

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, 2019
- 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
(State of Incorporation)
48 NW 25th Street, Suite 102, Miami, FL
(Address of Principal Executive Offices)

39-1144397
(I.R.S. Employer Identification No.)
33127
(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
Non-accelerated filer

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 10, 2020, the registrant had 65,193,375 shares of \$0.01 par value common stock outstanding.

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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 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 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;
- risks related to our ability to obtain sufficient financing on acceptable terms when needed to fund product development and our operations;
- risks related to the development of our product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market;
- 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 developments, including a reclassification of products;
- 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 and/or of our ability to supply product due to raw materials shortages, labor shortages, physical damage to our facilities, an outbreak of a contagious disease (such as the coronavirus), 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, including our 2018 South Africa tender award, indicates acceptance of the bidder's price rather than an order or guarantee of the purchase of any minimum number of units, and as a result government ministries or other public sector customers may order and purchase fewer units than the full maximum tender amount;

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- our 2018 South Africa tender award could be subject in the future to reallocation for potential local manufacturing initiatives, which could reduce the size of the award to us;
- 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, 2019 and Part II, Item 1A of this Form 10-Q. 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.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

| | December 31, 2019 | September 30, 2019 |
|---|------------------------------|-------------------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 4,174,957 | \$ 6,295,152 |
| Accounts receivable, net | 5,970,163 | 5,021,057 |
| Inventory, net | 4,595,390 | 3,647,406 |
| Prepaid expenses and other current assets | 2,075,414 | 1,843,297 |
| Total current assets | 16,815,924 | 16,806,912 |
| Plant and equipment, net | 336,171 | 351,895 |
| Operating lease right-of-use assets | 1,153,779 | — |
| Deferred income taxes | 8,586,279 | 8,433,669 |
| Intangible assets, net | 20,089,403 | 20,168,495 |
| Goodwill | 6,878,932 | 6,878,932 |
| Other assets | 675,910 | 988,867 |
| Total assets | <u>\$ 54,536,398</u> | <u>\$ 53,628,770</u> |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 3,827,874 | \$ 3,124,751 |
| Accrued research and development costs | 2,636,054 | 2,475,490 |
| Accrued compensation | 1,340,971 | 1,597,197 |
| Accrued expenses and other current liabilities | 2,126,387 | 1,436,888 |
| Credit agreement, short-term portion | 6,547,339 | 5,385,649 |
| Operating lease liability, short-term portion | 430,081 | — |
| Total current liabilities | 16,908,706 | 14,019,975 |
| Credit agreement, long-term portion | 1,913,573 | 2,886,382 |
| Residual royalty agreement | 4,768,696 | 3,845,518 |
| Operating lease liability, long-term portion | 970,378 | — |
| Deferred income taxes | 296,605 | 296,605 |
| Other liabilities | 35,907 | 247,154 |
| Total liabilities | 24,893,865 | 21,295,634 |
| Commitments and contingencies (Note 12) | | |
| Stockholders' equity: | | |
| Preferred stock; no shares issued and outstanding at December 31, 2019 and September 30, 2019 | — | — |
| Common stock, par value \$0.01 per share; 154,000,000 shares authorized, 67,222,818 and 67,221,951 shares issued and 65,039,114 and 65,038,247 shares outstanding at December 31, 2019 and September 30, 2019, respectively | 672,228 | 672,220 |
| Additional paid-in-capital | 110,882,547 | 110,268,057 |
| Accumulated other comprehensive loss | (581,519) | (581,519) |
| Accumulated deficit | (73,524,118) | (70,219,017) |
| Treasury stock, 2,183,704 shares, at cost | (7,806,605) | (7,806,605) |
| Total stockholders' equity | 29,642,533 | 32,333,136 |
| Total liabilities and stockholders' equity | <u>\$ 54,536,398</u> | <u>\$ 53,628,770</u> |

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

| | Three Months Ended | |
|--|--------------------|----------------|
| | December 31, | |
| | 2019 | 2018 |
| Net revenues | \$ 10,578,016 | \$ 6,371,809 |
| Cost of sales | 3,308,921 | 1,727,729 |
| Gross profit | 7,269,095 | 4,644,080 |
| Operating expenses: | | |
| Research and development | 5,299,974 | 2,361,823 |
| Selling, general and administrative | 3,753,514 | 3,293,984 |
| Total operating expenses | 9,053,488 | 5,655,807 |
| Operating loss | (1,784,393) | (1,011,727) |
| Non-operating (expenses) income: | | |
| Interest expense | (1,141,425) | (1,278,423) |
| Change in fair value of derivative liabilities | (394,000) | 225,000 |
| Foreign currency transaction loss | (70,009) | (17,544) |
| Other income, net | 7,983 | 26,394 |
| Total non-operating expenses | (1,597,451) | (1,044,573) |
| Loss before income taxes | (3,381,844) | (2,056,300) |
| Income tax (benefit) expense | (76,743) | 92,498 |
| Net loss | \$ (3,305,101) | \$ (2,148,798) |
| Net loss per basic and diluted common share outstanding | \$ (0.05) | \$ (0.03) |
| Basic and diluted weighted average common shares outstanding | 65,038,511 | 62,553,791 |

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

| | Preferred Stock | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Loss | Accumulated Deficit | Treasury Stock, at Cost | Total |
|---|--------------------|-------------------|-------------------|----------------------------------|---|------------------------|-------------------------------|---------------------|
| | | Shares | Amount | | | | | |
| 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 | <u>\$ —</u> | <u>67,222,818</u> | <u>\$ 672,228</u> | <u>\$ 110,882,547</u> | <u>\$ (581,519)</u> | <u>\$(73,524,118)</u> | <u>\$(7,806,605)</u> | <u>\$29,642,533</u> |
| Balance at September 30, 2018 | \$ — | 57,468,660 | \$ 574,687 | \$ 95,496,506 | \$ (581,519) | \$(58,201,651) | \$(7,806,605) | \$29,481,418 |
| Share-based compensation | — | — | — | 417,256 | — | — | — | 417,256 |
| Shares issued in connection with public offering of common stock, net of fees and costs | — | 7,142,857 | 71,428 | 9,060,539 | — | — | — | 9,131,967 |
| Issuance of shares pursuant to share-based awards | — | 190,000 | 1,900 | (1,900) | — | — | — | — |
| Net loss | — | — | — | — | — | (2,148,798) | — | (2,148,798) |
| Balance at December 31, 2018 | <u>\$ —</u> | <u>64,801,517</u> | <u>\$ 648,015</u> | <u>\$ 104,972,401</u> | <u>\$ (581,519)</u> | <u>\$(60,350,449)</u> | <u>\$(7,806,605)</u> | <u>\$36,881,843</u> |

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

| | Three Months Ended December 31, | |
|---|------------------------------------|----------------|
| | 2019 | 2018 |
| OPERATING ACTIVITIES | | |
| Net loss | \$ (3,305,101) | \$ (2,148,798) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 37,531 | 42,554 |
| Amortization of intangible assets | 79,092 | 77,309 |
| Noncash change in right-of-use assets | 76,147 | — |
| Noncash interest expense | 1,141,425 | 1,278,423 |
| Share-based compensation | 614,498 | 417,256 |
| Deferred income taxes | (152,610) | 48,144 |
| Provision for obsolete inventory | 151,922 | 22,245 |
| Change in fair value of derivative liabilities | 394,000 | (225,000) |
| Other | — | (1,832) |
| Changes in current assets and liabilities: | | |
| (Increase) decrease in accounts receivable | (642,764) | 1,485,536 |
| Increase in inventory | (1,099,906) | (418,522) |
| Increase in prepaid expenses and other assets | (209,177) | (58,810) |
| Increase (decrease) in accounts payable | 703,123 | (1,231,443) |
| Decrease in unearned revenue | — | (138,064) |
| Decrease in accrued expenses and other current liabilities | (245,398) | (655,479) |
| Decrease in operating lease liabilities | (53,284) | — |
| Net cash used in operating activities | (2,510,502) | (1,506,481) |
| INVESTING ACTIVITIES | | |
| Capital expenditures | (21,807) | — |
| Net cash used in investing activities | (21,807) | — |
| FINANCING ACTIVITIES | | |
| Proceeds from sale of shares in public offering, net of fees | — | 9,400,000 |
| Payment of costs related to public offering | — | (114,568) |
| Installment payments on SWK credit agreement | (423,366) | (2,559,277) |
| Proceeds from premium finance agreement | 836,780 | — |
| Cash paid for debt portion of finance lease | (1,300) | — |
| Net cash provided by financing activities | 412,114 | 6,726,155 |
| Net (decrease) increase in cash | (2,120,195) | 5,219,674 |
| CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD | 6,295,152 | 3,759,509 |
| CASH AND CASH EQUIVALENTS AT END OF PERIOD | \$ 4,174,957 | \$ 8,979,183 |
| Supplemental disclosure of noncash activities: | | |
| Costs related to public offering in accounts payable | \$ — | \$ 153,465 |
| Right-of-use assets recorded in exchange for lease liabilities | \$ 1,229,926 | \$ — |

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, 2019. The accompanying condensed consolidated balance sheet as of September 30, 2019 has been derived from our audited financial statements. The unaudited condensed consolidated statements of operations for the three months ended December 31, 2019 and cash flows for the three months ended December 31, 2019 are not necessarily indicative of the results to be expected for any future period or for the fiscal year ending September 30, 2020.

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. Prior to the completion of the October 31, 2016 acquisition (the “APP Acquisition”) of APP through the merger of a wholly owned subsidiary of the Company into APP, the Company had been a single product company engaged in marketing, manufacturing and distributing a consumer healthcare product, the FC2 Female Condom/FC2 Internal Condom® (“FC2”). The completion of the APP Acquisition transitioned the Company into a biopharmaceutical company focused on oncology and urology with multiple drug products under clinical development. Most of the Company’s net revenues during the three months ended December 31, 2019 and 2018 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.

Leases: Leases are classified as either operating or finance leases at inception. A right-of-use (“ROU”) asset and corresponding lease liability are established at an amount equal to the present value of fixed lease payments over the lease term at the commencement date. The ROU asset includes any initial direct costs incurred and lease payments made at or before the commencement date and is reduced by lease incentive payments. The Company has elected not to separate the lease and nonlease components for all classes of underlying assets. The Company uses its incremental borrowing rate as the discount rate to determine the present value of the lease payments for leases that do not have a readily determinable implicit discount rate. The incremental borrowing rate is the rate of interest that the Company would be charged to borrow on a collateralized basis over a similar term and amount in a similar economic environment. The Company determines the incremental borrowing rates for its leases by adjusting the risk-free interest rate with a credit risk premium corresponding to the Company’s credit rating.

Operating lease costs are recognized for fixed lease payments on a straight-line basis over the term of the lease. Finance lease costs are a combination of the amortization expense for the ROU asset and interest expense for the outstanding lease liability using the applicable discount rate. Variable lease payments are recognized when incurred based on occurrence or usage. Short-term leases with an initial term of 12 months or less are not recorded on the balance sheet; we recognize lease expense for short-term leases on a straight-line basis over the lease term.

Other comprehensive loss: Accounting principles generally require that recognized revenue, expenses, gains and losses be included in net 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 loss, are components of other comprehensive loss. For the three months ended December 31, 2019 and 2018, comprehensive loss is equivalent to the reported net loss.

Recently Issued Accounting Pronouncements: In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2016-02, *Leases (Topic 842)*, which requires that lessees recognize an ROU asset and a lease liability for all leases with lease terms greater than twelve months in the balance sheet. ASU 2016-02 distinguishes leases as either a finance lease or an operating lease, which affects how the leases are measured and presented in the statement of operations and statement of cash flows, and requires disclosure of key information about leasing arrangements. A modified retrospective transition approach is required upon adoption. In July 2018, the FASB issued ASU No. 2018-10, *Codification Improvements to Topic 842, Leases* to clarify the implementation guidance and ASU No. 2018-11, *Leases (Topic 842) Targeted Improvements*. This updated guidance provides an optional transition method, which allows for the initial application of the new accounting standard at the adoption date and the recognition of a cumulative-effect adjustment to the opening balance of retained earnings as of the beginning of the period of adoption. In December 2018, the FASB issued ASU 2018-20, *Leases (Topic 842): Narrow-Scope Improvements for Lessors* to address certain implementation issues facing lessors when adopting ASU 2016-02. In March 2019, the FASB issued ASU 2019-01, *Leases (Topic 842): Codification Improvements* to address, among other things, certain transition disclosure requirements subsequent to the adoption of ASU 2016-02.

The Company adopted the new lease accounting standard using the modified retrospective approach on October 1, 2019 and elected certain practical expedients, including the optional transition method that allows for the application of the new standard at its adoption date with no restatement of prior period amounts. We elected the package of practical expedients permitted under the transition guidance, which allowed us to not reassess our prior conclusions about lease identification, lease classification, and initial direct costs. Adoption of the new standard resulted in the recording of ROU assets and lease liabilities of approximately \$1.2 million and \$1.5 million, respectively, and the derecognition of prepaid expenses and operating lease deferred rent liabilities of \$23,000 and \$247,000, respectively, as of October 1, 2019 with zero cumulative-effect adjustment to retained earnings. The new standard did not materially impact our consolidated statement of operations or cash flows.

In June 2018, the FASB issued ASU 2018-07, *Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. The purpose of ASU 2018-07 is to expand the scope of *Topic 718, Compensation—Stock Compensation* (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The Company has issued share-based payments to nonemployees in the past but is not able to predict the amount of future share-based payments to nonemployees, if any. We adopted ASU 2018-07 effective October 1, 2019. The adoption of ASU 2018-07 did not have a material impact on our consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740). Simplifying the Accounting for Income Taxes*. The new guidance eliminates certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period, and the recognition of deferred tax liabilities for outside basis differences. It also clarifies and simplifies other aspects of the accounting for income taxes. ASU 2019-12 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. Early adoption is permitted. The adoption of ASU 2019-12 is not expected to have a material effect on our consolidated financial statements and related disclosures.

Note 2 – Liquidity

The Company has incurred quarterly operating losses since the fourth quarter of fiscal 2016 and anticipates that it will continue to consume cash and incur substantial net losses 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, cash expected to be generated from sales of the Company's commercial products, and its ability to secure equity financing or other financing alternatives are adequate to fund planned operations of the Company for the next 12 months. Such financing alternatives may include debt financing, common stock offerings, including existing purchasing agreements, or financing involving convertible debt or other equity-linked securities and may include financings under the Company's effective shelf registration statement on Form S-3 (File No. 333-221120) (the "Shelf Registration Statement"). The Company intends to be opportunistic when pursuing equity or debt financing which could include selling common stock under its common stock purchase agreement with Aspire Capital Fund, LLC (see Note 9).

Note 3 – 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.

We review the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels of certain securities within the fair value hierarchy. There were no transfers between Level 1, Level 2 and Level 3 during the three months ended December 31, 2019 and 2018.

As of December 31, 2019 and September 30, 2019, 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 Company determines the fair value of hybrid instruments based on available market data using appropriate valuation models, considering all of the rights and obligations of each instrument. The Company estimates the fair value of hybrid instruments using various techniques (and combinations thereof) that are considered to be consistent with the objective of measuring fair value. In selecting the appropriate technique, the Company considers, among other factors, the nature of the instrument, the market risks that it embodies and the expected means of settlement. Estimating the fair value of derivative financial instruments requires the development of significant and subjective estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. Increases in fair value during a given financial quarter result in the recognition of non-cash derivative expense. Conversely, decreases in fair value during a given financial quarter would result in the recognition of non-cash derivative income.

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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, 2019 and 2018:

| | Three Months Ended | |
|--|---------------------------|---------------------|
| | December 31, | |
| | 2019 | 2018 |
| Beginning balance | \$ 3,625,000 | \$ 2,426,000 |
| Change in fair value of derivative liabilities | 394,000 | (225,000) |
| Ending balance | <u>\$ 4,019,000</u> | <u>\$ 2,201,000</u> |

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 8 for additional information. There is no current observable market for these types of derivatives. The Company determined the fair value of the embedded derivatives using a Monte Carlo simulation model to value the financial liabilities at inception and on subsequent valuation dates. This valuation model incorporates transaction details such as the contractual terms, expected cash outflows, expected repayment dates, probability of a change of control, expected volatility, and risk-free interest rates. A significant acceleration of the estimated repayment date or a significant decrease in the probability of a change of control event prior to repayment of the Credit Agreement, in isolation, would result in a significantly lower 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, 2019 and September 30, 2019:

| <u>Valuation Methodology</u> | <u>Significant Unobservable Input</u> | <u>Weighted Average (range, if applicable)</u> | |
|------------------------------|---------------------------------------|--|------------------------------------|
| | | <u>December 31, 2019</u> | <u>September 30, 2019</u> |
| Monte Carlo Simulation | Estimated change of control dates | September 2020 to December 2021 | September 2020 to December 2021 |
| | Discount rate | 14.5% to 16.6% | 14.4% to 16.8% |
| | Probability of change of control | 10% to 90% | 10% to 90% |

Note 4 – 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.

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The Company's revenue is from direct product sales of FC2 in the global public sector, sales of FC2 in the U.S. prescription channel, and sales of PREBOOST® medicated wipes for prevention of premature ejaculation. The following table presents net revenues from these three categories:

| | Three Months Ended December 31, | |
|---------------------------|------------------------------------|--------------|
| | 2019 | 2018 |
| FC2 | | |
| Public sector | \$ 4,373,794 | \$ 3,884,352 |
| U.S. prescription channel | 6,051,130 | 2,440,045 |
| Total FC2 | 10,424,924 | 6,324,397 |
| PREBOOST® | 153,092 | 47,412 |
| Net revenues | \$ 10,578,016 | \$ 6,371,809 |

The following table presents net revenue by geographic area:

| | Three Months Ended December 31, | |
|----------------------|------------------------------------|--------------|
| | 2019 | 2018 |
| United States | \$ 6,491,154 | \$ 3,009,603 |
| United Arab Emirates | 1,605,000 | — |
| Zimbabwe | — | 1,358,000 |
| Nigeria | * | 750,000 |
| Other | 2,481,862 | 1,254,206 |
| Net revenues | \$ 10,578,016 | \$ 6,371,809 |

*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 balances of the Company's contract liability, included in accrued expenses and other current liabilities on the accompanying unaudited condensed consolidated balances sheets, was approximately \$91,000 and \$249,000 at December 31, 2019 and September 30, 2019, respectively.

The Company records an unearned revenue liability if a customer pays consideration for product that was shipped by the Company but revenue recognition criteria have not been met under the terms of a contract. Unearned revenue is recognized as revenue after control of the product is transferred to the customer and all revenue recognition criteria have been met. The Company had no unearned revenue at December 31, 2019 or September 30, 2019.

The Company recognized revenue of \$210,000 and \$187,000 during the three months ended December 31, 2019 and 2018, respectively, after satisfying its contract obligations and transferring control for previously recorded contract liabilities or unearned revenue.

Note 5 – 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 180 days subsequent to clearance of the product by the Ministry of Health in Brazil. The Company does not have any trade receivables classified as long-term as of December 31, 2019. The Company classified approximately \$300,000 of trade receivables with its distributor in Brazil as long-term as of September 30, 2019 because payment was expected in greater than one year. The long-term portion of trade receivables is included in other assets on the accompanying unaudited condensed consolidated balance sheets.

The components of accounts receivable consist of the following at December 31, 2019 and September 30, 2019:

| | December 31, 2019 | September 30, 2019 |
|--|------------------------------|-------------------------------|
| Accounts receivable | \$ 6,064,408 | \$ 5,103,823 |
| Less: allowance for doubtful accounts | (33,143) | (33,143) |
| Less: allowance for sales and payment term discounts | (61,102) | (49,623) |
| Accounts receivable, net | <u>\$ 5,970,163</u> | <u>\$ 5,021,057</u> |

At December 31, 2019, one customer had an accounts receivable balance that represented 11% of current assets. At September 30, 2019, no customers had an accounts receivable balance that represented greater than 10% of current assets.

At December 31, 2019, three customers had an accounts receivable balance greater than 10% of net accounts receivable, representing 87% of net accounts receivable in the aggregate. At September 30, 2019, two customers had an accounts receivable balance greater than 10% of net accounts receivable, representing 64% of net accounts receivable 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. For the three months ended December 31, 2018, there were three customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 77% 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, 2019 and 2018.

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 6 – 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.

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Inventory consisted of the following at December 31, 2019 and September 30, 2019:

| | December 31, 2019 | September 30, 2019 |
|--------------------------|------------------------------|-------------------------------|
| FC2 | | |
| Raw material | \$ 701,131 | \$ 426,590 |
| Work in process | 60,358 | 187,970 |
| Finished goods | 3,883,653 | 3,157,952 |
| FC2, gross | 4,645,142 | 3,772,512 |
| Less: inventory reserves | (92,755) | (125,106) |
| FC2, net | 4,552,387 | 3,647,406 |
| PREBOOST® | | |
| Finished goods | 43,003 | — |
| Inventory, net | <u>\$ 4,595,390</u> | <u>\$ 3,647,406</u> |

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, 2019 and September 30, 2019:

| | Estimated Useful Life | December 31, 2019 | September 30, 2019 |
|---|----------------------------------|------------------------------|-------------------------------|
| Plant and equipment: | | | |
| Manufacturing equipment | 5 - 8 years | \$ 2,730,018 | \$ 2,716,647 |
| Office equipment, furniture and fixtures | 3 - 10 years | 803,664 | 795,228 |
| Leasehold improvements | 3 - 8 years | 298,886 | 298,886 |
| Total plant and equipment | | 3,832,568 | 3,810,761 |
| Less: accumulated depreciation and amortization | | (3,496,397) | (3,458,866) |
| Plant and equipment, net | | <u>\$ 336,171</u> | <u>\$ 351,895</u> |

Note 7 – Intangible Assets and Goodwill

Intangible Assets

The gross carrying amounts and net book value of intangible assets are as follows at December 31, 2019:

| | Gross Carrying Amount | Accumulated Amortization | Net Book Value |
|---|----------------------------------|-------------------------------------|---------------------------|
| Intangible assets with finite lives: | | | |
| Developed technology - PREBOOST® | \$ 2,400,000 | \$ 584,407 | \$ 1,815,593 |
| Covenants not-to-compete | 500,000 | 226,190 | 273,810 |
| Total intangible assets with finite lives | 2,900,000 | 810,597 | 2,089,403 |
| Acquired in-process research and development assets | 18,000,000 | — | 18,000,000 |
| Total intangible assets | <u>\$ 20,900,000</u> | <u>\$ 810,597</u> | <u>\$ 20,089,403</u> |

The gross carrying amounts and net book value of intangible assets are as follows at September 30, 2019:

| | Gross Carrying Amount | Accumulated Amortization | Net Book Value |
|---|----------------------------------|-------------------------------------|---------------------------|
| Intangible assets with finite lives: | | | |
| Developed technology - PREBOOST® | \$ 2,400,000 | \$ 523,172 | \$ 1,876,828 |
| Covenants not-to-compete | 500,000 | 208,333 | 291,667 |
| Total intangible assets with finite lives | 2,900,000 | 731,505 | 2,168,495 |
| Acquired in-process research and development assets | 18,000,000 | — | 18,000,000 |
| Total intangible assets | <u>\$ 20,900,000</u> | <u>\$ 731,505</u> | <u>\$ 20,168,495</u> |

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For the three months ended December 31, 2019 and 2018, amortization expense was approximately \$79,000 and \$77,000, respectively.

Goodwill

The carrying amount of goodwill at December 31, 2019 and September 30, 2019 was \$6.9 million. There was no change in the balance during the three months ended December 31, 2019 and 2018.

Note 8 – 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 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 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 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, 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.

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The Credit Agreement contains customary representations and warranties in favor of the Agent and the Lenders and certain covenants, 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 completed 12-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 allocated between 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 will be adjusted to fair market value at each subsequent 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 in 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, 2019 and September 30, 2019, the Credit Agreement liability consisted of the following:

| | December 31, 2019 | September 30, 2019 |
|--|------------------------------|-------------------------------|
| Aggregate repayment obligation | \$ 17,650,000 | \$ 17,650,000 |
| Less: cumulative payments | (6,001,451) | (5,578,085) |
| Less: unamortized discounts | (3,728,988) | (4,590,974) |
| Less: unamortized deferred issuance costs | (87,649) | (107,910) |
| Credit agreement, excluding embedded derivative liability, net | 7,831,912 | 7,373,031 |
| Add: embedded derivative liability at fair value (see Note 3) | 629,000 | 899,000 |
| Credit agreement, net | 8,460,912 | 8,272,031 |
| Credit agreement, short-term portion | (6,547,339) | (5,385,649) |
| Credit agreement, long-term portion | \$ 1,913,573 | \$ 2,886,382 |

The short-term portion of the Credit Agreement represents the aggregate of the estimated quarterly revenue-based payments payable during the 12-month periods subsequent to December 31, 2019 and September 30, 2019, respectively.

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At December 31, 2019 and September 30, 2019, the Residual Royalty Agreement liability consisted of the following:

| | <u>December 31,</u> <u>2019</u> | <u>September 30,</u> <u>2019</u> |
|---|------------------------------------|-------------------------------------|
| Residual royalty agreement liability, fair value at inception | \$ 346,000 | \$ 346,000 |
| Add: accretion of liability using effective interest rate | 1,032,696 | 773,518 |
| Residual royalty agreement liability, excluding embedded derivative liability | 1,378,696 | 1,119,518 |
| Add: embedded derivative liability at fair value (see Note 3) | 3,390,000 | 2,726,000 |
| Residual royalty agreement liability | <u>\$ 4,768,696</u> | <u>\$ 3,845,518</u> |

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, 2019 and 2018, interest expense related to the Credit Agreement and Residual Royalty Agreement was as follows:

| | <u>Three Months Ended</u> <u>December 31,</u> | |
|---|--|---------------------|
| | <u>2019</u> | <u>2018</u> |
| Amortization of discounts | \$ 861,986 | \$ 1,158,206 |
| Accretion of residual royalty agreement | 259,178 | 92,351 |
| Amortization of deferred issuance costs | 20,261 | 27,866 |
| Interest expense | <u>\$ 1,141,425</u> | <u>\$ 1,278,423</u> |

Premium Finance Agreement

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 is payable in three quarterly installments of principal and interest, beginning on January 1, 2020. 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, 2019.

Note 9 – Stockholders’ Equity

Preferred Stock

The Company has 5,000,000 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, 2019 and September 30, 2019. The Company has 15,000 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, 2019 and September 30, 2019.

Common Stock

On March 27, 2019, following approval by stockholders at the Company’s annual meeting of stockholders held on March 26, 2019, the Company filed an amendment to its articles of incorporation to increase the number of authorized shares of common stock from 77,000,000 to 154,000,000 shares.

Common Stock Offering

On October 1, 2018, we completed an underwritten public offering of 7,142,857 shares of our common stock, at a public offering price of \$1.40 per share. Net proceeds to the Company from this offering were \$9.1 million after deducting underwriting discounts and commissions and costs paid by the Company. All of the shares sold in the offering were by the Company. The offering was made pursuant to the Shelf Registration Statement.

Common Stock Purchase Warrants

In connection with the closing of the APP Acquisition, the Company issued a warrant to purchase up to 2,585,379 shares of the Company's common stock to Torrey Capital, the Company's financial advisor (the "Financial Advisor Warrant"). The Financial Advisor Warrant has 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 Warrant vested upon issuance and remains outstanding at December 31, 2019.

Aspire Capital Purchase Agreement

On December 29, 2017, the Company entered into a common stock purchase agreement (the "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 Purchase Agreement, to direct Aspire Capital to purchase up to \$15.0 million of the Company's common stock in the aggregate. Concurrently with entering into the 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 and under the Shelf Registration Statement, a 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 Purchase Agreement.

Under the 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, up to \$15.0 million of the Company's common stock in the aggregate 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 to 200,000 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 Purchase Agreement, we have sold 3,717,010 shares of common stock to Aspire Capital resulting in proceeds to the Company of \$6.6 million. As of December 31, 2019, the amount remaining under the Purchase Agreement was \$8.4 million.

In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, the Company issued to Aspire Capital 304,457 shares of the Company's common stock. The shares of common stock issued as consideration were valued at approximately \$347,000. This amount and related expenses of approximately \$78,000, which total approximately \$425,000, were recorded as deferred costs. The unamortized amount of deferred costs of approximately \$238,000 at December 31, 2019 and September 30, 2019 is included in other assets on the accompanying unaudited condensed consolidated balance sheets.

Note 10 – 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, 2019 and 2018, we recorded share-based compensation expenses as follows:

| | Three Months Ended | |
|-------------------------------------|---------------------------|-------------------|
| | December 31, | |
| | 2019 | 2018 |
| Cost of sales | \$ 14,545 | \$ 7,952 |
| Selling, general and administrative | 471,695 | 327,009 |
| Research and development | 128,258 | 82,295 |
| Share-based compensation | <u>\$ 614,498</u> | <u>\$ 417,256</u> |

Equity Plans

In March 2018, the Company's stockholders approved the Company's 2018 Equity Incentive Plan (the "2018 Plan"). On March 26, 2019, the Company's stockholders approved an increase in the number of shares that may be issued under the 2018 Plan to 6.0 million. As of December 31, 2019, 964,821 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 7.7 million shares are authorized for issuance under the 2017 Plan. As of December 31, 2019, 70,181 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, 2019 and 2018:

| | Three Months Ended | |
|--------------------------------------|---------------------------|----------------|
| | December 31, | |
| | 2019 | 2018 |
| <u>Weighted Average Assumptions:</u> | | |
| Expected volatility | 63.03% | 67.61% |
| Expected dividend yield | 0.00% | 0.00% |
| Risk-free interest rate | 1.67% | 2.75% |
| Expected term (in years) | 5.9 | 5.5 |
| Fair value of options granted | <u>\$ 1.11</u> | <u>\$ 0.83</u> |

During the three months ended December 31, 2019 and 2018, 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.

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The following table summarizes the stock options outstanding and exercisable at December 31, 2019:

| | Number of Shares | Weighted Average | | Aggregate Intrinsic Value |
|-----------------------------------|---------------------|-----------------------------|--|---------------------------------|
| | | Exercise Price Per Share | Remaining Contractual Term (years) | |
| Outstanding at September 30, 2019 | 7,027,989 | \$ 1.58 | | |
| Granted | 2,140,327 | \$ 1.92 | | |
| Exercised | (1,666) | \$ 1.05 | | |
| Forfeited | (158,201) | \$ 1.50 | | |
| Outstanding at December 31, 2019 | 9,008,449 | \$ 1.66 | 8.22 | \$ 15,215,966 |
| Exercisable at December 31, 2019 | 3,358,771 | \$ 1.45 | 7.21 | \$ 6,387,894 |

The aggregate intrinsic values in the table above are before income taxes and represent 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, 2019 of \$3.35, 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, 2019 was approximately \$2,000. There were no options exercised during the three months ended December 31, 2018.

As of December 31, 2019, the Company had unrecognized compensation expense of approximately \$4.6 million related to unvested stock options. This expense is expected to be recognized over approximately three years.

Stock Appreciation Rights

In connection with the closing of the APP Acquisition, the Company issued stock appreciation rights based on 50,000 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, 2019, vested stock appreciation rights based on 50,000 shares of common stock remain outstanding.

Note 11 – 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 six 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, 2019. 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.

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

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

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

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 sheet as of December 31, 2019. The Company's finance lease ROU asset was \$41,000 as of December 31, 2019 and is included in property and equipment, net on the accompanying unaudited condensed consolidated balance sheet. The current and long-term finance lease liabilities were \$20,000 and \$21,000, respectively, and are included in accrued expenses and other current liabilities and other liabilities, respectively, on the accompanying unaudited condensed consolidated balance sheet as of December 31, 2019.

Other information related to the Company's leases as of December 31, 2019 was as follows:

| | December 31, 2019 | |
|---------------------------------------|--------------------------|--------|
| Operating Leases | | |
| Weighted-average remaining lease term | | 4.5 |
| Weighted-average discount rate | | 12.04% |
| Finance Leases | | |
| Weighted-average remaining lease term | | 2.2 |
| Weighted average discount rate | | 13.86% |

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.

As of December 31, 2019, maturities of lease liabilities were as follows:

| Fiscal year ended September 30, | Operating Leases | Finance Leases | Sublease Income |
|--|-----------------------------|-----------------------|------------------------|
| 2020 | \$ 348,717 | \$ 16,192 | \$ 145,417 |
| 2021 | 438,725 | 22,199 | 198,668 |
| 2022 | 357,718 | 9,496 | 203,584 |
| 2023 | 302,921 | — | 190,749 |
| 2024 | 199,093 | — | — |
| Thereafter | 171,466 | — | — |
| Total lease payments | 1,818,640 | 47,887 | \$ 738,418 |
| Less imputed interest | (418,181) | (6,876) | |
| Total lease liabilities | \$ 1,400,459 | \$ 41,011 | |

Under FASB ASC 840, the lease accounting guidance prior to the Company's adoption of FASB ASC 842, the Company had net capital lease assets of \$43,000 included in property and equipment, net and a related capital lease obligation of \$42,000 included in accrued expenses and other current liabilities and other liabilities on the accompanying unaudited condensed consolidated balance sheet as of September 30, 2019.

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Under FASB ASC 840, future minimum payments under operating leases consisted of the following as of September 30, 2019:

| | <u>Operating Leases</u> | <u>Sublease Income</u> | <u>Net Total</u> |
|------------------------------|-----------------------------|----------------------------|-------------------|
| 2020 | \$ 469,002 | \$ 193,753 | \$ 275,249 |
| 2021 | 433,751 | 198,668 | 235,083 |
| 2022 | 337,456 | 203,584 | 133,872 |
| 2023 | 114,493 | 190,749 | (76,256) |
| 2024 | 11,238 | — | 11,238 |
| Total minimum lease payments | <u>\$ 1,365,940</u> | <u>\$ 786,754</u> | <u>\$ 579,186</u> |

The minimum lease payments presented above do not include real estate taxes, common area maintenance charges or insurance charges payable under the Company's operating leases for office and manufacturing facility space. These amounts are generally not fixed and can fluctuate from year to year.

Note 12 – 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 13 – 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 and tax credit carryforwards.

The Tax Cuts and Jobs Act of 2017 (the "Tax Act") repealed the alternative minimum tax ("AMT") for corporations. The law provides that AMT carryovers can be utilized to reduce or eliminate the tax liability in subsequent years or to obtain a tax refund. For tax years beginning in 2018, 2019 and 2020, to the extent the AMT credit carryovers exceed regular tax liability, 50% of the excess AMT credit carryovers will be refundable. Any remaining credits will be fully refundable in 2021. At December 31, 2019, the Company has \$0.5 million of AMT credit carryovers in prepaid expenses and other current assets and other assets due to the expectation that the AMT credits will be refundable over the next several years.

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As of September 30, 2019, the Company had U.S. federal and state net operating loss carryforwards of \$42.7 million and \$25.4 million, respectively, for income tax purposes with \$14.4 million and \$20.5 million, respectively, expiring in years 2022 to 2038 and \$28.3 million and \$4.9 million, respectively, which can be carried forward indefinitely. The Company's U.K. subsidiary has U.K. net operating loss carryforwards of \$61.7 million as of September 30, 2019, which can be carried forward indefinitely to be used to offset future U.K. taxable income.

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

| | Three Months Ended | |
|--|---------------------------|------------------|
| | December 31, | |
| | 2019 | 2018 |
| Income tax benefit at U.S. federal statutory rates | \$ (710,188) | \$ (431,823) |
| State income tax benefit, net of federal benefits | (55,000) | (102,342) |
| Effect of foreign income tax rates | 42,554 | (8,357) |
| Effect of deemed dividend and repatriation tax | 50,451 | 31,309 |
| Change in valuation allowance | 592,710 | 623,130 |
| Other, net | 2,730 | (19,419) |
| Income tax (benefit) expense | <u>\$ (76,743)</u> | <u>\$ 92,498</u> |

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

| | December 31, | September 30, |
|---|---------------------|----------------------|
| | 2019 | 2019 |
| Deferred tax assets: | | |
| Federal net operating loss carryforwards | \$ 9,178,717 | \$ 8,971,569 |
| State net operating loss carryforwards | 1,708,787 | 1,689,536 |
| Foreign net operating loss carryforwards – U.K. | 10,576,169 | 10,486,476 |
| Foreign capital allowance – U.K. | 103,400 | 103,400 |
| Share-based compensation | 928,679 | 804,378 |
| Interest expense | 259,917 | — |
| Other, net – U.K. | 50,780 | 50,781 |
| Other, net – U.S. | 461,879 | 434,764 |
| Gross deferred tax assets | <u>23,268,328</u> | <u>22,540,904</u> |
| Valuation allowance for deferred tax assets | (10,422,919) | (9,830,209) |
| Net deferred tax assets | <u>12,845,409</u> | <u>12,710,695</u> |
| Deferred tax liabilities: | | |
| In-process research and development | (4,072,740) | (4,072,740) |
| Developed technology | (410,802) | (424,657) |
| Covenant not-to-compete | (61,953) | (65,993) |
| Other, net – Malaysia | (3,865) | (3,865) |
| Other, net – U.S. | (6,375) | (6,376) |
| Net deferred tax liabilities | <u>(4,555,735)</u> | <u>(4,573,631)</u> |
| Net deferred tax asset | <u>\$ 8,289,674</u> | <u>\$ 8,137,064</u> |

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

| | December 31, | September 30, |
|-----------------------------------|---------------------|----------------------|
| | 2019 | 2019 |
| Deferred tax asset – U.K. | \$ 8,586,279 | \$ 8,433,669 |
| Total deferred tax asset | <u>\$ 8,586,279</u> | <u>\$ 8,433,669</u> |
| Deferred tax liability – U.S. | (292,740) | (292,740) |
| Deferred tax liability – Malaysia | (3,865) | (3,865) |
| Total deferred tax liability | <u>\$ (296,605)</u> | <u>\$ (296,605)</u> |

Note 14 – Net Loss Per Share

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing net income 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 warrants, and the vesting of unvested restricted stock and restricted stock units. Due to our net loss for the periods presented, all potentially dilutive instruments were excluded because their inclusion would have been anti-dilutive. See Notes 9 and 10 for a discussion of our dilutive potential common shares.

Note 15 – Industry Segments

The Company currently operates in two reporting segments: Commercial and Research and Development. The Commercial segment consists of FC2 and PREBOOST®. The Research and Development segment consists of multiple drug products under clinical development for oncology and urology. 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, | |
| | 2019 | 2018 |
| Commercial | \$ 5,803,593 | \$ 3,359,181 |
| Research and development | (5,246,381) | (2,361,823) |
| Corporate | (2,341,605) | (2,009,085) |
| Operating loss | <u>\$ (1,784,393)</u> | <u>\$ (1,011,727)</u> |

All of our net revenues, which are primarily derived from the sale of FC2, are attributed to our Commercial reporting segment. See Note 4 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 Commercial segment. 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 Inc., The Prostate Cancer Company, is an oncology and urology biopharmaceutical company developing novel medicines for the management of prostate cancer.

The Company's prostate cancer pipeline includes VERU-111, zuclomiphene citrate, and VERU-100. VERU-111 is an oral, next-generation, first-in-class small molecule that targets alpha and beta tubulin subunits of microtubules in cells to treat metastatic prostate cancer patients whose disease is resistant to both castration and novel androgen-blocking agents (e.g., abiraterone or enzalutamide). VERU-111 is being evaluated in men with metastatic castration and androgen-blocking agent resistant prostate cancer in an open label Phase 1b/2 clinical trial. The clinical development program for VERU-111 is being expanded with plans to initiate two additional Phase 2 studies: metastatic pancreatic cancer and metastatic bladder cancer. Zuclomiphene citrate is an oral nonsteroidal estrogen receptor agonist being evaluated for estrogenic activity in a Phase 2 trial (Stage 1 testing placebo, Zuclomiphene 10mg, and Zuclomiphene 50 mg) to treat hot flashes, a common side effect caused by androgen deprivation therapy (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 in the first half of calendar year 2020. VERU-100 is a novel, proprietary peptide formulation for ADT with multiple potential beneficial clinical attributes addressing the shortfalls of current FDA-approved ADT formulations for the treatment of advanced prostate cancer. VERU-100 is a long-acting gonadotropin-releasing hormone (GnRH) antagonist designed to be administered as a small volume subcutaneous 3-month depot injection without a loading dose. VERU-100 will immediately suppress testosterone with no testosterone surge upon initial or repeated administration—a problem which occurs with currently approved luteinizing hormone-releasing hormone (LHRH) agonists used for ADT. Currently, there are no GnRH antagonists commercially approved beyond a one-month injection. VERU-100 is anticipated to enter a Phase 2 dose-finding study in early calendar year 2020.

The Company is also advancing new drug formulations in its specialty pharmaceutical pipeline addressing unmet medical needs in urology such as TADFIN[®] for the administration of tadalafil 5mg and finasteride 5mg combination formulation dosed daily to treat urinary tract symptoms caused by BPH. Tadalafil (CIALIS[®]) is currently approved for treatment of benign prostatic hyperplasia (BPH) and erectile dysfunction and finasteride is currently approved for treatment of BPH (finasteride 5mg PROSCAR[®]) and male pattern hair loss (finasteride 1mg PROPECIA[®]). The co-administration of tadalafil and finasteride has been shown to be more effective for the treatment of BPH than by finasteride alone. The Company had a successful pre-NDA meeting with the FDA and the expected submission of the NDA for TADFIN is second half of calendar year 2020. The Company is also developing Tamsulosin XR capsules which is a formulation of tamsulosin, the active ingredient in FLOMAX[®], which the Company has designed to avoid the "food effect" inherent in currently marketed versions of the drug, allowing for potentially safer administration and improved patient compliance.

The Company's commercial products include FC2, an FDA-approved product for the dual protection against unwanted pregnancy and sexually transmitted infections, and the PREBOOST[®] 4% benzocaine medicated individual wipe for the treatment of premature ejaculation. The Company's Female Health Company Division markets and sells FC2 commercially and in the public health sector both in the U.S. and globally. In the U.S., FC2 is available by prescription through the Company's multiple telemedicine and internet pharmacy partners and retail pharmacies, as well as OTC through the Company's website at www.fc2.us.com. In the global public health sector, the Company markets FC2 to entities, including ministries of health, government health agencies, U.N. agencies, nonprofit organizations and commercial partners, that work to support and improve the lives, health and well-being of women around the world. PREBOOST[®] is marketed online in the U.S. through an exclusive marketing arrangement under the Roman[®] Swipes brand name by Roman Health Ventures Inc. Roman is a leading telemedicine company that sells men's health products via the internet website www.getroman.com.

In October 2016, we completed the APP Acquisition. Prior to the completion of the APP Acquisition, the Company had been a single product company, focused on manufacturing, marketing and selling FC2 in the public sector. Most of the Company's net revenues are currently derived from sales of FC2 in the public and commercial sectors.

Sales of FC2 in the public and commercial sectors

FC2 Public Sector. FC2's primary use is for the prevention of HIV/AIDS and other sexually transmitted diseases and family planning, and the global public health sector has been the Company's main 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 unwanted 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 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 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, process errors, changes in leadership, funding priorities and/or other pressures may delay or derail the process and affect the purchasing patterns of public sector customers. As a result, the Company may experience significant quarter-to-quarter sales variances in the global public 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.

FC2 Commercial Sector. In April 2017, the Company launched a small-scale marketing and sales program to support the promotion of FC2 in the U.S. market. The commercial team developed a plan to confirm the "proof of concept" that FC2 represented a significant business opportunity. This required changes in the distribution process for FC2 in the U.S. As part of this strategy the Company announced new distribution agreements with three of the country's largest distributors that support the pharmaceutical industry. This newly developed network now allows up to 92% of major retail pharmacies the ability to make FC2 available to their customers. In addition to the distribution system, the Company expanded sales and market access efforts that resulted in FC2 now being available through the following access points: community-based organizations, by prescription, through leading telemedicine providers, through 340B covered entities, colleges and universities and our patient assistance program. We continue to increase healthcare provider awareness, education and acceptance, which has resulted in more women utilizing FC2 in the U.S. In 2018, we dissolved our small-scale marketing and sales program to focus our efforts in partnering with 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 in a cost-effective and highly convenient manner.

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

| Period | 2020 | 2019 | 2018 | 2017 | 2016 |
|-------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| October 1 — December 31 | 10,070,700 | 7,382,524 | 4,399,932 | 6,389,320 | 15,380,240 |
| January 1 — March 31 | — | 9,792,584 | 4,125,032 | 4,549,020 | 9,163,855 |
| April 1 — June 30 | — | 10,876,704 | 10,021,188 | 8,466,004 | 10,749,860 |
| July 1 — September 30 | — | 9,842,020 | 6,755,124 | 6,854,868 | 6,690,080 |
| Total | 10,070,700 | 37,893,832 | 25,301,276 | 26,259,212 | 41,984,035 |

Revenues. The Company's revenues are primarily derived from sales of FC2 in the global public sector and the U.S. prescription channel. Other revenues are from sales of PREBOOST® (Roman® Swipes). 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 global public health sector agencies who purchase and/or distribute FC2 for use in preventing the transmission of HIV/AIDS and/or family planning and, in the U.S., telemedicine providers who sell into the prescription channel.

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.

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 Patient Protection and Affordable Care Act (the "ACA") and the laws of 20+ states prior to enactment of the ACA. The Company supplies FC2 to a leading telemedicine provider, which has become one of our largest customers. The Company has developed and is working to develop additional supply and distributor relationships with telemedicine and other providers.

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 material portion of the Company's future 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 of 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. Since the completion of the APP Acquisition 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 \$5.3 million and \$2.4 million for the three months ended December 31, 2019 and 2018, 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, 2019 COMPARED TO THREE MONTHS ENDED DECEMBER 31, 2018

The Company generated 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, compared to net revenues of \$6.4 million and net loss of \$2.1 million, or \$(0.03) per basic and diluted common share, for the three months ended December 31, 2018. Net revenues increased 66% year over year.

FC2 net revenues represented 99% of total net revenues. FC2 net revenues increased 65% year over year. There was a 36% increase in total FC2 unit sales and an increase in FC2 average sales price per unit of 21%. The principal factor for the increase in the FC2 average sales price per unit compared to prior year was the increase in net revenues in the U.S. prescription channel. The Company experienced an increase in FC2 net revenues in both the global public sector and the U.S. prescription channel. The global public sector net revenues increased 13% and the U.S. prescription channel net revenues increased 148%.

Cost of sales increased to \$3.3 million in the three months ended December 31, 2019 from \$1.7 million in the three months ended December 31, 2018 primarily due to the increase in unit sales.

Gross profit increased to \$7.3 million in the three months ended December 31, 2019 from \$4.6 million in the three months ended December 31, 2018. Gross profit margin for the 2019 period was 69% of net revenues, compared to 73% of net revenues for the 2018 period. The reduction in the gross profit margin is primarily due to an increase in labor, transportation, 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 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 \$5.3 million in the three months ended December 31, 2019 from \$2.4 million in the same period in fiscal 2019. The increase is primarily due to increased costs associated with the in-process research and development projects acquired pursuant to the APP Acquisition and increased personnel costs.

Selling, general and administrative expenses increased to \$3.8 million in the three months ended December 31, 2019 from \$3.3 million in the three months ended December 31, 2018. The increase is primarily due to increased personnel, personnel costs, and related benefits.

Interest expense, which consists of items related to the Credit Agreement and Residual Royalty Agreement, was \$1.1 million in the three months ended December 31, 2019, which is consistent with \$1.3 million in the three months ended December 31, 2018.

Expense associated with the change in fair value of the embedded derivatives related to the Credit Agreement and Residual Royalty Agreement was \$0.4 million in the three months ended December 31, 2019 compared to income of \$0.2 million in the three months ended December 31, 2018. The liabilities associated with embedded derivatives represent the fair value of the change of control provisions in the SWK Credit Agreement and Residual Royalty Agreement. See Note 3 and Note 8 to the financial statements included in this report for additional information.

The Company realized a foreign currency transaction loss of \$70,000 in the first quarter of fiscal 2020, compared to \$18,000 in the first quarter of fiscal 2019. This foreign currency transaction loss was primarily due to the adverse movement of the U.S. dollar against the Malaysian Ringgit during the period.

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The income tax benefit in the first quarter of fiscal 2020 was \$76,000, compared to income tax expense of \$92,000 in the first quarter of fiscal 2019. The increase in the income tax benefit of \$169,000 is primarily due to an increase in the income tax benefit of \$231,000 related to the increase in the loss before income taxes during the current period partially offset by a decrease of \$51,000 for the effect of lower foreign income tax rates.

Liquidity and Sources of Capital

Liquidity

Our cash on hand at December 31, 2019 was \$4.2 million, compared to \$6.3 million at September 30, 2019. At December 31, 2019, the Company had negative working capital of \$0.1 million and stockholders' equity of \$29.6 million compared to working capital of \$2.8 million and stockholders' equity of \$32.3 million as of September 30, 2019. The decrease in working capital is primarily due to an increase in the current portion of the Credit Agreement liability and the recognition of a current liability for operating leases as a result of the Company's adoption of the new lease accounting standard, as described in Note 1 to the financial statements included in this report.

We have incurred quarterly operating losses since the fourth quarter of fiscal 2016 and anticipate that we will continue to consume cash and incur substantial net losses 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, 2019, for a description of certain risks that will affect our future capital requirements.

The Company believes its current cash position, cash expected to be generated from sales of the Company's commercial products, and its ability to secure equity financing or other financing alternatives are adequate to fund planned operations of the Company for the next 12 months. Such financing alternatives may include debt financing, common stock offerings, including existing purchase agreements, or financing involving convertible debt or other equity-linked securities and may include financings under the Company's effective shelf registration statement on Form S-3 (File No. 333-221120) (the "Shelf Registration Statement"). The Company intends to be opportunistic when pursuing equity or debt financing which could include selling common stock under the Purchase Agreement with Aspire Capital. 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, 2019, for a description of certain risks related to our ability to raise capital on acceptable terms.

Operating activities

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 \$15 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 derivative 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 \$06 million and an increase in inventories of \$1.1 million. These were partially offset by an increase in accounts payable of \$0.7 million.

Our operating activities used cash of \$1.5 million in the three months ended December 31, 2018. Cash used in operating activities included a net loss of \$2.2 million, adjustments for noncash items totaling \$1.7 million and changes in operating assets and liabilities of \$1.0 million. Adjustments for noncash items primarily consisted of \$1.3 million of noncash interest expense related to the Credit Agreement and Residual Royalty Agreement and \$0.4 million of share-based compensation. The decrease in cash from changes in operating assets and liabilities included a decrease in accounts payable of \$1.2 million, a decrease in accrued expenses and other current liabilities of \$0.7 million, and an increase in inventory of \$0.4 million, offset by a decrease in net accounts receivable of \$1.5 million.

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Investing activities

Net cash used in investing activities in the three months ended December 31, 2019 was \$22,000 and was primarily 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, 2019 was \$0.4 million and primarily consisted 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.

Net cash provided by financing activities in the three months ended December 31, 2018 was \$6.7 million and consisted of net proceeds from the underwritten public offering of the Company's common stock of \$9.3 million (see discussion below), less payments on the Credit Agreement (see discussion below) totaling \$2.6 million.

Sources of Capital

Common Stock Offering

On October 1, 2018, we completed an underwritten public offering of 7,142,857 shares of our common stock, at a public offering price of \$1.40 per share. Net proceeds to the Company from this offering were \$9.1 million after deducting underwriting discounts and commissions and costs paid by the Company. All of the shares sold in the offering were by the Company. The offering was made pursuant to the Shelf Registration Statement.

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 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 \$0.4 million and \$2.6 million during the three months ended December 31, 2019 and 2018, respectively. As a result of the Second Amendment, the Company currently estimates the aggregate amount of quarterly revenue-based payments payable during the 12-month period subsequent to December 31, 2019 will be approximately \$6.5 million.

Aspire Capital Purchase Agreement

On December 29, 2017, the Company entered into the Purchase Agreement with 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 and in its sole discretion during the 36-month term of the Purchase Agreement, to direct Aspire Capital purchase up to \$15.0 million of the Company's common stock in the aggregate. Other than the 304,457 shares of common stock issued to Aspire Capital in consideration for entering into the Purchase Agreement, the Company has no obligation to sell any shares of common stock pursuant to the 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 Purchase Agreement. During fiscal 2019, we sold 2,000,000 shares of common stock to Aspire Capital under the Purchase Agreement resulting in proceeds to the Company of \$3.6 million. As of December 31, 2019, the amount remaining under the Purchase Agreement was \$8.4 million.

Fair Value Measurements

As of December 31, 2019 and September 30, 2019, 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 8 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, expected cash outflows, expected repayment dates, probability of a change of control, expected volatility, and risk-free interest rates. 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 3 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, 2019. There have been no material changes to such exposures since September 30, 2019.

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 the supervision 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, 2019. 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, 2019, except for the following additional risk factor.

We have significant international operations and face the risk that the coronavirus or other health epidemics could disrupt our operations or the operations of our suppliers.

Our business could be adversely affected by the effects of a widespread outbreak of contagious disease, such as the recent outbreak of respiratory illness caused by a coronavirus first identified in Wuhan, Hubei Province, China. Because we manufacture FC2 in a single facility located in Malaysia, we may be vulnerable to an outbreak of the coronavirus or other contagious diseases in that region. The effects of such an outbreak could include disruptions or restrictions on our ability to travel, our ability to manufacture FC2 and our ability to ship FC2 to customers as well as disruptions that may affect our suppliers. Any disruption of our ability to manufacture or distribute FC2 or of the ability of our suppliers to deliver key raw materials on a timely basis could have a material adverse effect on our sales and operating results. In addition, a significant outbreak of contagious diseases in the human population could result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could affect demand for FC2 and impact our operating results.

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Item 6. Exhibits

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|---|
| 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. * |

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| 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 ended December 31, 2019, 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 12, 2020

/s/ Mitchell S. Steiner

Mitchell S. Steiner

Chairman, Chief Executive Officer and President

DATE: February 12, 2020

/s/ Michele Greco

Michele Greco

Chief Financial Officer and Chief Administrative Officer

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 12, 2020

/s/Mitchell S. Steiner

Mitchell S. Steiner
Chairman, Chief Executive Officer and President

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 12, 2020

/s/Michele Greco

Michele Greco
Chief Financial Officer and Chief Administrative Officer

**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, 2019 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 12, 2020

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

Date: February 12, 2020

/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.
