Officer.

The Company's operating income (loss) by segment is as follows:

	Three Months Ended December 31,	
	2020	2019
Sexual health business	$ 9,910,779	$ 5,969,063
Research and development	(5,858,837)	(5,289,859)
Corporate	15,135,215	(2,463,597)
Operating income (loss)	$ 19,187,157	$ (1,784,393)

All of our net revenues, which are primarily derived from the sale of FC2, are attributed to the Sexual Health Business reporting segment. See Note 5 for additional information regarding our net revenues. Costs related to the office located in London, England are fully dedicated to FC2 and are presented as a component of the Sexual Health Business segment. Drug commercialization costs are included in the Research and Development segment. Certain expenses in the three months ended December 31, 2019 have been reclassified to conform to the current period presentation. The gain on sale of the PREBOOST® business and depreciation and amortization related to long-lived assets that are not utilized in the production of FC2 are not reported as part of the reporting segments or reviewed by the CODM. These amounts are included in Corporate in the reconciliations above. Total assets are not presented by reporting segment as they are not reviewed by the CODM when evaluating the reporting segments' performance.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

Veru is an oncology biopharmaceutical company with a focus on developing novel medicines for the management of prostate and breast cancers.

The Company's prostate cancer drug pipeline includes VERU-111, VERU-100 and Zuclomiphene citrate.

VERU-111 for the treatment of men with metastatic castration resistant prostate cancer who have also become resistant to at least one androgen receptor targeting agent

VERU-111 is an oral, first-in-class, new chemical entity that targets, crosslinks, and disrupts alpha and beta tubulin subunits of microtubules to disrupt the cytoskeleton. VERU-111 is being evaluated in open label Phase 1b and Phase 2 clinical studies 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 1b study has yielded promising efficacy and safety clinical data. Daily chronic drug administration appears feasible and safe. At the recommended Phase 2 dose, there were no reports of neutropenia, neurotoxicity, or Grade 3 diarrhea. The Phase 2 clinical study has completed enrollment of 40 men with metastatic castration resistant prostate cancer who have also become resistant to at least one androgen receptor targeting agent, such as abiraterone or enzalutamide, but prior to proceeding to IV chemotherapy. In July 2020, the Company had an FDA meeting and received positive input from the FDA on the pivotal Phase 3 trial design for VERU-111. The Company received regulatory clarity that the indication of treatment in men with metastatic castration resistant prostate cancer who have failed one androgen receptor targeting agent, but prior the IV chemotherapy was acceptable, that an open label, randomized study using an alternative androgen receptor targeting agent as the active control is reasonable, and that the primary endpoint may be radiographic progression-free survival. By allowing radiographic progression-free survival as the primary endpoint, the sample size of the Phase 3 study could be potentially between 200 and 300 men. The Company anticipates starting its VERACITY Phase 3 pivotal study evaluating VERU-111 for men with metastatic castration resistant prostate cancer who have also become resistant to one androgen receptor targeting agent in the first quarter of calendar year 2021.

VERU-100 androgen deprivation therapy for the treatment of advanced prostate cancer

VERU-100 is a novel, proprietary long-acting gonadotropin-releasing hormone (GnRH) antagonist peptide three-month subcutaneousdepot formulation designed to address the current limitations of commercially available androgen deprivation therapies (ADT). Androgen deprivation therapy is currently the mainstay of advanced prostate cancer treatment and is used as a foundation of treatment throughout the course of the disease. Furthermore, ADT is continued even as other endocrine, chemotherapy, or radiation treatments are added or stopped. Specifically, VERU-100 is a chronic, long-acting GnRH antagonist peptide administered as a small volume, three-month depot subcutaneous injection without a loading dose. VERU-100 immediately suppresses testosterone with no testosterone surge upon initial or repeated administration, a problem that occurs with currently approved luteinizing hormone-releasing hormone (LHRH) agonists used for ADT. There are no GnRH antagonist depot injectable formulations commercially approved beyond a one-month injection. A Phase 2 study to evaluate VERU-100 dosing is anticipated to begin in the first quarter of calendar year 2021 and a Phase 3 registration clinical trial is anticipated to begin in the second half of calendar year 2021.

Zuclomiphene citrate for the treatment of men who have hot flashes caused by androgen deprivation therapy 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. 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.

The Company’s breast cancer drug pipeline includes Enobosarm and VERU-111.

Enobosarm, selective androgen receptor targeted agonist, for the treatment of androgen receptor positive (AR+), estrogen receptor positive (ER+) and human epidermal growth factor receptor 2 (HER2-) metastatic breast cancer

Enobosarm is the first new class of targeting endocrine therapy in advanced breast cancer in decades. Enobosarm is an oral, first-in-class, new chemical entity, selective androgen receptor agonist that activates the androgen receptor (AR)in AR+/ER+/HER2- metastatic breast cancer, which results in antitumor activity without the unwanted virilizing side effects. Enobosarm has extensive nonclinical and clinical experience having been evaluated in 25 separate clinical studies in approximately 2,100 subjects, including five prior 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 and was well tolerated with a favorable safety profile. In the fourth quarter of calendar 2020, the FDA agreed to the Phase 3 registration clinical trial design to evaluate the efficacy and safety of enobosarm, selective androgen receptor targeting agent, versus physician’s choice of either exemestane or tamoxifen as an active comparator 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 and prior to IV chemotherapy. The primary endpoint is radiographic progression-free survival. The pivotal Phase 3, open label, randomized, active control ARTEST study is anticipated to commence in the second quarter of calendar year 2021.

Enobosarm was also part of the focus of a recent article in*Nature Medicine*, Volume 27, Issue 2, February, 2021, entitled: “The Androgen Receptor is a Tumor Suppressor in Estrogen Receptor-Positive Breast Cancer”. In the *Nature Medicine* publication, the researchers and authors provide scientific evidence supporting a new discovery in breast cancer demonstrating that the androgen receptor acts like a tumor suppressor. This important new work establishes that the androgen receptor is a tumor suppressor and that enobosarm, as an AR targeted agent, may have antitumor activity not only in AR+ ER+ metastatic breast cancer that has become resistance to estrogen receptor targeted endocrine and CDK4/6 inhibitor treatments, but also that enobosarm in combination with a CDK4/6 inhibitor (e.g. Palbociclib) may potentially restore CDK4/6 inhibitor sensitivity in ER+ breast cancer that has become resistant to CDK4/6 inhibitors.

VERU-111 for treatment of taxane resistant metastatic triple negative breast cancer

Metastatic triple negative breast cancer (TNBC) is an aggressive form of breast cancer that occurs in approximately 15% of all breast cancers. This form of breast cancer does not express ER, progesterone receptor (PR), or HER2 and is resistant to endocrine therapies. The first line of treatment usually includes IV taxane chemotherapy. Almost all women will eventually develop taxane resistance. VERU-111 is an oral, first-in-class, new chemical entity that targets, crosslinks, and binds to alpha and beta tubulin subunits of microtubules to disrupt the cytoskeleton and is not a substrate for P-glycoprotein drug resistance protein. Over expression of P-glycoprotein is a common mechanism that results in taxane resistance in TNBC. 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 (taxane). Using the safety information from the Phase 1b and Phase 2 VERU-111 prostate cancer clinical studies in a total of approximately 80 men, the Company plans to meet with the FDA in first half of calendar year 2021 and to commence a Phase 2b clinical study in the fourth quarter of calendar year 2021 to evaluate oral daily dosing of VERU-111 in approximately 200 women with metastatic TNBC that has become resistant to taxane IV chemotherapy.

Anti-viral and Anti-inflammatory Drug Candidate – COVID-19

VERU-111 for the treatment of SARS-CoV-2 in subjects 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 anti-viral and anti-inflammatory activities which may serve as a two-pronged approach to the treatment of COVID-19 virus infection and the subsequent debilitating inflammatory effects thatcan lead to Acute Respiratory Distress Syndrome (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 hospitalized COVID-19 patients who were at high risk for ARDS. This trial was conducted in 5 sites across the United States. Patients that were hospitalized with documented evidence of COVID-19 infection with symptoms and who were at high risk for ARDS were enrolled. Subjects received either VERU-111 18mg or placebo as well as standard of care for 21 days or until released from the hospital. The primary efficacy endpoint was the proportion of patients that were alive without respiratory failure at Day 29. On February 8, 2020, we announced positive results from this Phase 2 clinical trial evaluating VERU-111 for the treatment of hospitalized patients with COVID-19 who were high risk for ARDS. For the primary endpoint in hospitalized patients that hadgreater than one dose of study drug, VERU-111 treatment compared to placebo had a statistically significant and clinically meaningfulimprovement in the proportion of patients with treatment failures (death or alive with respiratory failure) being 5.6%in the VERU-111 treated group (n=18) and 30% in the placebo treated group (n=20) at Day 29. This represents an 81%relative reduction in treatment failures and shows statistical significance with p=0.05. VERU-111 was 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 completed 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 SARS-CoV-2 virus infection 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.

Sexual Health Division

The Company's Sexual Health Division includes a drug candidate, TADFIN™, for the treatment of benign prostatic hyperplasia (BPH) and a commercial product, the FC2 Female Condom/FC2 Internal Condom® (FC2), an FDA-approved product for the dual protection against unplanned pregnancy and the transmission of sexually transmitted infections.

TADFIN™ (tadalafil 5mg and finasteride 5mg combination capsule) is being 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 by finasteride alone. The Company had a successful pre-New Drug Application (NDA) meeting with the FDA and expects to submit the NDA for TADFIN™ in February 2021. The Company's Sexual Health Business segment will include future revenues for TADFIN™. Costs associated with the development of TADFIN™ are currently included in our Research and Development segment.

The Company sells FC2 in both the commercial sector in the U.S. and in the public health sector in the U.S. and globally. In the U.S., FC2 is available by prescription through multiple telemedicine (telemedicine being the remote diagnosis and treatment of patients by means of telecommunications technology) and internet pharmacy channels as well as retail pharmacies. It is also available to public health sector entities such as state departments of health and 501(c)(3) organizations. 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.

Most of the Company's net revenues during the three months ended December 31, 2020 and 2019 were derived from sales of FC2 in the commercial and public health sectors.

Sale of PREBOOST® Business

On December 8, 2020, the Company entered into an Asset Purchase Agreement (the "Purchase Agreement"), pursuant to which the Company sold substantially all of the assets related to the Company's PREBOOST® business. PREBOOST® is a 4% benzocaine medicated individual wipe for the treatment of premature ejaculation and was a commercial product in the Company's Sexual Health Division during fiscal 2020. The transaction closed on December 8, 2020. The purchase price for the transaction was $20.0 million, consisting of $15.0 million paid at closing, $2.5 million payable 12 months after closing and $2.5 million payable 18 months after closing.

COVID-19 Environment

In December 2019, a novel strain of coronavirus was reported to have emerged in Wuhan, China. COVID-19, the disease caused by the coronavirus, has since spread to over 100 countries, including every state in the United States. On March 11, 2020, the World Health Organization declared COVID-19 a pandemic, and on March 13, 2020, the United States declared a national emergency with respect to the COVID-19 outbreak.

In an effort to contain and mitigate the spread of COVID-19, many countries, including the United States, the United Kingdom and Malaysia, have imposed unprecedented restrictions on travel, and there have been business closures and a substantial reduction in economic activity in countries that have had significant outbreaks of COVID-19. In addition and in an attempt to slow the rapid growth of the COVID-19 infection rate, many governments around the world, including in the United States at the federal, state and local levels as well as in the United Kingdom and Malaysia, have imposed mandatory sheltering in place and social distancing restrictions that severely limit the ability of its citizens to travel freely and to conduct activities.

The COVID-19 pandemic has substantially impacted the global healthcare system, including the conduct of clinical trials. Many healthcare systems have restructured operations to prioritize caring for those suffering from COVID-19 and to limit or cease other activities. The severe burden on healthcare systems caused by this pandemic has also impaired the ability of many research sites to start new clinical trials or to enroll new patients in clinical trials. The imposed mandatory sheltering in place and social distancing restrictions may delay the recruitment of patients and impede their ability to effectively participate in such trials. Significant fees may also be owed to contract research organizations associated with starting and stopping clinical trials, typically more so than delaying the start of a clinical trial.

The Phase 1b portion of our ongoing VERU-111 clinical trial is fully enrolled. The Phase 2 clinical study has completed enrollment of approximately 40 men with metastatic castration resistant prostate cancer who have also become resistant to androgen receptor targeting agents, such as abiraterone, enzalutamide, or apalutamide, but prior to proceeding to IV chemotherapy. However, there is a risk that changing circumstances relating to the COVID-19 pandemic may not allow our healthcare clinical trial investigators, their healthcare facilities, or other necessary parties to continue to participate in these trials through completion.

To date, COVID-19 has not impacted the Company's ability to supply product demand. At the start of the pandemic, we did experience some temporary disruption to our manufacturing facility due to the implementation of local government policies. On March 16, 2020, the Malaysian government issued an order closing non-essential businesses in that country due to the COVID-19 pandemic. As a result, the sole facility where the Company manufactures FC2 was unable to manufacture or ship product starting March 16, 2020. Because FC2 is a health product, the Company received an exemption to reopen the facility with limited staff to ship existing inventory on March 27, 2020, to reopen for manufacturing with 50% of the regular number of workers and social distancing requirements on April 20, 2020 and to return to 100% of the regular number of workers but with continued social distancing requirements on May 4, 2020. The Company has had a sufficient quantity of FC2 inventory both inside and outside of Malaysia to continue to satisfy customer demand. The Company has adopted measures to protect the employees at its Malaysian facility, to respond in the event an employee at the facility is determined to have tested positive for COVID-19, and to mitigate the impact of COVID-19 on the Company's Malaysian manufacturing operations. However, no such measures can eliminate risks relating to the COVID-19 pandemic, and if the Company's Malaysian manufacturing facility is subject to government mandates to counter COVID-19 or encounters labor or raw material shortages, transportation delays or other issues, our ability to supply product to our customers could be disrupted. There have been no additional closures of non-essential businesses by the Malaysian government.

The sole supplier of the nitrile polymer sheath for FC2also produces surgical gloves and has at times prioritized their productionduring the COVID-19 pandemic and may continue to do so, which could disrupt the Company's supply of a critical raw material. Malaysian ports are currently open for shipment but at reduced capacity, and the Company may also encounter issues shipping product into key markets or through freight or other carriers. To mitigate these factors, the Company continues to build strategic stock to ensure supply is available during a period of potential disruption. The COVID-19 pandemic and related economic disruption may also adversely affect customer demand for FC2. For example, sales of FC2 could be impacted in the U.S. prescription market if insurance coverage is affected by job losses and in the global public health sector if governments delay future tenders or reduce spending on female condoms due to financial strains or changed spending priorities caused by the COVID-19 pandemic. The COVID-19 pandemic did not have a material net impact on our consolidated operating results during the three months ended December 31, 2020.

To protect the health and safety of our workforce, we have closed our offices in the United States and the United Kingdomto non-essential staff and our personnel have largely been working remotely. Travel between our facilities in the United States, the United Kingdom and Malaysia has also been restricted. As of the date of this report, our operations have not been significantly impacted by such remote work requirements and travel restrictions.

Significant uncertainty remains as to the potential impact of the COVID-19 pandemic on our operations, and on the global economy. It is currently not possible to predict how long the pandemic will last or the time that it will take for economic activity to return to prior levels as a result of uncertainties, including the extent and rate of the spread of the virus that continue to fluctuate, the potential for additional peaks in infection rates, and the timing and availability of vaccines, treatments or cures to slow and eventually stop the spread. We do not yet know the full extent of any impact on our business or our operations; however, we will continue to monitor the COVID-19 situation and its impact on our business closely and expect to reevaluate the timing of our anticipated clinical trials as the impact of COVID-19 on our industry becomes clearer.

Sales of FC2 in the public health and commercial sectors

FC2 Commercial Sector. In 2017, the Company began expanding access to FC2 in the U.S. by making it available by prescription. With a prescription, FC2 is covered by most insurance companies with no copay under the ACA and the laws of 20+ states prior to enactment of the ACA. In 2018, we dissolved our small-scale marketing and sales program to focus our efforts in accessing fast-growing, highly reputable telemedicine firms (telemedicine being the remote diagnosis and treatment of patients by means of telecommunications technology) to bring our much-needed FC2 product to patients with a prescription in a cost-effective and highly convenient manner. As a result of these efforts, the Company now supplies FC2 to telemedicine providers in the U.S. prescription channel. The Company is working to develop supply and distributor relationships with additional telemedicine and other providers.

FC2 Public Health Sector. FC2's use is for the prevention of HIV/AIDS and the transmission of other sexually transmitted diseases and family planning, and the global public health sector has been an important market for FC2. Within the global public health sector, various organizations supply critical products such as FC2, at no cost or low cost, to those who need but cannot afford to buy such products for themselves.

FC2 has been distributed in the U.S. and 149 other countries. A significant number of countries with the highest demand potential are in the developing world. The incidence of HIV/AIDS, other sexually transmitted infections and unintended pregnancy in these countries represents a remarkable potential for significant sales of a product that benefits some of the world's most underprivileged people. However, conditions in these countries can be volatile and result in unpredictable delays in program development, tender applications and processing orders.

The Company is working to further develop a global market and distribution network for FC2 by maintaining relationships with global public health sector groups and completing strategic arrangements with companies with the necessary marketing and financial resources and local market expertise.

The Company currently has a limited number of customers for FC2 in the global public health sector who generally purchase in large quantities. Over the past few years, significant customers have included large global agencies, such as UNFPA, USAID, the Brazil Ministry of Health either through UNFPA or Semina Indústria e Comércio Ltda (Semina), the Company's distributor in Brazil, and the Republic of South Africa health authorities that purchase through the Company's various local distributors. Other customers include ministries of health or other governmental agencies, which either purchase directly or via in-country distributors, and NGOs.

Purchasing patterns for FC2 in the public health sector vary significantly from one customer to another and may reflect factors other than simple demand. For example, some governmental agencies purchase FC2 through a formal procurement process in which a tender (request for bid) is issued for either a specific or a maximum unit quantity. Tenders also define the other elements required for a qualified bid submission (such as product specifications, regulatory approvals, clearance by WHO, unit pricing and delivery timetable). Bidders have a limited period of time in which to submit bids. Bids are subjected to an evaluation process which is intended to conclude with a tender award to the successful bidder. The entire tender process, from publication to award, may take many months to complete, including administrative actions or appeals. A tender award indicates acceptance of the bidder's price rather than an order or guarantee of the purchase of any minimum number of units. Many governmental tenders are stated to be "up to" the maximum number of units, which gives the applicable government agency discretion to purchase less than the full maximum tender amount. Orders are placed after the tender is awarded; there are often no set dates for orders in the tender and there are no guarantees as to the timing or amount of actual orders or shipments. Orders received may vary from the amount of the tender award based on a number of factors including vendor supply capacity, quality inspections and changes in demand. Administrative issues, politics, bureaucracy, exchange rate risk, process errors, changes in leadership, funding priorities and/or other pressures may delay or derail the process and affect the purchasing patterns of public health sector customers. As a result, the Company may experience significant quarter-to-quarter sales variances in the global public health sector due to the timing and shipment of large orders of FC2.

On August 27, 2018, the Company announced that through six of its distributors in the Republic of South Africa, the Company had received a tender award to supply 75% of a tender covering up to 120 million female condoms over three years. The Company began shipping units under this tender award in the third quarter of fiscal 2019 and we have shipped approximately 12.2 million units through December 31, 2020. In October 2020, the Company was awarded 20 million units through its distributor in Brazil under the new Brazil female condom tender. These units are expected to be delivered over two years.

FC2 Unit Sales. Details of the quarterly unit sales of FC2 for the last five fiscal years are as follows:

Period	**2021**	**2020**	**2019**	**2018**	**2017**
October 1 — December 31	12,318,988	10,070,700	7,382,524	4,399,932	6,389,320
January 1 — March 31		6,884,472	9,792,584	4,125,032	4,549,020
April 1 — June 30		10,532,048	10,876,704	10,021,188	8,466,004
July 1 — September 30		5,289,908	9,842,020	6,755,124	6,854,868
Total	12,318,988	32,777,128	37,893,832	25,301,276	26,259,212

Revenues. Most of the Company's net revenues during the three months ended December 31, 2020 and 2019 were derived from sales of FC2 in the U.S. prescription channel and global public health sector. The Company also had revenues from sales of PREBOOST® (Roman Swipes) through the date the PREBOOST® business was sold on December 8, 2020. These sales are recognized upon shipment or delivery of the product to the customers depending on contract terms.

The Company's most significant customers have been telemedicine providers in the U.S. who sell into the prescription channel and global public health sector agencies who purchase and/or distribute FC2 for use in preventing the transmission of HIV/AIDS and/or family planning.

The Company manufactures FC2 in a leased facility located in Selangor D.E., Malaysia, resulting in a portion of the Company's operating costs being denominated in foreign currencies. While a significant portion of the Company's future unit sales are likely to be in foreign markets, all sales are denominated in the U.S. dollar. Effective October 1, 2009, the Company's U.K. and Malaysia subsidiaries adopted the U.S. dollar as their functional currency, further reducing the Company's foreign currency risk.

Operating Expenses. The Company manufactures FC2 at its Malaysian facility. The Company's cost of sales consists primarily of direct material costs, direct labor costs and indirect production and distribution costs. Direct material costs include raw materials used to make FC2, principally a nitrile polymer. Indirect production costs include logistics, quality control and maintenance expenses, as well as costs for electricity and other utilities. All the key components for the manufacture of FC2 are essentially available from either multiple sources or multiple locations within a source.

Conducting research and development is central to our business model. The Company's Research and Development segment includes multiple products and management routinely evaluates each product in its portfolio of products. Advancement is limited to available working capital and management's understanding of the prospects for each product. If future prospects do not meet management's strategic goals, advancement may be discontinued. We have invested and expect to continue to invest significant time and capital in our research and development operations. Our research and development expenses were $5.7 million and $5.3 million for the three months ended December 31, 2020 and 2019, respectively. We expect to continue this trend of increased expenses relating to research and development due to advancement of multiple drug candidates.

Results of Operations

THREE MONTHS ENDED DECEMBER 31, 2020 COMPARED TO THREE MONTHS ENDED DECEMBER 31, 2019

The Company generated net revenues of $14.6 million and net income of $17.2 million, or $0.25 per basic common share and $0.23 per diluted common share, for the three months ended December 31, 2020, compared to net revenues of $10.6 million and net loss of $3.3 million, or $(0.05) per basic and diluted common share, for the three months ended December 31, 2019. Net revenues increased 38% over the prior period.

FC2 net revenues represented 94% of total net revenues for the three months ended December 31, 2020. FC2 net revenues increased 32% year over year. There was a 22% increase in total FC2 unit sales and an increase in FC2 average sales price per unit of 8%. The principal factor for the increase in the FC2 average sales price per unit compared to prior period was the change in the sales mix with the U.S. prescription channel representing 66% of total FC2 net revenues in the current year period compared to 58% of total FC2 net revenues in the prior year period. The Company experienced an increase of 50% in FC2 net revenues in the U.S. prescription channel and an increase of 6% in FC2 net revenues in the global public health sector.

Cost of sales increased to $3.8 million in the three months ended December 31, 2020 from $3.3 million in the three months ended December 31, 2019 primarily due to an increase in unit sales.

Gross profit increased to $10.8 million in the three months ended December 31, 2020 from $7.3 million in the three months ended December 31, 2019. Gross profit margin for the fiscal 2021 period was 74% of net revenues, compared to 69% of net revenues for the fiscal 2020 period. The increase in the gross profit margin is primarily due to an increase in net revenues in the U.S. prescription channel and a decrease in labor and equipment maintenance costs.

Significant quarter-to-quarter variances in the Company's results have historically resulted from the timing and shipment of large orders rather than from any fundamental changes in the business or the underlying demand for FC2. The Company is also currently seeing pressure on pricing for FC2 by large global agencies and donor governments in the developed world. As a result, the Company may continue to experience challenges for revenue from sales of FC2 in the global public health sector. The Company is experiencing a significant increase in revenue from sales in the U.S. prescription channel, which is helping grow net revenues quarter to quarter and year to year.

Research and development expenses increased to $5.7 million in the three months ended December 31, 2020 from $5.3 million in the same period in fiscal 2020. The increase is primarily due to increased costs associated with the multiple in-process research and development projects and increased personnel costs.

Selling, general and administrative expenses increased to $4.4 million in the three months ended December 31, 2020 from $3.8 million in the three months ended December 31, 2019. The increase is due primarily to increased patent-related legal costs, increased insurance costs, and increased personnel costs.

During the first quarter of fiscal 2021, we recorded a pre-tax gain on sale of the Company's PREBOOST® business of $18.4 million. See Note 3 to the financial statements included in this report for additional information.

Interest expense, which consists of items related to the Credit Agreement and Residual Royalty Agreement, was $1.2 million in the three months ended December 31, 2020, which is comparable with $1.1 million in the three months ended December 31, 2019.

Expense associated with the change in fair value of the embedded derivatives related to the Credit Agreement and Residual Royalty Agreement was $0.6 million in the three months ended December 31, 2020 compared to $0.4 million in the three months ended December 31, 2019. The liabilities associated with embedded derivatives represent the fair value of the change of control provisions in the Credit Agreement and Residual Royalty Agreement. See Note 4 and Note 9 to the financial statements included in this report for additional information.

Income tax expense in the first quarter of fiscal 2021 was $78,000, compared to income tax benefit of $77,000 in the first quarter of fiscal 2020. The increase in the income tax expense of $0.2 million is primarily due to the increase in income before income taxes of $20.7 million due to the gain on the sale of the PREBOOST® business resulting in an increase of $4.7 million in income tax expense, partially offset by the effect of common stock purchase warrants exercised of $2.0 million and by a decrease in the change in the valuation allowance of $2.3 million.

Liquidity and Sources of Capital

Liquidity

Our cash and cash equivalents on hand at December 31, 2020was $30.9 million, compared to $13.6 million at September 30, 2020. At December 31, 2020, the Company had working capital of $30.5 million and stockholders' equity of $48.7 million compared to working capital of $12.3 million and stockholders' equity of $30.1 million as of September 30, 2020. The increase in working capital is primarily due to the increase in cash on hand and the current portion of the note receivable related to the sale of the PREBOOST® business, partially offset by an increase in accrued expenses and other current liabilities.

We anticipate that we will continue to consume cash as we develop our drug candidates. Because of the numerous risks and uncertainties associated with the development of pharmaceutical products, we are unable to estimate the exact amounts of capital outlays and operating expenditures necessary to fund development of our drug candidates and obtain regulatory approvals. Our future capital requirements will depend on many factors. See Part I, Item 1A, "Risk Factors - Risks Related to Our Financial Position and Need for Capital" in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2020 for a description of certain risks that will affect our future capital requirements.

The Company believes its current cash position and cash expected to be generated from sales of the Company's commercial product are adequate to fund planned operations of the Company for the next 12 months. To the extent the Company may need additional capital for its operations, it may access financing alternatives that may include debt financing, common stock offerings, or financing involving convertible debt or other equity-linked securities and may include financings under the Company's current effective shelf registration statement on Form S-3 (File No. 333-239493). The Company intends to be opportunistic when pursuing equity or debt financing which could include selling common stock under the 2020 Purchase Agreement with Aspire Capital (see discussion below). See Part I, Item 1A, "Risk Factors - Risks Related to Our Financial Position and Need for Capital" in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2020 for a description of certain risks related to our ability to raise capital on acceptable terms.

Operating activities

Net cash from operating activities was $0.7 million in the three months ended December 31, 2020. Cash from operating activities included net income of $17.2 million, adjustments to reconcile net income to net cash provided by operating activities totaling a reduction of $16.7 million and changes in operating assets and liabilities of $0.1 million. Adjustments to net income primarily consisted of $18.4 million related to the gain on sale of the PREBOOST® business, $0.8 million of share-based compensation, and $0.6 million for the change in fair value of derivative liabilities. The increase in cash from changes in operating assets and liabilities included a decrease in accounts receivable of $1.1 million, an increase in accounts payable of $0.5 million, and an increase in accrued expenses and other current liabilities of $0.4 million, partially offset by an increase in prepaid expenses and other assets of $1.8 million.

Our operating activities used cash of $2.5 million in the three months ended December 31, 2019. Cash used in operating activities included a net loss of $3.3 million, adjustments for noncash items totaling $2.3 million and changes in operating assets and liabilities of $1.5 million. Adjustments for noncash items primarily consisted of $1.1 million of noncash interest expense, $0.6 million of share-based compensation, and $0.4 million for the increase in the fair value of the derivate liabilities related to the Credit Agreement and Residual Royalty Agreement. The decrease in cash from changes in operating assets and liabilities included an increase in accounts receivable of $0.6million and an increase in inventories of $1.1 million. These were partially offset by an increase in accounts payable of $0.7million.

Investing activities

Net cash from investing activities was $15.0 million in the three months ended December 31, 2020, attributed to $15.0 million received from the sale of the Company's PREBOOST® business.

Net cash used in investing activities in the three months ended December 31, 2019 was $22,000and was associated with capital expenditures at our U.K. and Malaysia locations.

Financing activities

Net cash provided by financing activities in the three months ended December 31, 2020 was $1.7 million and consistec proceeds from the Premium Finance Agreement of $1.1 million, which were used to finance the Company's directors and officers liability insurance premium, and proceeds from stock option exercises of $0.6 million.

Net cash provided by financing activities in the three months ended December 31, 2019 was $0.4 million and primarilyconsisted of proceeds from the Premium Financing Agreement of $0.8 million, which were used to finance the Company's directors and officers liability insurance premium, less payments on the Credit Agreement (see discussion below) of $0.4 million.

Sources of Capital

SWK Credit Agreement

On March 5, 2018, the Company entered into a Credit Agreement (as amended, the "Credit Agreement") with the financial institutions party thereto from time to time (the "Lenders") and SWK Funding LLC, as agent for the Lenders (the "Agent"), for a synthetic royalty financing transaction. On and subject to the terms of the Credit Agreement, the Lenders provided the Company with a term loan of $10.0 million, which was advanced to the Company on the date of the Credit Agreement. Under the Credit Agreement, the Company is required to make quarterly payments on the term loan based on the Company's product revenue from net sales of FC2 until the earlier of receipt by the Lenders of a return premium specified in the Credit Agreement or a required payment upon termination of the Credit Agreement on March 5, 2025 or an earlier change of control of the Company or sale of the FC2 business. The recourse of the Lenders and the Agent for obligations under the Credit Agreement is limited to assets relating to FC2. On May 13, 2019, the Company entered into an amendment to the Credit Agreement (the "Second Amendment") which included a reduction to the percentages to be used to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar year 2019, a return to the original percentages to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar year 2020 and an increase to the percentages to be used to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar year 2021 and thereafter until the loan has been repaid.

In connection with the Credit Agreement, Veru and the Agent also entered into a Residual Royalty Agreement, dated as of March 5, 2018 (as amended, the "Residual Royalty Agreement"), which provides for an ongoing royalty payment of 5% of product revenue from net sales of FC2 commencing after the Lenders would have received their return premium based on the return premium and calculation of revenue-based payments under the Credit Agreement without taking into account the amendments effected by the Second Amendment. The Residual Royalty Agreement will terminate upon (i) a change of control or sale of the FC2 business and the payment by the Company of the amount due in connection therewith pursuant to the Credit Agreement, or (ii) mutual agreement of the parties.

The Company made total payments under the Credit Agreement of $1.1 million and $0.4 million during the three months ended December 31, 2020 and 2019, respectively. As a result of the Second Amendment, theCompany currently estimates the aggregate amount of quarterly revenue-based payments payable during the 12-month period subsequent to December 31, 2020 will be approximately $5.3 million under the Credit Agreement. The Company also estimates that it will begin making payments under the Residual Royalty Agreement during the 12-month period subsequent to December 31, 2020, and estimates such payments within that period to be approximately $1.9 million.

Aspire Capital Purchase Agreement

On June 26, 2020, the Company entered into a common stock purchase agreement (the "2020 Purchase Agreement") with Aspire Capital Fund, LLC (Aspire Capital) which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right, from time to time in its sole discretion during the 36-month term of the 2020 Purchase Agreement, to direct Aspire Capital to purchase up to $23.9 million of the Company's common stock in the aggregate. Upon execution of the 2020 Purchase Agreement, the Company issued and sold to Aspire Capital under the 2020 Purchase Agreement 1,644,737 shares of common stock at a price per share of $3.04, for an aggregate purchase price of $5,000,000. Other than the 212,130 shares of common stock issued to Aspire Capital in consideration for entering into the 2020 Purchase Agreement and the initial sale of 1,644,737 shares of common stock, the Company has no obligation to sell any shares of common stock pursuant to the 2020 Purchase Agreement and the timing and amount of any such sales are in the Company's sole discretion subject to the conditions and terms set forth in the 2020 Purchase Agreement. As of December 31, 2020, the amount remaining under the 2020 Purchase Agreement was $18.9 million, which is registered under the Company's 2020 shelf registration statement on Form S-3 (File No. 333-239493). Effective June 26, 2020, upon the execution of the 2020 Purchase Agreement, the Company's prior purchase agreement with Aspire Capital was terminated.

Fair Value Measurements

As of December 31, 2020 and September 30, 2020, the Company's financial liabilities measured at fair value on a recurring basis, which consisted of embedded derivatives, represent the fair value of the change of control provisions in the Credit Agreement and Residual Royalty Agreement. See Note 9 to the financial statements included in this report for additional information.

The fair values of these liabilities were estimated based on unobservable inputs (Level 3 measurement), which requires highly subjective judgment and assumptions. The Company determined the fair value of the embedded derivatives at inception and on subsequent valuation dates using a Monte Carlo simulation model. This valuation model incorporates transaction details such as the contractual terms of the instruments and assumptions including projected FC2 revenues, expected cash outflows, expected repayment dates, probability and estimated dates of a change of control, expected volatility, and risk-free interest rates and applicable credit risk. The assumptions used in calculating the fair value of financial instruments represent the Company's best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, the use of different estimates or assumptions would result in a higher or lower fair value and different amounts being recorded in the Company's financial statements. Material changes in any of these inputs could result in a significantly higher or lower fair value measurement at future reporting dates, which could have a material effect on our results of operations. See Note 4 to the financial statements included in this report for additional information.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The Company's exposure to market risk was discussed in the “Quantitative and Qualitative Disclosures About Market Risk” section contained in the Company’s Annual Report on Form 10-K for the fiscal year ended September 30, 2020. There have been no material changes to such exposures since September 30, 2020.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, the Company carried out an evaluation, under thesupervision and with the participation of the Company’s management, including the Company’s Chief Executive Officer and the Company’s Chief Financial Officer, of the effectiveness of the design and operation of the Company’s disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Based on this evaluation, the Company’s Chief Executive Officer and Chief Financial Officer concluded that the Company’s disclosure controls and procedures were effective. It should be noted that in designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. The Company has designed its disclosure controls and procedures to reach a level of reasonable assurance of achieving desired control objectives and, based on the evaluation described above, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective at reaching that level of reasonable assurance.

Changes in Internal Control over Financial Reporting

There were no changes in the Company’s internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended) during the Company's most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Neither the Company nor any of its subsidiaries is a party to any material pending legal proceedings at the date of filing of this Quarterly Report on Form 10-Q.

Item 1A. Risk Factors

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the risks and uncertainties relating to the Company's business disclosed in Part I, Item 1A, "Risk Factors," in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2020. There have been no material changes from the risk factors previously disclosed in Part I, Item 1A, "Risk Factors," in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2020.

Item 6. Exhibits

Exhibit Number	Description
2.1	Asset Purchase Agreement, dated as of December 8, 2020, between the Company and Roman Health Ventures Inc. (incorporated by reference to Exhibit 2.2 to the Company's Form 10-K (File No. 1-13602) filed with the SEC on December 10, 2020).
3.1	Amended and Restated Articles of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Form SB-2 Registration Statement (File No. 333-89273) filed with the SEC on October 19, 1999).
3.2	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 27,000,000 shares (incorporated by reference to Exhibit 3.2 to the Company's Form SB-2 Registration Statement (File No. 333-46314) filed with the SEC on September 21, 2000).
3.3	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 35,500,000 shares (incorporated by reference to Exhibit 3.3 to the Company's Form SB-2 Registration Statement (File No. 333-99285) filed with the SEC on September 6, 2002).
3.4	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 38,500,000 shares (incorporated by reference to Exhibit 3.4 to the Company's Form 10-QSB (File No. 1-13602) filed with the SEC on May 15, 2003).
3.5	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company designating the terms and preferences for the Class A Preferred Stock – Series 3 (incorporated by reference to Exhibit 3.5 to the Company's Form 10-QSB (File No. 1-13602) filed with the SEC on May 17, 2004).
3.6	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company designating the terms and preferences for the Class A Preferred Stock – Series 4 (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on November 2, 2016).
3.7	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company changing the corporate name to Veru Inc. and increasing the number of authorized shares of common stock to 77,000,000 shares (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on August 1, 2017).
3.8	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 154,000,000 shares (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on March 29, 2019).
3.9	Amended and Restated By-Laws (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on May 4, 2018).
4.1	Amended and Restated Articles of Incorporation, as amended (same as Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7 and 3.8).
4.2	Articles II, VII and XI of the Amended and Restated By-Laws (included in Exhibit 3.9).
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *

32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002). *, **
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter endedDecember 31, 2020, formatted in XBRL (Extensible Business Reporting Language): (1) the Unaudited Condensed Consolidated Balance Sheets, (2) the Unaudited Condensed Consolidated Statements of Operations, (3) the Unaudited Condensed Consolidated Statements of Stockholders' Equity, (4) the Unaudited Condensed Consolidated Statements of Cash Flows and (5) the Notes to the Unaudited Condensed Consolidated Financial Statements.

* Filed herewith

** This certification is not "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

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 thereunto duly authorized.

VERU INC.

DATE: February 10, 2021

/s/ Mitchell S. Steiner
Mitchell S. Steiner
Chairman, Chief Executive Officer and President

DATE: February 10, 2021

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

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mitchell S. Steiner, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Veru Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 10, 2021

/s/Mitchell S. Steiner
Mitchell S. Steiner
Chairman, Chief Executive Officer and President

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michele Greco, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Veru Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 10, 2021

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

Exhibit 32.1

Certification of Periodic Financial Report
Pursuant to 18 U.S.C. Section 1350

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned officers of Veru Inc. (the "Company") certifies that the Quarterly Report on Form 10-Q of the Company for the quarter ended December 31, 2020 fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934 and information contained in that Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 10, 2021

/s/Mitchell S. Steiner
Mitchell S. Steiner
Chairman, Chief Executive Officer and President

Date: February 10, 2021

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

This certification is made solely for purpose of 18 U.S.C. Section 1350, subject to the knowledge standard contained therein, and not for any other purpose.