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, 2018

☐ **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.

(Name of registrant as specified in its charter)

Wisconsin	**39-1144397**
(State of Incorporation)	**(I.R.S. Employer Identification No.)**
4400 Biscayne Boulevard, Suite 888	
Miami, FL	**33137**
(Address of principal executive offices)	**(Zip Code)**

305-509-6897
(Registrant's telephone number, including area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

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

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

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of February 11, 2019, the registrant had 62,784,480 shares of $0.01 par value common stock outstanding.

VERU INC.
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FORWARD LOOKING STATEMENTS

Certain statements included in this quarterly report on Form 10-Q which are not statements of historical fact are intended to be, and are hereby identified as, "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about future financial and operating results, plans, objectives, expectations and intentions, costs and expenses, 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 early stages of 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 relating to compliance and regulatory matters, including costs and delays resulting from extensive government regulation and reimbursement and coverage under healthcare insurance and regulation;
- risks inherent in doing business on an international level;
- the disruption of production at our manufacturing facilities due to raw material shortages, labor shortages and/or physical damage to our facilities;
- 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;
- a governmental tender award, including our recent 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;
- our recent 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 Form 10-K for the year ended September 30, 2018 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, 2018	September 30, 2018
Assets		
Current assets:		
Cash	$ 8,979,183	$ 3,759,509
Accounts receivable, net	2,487,096	3,972,632
Inventory, net	2,698,306	2,302,030
Prepaid expenses and other current assets	1,208,446	1,148,345
Total current assets	15,373,031	11,182,516
Plant and equipment, net	361,998	404,552
Deferred income taxes	8,546,718	8,543,758
Intangible assets, net	20,400,420	20,477,729
Goodwill	6,878,932	6,878,932
Other assets	773,861	965,152
Total assets	$ 52,334,960	$ 48,452,639
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,103,711	$ 3,226,036
Accrued research and development costs	569,873	981,357
Accrued expenses and other current liabilities	2,076,009	2,450,364
Credit agreement, short-term portion (Note 7)	4,943,543	6,692,718
Unearned revenue	49,095	202,452
Total current liabilities	9,742,231	13,552,927
Credit agreement, long-term portion (Note 7)	2,996,120	2,701,570
Residual royalty agreement (Note 7)	1,702,576	1,753,805
Other liabilities	30,000	30,000
Deferred rent	86,328	88,161
Deferred income taxes	895,862	844,758
Total liabilities	15,453,117	18,971,221
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock; no shares issued and outstanding at December 31, 2018 and September 30, 2018	—	—
Common stock, par value $0.01 per share; 77,000,000 shares authorized, 64,801,517 and 57,468,660 shares issued and 62,617,813 and 55,284,956 shares outstanding at December 31, 2018 and September 30, 2018, respectively	648,015	574,687
Additional paid-in-capital	104,972,401	95,496,506
Accumulated other comprehensive loss	(581,519)	(581,519)
Accumulated deficit	(60,350,449)	(58,201,651)
Treasury stock, 2,183,704 shares, at cost	(7,806,605)	(7,806,605)
Total stockholders' equity	36,881,843	29,481,418
Total liabilities and stockholders' equity	$ 52,334,960	$ 48,452,639

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended December 31,	
	2018	2017
Net revenues	$ 6,371,809	$ 2,586,613
Cost of sales	1,727,729	1,272,992
Gross profit	4,644,080	1,313,621
Operating expenses:		
Research and development	2,361,823	1,958,367
Selling, general and administrative	3,293,984	3,027,698
Loss on settlement of accounts receivable	—	3,764,137
Total operating expenses	5,655,807	8,750,202
Operating loss	(1,011,727)	(7,436,581)
Non-operating (expenses) income:		
Interest expense	(1,278,423)	—
Other income (expense), net	26,394	(13,169)
Change in fair value of derivative liabilities	225,000	—
Foreign currency transaction loss	(17,544)	(53,455)
Total non-operating expenses	(1,044,573)	(66,624)
Loss before income taxes	(2,056,300)	(7,503,205)
Income tax expense (benefit)	92,498	(3,246,053)
Net loss	$ (2,148,798)	$ (4,257,152)
Net loss per basic and diluted common share outstanding	$ (0.03)	$ (0.08)
Basic and diluted weighted average common shares outstanding	62,553,791	53,154,076

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Preferred Stock	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Treasury Stock, at Cost	Total
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	$ —	64,801,517	$648,015	$104,972,401	$ (581,519)	$(60,350,449)	$(7,806,605)	$36,881,843
Balance at September 30, 2017	$ —	55,392,193	$553,922	$ 90,550,669	$ (581,519)	$(34,263,262)	$(7,806,605)	$48,453,205
Share-based compensation	—	—	—	207,454	—	—	—	207,454
Shares issued in connection with common stock purchase agreement	—	304,457	3,045	344,036	—	—	—	347,081
Net loss	—	—	—	—	—	(4,257,152)	—	(4,257,152)
Balance at December 31, 2017	$ —	55,696,650	$556,967	$ 91,102,159	$ (581,519)	$(38,520,414)	$(7,806,605)	$44,750,588

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Three Months Ended December 31,	
	2018	2017
OPERATING ACTIVITIES		
Net loss	$ (2,148,798)	$ (4,257,152)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	42,554	44,229
Amortization of intangible assets	77,309	68,816
Noncash interest expense	1,278,423	—
Share-based compensation	417,256	207,454
Deferred income taxes	48,144	(3,297,000)
Loss on settlement of accounts receivable	—	3,764,137
Change in fair value of derivative liabilities	(225,000)	—
Other	20,413	(5,000)
Changes in current assets and liabilities:		
Decrease in accounts receivable	1,485,536	3,248,628
Increase in inventory	(418,522)	(299,112)
(Increase) decrease in prepaid expenses and other assets	(58,810)	46,671
Decrease in accounts payable	(1,231,443)	(168,347)
Decrease in unearned revenue	(153,357)	(24,501)
(Decrease) increase in accrued expenses and other current liabilities	(640,186)	967,839
Net cash (used in) provided by operating activities	(1,506,481)	296,662
INVESTING ACTIVITIES		
Capital expenditures	—	(1,914)
Net cash used in investing activities	—	(1,914)
FINANCING ACTIVITIES		
Proceeds from sale of shares in public offering, net of fees and costs	9,285,432	—
Installment payments on SWK credit agreement	(2,559,277)	—
Net cash provided by financing activities	6,726,155	—
Net increase in cash	5,219,674	294,748
CASH AT BEGINNING OF PERIOD	3,759,509	3,277,602
CASH AT END OF PERIOD	$ 8,979,183	$ 3,572,350
Schedule of noncash investing and financing activities:		
Shares issued in connection with common stock purchase agreement	$ —	$ 347,081
Increase in deferred assets from accrued expenses	$ —	$ 75,920
Costs related to common stock offering in accounts payable	$ 153,465	$ —

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, 2018. The accompanying condensed consolidated balance sheet as of September 30, 2018 has been derived from our audited financial statements. The unaudited condensed consolidated statements of operations and cash flows for the three months ended December 31, 2018 are not necessarily indicative of the results to be expected for any future period or for the fiscal year ending September 30, 2019.

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 health care 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. Nearly all of the Company's net revenues during the three months ended December 31, 2018 and 2017 were derived from sales of FC2.

Reclassifications: Certain prior period amounts in 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.

Cash concentration: The Company's cash is maintained primarily in three financial institutions, located in Chicago, Illinois, London, England and Kuala Lumpur, Malaysia.

Restricted cash: Restricted cash relates to security provided to one of the Company's U.K. banks for performance bonds issued in favor of customers. The Company has a facility of $250,000 for such performance bonds. Such security has been extended infrequently and only on occasions where it has been a contract term expressly stipulated as an absolute requirement by the customer or its provider of funds. The expiration of the bond is defined by the completion of the event such as, but not limited to, a period of time after the product has been distributed or expiration of the product shelf life. Restricted cash was approximately $132,000 and $135,000 at December 31, 2018 and September 30, 2018, respectively, and is included in cash on the accompanying unaudited condensed consolidated balance sheets.

Patents and trademarks: The costs for patents and trademarks are expensed when incurred.

Deferred financing costs: Costs incurred in connection with the common stock purchase agreement discussed in Note 8 have been included in other assets on the accompanying unaudited condensed consolidated balance sheets at December 31, 2018 and September 30, 2018. When shares of the Company's common stock are sold under the common stock purchase agreement, a pro-rata portion of the deferred costs is recorded to additional paid-in-capital.

As discussed in Note 8, in connection with the common stock offering that closed on October 1, 2018, we incurred costs of approximately $190,000 through September 30, 2018. This amount was included in other assets on the accompanying unaudited condensed consolidated balance sheet at September 30, 2018. These costs were charged to additional paid-in capital in the three months ended December 31, 2018 after the common stock offering was closed.

Costs incurred in connection with the issuance of debt discussed in Note 7 are presented as a reduction of the debt on the accompanying unaudited condensed consolidated balance sheets at December 31, 2018 and September 30, 2018. These issuance costs are being amortized using the effective interest method over the expected repayment period of the debt, which is currently estimated to occur in the fourth quarter of fiscal 2021. The amount of amortization was approximately $28,000 for the three months ended December 31, 2018 and is included in interest expense on the accompanying unaudited condensed consolidated statements of operations.

Fair value measurements: Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 820 – *Fair Value Measurements and Disclosures,* defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. FASB ASC Topic 820 requires disclosures about the fair value of all financial instruments, whether or not recognized, for financial statement purposes. Disclosures about the fair value of financial instruments are based on pertinent information available to us as of the reporting dates. Accordingly, the estimates presented in the accompanying unaudited condensed consolidated financial statements are not necessarily indicative of the amounts that could be realized on disposition of the financial instruments. See Note 3 for a discussion of fair value measurements.

The carrying amounts reported in the accompanying unaudited condensed consolidated balance sheets for cash, accounts receivable, accounts payable and other accrued liabilities approximate their fair value based on the short-term nature of these instruments. The carrying value of long-term debt, taking into consideration debt discounts and related derivative instruments, is estimated to approximate fair value.

Unearned revenue: The Company records an unearned revenue liability if a customer pays consideration before the Company transfers the product to the customer 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. Unearned revenue as of December 31, 2018 and September 30, 2018 was approximately $49,000 and $202,000, respectively, and was comprised mainly of sales made to a large distributor who has the right to return product under certain conditions.

Derivative instruments: The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. The Company reviews the terms of debt instruments it enters into to determine whether there are embedded derivative instruments, which are required to be bifurcated and accounted for separately as derivative financial instruments. Embedded derivatives that are not clearly and closely related to the host contract are bifurcated and are recognized at fair value with changes in fair value recognized as either a gain or loss in earnings. Liabilities incurred in connection with an embedded derivative are discussed in Note 7.

Revenue recognition: Revenue is recognized when control of the promised goods is transferred to the customer in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those products.

The Company generates nearly all of 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 Company does not typically have significant unusual payment terms beyond 120 days in its contracts with customers. See Note 4 for additional information regarding credit terms.

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.

Research and development costs: Research and development costs are expensed as they are incurred and include salaries and benefits, clinical trials costs and contract services. Nonrefundable advance payments made for goods or services to be used in research and development activities are deferred and capitalized until the goods have been delivered or the related services have been performed. If the goods are no longer expected to be delivered or the services are no longer expected to be performed, the Company would be required to expense the related capitalized advance payments. The Company did not have any capitalized nonrefundable advance payments as of December 31, 2018 and September 30, 2018.

The Company records estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies and clinical trials and contract manufacturing activities. These costs are a significant component of the Company's research and development expenses. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers under the service agreements. The Company makes significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. The Company has not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed, number of patients enrolled and the rate of patient enrollments may vary from the Company's estimates, resulting in adjustments to expense in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations.

Share-based compensation: The Company recognizes share-based compensation expense in connection with its share-based awards based on the estimated fair value of the awards on the date of grant, on a straight-line basis over the vesting period. Calculating share-based compensation expense requires the input of highly subjective judgment and assumptions, including estimates of the expected life of the share-based award, stock price volatility and risk-free interest rates.

Advertising: The Company's policy is to expense advertising costs as incurred. Advertising costs were immaterial to the Company's results of operations for the three months ended December 31, 2018 and 2017.

Income taxes: The Company files separate income tax returns for its foreign subsidiaries. FASB ASC Topic 740 requires recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statements and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Deferred tax assets are also provided for carryforwards for income tax purposes. In addition, the amount of any future tax benefits is reduced by a valuation allowance to the extent such benefits are not expected to be realized.

Foreign currency translation and operations: Effective October 1, 2009, the Company determined that there were significant changes in facts and circumstances, triggering an evaluation of its subsidiaries' functional currency. The evaluation indicated that the U.S. dollar is the currency with the most significant influence upon the subsidiaries. Because all of the U.K. subsidiary's future sales and cash flows would be denominated in U.S. dollars following the October 2009 cessation of production of the Company's first-generation product, FC1, the U.K. subsidiary adopted the U.S. dollar as its functional currency effective October 1, 2009. As the Malaysia subsidiary is a direct and integral component of the U.K. parent's operations, it, too, adopted the U.S. dollar as its functional currency as of October 1, 2009. The consistent use of the U.S. dollar as the functional currency across the Company reduces its foreign currency risk and stabilizes its operating results. The cumulative foreign currency translation loss included in

accumulated other comprehensive loss was $0.6 million as of December 31, 2018 and September 30, 2018. Assets located outside of the U.S. totaled approximately $4.6 million and $5.2 million at December 31, 2018 and September 30, 2018, respectively.

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.

The U.S. parent company and its U.K. subsidiary routinely purchase inventory produced by its Malaysia subsidiary for sale to their respective customers. These intercompany trade accounts are eliminated in consolidation. The Company's policy and intent is to settle the intercompany trade account on a current basis. Since the U.K. and Malaysia subsidiaries adopted the U.S. dollar as their functional currencies effective October 1, 2009, no foreign currency gains or losses from intercompany trade are recognized. For the three months ended December 31, 2018 and 2017, comprehensive loss is equivalent to the reported net loss.

Recently Issued Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09 *Revenue from Contracts with Customers (Topic 606)*. This new accounting guidance on revenue recognition provides for a single five-step model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations, and recognizing revenue when, or as, an entity satisfies a performance obligation. The new guidance also requires additional financial statement disclosures that will enable users to understand the nature, amount, timing and uncertainty of revenue and cash flows relating to customer contracts. The Company adopted the new guidance on October 1, 2018 using the modified retrospective method and elected to apply the guidance only to contracts that were not completed as of the date of adoption. The adoption of this guidance did not have a material effect on our consolidated financial statements and related disclosures. See discussion above for disclosures relating to the Company's revenue recognition.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. The amendments in this Update increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required upon adoption. Early adoption is permitted. 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. The Company will adopt the new accounting standard on October 1, 2019 and intends to elect 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 have begun to identify our significant lease contracts and are in the process of evaluating the effect of the new guidance on our consolidated financial statements and related disclosures.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*. The purpose of ASU 2016-18 is to clarify guidance and presentation related to restricted cash in the statements of cash flows as well as increased disclosure requirements. It requires beginning-of-period and end-of-period total amounts shown on the statements of cash flows to include cash and cash equivalents as well as restricted cash and restricted cash equivalents. We adopted ASU 2016-18 effective October 1, 2018. The adoption of ASU 2016-18 did not have a material effect on the presentation of our consolidated statements of cash flows or related disclosures.

In January 2017, the FASB issued ASU 2017-04, *Intangibles - Goodwill and Other Topics (Topic 350): Simplifying the Test for Goodwill Impairment*. The purpose of ASU 2017-04 is to reduce the cost and complexity of evaluating goodwill for impairment. It eliminates the need for entities to calculate the impaired fair value of goodwill by assigning the fair value of a reporting unit to all of its assets and liabilities as if that reporting unit had been acquired in a business combination. Under this amendment, an entity will perform its goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An impairment charge is recognized for the amount by

which the carrying value exceeds the reporting unit's fair value. ASU 2017-04 is effective for annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. We do not expect the adoption of ASU 2017-04 to have a material effect on our financial position or results of operations.

In May 2017, the FASB issued ASU 2017-09, *Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting*. The purpose of ASU 2017-09 is to provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The amendments in this Update should be applied prospectively to an award modified on or after the adoption date. We adopted ASU 2017-09 effective October 1, 2018. The adoption of ASU 2017-09 did not have a material effect on our financial position or results of operations.

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. ASU 2018-07 will be effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than the Company's adoption date of *Topic 606, Revenue from Contracts with Customers*. 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. The adoption of ASU 2018-07 is not expected to have a material effect on our financial position or results of operations but should simplify the process by which the Company measures compensation expense for share-based payments to nonemployees.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework – Change to the Disclosure Requirements for Fair Value Measurement*. ASU 2018-13 modifies the disclosure requirements by adding, removing, and modifying certain required disclosures for fair value measurements for assets and liabilities disclosed within the fair value hierarchy. ASU 2018-13 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019 and early adoption is permitted. The adoption of ASU 2018-13 is not expected to have a material effect on our financial position or results of operations as it modifies disclosure requirements only.

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 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 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 financing which could include selling common stock under its common stock purchase agreement with Aspire Capital Fund, LLC (see Note 7) and/or a marketed deal with an investment bank. The Company's ability to raise capital through equity financing may be limited by the number of authorized shares of the Company's common stock, which is currently 77 million shares. In order to raise significant additional amounts from equity financing, the Company will need to seek stockholder approval to amend our Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock, and any such amendment would require the approval of the holders of at least two-thirds of the outstanding shares of the Company's common stock.

Note 3 – Fair Value Measurements

FASB 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, 2018 and 2017.

As of December 31, 2018 and September 30, 2018, 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, giving consideration to 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.

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) for the three months ended December 31, 2018:

Beginning balance at October 1, 2018	$	2,426,000
Additions		—
Change in fair value of derivative liabilities		(225,000)
Ending balance at December 31, 2018	$	2,201,000

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

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 7 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 SWK 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, 2018:

Valuation Methodology	Significant Unobservable Input	Weighted Average (range, if applicable)
Monte Carlo Simulation	Estimated change of control dates	September 2019 to December 2021
	Discount rate	16.1% to 18.5%
	Probability of change of control	10% to 90%

Note 4 – 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. The Company has agreed to credit terms of up to 150 days with our distributor in the Republic of South Africa. For the order of 15 million units under the Brazil tender in 2014, the Company agreed to up to 360 days credit terms with our distributor in Brazil subject to earlier payment upon receipt of payment by the distributor from the Brazilian Government. For the 12-month period ended December 31, 2018, the Company's average days' sales outstanding was approximately 61 days.

The components of accounts receivable consist of the following at December 31, 2018 and September 30, 2018:

	December 31, 2018	September 30, 2018
Accounts receivable	$ 2,558,328	$ 4,046,733
Less: allowance for doubtful accounts	(36,201)	(36,201)
Less: allowance for sales and payment term discounts	(35,031)	(37,900)
Accounts receivable, net	$ 2,487,096	$ 3,972,632

On December 27, 2017, we entered into a settlement agreement with Semina, our distributor in Brazil, pursuant to which Semina made a payment of $2.2 million and was obligated to make a second payment of $1.5 million by February 28, 2018, to settle net amounts due to us totaling $7.5 million relating to the Brazil tender in 2014. The settlement was not related to our belief in the ultimate collectability of the receivables or in the creditworthiness of Semina. We elected to settle these amounts due to the uncertainty regarding the timing of payment by the Brazilian Government and, ultimately to us, on the remaining amounts due. The result of the settlement was a net loss of $3.8 million in the three months ended December 31, 2017, which is presented as a separate line item in the accompanying unaudited condensed consolidated statements of operations. Semina did not make its second payment of $1.5 million by February 28, 2018. In July 2018, the Company agreed to accept $1.3 million as settlement of the $1.5 million that was owed, which resulted in an additional loss of $0.2 million in the third quarter of fiscal 2018.

At December 31, 2018, no single customer's accounts receivable balance accounted for more than 10% of current assets. At September 30, 2018, one customer had an accounts receivable balance that represented 15% of current assets.

At December 31, 2018, two customers had an accounts receivable balance greater than 10% of net accounts receivable, representing 65% of net accounts receivable in the aggregate. At September 30, 2018, three customers had an accounts receivable balance greater than 10% of net accounts receivable, representing 74% of net accounts receivable 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. For the three months ended December 31, 2017, there were three customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 59% 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. The table below summarizes the change in the allowance for doubtful accounts for the three months ended December 31, 2018 and 2017.

	Three Months Ended December 31,	
	2018	2017
Beginning balance	$ 36,201	$ 38,103
Charges to expense	—	—
Charge-offs	—	(5,000)
Ending balance	$ 36,201	$ 33,103

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 5 – Balance Sheet Information

Inventory

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

Inventory consisted of the following at December 31, 2018 and September 30, 2018:

	December 31, 2018	September 30, 2018
FC2		
Raw material	$ 491,617	$ 366,220
Work in process	51,944	77,669
Finished goods	2,550,032	2,232,864
Inventory, gross	3,093,593	2,676,753
Less: inventory reserves	(397,635)	(391,861)
FC2, net	2,695,958	2,284,892
PREBOOST®		
Finished goods	2,348	17,138
Inventory, net	$ 2,698,306	$ 2,302,030

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 which range as follows:

Manufacturing equipment	5 – 10 years
Office equipment	3 – 5 years
Furniture and fixtures	7 – 10 years

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, 2018 and September 30, 2018:

	December 31, 2018	September 30, 2018
Equipment, furniture and fixtures	$ 4,018,284	$ 4,018,284
Leasehold improvements	287,686	287,686
	4,305,970	4,305,970
Less: accumulated depreciation and amortization	(3,943,972)	(3,901,418)
Plant and equipment, net	$ 361,998	$ 404,552

Note 6 – Intangible Assets and Goodwill

Intangible Assets

Intangible assets acquired in the APP Acquisition included in-process research and development ("IPR&D"), developed technology consisting of PREBOOST® medicated wipes for prevention of premature ejaculation, and covenants not-to-compete. IPR&D represents incomplete research and development projects at APP as of the date of the APP Acquisition. These intangible assets are carried at cost less accumulated amortization. Intangible assets with finite lives are tested for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. IPR&D is tested for impairment at least annually in the fourth quarter of each fiscal year until the underlying projects are completed or abandoned.

The gross carrying amounts and net book value of intangible assets are as follows at December 31, 2018:

	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Intangible assets with finite lives:			
Developed technology - PREBOOST®	$ 2,400,000	$ 344,818	$ 2,055,182
Covenants not-to-compete	500,000	154,762	345,238
Total intangible assets with finite lives	2,900,000	499,580	2,400,420
Acquired in-process research and development assets	18,000,000	—	18,000,000
Total intangible assets	$ 20,900,000	$ 499,580	$ 20,400,420

The gross carrying amounts and net book value of intangible assets are as follows at September 30, 2018:

	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Intangible assets with finite lives:			
Developed technology - PREBOOST®	$ 2,400,000	$ 285,366	$ 2,114,634
Covenants not-to-compete	500,000	136,905	363,095
Total intangible assets with finite lives	2,900,000	422,271	2,477,729
Acquired in-process research and development assets	18,000,000	—	18,000,000
Total intangible assets	$ 20,900,000	$ 422,271	$ 20,477,729

Amortization is recorded over the projected related revenue stream for the PREBOOST® developed technology over 10 years and on a straight-line basis over seven years for the covenants not-to-compete. The amortization expense is recorded in selling, general and administrative expenses in the accompanying unaudited condensed consolidated statements of operations. The IPR&D assets will not be amortized until the underlying development projects are completed. If and when development is complete, which generally occurs when regulatory approval to market the product is obtained, the associated IPR&D assets would be accounted for as finite-lived intangible assets and amortized over the estimated period of economic benefit. If a development project is abandoned, the associated IPR&D assets would be charged to expense.

Amortization expense was approximately $77,000 and $69,000, for the three months ended December 31, 2018 and 2017, respectively. Based on finite-lived intangible assets recorded as of December 31, 2018, the estimated future amortization expense is as follows:

Fiscal Year Ending September 30,		**Estimated Amortization Expense**
2019	$	231,925
2020		316,368
2021		323,706
2022		331,316
2023		339,062
Thereafter		858,043
Total	$	2,400,420

Intangible assets are highly vulnerable to impairment charges, particularly newly acquired assets for recently launched products. These assets are initially measured at fair value and therefore any reduction in expectations used in the valuations could potentially lead to impairment. Some of the more common potential risks leading to impairment include competition, earlier than expected loss of exclusivity, pricing pressures, adverse regulatory changes or clinical trial results, delay or failure to obtain regulatory approval, additional development costs, inability to achieve expected synergies, higher operating costs, changes in tax laws and other macro-economic changes. The complexity in estimating the fair value of intangible assets in connection with an impairment test is similar to the initial valuation. Considering the high-risk nature of research and development and the industry's success rate of bringing developmental compounds to market, IPR&D impairment charges are likely to occur in future periods.

Goodwill

The carrying amount of goodwill at December 31, 2018 and September 30, 2018 was $6.9 million. There was no change in the balance during the three months ended December 31, 2018 and 2017. Goodwill represents the difference between the purchase price and the estimated fair value of the net assets acquired in the APP Acquisition. Goodwill from the APP Acquisition principally relates to intangible assets that do not qualify for separate recognition, our expectation to develop and market new products, and the deferred tax liability generated as a result of the transaction. Goodwill is not tax deductible for income tax purposes and was assigned to the Company's Research and Development reporting unit, which consists of multiple drug products under clinical development for oncology and urology.

Goodwill is tested for impairment at least annually in the fourth quarter of each fiscal year or when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable, by assessing qualitative factors or performing a quantitative analysis in determining whether it is more likely than not that its fair value exceeds the carrying value. Examples of qualitative factors include our share price, our financial performance compared to budgets, long-term financial plans, macroeconomic, industry and market conditions as well as the substantial excess of fair value over the carrying value of net assets from the annual impairment test previously performed.

The estimated fair value of a reporting unit is highly sensitive to changes in projections and assumptions; therefore, in some instances changes in these assumptions could potentially lead to impairment. We perform sensitivity analyses around our assumptions in order to assess the reasonableness of the assumptions and the results of our testing. Ultimately, future potential changes in these assumptions may impact the estimated fair value of a reporting unit and cause the fair value of the reporting unit to be below its carrying value. We believe that our estimates are consistent with assumptions that marketplace participants would use in their estimates of fair value; however, if actual results are not consistent with our estimates and assumptions, we may be exposed to an impairment charge that could be material.

Note 7 – Debt

SWK Credit Agreement

On March 5, 2018, the Company entered into a Credit Agreement (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 agreed to provide the Company with a multi-draw term loan of up to $12.0 million, with $10.0 million advanced to the Company on the date of the Credit Agreement. The Company may draw up to an additional $1.0 million if the Company enters into an agreement to distribute at least 47.5 million units of FC2 in Brazil upon the terms described in the Credit Agreement and up to an additional $1.0 million if the Company enters into an agreement to distribute at least 30 million units of FC2 in South Africa upon the terms described in 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 175% 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 the sum of 25% 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 10% 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 175% of the aggregate amount advanced to the Company under the Credit Agreement less the amounts previously paid by the Company from product revenue.

The first quarterly revenue-based payment due May 15, 2018 was approximately $642,000 and was paid on that date. On August 10, 2018, the Company entered into an amendment (the "Credit Agreement Amendment") to the Credit Agreement. The Credit Agreement Amendment deferred until November 15, 2018 the due date for the quarterly revenue-based payment that would have otherwise been due on August 15, 2018. The Company made a payment of approximately $2.6 million on November 15, 2018, consisting of approximately $1.4 million for the quarterly revenue-based payment originally due on August 15, 2018 and approximately $1.2 million for the quarterly revenue-based payment due on November 15, 2018.

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) 175% 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.

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 (the "Residual Royalty Agreement"), which provides for an ongoing royalty payment of 5% of product revenue from net sales of FC2 commencing upon the payment in full by the Company of the required amount pursuant to the Credit Agreement. 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 occurs prior to payment in full of the Credit Agreement, there will be no payment due with respect to the Residual Royalty

Agreement. If a change of control occurs after the 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.

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 initial $10.0 million advance under the Credit Agreement.

For accounting purposes, the initial $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.

At December 31, 2018 and September 30, 2018, the Credit Agreement consisted of the following:

	December 31, 2018	September 30, 2018
Aggregate repayment obligation	$ 17,500,000	$ 17,500,000
Less: Payments	(3,201,762)	(642,485)
Less: Unamortized discounts	(7,320,088)	(8,475,874)
Less: Unamortized deferred issuance costs	(176,487)	(204,353)
Credit agreement, net	6,801,663	8,177,288
Add: Embedded derivative liability at fair value (see Note 3)	1,138,000	1,217,000
	7,939,663	9,394,288
Credit agreement, short-term portion	(4,943,543)	(6,692,718)
Credit agreement, long-term portion	$ 2,996,120	$ 2,701,570

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, 2018 and September 30, 2018, respectively.

At December 31, 2018 and September 30, 2018, the Residual Royalty Agreement liability consisted of the following:

	December 31, 2018	September 30, 2018
Residual Royalty Agreement liability, fair value at inception	$ 346,000	$ 346,000
Less: Unamortized discounts	—	(2,420)
Add: Accretion of liability using effective interest rate	293,576	201,225
Residual Royalty Agreement liability, net	639,576	544,805
Add: Embedded derivative liability at fair value (see Note 3)	1,063,000	1,209,000
Residual Royalty Agreement liability	$ 1,702,576	$ 1,753,805

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

	Three Months Ended December 31, 2018
Amortization of Credit Agreement and Residual Royalty Agreement discounts	$ 1,158,206
Accretion of Residual Royalty Agreement liability	92,351
Amortization of deferred issuance costs	27,866
	$ 1,278,423

Note 8 – 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, 2018 and September 30, 2018. 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, 2018 and September 30, 2018.

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 $9.3 million after deducting underwriting discounts and commissions and costs paid by the Company through December 31, 2018. An additional $153,000 of costs is included in accounts payable at December 31, 2018. 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 Torreya Capital, the Company's financial advisor (the "Financial Advisor Warrant"). The Financial Advisor Warrant has a five-year term, 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, 2018.

In May 2018, the Company issued two warrants to purchase a total of up to 750,000 shares of the Company's common stock in connection with a consulting services agreement. The first warrant allows the consultant to purchase up to 300,000 shares of the Company's common stock at $2.31 per share subject to achievement of specified performance goals that will be measured at March 31, 2019. The second warrant allows the consultant to

purchase up to 450,000 shares of the Company's common stock at $2.31 per share subject to achievement of specified performance goals that will be measured at March 31, 2020. The warrants provide for early exercisability if certain events occur related to the Company's FC2 business. If the warrants become exercisable, they will expire to the extent not exercised on or before April 2, 2023. The warrants have a cashless exercise feature. If the performance goals defined in the warrant agreements are not achieved, the warrants will be forfeited. For measurement and recognition purposes, the Company utilized the lowest aggregate amount within the range of potential values, which was zero. Therefore, at December 31, 2018, the Company has determined the fair value of these warrants to be zero and has not recognized any compensation expense related to these warrants for the three months ended December 31, 2018.

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.

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.

During fiscal 2018, we sold an aggregate of 1,717,010 shares of common stock to Aspire Capital under the Purchase Agreement resulting in proceeds to the Company of $3.0 million. As a result of these sales, we recorded approximately $85,000 of the deferred costs noted above to additional paid-in capital. The unamortized amount of deferred costs of approximately $340,000 is included in other assets on the accompanying unaudited condensed consolidated balance sheets at December 31, 2018 and September 30, 2018. As of December 31, 2018, the amount remaining under the Purchase Agreement was $12.0 million. However, based on the current market price of the Company's common stock and the number of shares of the Company's common stock that are unreserved and available for issuance, the Company will need to seek stockholder approval to amend its Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock to use the full remaining availability under the Purchase Agreement.

Note 9 – 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, 2018 and 2017, we recorded share-based compensation expenses as follows:

	Three Months Ended December 31,	
	2018	2017
Cost of sales	$ 7,952	$ 3,265
Selling, general and administrative	327,009	175,337
Research and development	82,295	28,852
	$ 417,256	$ 207,454

Equity Plans

In March 2018, the Company's stockholders approved the Company's 2018 Equity Incentive Plan (the "2018 Plan"). A total of 2.0 million shares are authorized for issuance under the 2018 Plan. As of December 31, 2018, 409,498 shares remain available for issuance under the 2018 Plan.

In July 2017, the Company's stockholders approved the Company's 2017 Equity Incentive Plan (the "2017 Plan"). A total of 4.7 million shares are authorized for issuance under the 2017 Plan. As of December 31, 2018, 12,534 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 quoted market price 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, 2018 and 2017:

	Three Months Ended December 31,	
Weighted Average Assumptions:	2018	2017
Expected volatility	67.61%	60.60%
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	2.75%	2.24%
Expected term (in years)	5.5	5.7
Fair value of options granted	$ 0.83	$ 0.65

During the three months ended December 31, 2018 and 2017, the Company used historical volatility of our common stock over a period equal to the expected life of the options to estimate their fair value. The dividend yield assumption is based on the Company's recent history and expectation of future dividend payouts on the common stock. The risk-free interest rate is based on the implied yield available on U.S. treasury zero-coupon issues with an equivalent remaining term.

The following table summarizes the stock options outstanding and exercisable at December 31, 2018:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2018	5,645,312	$ 1.59		$
Granted	583,656	1.38		
Exercised	—	—		
Forfeited	(118,500)	1.25		
Outstanding at December 31, 2018	6,110,468	$ 1.57	8.51	$ 646,633
Exercisable at December 31, 2018	1,777,286	$ 1.29	6.76	$ 381,186

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 December 31, 2018 of $1.40, less the respective weighted average exercise price per share at period end.

No stock options were exercised during the three months ended December 31, 2018 and 2017.

As of December 31, 2018, the Company had unrecognized compensation expense of approximately $3.3 million related to unvested stock options. This expense is expected to be recognized over approximately three years.

Restricted Stock

The Company has issued restricted stock to employees, directors and consultants. Such issuances had vesting periods that ranged from one to three years. All such shares of restricted stock vest provided the grantee has not voluntarily terminated service or been terminated for cause prior to the vesting date. There were no shares of restricted stock outstanding at December 31, 2018 and September 30, 2018.

Restricted Stock Units

In connection with the closing of the APP Acquisition, the Company issued 50,000 and 140,000 restricted stock units to an employee and an outside director, respectively, that vested on October 31, 2018. The restricted stock units were settled in common stock issued under the 2017 Plan. As of December 31, 2018, there are no outstanding restricted stock units.

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. The stock appreciation rights will be settled in common stock issued under the 2017 Plan. As of December 31, 2018, these vested stock appreciation rights remain outstanding.

Note 10 – Contingent Liabilities

The testing, manufacturing and marketing of consumer products by the Company 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

In response to the APP Acquisition, two purported derivative and class action lawsuits were filed against the Company and certain of its officers and directors in the Circuit Court of Cook County, Illinois, captioned Glotzer v. The Female Health Company, et al., Case No. 2016-CH-13815, and Schartz v. Parrish, et al., Case No. 2016-CH-14488. These lawsuits were originally filed on or about October 21, 2016 and November 7, 2016, respectively. On

January 9, 2017, these two lawsuits were consolidated. On March 31, 2017, the plaintiffs filed a consolidated complaint. The consolidated complaint named as defendants Veru, the members of our board of directors prior to the closing of the APP Acquisition and the members of our board of directors after the closing of the APP Acquisition. The consolidated complaint alleged, among other things, that the directors breached their fiduciary duties, or aided and abetted such breaches, by consummating the APP Acquisition in violation of the Wisconsin Business Corporation Law and NASDAQ voting requirements and by causing us to issue the shares of our common stock and Series 4 Preferred Stock to the former stockholders of APP pursuant to the APP Acquisition in order to evade the voting requirements of the Wisconsin Business Corporation Law. The consolidated complaint also alleged that Dr. Steiner, a director and the Chairman, President and Chief Executive Officer of Veru and a co-founder of APP, and Dr. Fisch, a director and Vice Chairman of Veru and a co-founder of APP, were unjustly enriched in receiving shares of our common stock and Series 4 Preferred Stock in the APP Acquisition.

On May 5, 2017, the defendants filed a motion to dismiss the consolidated complaint. On August 15, 2017, the court entered an order dismissing without prejudice the claims that the post-acquisition directors aided and abetted the alleged breaches of fiduciary duties by the pre-acquisition directors and that Dr. Steiner and Dr. Fisch were unjustly enriched. The court did not dismiss the claims that our directors prior to the closing of the APP Acquisition breached their fiduciary duties and the claims that Veru consummated the APP Acquisition in violation of the Wisconsin Business Corporation Law and NASDAQ voting requirements. On November 30, 2018, plaintiffs filed an Amended Consolidated Complaint. The Amended Consolidated Complaint makes allegations similar to those in the original consolidated complaint as to the claims that were not dismissed and names as defendants Veru and the members of our board of directors prior to the closing of the APP Acquisition. The Amended Consolidated Complaint also makes claims against Dr. Steiner for allegedly aiding and abetting the pre-acquisition directors' breach of fiduciary duty and for unjust enrichment. Like the original consolidated complaint, the Amended Consolidated Complaint seeks equitable relief, including rescission of the APP Acquisition, money damages, disgorgement of the shares of our common stock and Series 4 Preferred Stock issued to Dr. Steiner, and costs and expenses of the litigation, including attorneys' fees. On December 14, 2018, the defendants filed their answer to the Amended Consolidated Complaint wherein they denied any and all liability and asserted additional defenses. On January 14, 2019, the plaintiffs filed a motion for class certification. The defendants' response to plaintiffs' motion for class certification is due on February 15, 2019. Veru believes that this action is without merit and is vigorously defending itself. No amount has been accrued for possible losses relating to this litigation as any such losses are not both probable and reasonably estimable.

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 in the accompanying unaudited condensed consolidated financial statements for any of these contingencies.

Note 11 – 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.

On December 22, 2017, significant changes were enacted to the U.S. tax law pursuant to the federal tax legislation commonly referred to as the Tax Cuts and Jobs Act of 2017 (the "Tax Act"). The Tax Act includes a permanent reduction in the U.S. federal corporate income tax rate from 35% to 21%, a one-time repatriation tax on deferred foreign income, and changes to deductions, credits and business-related exclusions.

The Tax Act also repealed the alternative minimum tax ("AMT") for corporations. The new 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 September 30, 2018, the Company reclassified $0.5 million of its AMT credit carryovers from its deferred tax assets to other assets due to the expectation that the AMT credits will be refundable over the next several years.

Within the calculation of the Company's annual effective tax rate the Company has used assumptions and estimates that may change as a result of future guidance, interpretations, and rule-making from the Internal Revenue Service, the SEC, the FASB and/or various other taxing jurisdictions. For example, the Company anticipates that state jurisdictions will continue to determine and announce their conformity to the Tax Act which would have an impact on the annual effective tax rate. The Company's calculations are based on the information available, prepared or analyzed (including computations) in reasonable detail.

The Company completes a detailed analysis of its deferred income tax valuation allowances on an annual basis or more frequently if information comes to its attention that would indicate that a revision to its estimates is necessary. In evaluating the Company's ability to realize its deferred tax assets, management considers all available positive and negative evidence on a country-by-country basis, including past operating results, forecasts of future taxable income, and the potential Section 382 limitation on the net operating loss carryforwards due to a change in control. In determining future taxable income, management makes assumptions to forecast U.S. federal and state, U.K. and Malaysia operating income, the reversal of temporary differences, and the implementation of any feasible and prudent tax planning strategies. These assumptions require significant judgment regarding the forecasts of the future taxable income in each tax jurisdiction and are consistent with the forecasts used to manage the Company's business. It should be noted that the Company realized significant losses through 2005 on a consolidated basis. From fiscal year 2006 through fiscal year 2015, the Company generated taxable income on a consolidated basis. However, the Company had a cumulative pretax loss in the U.S. for fiscal 2018 and the two preceding fiscal years. Forming a conclusion that a valuation allowance is not needed is difficult when there is significant negative evidence such as cumulative losses in recent years. Management has projected future taxable losses in the U.S. driven by the investment in research and development, and based on their analysis concluded that a valuation allowance should continue to be recorded against the U.S. deferred tax assets related to federal and state net operating loss carryforwards as of December 31, 2018. An additional valuation allowance has been recorded against the U.S. deferred tax assets and net operating loss carryforwards as of December 31, 2018 of $0.6 million. In addition, the Company's holding company for the non-U.S. operating companies, The Female Health Company Limited, continues to have a full valuation allowance. The operating U.K. subsidiary, The Female Health Company (UK) plc does not have a valuation allowance due to projections of future taxable income for the next 10 years.

As of September 30, 2018, the Company had U.S. federal and state net operating loss carryforwards of approximately $33.2 million and $36.2 million, respectively, for income tax purposes with $14.4 million and $19.6 million, respectively, expiring in years 2022 to 2037 and $18.8 million and $16.6 million, respectively, which can be carried forward indefinitely. The Company's U.K. subsidiary has U.K. net operating loss carryforwards of approximately $62.3 million as of September 30, 2018, which can be carried forward indefinitely to be used to offset future U.K. taxable income.

ASC Topic 740 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. ASC Topic 740 developed a two-step process to evaluate a tax position and also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The Company has not recorded a reserve for any tax positions for which the ultimate deductibility is highly certain but for which there is uncertainty about the timing of such deductibility.

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

	Three Months Ended December 31,	
	2018	2017
Income tax benefit at statutory rates	$ (431,823)	$ (2,551,000)
State income tax benefit, net of federal benefits	(102,342)	(563,000)
Effect of change in U.S. tax rate	—	(187,000)
Non-deductible expenses – other	2,420	4,000
Effect of lower foreign income tax rates	(8,357)	29,405
Effect of deemed dividend	31,309	—
Other	(21,839)	21,542
Change in valuation allowance	623,130	—
Income tax expense (benefit)	$ 92,498	$ (3,246,053)

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

Deferred tax assets:	December 31, 2018	September 30, 2018
Federal net operating loss carryforwards	$ 7,357,498	$ 6,973,047
State net operating loss carryforwards	2,294,400	2,195,865
Foreign net operating loss carryforwards – U.K.	10,598,452	10,595,518
Foreign capital allowance – U.K.	102,098	102,098
U.K. bad debts	1,700	1,700
Restricted stock – U.K.	17,586	17,586
U.S. deferred rent	22,425	22,902
Share-based compensation	670,536	622,442
Other, net – U.S.	113,237	91,419
Other, net – Malaysia	33,868	33,843
Gross deferred tax assets	21,211,800	20,656,420
Valuation allowance for deferred tax assets	(8,254,208)	(7,631,078)
Net deferred tax assets	12,957,592	13,025,342
Deferred tax liabilities:		
In process research and development	(4,675,860)	(4,675,860)
Developed technology	(533,875)	(549,318)
Covenant not-to-compete	(89,683)	(94,321)
Other	(7,318)	(6,843)
Net deferred tax liabilities	(5,306,736)	(5,326,342)
Net deferred tax asset	$ 7,650,856	$ 7,699,000

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

	December 31, 2018	September 30, 2018
Long-term deferred tax asset – U.K.	8,512,850	8,509,915
Long-term deferred tax asset – Malaysia	33,868	33,843
Total long-term deferred tax asset	$ 8,546,718	$ 8,543,758
Long-term deferred tax liability – U.S.	(895,862)	(844,758)
Total long-term deferred tax liability	$ (895,862)	$ (844,758)

Note 12 – 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 8 and 9 for a discussion of our dilutive potential common shares.

Note 13 – Industry Segments and Financial Information about Foreign and Domestic Operations

The Company currently operates in two reporting segments: Commercial and Research and Development. The Commercial segment consists of FC2, PREBOOST and drug commercialization costs. 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.

Information about the Company's operations by segment and geographic area is as follows:

	For the three months ended December 31,	
	2018	2017
Operating (loss) income:	(In thousands)	
Commercial	$ 3,728	$ 116
Research and Development	(2,362)	(1,951)
Corporate	(2,378)	(5,602)
	$ (1,012)	$ (7,437)
Revenues:		
United States	$ 3,010	$ 994
South Africa	209	318
Zimbabwe	1,358	300
Mozambique	460	—
Nigeria	750	—
Other	585	975
	$ 6,372	$ 2,587

All of our net revenues, which are primarily derived from the sale of FC2, are attributed to our Commercial reporting 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. is an oncology and urology biopharmaceutical company developing novel medicines for the prostate cancer continuum of care and urology specialty pharmaceuticals.

The Company's prostate cancer pipeline includes VERU-944 (zuclomiphene citrate, which is also known as cis-clomiphene) and VERU-111 (bisindole). Zuclomiphene citrate is an estrogen receptor agonist being evaluated in a Phase 2 trial to treat hot flashes, a common side effect caused by hormone treatment for men with advanced prostate cancer. VERU-111 is an oral, next-generation, first-in-class selective small molecule that targets and disrupts alpha and beta subunits of microtubules in cells to treat metastatic prostate cancer patients whose disease is resistant to both castration and androgen-blocking agent (abiraterone or enzalutamide) therapies. VERU-111 is being evaluated in men with metastatic refractory prostate cancer in an open label Phase 1b/2 clinical trial. The Company also plans to evaluate VERU-111 for a variety of other malignancies. In June 2018, as part of the American Society of Clinical Oncology (ASCO) Annual Meeting, the Company reported preclinical results showing the activity of VERU-111 against novel androgen blocking agent-resistant human prostate cancer, and it also reported preclinical data showing VERU-111's anti-tumor activity against paclitaxel sensitive and resistant triple negative breast, ovarian and pancreatic cancers.

The Company is also advancing new drug formulations in its specialty pharmaceutical pipeline addressing unmet medical needs in urology. The clinical trial of the Company's proprietary Tadalafil and Finasteride Combination tablet (TADFIN™ tablet) met FDA requirements for bioavailability and bioequivalence for the co-administration of tadalafil 5mg and finasteride 5mg dosed daily for benign prostatic hyperplasia (BPH). Tadalafil (CIALIS®) is currently approved for treatment of BPH and erectile dysfunction and finasteride (PROSCAR®) is currently approved for treatment of BPH and male pattern hair loss. The co-administration of tadalafil and finasteride has been shown to be more effective for the treatment of BPH than finasteride alone. The Company anticipates submitting an NDA for its TADFIN™ tablet under the 505(b)(2) regulatory pathway in the second half of calendar year 2019. The Company is also developing Tamulosin DRS (Delayed Release Sachet) granules and Tamulosin XR (Extended Release) capsules which are formulations 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 the FC2 Female Condom/FC2 Internal Condom® ("FC2"), an FDA-approved product for the dual protection of unwanted pregnancy and sexually transmitted infections ("STIs"), and the PREBOOST® medicated individual wipe for the prevention 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. FC2 is available by prescription in the U.S. 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. For PREBOOST, the Company has a co-promotion and distribution agreement with Timm Medical Technologies, Inc., a specialty urology sales organization, and the Company has also entered into a U.S. distributor agreement with Roman Health Ventures Inc., a premier and fast-growing men's health and telemedicine company that discreetly sells men's health products via the internet.

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. The Centers for Disease Control and Prevention has referenced the use of condoms, including female condoms, as a means to reduce the risk of transmitting STIs, including HIV/AIDS, and the transmission of Zika by sex. Nearly all of the Company's net revenues are currently derived from sales of FC2.

FC2's primary use is for disease prevention 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 STIs 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.

FC2 has a relatively small customer base, with a limited number of customers who generally purchase in large quantities. Over the past few years, significant customers have included large global agencies, such as the United Nations Population Fund (UNFPA) and the United States Agency for International Development (USAID). Other customers include ministries of health or other governmental agencies, which either purchase directly or via in-country distributors, and non-governmental organizations ("NGOs").

Purchasing patterns for FC2 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 due to the timing and shipment of large orders of FC2.

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 reorganization 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 98% 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, partnering with leading telemedicine providers including the "HeyDoctor" App, 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. We believe that the initial results from these efforts support the U.S. market opportunity and that we will continue to see increased utilization of FC2. We are experiencing an increase in revenue from sales in the prescription channel in the U.S.

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, which includes an award to the Company of up to 29.8 million units of the 40 million total units for the first year.

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

Period	2019	2018	2017	2016	2015
October 1 — December 31	7,382,524	4,399,932	6,389,320	15,380,240	12,154,570
January 1 — March 31	—	4,125,032	4,549,020	9,163,855	20,760,519
April 1 — June 30	—	10,021,188	8,466,004	10,749,860	14,413,032
July 1 — September 30	—	6,755,124	6,854,868	6,690,080	13,687,462
Total	7,382,524	25,301,276	26,259,212	41,984,035	61,015,583

Revenues. The Company's revenues are primarily derived from sales of FC2 in the global public sector and into the prescription channel in the U.S. Generally, these sales are recognized upon shipment of the product to the customers.

Other revenues are from sales of PREBOOST; however, these revenues were not material to our results for the three months ended December 31, 2018 or 2017.

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 partnership arrangements with companies with the necessary marketing and financial resources and local market expertise.

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

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. The Company retained an independent sales organization to help educate doctors, pharmacists, clinics and student health centers on the benefits of FC2. In the U.S., FC2 is sold to major distributors and telemedicine providers for sale into the prescription channel and sold directly to city and state public health departments and non-profit organizations.

Because the Company manufactures FC2 in a leased facility located in Malaysia, a portion of the Company's operating costs are 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 facility located in Selangor D.E., Malaysia. 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 $2.4 million and $2.0 million for the three months ended December 31, 2018 and 2017, respectively. For the remainder of fiscal 2019, we expect to increase our expenses relating to research and development due to advancement of multiple drug candidates.

THREE MONTHS ENDED DECEMBER 31, 2018 COMPARED TO THREE MONTHS ENDED DECEMBER 31, 2017

The Company generated 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, compared to net revenues of $2.6 million and net loss of $4.3 million, or $(0.08) per basic and diluted common share, for the three months ended December 31, 2017.

Net revenues increased 146%, of which 145% relate to FC2. There was a 68% increase in FC2 unit sales and an increase in FC2 average sales price per unit of 46%. The principal factors for the increase in the FC2 average sales price per unit compared to the same period last year were changes in customer mix and unit price increases for customers in the U.S.

Cost of sales increased to $1.7 million in the three months ended December 31, 2018 from $1.3 million for the same period last year. The increase is primarily due to the increase in unit sales.

Gross profit increased to $4.6 million for the three months ended December 31, 2018 from $1.3 million for the three months ended December 31, 2017. Gross profit margin for the three months ended December 31, 2018 was 73% of net revenues, compared to 51% of net revenues for the same period in 2017. In the three months ended December 31, 2018, the Company experienced an increase in FC2 sales into the prescription channel in the U.S. with higher profit margins.

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 spending for FC2 by large global agencies and donor governments in the developed world. As a result, the Company may continue to experience challenges for unit sales of FC2 in the global public sector. The Company is experiencing an increase in revenue from sales in the prescription channel, which should help smooth quarter to quarter and year to year revenue fluctuations.

Research and development expenses increased to $2.4 million for the three months ended December 31, 2018 from $2.0 million in the prior year period. 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 $3.3 million for the three months ended December 31, 2018 from $3.0 million in the prior year period. The increase primarily relates to additional corporate personnel, investor relations and shared-based compensation expenses, partially offset by the decrease in the Company's U.S. commercial sales force.

The Company incurred a loss on net accounts receivable of approximately $3.8 million in the first quarter of fiscal 2018 in connection with a settlement agreement we entered with Semina, our distributor in Brazil, in December 2017. This amount is presented as a separate line item in the accompanying unaudited condensed consolidated statement of operations for the three months ended December 31, 2017.

Interest expense was approximately $1.3 million for the three months ended December 31, 2018, which included $1.2 million of amortization of the discounts on the SWK Credit Agreement, $92,000 of accretion of the liability for the SWK Residual Royalty Agreement and $28,000 of amortization of the deferred issuance costs related to the SWK Credit Agreement.

The Company realized a foreign currency transaction loss of approximately $18,000 in the most recent quarter, compared to approximately $53,000 for the same period last year. This foreign currency transaction loss was primarily due to the adverse movement of the U.S. dollar against the Malaysian Ringgit during the periods.

The income tax expense for the three months ended December 31, 2018 was $0.1 million, compared to an income tax benefit of $3.2 million for the same period in fiscal 2017. The increase in income tax expense of $3.3 million is primarily due a valuation allowance recorded against the U.S. net deferred tax assets of $0.6 million, a decrease in the income tax benefit of $2.6 million due to the change in the U.S. federal corporate income tax rate from 35% to 21% under the Tax Act and the decrease in the loss before income taxes in addition to $0.1 million for the effect of change in the U.S. and foreign tax rates.

Liquidity

Our cash on hand (including restricted cash) at December 31, 2018 was $9.0 million, compared to $3.8 million at September 30, 2018. At December 31, 2018, the Company had working capital of $5.6 million and stockholders' equity of $36.9 million compared to negative working capital of $2.4 million and stockholders' equity of $29.5 million as of September 30, 2018. The increase in working capital is primarily due to the net proceeds from the common stock offering discussed below.

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, 2018, for a description of certain risks that will affect our future capital requirements.

The Company believes its current cash position 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 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 financing which could include selling common stock under the Purchase Agreement with Aspire Capital and/or a marketed deal with an investment bank. The Company's ability to raise capital through equity financing may be limited by the number of authorized shares of the Company's common stock, which is currently 77 million shares. In order to raise significant additional amounts from equity financing, the Company will need to seek stockholder approval to amend our Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock, and any such amendment would require the approval of the holders of at least two-thirds of the outstanding shares of the Company's common stock. 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, 2018, for a description of certain risks related to our ability to raise capital on acceptable terms.

Operating activities

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 $2.1 million, adjustments for non-cash items totaling $1.6 million and changes in operating assets and liabilities of $1.0 million. Adjustments for non-cash items primarily consisted of $1.3 million of non-cash interest expense related to the SWK Credit Agreement and $0.4 million of share-based compensation. The decrease in cash from changes in operating assets and liabilities included decreases in accounts payable and accrued expenses of $1.9 million and an increase in inventories of $0.4 million. These usages were partially offset by a cash increase from collection of accounts receivable of $1.5 million.

Our operating activities provided cash of $0.3 million in the three months ended December 31, 2017. Cash provided by operating activities included a net loss of $4.3 million, adjustments for non-cash items totaling $0.8 million and cash from changes in operating assets and liabilities of $3.8 million. Adjustments for non-cash items primarily consisted of a $3.8 million loss on the settlement of net accounts receivable, which was partially offset by a $3.3 million change in deferred income taxes. The increase in cash from changes in operating assets and liabilities included a decrease in net accounts receivable and long-term other receivables of $3.2 million and increases in accounts payable and accrued expenses of $0.8 million.

On December 27, 2017, we entered into a settlement agreement with Semina, our distributor in Brazil, pursuant to which Semina made a payment of $2.2 million and was obligated to make a second payment of $1.5 million by February 28, 2018, to settle net amounts due to us totaling $7.5 million relating to the Brazil tender in 2014. The settlement was not related to our belief in the ultimate collectability of the receivables or in the creditworthiness of Semina. We elected to settle these amounts due to the uncertainty regarding the timing of payment by the Brazilian Government and, ultimately to us, on the remaining amounts due. The result of the settlement was a net loss of

$3.8 million in the three months ended December 31, 2017, which is presented as a separate line item in the accompanying unaudited condensed consolidated statements of operations. Semina did not make its second payment of $1.5 million by February 28, 2018. In July 2018, the Company agreed to accept $1.3 million as settlement of the second payment of $1.5 million that was owed, which resulted in an additional loss of $0.2 million in the third quarter of fiscal 2018.

Investing activities

Net cash used in investing activities in the three months ended December 31, 2017 was $2,000 and was associated with office equipment purchases at our Miami headquarters.

Financing activities

Net cash provided by financing activities in the three months ended December 31, 2018 was $6.7 million and primarily consisted of the net proceeds from the underwritten public offering of the Company's common stock of $9.3 million (see discussion below), less payments on the SWK 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 $9.3 million after deducting underwriting discounts and commissions and costs paid by the Company through December 31, 2018. An additional $153,000 of costs is included in accounts payable at December 31, 2018. 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 (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 agreed to provide the Company with a multi-draw term loan of up to $12.0 million, with $10.0 million advanced to the Company on the date of the Credit Agreement. The Company may draw up to an additional $1.0 million if the Company enters into an agreement to distribute at least 47.5 million units of FC2 in Brazil upon the terms described in the Credit Agreement and up to an additional $1.0 million if the Company enters into an agreement to distribute at least 30 million units of FC2 in South Africa upon the terms described in 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.

In connection with the Credit Agreement, Veru and the Agent also entered into a Residual Royalty Agreement, dated as of March 5, 2018 (the "Residual Royalty Agreement"), which provides for an ongoing royalty payment of 5% of product revenue from net sales of FC2 commencing upon the payment in full by the Company of the required amount pursuant to the Credit Agreement. 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.

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 initial $10.0 million advance under the Credit Agreement. The first quarterly revenue-based payment due May 15, 2018 was approximately $642,000 and was paid on that date. On August 10, 2018, the Company entered into an amendment (the "Credit Agreement Amendment") to the Credit Agreement. The Credit Agreement Amendment deferred until November 15, 2018 the due date for the quarterly revenue-based payment that would have otherwise been due on August 15, 2018. The Company made a payment of approximately $2.6 million on November 15, 2018, consisting of approximately $1.4 million for the quarterly revenue-based payment originally due on August 15, 2018 and

approximately $1.2 million for the quarterly revenue-based payment due on November 15, 2018. The Company currently estimates the aggregate amount of quarterly revenue-based payments payable during the 12-month period subsequent to December 31, 2018 will be approximately $4.9 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 2018, we sold an aggregate of 1,717,010 shares of common stock to Aspire Capital under the Purchase Agreement resulting in proceeds to the Company of $3.0 million. As of December 31, 2018, the amount remaining under the Purchase Agreement was $12.0 million. However, based on the current market price of the Company’s common stock and the number of shares of the Company’s common stock that are unreserved and available for issuance, the Company will need to seek stockholder approval to amend its Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock to use the full remaining availability under the Purchase Agreement.

Fair Value Measurements

As of December 31, 2018 and September 30, 2018, 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 SWK Credit Agreement and Residual Royalty Agreement. See Note 7 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 is limited to fluctuations in raw material commodity prices, particularly the nitrile polymer used to manufacture FC2, and foreign currency exchange rate risk associated with the Company's foreign operations. The Company does not utilize financial instruments for trading purposes or to hedge risk and holds no derivative financial instruments which would expose it to significant market risk. Effective October 1, 2009, the Company's U.K. subsidiary and Malaysia subsidiary each adopted the U.S. dollar as its functional currency. The consistent use of the U.S. dollar as the functional currency across the Company reduces its foreign currency risk and stabilizes its operating results. The Company's distributors are subject to exchange rate risk as their orders are denominated in U.S. dollars and they generally sell to their customers in the local country currency. If currency fluctuations have a material impact on a distributor it may ask the Company for pricing concessions or other financial accommodations. The Company currently has no significant exposure to interest rate risk.

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

In response to the APP Acquisition, two purported derivative and class action lawsuits were filed against the Company and certain of its officers and directors in the Circuit Court of Cook County, Illinois, captioned Glotzer v. The Female Health Company, et al., Case No. 2016-CH-13815, and Schartz v. Parrish, et al., Case No. 2016-CH-14488. These lawsuits were originally filed on or about October 21, 2016 and November 7, 2016, respectively. On January 9, 2017, these two lawsuits were consolidated. On March 31, 2017, the plaintiffs filed a consolidated complaint. The consolidated complaint named as defendants Veru, the members of our board of directors prior to the closing of the APP Acquisition and the members of our board of directors after the closing of the APP Acquisition. The consolidated complaint alleged, among other things, that the directors breached their fiduciary duties, or aided and abetted such breaches, by consummating the APP Acquisition in violation of the Wisconsin Business Corporation Law and NASDAQ voting requirements and by causing us to issue the shares of our common stock and Series 4 Preferred Stock to the former stockholders of APP pursuant to the APP Acquisition in order to evade the voting requirements of the Wisconsin Business Corporation Law. The consolidated complaint also alleged that Dr. Steiner, a director and the Chairman, President and Chief Executive Officer of Veru and a co-founder of APP, and Dr. Fisch, a director and Vice Chairman of Veru and a co-founder of APP, were unjustly enriched in receiving shares of our common stock and Series 4 Preferred Stock in the APP Acquisition.

On May 5, 2017, the defendants filed a motion to dismiss the consolidated complaint. On August 15, 2017, the court entered an order dismissing without prejudice the claims that the post-acquisition directors aided and abetted the alleged breaches of fiduciary duties by the pre-acquisition directors and that Dr. Steiner and Dr. Fisch were unjustly enriched. The court did not dismiss the claims that our directors prior to the closing of the APP Acquisition breached their fiduciary duties and the claims that Veru consummated the APP Acquisition in violation of the Wisconsin Business Corporation Law and NASDAQ voting requirements. On November 30, 2018, plaintiffs filed an Amended Consolidated Complaint. The Amended Consolidated Complaint makes allegations similar to those in the original consolidated complaint as to the claims that were not dismissed and names as defendants Veru and the members of our board of directors prior to the closing of the APP Acquisition. The Amended Consolidated Complaint also makes claims against Dr. Steiner for allegedly aiding and abetting the pre-acquisition directors' breach of fiduciary duty and for unjust enrichment. Like the original consolidated complaint, the Amended Consolidated Complaint seeks equitable relief, including rescission of the APP Acquisition, money damages, disgorgement of the shares of our common stock and Series 4 Preferred Stock issued to Dr. Steiner, and costs and expenses of the litigation, including attorneys' fees. On December 14, 2018, the defendants filed their answer to the Amended Consolidated Complaint wherein they denied any and all liability and asserted additional defenses. On January 14, 2019, the plaintiffs filed a motion for class certification. The defendants' response to plaintiffs' motion for class certification is due on February 15, 2019. Veru believes that this action is without merit and is vigorously defending itself.

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," of the Company's Form 10-K for the year ended September 30, 2018. There have been no material changes from the risk factors previously disclosed in Part I, Item 1A, "Risk Factors," of the Company's Form 10-K for the year ended September 30, 2018, except for the following additional risk factor.

Disruptions from an exit of the United Kingdom from the European Union could adversely affect our business and results of operations.

On June 23, 2016, the United Kingdom held a referendum in which voters approved an exit from the European Union, commonly referred to as "Brexit." At this time, the exact timing of Brexit and the terms of the United Kingdom's relationship with the European Union after Brexit takes effect are uncertain. We have operations and government oversight in the United Kingdom relating to our FC2 business and a modest amount of sales of FC2 in the European Union. It is possible that changes made as a result of Brexit could subject us to heightened risks in that region, including disruptions to trade, increased foreign exchange volatility with respect to the British pound and additional legal and economic uncertainty. Such changes may adversely affect our business and results of operations.

Item 6. Exhibits

Exhibit Number	Description
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	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 and 3.7).
4.2	Articles II, VII and XI of the Amended and Restated By-Laws (included in Exhibit 3.8).
10.1	Employment Agreement, dated as of January 2, 2019, between the Company and Charles T. Todd, Jr. (1) (2)
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. (2)
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. (2)

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). (2) (3)
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended December 31, 2018, 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.

(1) Management contract or compensatory plan or arrangement
(2) Filed herewith
(3) 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 13, 2019

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

DATE: February 13, 2019

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

Exhibit 10.1

Executive Employment Agreement

This Employment Agreement (the "**Agreement**") is made and entered into as of January 2, 2019 (the "Effective Date") by and between Charles T. Todd, Jr., an individual residing at 23 Newport Drive, New Durham, NH 03855 (the **"Executive**") and Veru Inc., a Wisconsin corporation d/b/a The Female Health Company, with its corporate headquarters at 4400 Biscayne Blvd., Suite 888, Miami FL 33137 (the **"Company"**).

WHEREAS, the Company desires to employ the Executive on the terms and conditions set forth herein;

WHEREAS, the Executive desires to be employed by the Company on such terms and conditions; and

WHEREAS, it is a condition precedent of Executive's employment hereunder that Executive sign this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants, promises and obligations set forth herein, the parties agree as follows:

1. **Employment At-Will; Start Date.** The Executive's employment hereunder shall be for no definite or determinable period of time and the Executive's employment hereunder may be terminated by either the Company or the Executive at any time and for any reason subject to the provisions of Section 5 below. The start date for the Executive in this new role will be immediately upon execution of this Agreement by both Executive and Company.

2. **Position and Duties.**

(a) **Position.** During the Executive's employment with the Company, the Executive shall serve as Chief Executive Officer of The Female Health Company Division of the Company, subject to the Company's Board approval of the new role by resolution or consent. In such position, the Executive shall have such duties, authority and responsibility as are customary for an executive in Executive's position and such others as shall be determined from time to time by the Company's Chairman, Chief Executive Officer and President ("CEO"). The Executive shall report directly to the CEO.

(b) **Duties**. During the Executive's employment with the Company pursuant to this Agreement, the Executive shall devote substantially all of his business time and attention to the performance of the Executive's duties hereunder and will not engage in any other business, profession or occupation for compensation or otherwise which would conflict or interfere with the performance of such services either directly or indirectly without the prior written consent of the CEO. Notwithstanding the foregoing, the Executive will be permitted to (a) with the prior consent of the CEO and which consent can be withheld by the CEO in his discretion, act or serve as a director, trustee, committee member or principal of any type of business, civic or charitable organization as long as such activities are disclosed in writing to the Company's CEO, and (b) purchase or own less than five percent (5%) of the publicly traded securities of any corporation; provided that, such ownership represents a passive investment and that the Executive is not a controlling person of, or a member of a group that controls, such corporation; provided further that, the activities described in clauses (a) and (b) do not interfere with the performance of the Executive's duties and responsibilities to the Company as provided hereunder, including, but not limited to, the obligations set forth in this Section 2.

3. **Place of Performance**. The principal place of Executive's employment shall be: (i) Executive's home office located at 23 Newport Drive, New Durham, NH 03855; or (ii) potentially in the future should the CEO request, and should the Executive mutually agree, the Company's headquarters; any of (i) or (ii) preceding could be considered as Executive's principal place of employment for purposes of this Agreement. Should the Executive relocate to Miami at the Company's request, the Company shall pay Executive's reasonable relocation expenses. Executive will be required to travel on Company business during the Executive's employment with the Company.

4. **Compensation.**

4.1 **Base Salary**. Subject to section 5.2(b)(i) hereof, the Company shall pay the Executive an annual rate of base salary of two hundred eighty-seven thousand nine hundred dollars ($287,900) in periodic installments in accordance with the Company's customary payroll practices, but no less frequently than monthly. The Executive's base salary shall be reviewed at least annually by the Company's CEO, and the CEO may, but shall not be required to, increase the base salary during the Executive's employment with the Company. The Executive's annual base salary, as in effect from time to time, is hereinafter referred to as **"Base Salary".**

4.2 **Annual Cash Incentive Bonus**.

(a) For each fiscal year during the Executive's employment pursuant to this Agreement, the Executive shall be eligible to receive an annual cash incentive bonus equal to forty percent (40%) of his Base Salary based on meeting certain Company and personal goals to be mutually agreed upon by the Executive and the CEO (the "**Annual Bonus**"). However, the decision to provide any Annual Bonus and the amount and terms of any Annual Bonus shall be at the discretion of the Company's CEO.

(b) The Annual Bonus, if any, will be paid no later than the end of the first quarter of the fiscal year after the fiscal year in which an Annual Bonus, if any, is awarded; provided, however, that in order to be entitled to an Annual Bonus the Executive must be employed by the Company on the date of payment thereof, except as expressly otherwise provided herein, such as section 5.2(a)(ii) in the event of termination by the Company without cause or by the Executive for good reason.

4.3 **Equity Awards.** The non-qualified stock option to purchase 280,000 shares of common stock (the "Stock Option") issued to Executive on March 20, 2018 under the Company's 2017 Equity Incentive Plan ("Plan") shall vest on such vesting dates and be eligible to be exercised pursuant to and in accordance with the Plan, the grant agreement for such option and the terms of this Agreement. In addition, The Compensation Committee of the Company's Board of Directors has approved and authorized an additional grant to Executive on the Effective Date under the Plan and/or the Company's 2018 Equity Incentive Plan (collectively, the "Equity Plans") of non-qualified stock options to purchase a total of 42,226 shares of the Company's common stock ("Second Stock Option"), with the Second Stock Option vesting on the one year anniversary of the Effective Date and having an exercise price equal to the closing price of the Company's common stock on the Effective Date. The grant of the Second Stock Option is subject to the terms and conditions of the applicable stock option grant agreement and the applicable Equity Plan.

4.4 **Employee Benefits.** During the Executive's employment with the Company pursuant to this Agreement, the Executive shall be entitled to participate in all employee benefit plans, practices and programs maintained by the Company, as in effect from time to time (collectively, **"Employee Benefit Plans"**) on a basis that is at least as favorable as those provided to other similarly situated executives of the Company and to the extent consistent with applicable law, the terms of the applicable Employee Benefit Plans, and the Company's policy for sharing the cost of such benefits as in effect from time to time. The Company reserves the right to

amend or cancel any Employee Benefit Plans at any time in its sole discretion, subject to the terms of such Employee Benefit Plans and applicable law. Executive will be immediately eligible to participate in the US health, dental, vision, disability and life insurance programs of which the premiums are currently fully paid by the Company.

4.5 **Vacation; Paid Time-off.** During the Executive's employment with Company pursuant to this Agreement, the Executive will be entitled to accrue four weeks (4) paid vacation per fiscal year. The Executive shall receive other paid time-off in accordance with the Company's policies for officers as such policies may exist from time to time.

4.6 **Business Expenses.** The Executive shall be entitled to reimbursement for all reasonable and necessary out-of-pocket business, entertainment and travel expenses incurred by the Executive in connection with the performance of the Executive's duties hereunder in accordance with the Company's expense reimbursement policies and procedures.

4.7 **Sign-On Bonus**. The Company shall pay Executive a one-time cash bonus of $5,000.00 on the next regularly scheduled payroll date following the one-month anniversary of Executive's employment.

5. **Termination of Employment.** This Agreement and the Executive's employment hereunder are for no definite or determinable period of time and may be terminated by either the Company or the Executive at any time and for any reason subject to the provisions of this Section 5. Upon termination of this Agreement and the Executive's employment hereunder, the Executive shall be entitled to the compensation and benefits described in this Section 5 and shall have no further rights to any compensation or any other benefits from the Company or any of its affiliates.

5.1 **Termination by the Company for Cause or by the Executive without Good Reason**.

(a) The Executive's employment hereunder may be terminated by the Company immediately for Cause (as defined below) or by the Executive without Good Reason (as defined below). If the Executive's employment is terminated by the Company for Cause or by the Executive without Good Reason, the Executive shall be entitled to receive:

(i) any accrued but unpaid Base Salary and accrued but unused vacation which shall be paid on the pay date immediately following the Termination Date (as defined below) in accordance with the Company's customary payroll procedures;

(ii) any unpaid Annual Bonus with respect to any completed fiscal year immediately preceding the Termination Date, if the Executive was still employed by the Company on the last day of the first quarter of the fiscal year after the fiscal year in which an Annual Bonus, if any, was awarded; provided further that, if the Executive's employment is terminated by the Company for Cause, then any such unpaid Annual Bonus shall be forfeited;

(iii) reimbursement for unreimbursed business expenses properly incurred by the Executive, which shall be subject to and paid in accordance with the Company's expense reimbursement policy; and

(iv) such employee benefits, if any, to which the Executive may be entitled under the Company's Employee Benefit Plans as of the Termination Date.

Items 5.1(a)(i) through 5.1(a)(iv) are referred to herein collectively as the **"Accrued Amounts"**.

(c) For purposes of this Agreement, "Cause" shall mean:

(i) the Executive's failure to perform his duties (other than any such failure resulting from incapacity due to physical or mental illness or disability);

(ii) the Executive's failure to comply with any valid and legal directive of the CEO;

(iii) the Executive's engagement in dishonesty, illegal conduct or misconduct, which is, in each case, injurious to the Company or its affiliates;

(iv) the Executive's embezzlement, misappropriation or fraud, whether or not related to the Executive's employment with the Company;

(v) the Executive's conviction of or plea of guilty or nolo contendere to a crime that constitutes a felony (or state law equivalent) or a crime that constitutes a misdemeanor involving moral turpitude or results in harm to the Company or its affiliates;

(vi) the Executive's breach of the duty of loyalty or breach of fiduciary duty;

(vii) the Executive's unauthorized disclosure of Confidential Information (as defined below);

(viii) Executive's material breach of any material obligation under this Agreement or any other written agreement between the Executive and the Company; or

(ix) any material failure by the Executive to comply with the Company's written policies or rules, as they may be in effect from time to time during the Executive's employment with the Company.

5.2 **Termination by the Company Without Cause or by the Executive for Good Reason**.

(a) This Agreement and the Executive's employment hereunder may be terminated by the Company without Cause or by the Executive for Good Reason in accordance with the provisions set forth herein. In the event of such termination, the Executive shall be entitled to receive the Accrued Amounts and, subject to the Executive's compliance with Sections 6 through 9 of this Agreement and his execution of a general release of claims in favor of the Company and all of its related entities and individuals (the **"Release"**), which shall include a re-affirmation of Executive's non-disparagement obligation and his obligation to comply with Sections 6 through 9 of this Agreement and such Release becoming effective within the number of days permitted under applicable law following the Termination Date (the "Release Effective Date"), the Executive shall be entitled to receive the following:

(i) continued Base Salary for six (6) months following the Termination Date payable in equal installments in accordance with the Company's normal payroll practices, but no less frequently than monthly, which shall commence on the Company's regular pay day for the pay period immediately following the pay period that includes the Release Effective Date;

(ii) any unpaid Annual Bonus with respect to any completed fiscal year immediately preceding the Termination Date if the Executive was still employed by the Company on the last day of the preceding fiscal year;

(iii) a pro-rated payment equal to the Executive's target bonus for the year in which the Termination occurs as defined in section 4.2(a) hereof multiplied by the percentage of days the Executive was employed by the Company in the year of termination, and payable as and when such bonuses are normally paid for other executives of the Company; and

(iv) if the Executive timely and properly elects health continuation coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("**COBRA**") or comparable State continuation law, the Company shall reimburse the Executive for the difference between the monthly COBRA or comparable State continuation law premium paid by the Executive for himself and his dependents and the monthly premium amount paid by similarly situated active executives. Such reimbursement shall be paid to the Executive on the fifteenth of the month immediately following the month in which the Executive timely remits the premium payment. The Executive shall be eligible to receive such reimbursement until the earliest of: (i) the six (6) month anniversary of the Termination Date; (ii) the date the Executive (in the case of his) or any of his dependents (in the case of such dependent) is no longer eligible to receive COBRA or comparable State law continuation coverage; and (iii) the date on which the Executive (in the case of his) or any of his dependents (in the case of such dependent) becomes eligible to receive substantially similar coverage from another employer or other source.

(b) For purposes of this Agreement**, "Good Reason"** shall mean the occurrence of any of the following, in each case during the Executive's employment under this Agreement without the Executive's written consent:

(i) a reduction in the Executive's Base Salary of more than ten percent (10%) other than a general reduction in Base Salary that affects all similarly situated executives in substantially the same proportions;

(ii) a relocation of the Executive's principal place of employment outside of the metropolitan area where the Executive currently has his principal office;

(iii) any material breach by the Company of any material provision of this Agreement; or

(iv) a material, adverse change in the Executive's authority, duties or responsibilities (other than temporarily while the Executive is physically or mentally incapacitated or as required by applicable law) taking into account the Company's size, status as a public company and capitalization as of the date of this Agreement.

The Executive cannot terminate his employment for Good Reason unless he has provided written notice to the Company of the existence of the circumstances providing grounds for termination for Good Reason within thirty (30) days of the initial existence of such grounds, and the Company has had thirty (30) days from the date on which such notice is provided to cure such circumstances. If the Company has not cured such Good Reason within thirty (30) days of such notice, the Executive shall have up to thirty (30) days after such cure period to terminate his employment hereunder for Good Reason. If the Executive does not provide written notice to the Company to terminate his employment for Good Reason within the time period specified herein, then the Executive will be deemed to have waived his right to terminate for Good Reason with respect to such grounds.

5.3 **Death or Disability**.

(a) The Executive's employment hereunder shall terminate automatically upon the Executive's death during the Executive's employment under this Agreement, and the Company may terminate the Executive's employment on account of the Executive's Disability (as defined below).

(b) If the Executive's employment is terminated during the Employment Term on account of the Executive's death or Disability, the Executive (or the Executive's estate and/or beneficiaries, as the case may be) shall be entitled to receive the following:

(i) pay for any of the Executive's accrued but unpaid Base Salary and the Executive's accrued but unused vacation as of the date of death or Disability;

(ii) any earned but unpaid Annual Bonus with respect to any completed fiscal year immediately preceding the Executive's date of death or Disability, if the Executive was still employed by the Company on the last day of the preceding fiscal year;

(iii) reimbursement for unreimbursed business expenses properly incurred by the Executive, which shall be subject to and paid in accordance with the Company's expense reimbursement policy; and

(iv) such employee benefits, if any, to which the Executive may be entitled under the Company's Employee Benefit Plans as of the date of the Executive's death or Disability.

(c) For purposes of this Agreement, "Disability" shall mean the Executive is entitled to receive long-term disability benefits under the Company's long-term disability plan, or if there is no such plan, the Executive's inability, due to physical or mental incapacity, to substantially perform all of the essential duties and responsibilities under this Agreement, with or without reasonable accommodation, for one hundred eighty (180) days out of any three hundred sixty-five (365) day period or one hundred twenty (120) consecutive days; provided however, in the event the Company temporarily replaces the Executive, or transfers the Executive's duties or responsibilities to another individual on account of the Executive's inability to perform such duties due to a mental or physical incapacity which is, or is reasonably expected to become, a Disability, then the Executive's employment shall not be deemed terminated by the Company and the Executive shall not be able to resign with Good Reason as a result thereof. Any question as to the existence of the Executive's Disability as to which the Executive and the Company cannot agree shall be determined in writing by a qualified independent physician mutually acceptable to the Executive and the Company. If the Executive and the Company cannot agree as to a qualified independent physician, each shall appoint such a physician and those two physicians shall select a third who shall make such determination in writing. The determination of Disability made in writing to the Company and the Executive shall be final and conclusive for all purposes of this Agreement.

5.4 **Change in Control Termination**.

(a) Notwithstanding any other provision contained herein, if the Executive's employment hereunder is terminated by the Executive for Good Reason or by the Company without Cause (other than on account of the Executive's death or Disability) within six (6) months following a Change in Control, the Executive shall be entitled to receive, subject to the Executive's compliance with Sections 6 through 9 of this Agreement and his execution of the Release and reaffirmations referred to in Section 5.2, the following:

(i) all items of compensation set forth in Section 5.2(a)(i-iv); and

(ii) acceleration of unvested equity compensation in accordance with the terms of the Company's applicable equity compensation plans and grant agreements.

(b) For purposes of this Agreement, **"Change in Control"** shall have the meaning set forth in the Company's applicable equity plans and grant agreements.

5.5 **Notice of Termination**. Any termination of the Executive's employment hereunder by the Company or by the Executive during the Executive's employment under this Agreement (other than termination pursuant to Section 5.3(a) on account of the Executive's death) shall be communicated by written notice of termination (**"Notice of Termination"**) to the other party hereto in accordance with Section 25 of this Agreement. The Notice of Termination shall specify:

(a) The termination provision of this Agreement relied upon;

(b) To the extent applicable, the facts and circumstances claimed to provide a basis for termination of the Executive's employment under the provision so indicated; and

(c) The applicable Termination Date.

5.6 **Termination Date**. The Executive's **"Termination Date"** shall be:

(a) If the Executive's employment hereunder terminates on account of the Executive's death, the date of the Executive's death;

(b) If the Executive's employment hereunder is terminated on account of the Executive's Disability, the date that it is specified in the Company's Notice of Termination after it is determined that the Executive has a Disability;

(c) If the Company terminates the Executive's employment hereunder for Cause, the date the Notice of Termination is delivered to the Executive;

(d) If the Company terminates the Executive's employment hereunder without Cause, the date specified in the Notice of Termination, which shall be no less than ten (10) business days following the date on which the Notice of Termination is delivered; provided that during said notice period, the Company shall have the right to change or eliminate the Executive's duties within its discretion, which shall not be deemed a Good Reason hereunder; or

(e) If the Executive terminates employment hereunder with or without Good Reason, the date specified in the Executive's Notice of Termination, which shall be no less than ten (10) business days following the date on which the Notice of Termination is delivered; provided that, the Company may waive all or any part of the ten (10) day notice period without further accrual or payment of salary or benefits upon written notice to the Executive, and the Executive's Termination Date shall be the date determined in such notice by the Company.

Notwithstanding anything contained herein, the Termination Date shall not occur until the date on which the Executive incurs a "separation from service" within the meaning of Section 409A.

5.7 **Resignation of All Other Positions**. Upon termination of the Executive's employment hereunder for any reason, the Executive shall be deemed to have resigned from all positions that the Executive holds as an officer or member of the board of directors (or a committee thereof) of the Company or any of its affiliates.

5.8 **Section 280G**.

(a) If any of the payments or benefits received or to be received by the Executive (including, without limitation, any payment or benefits received in connection with a Change in Control or the Executive's termination of employment, whether pursuant to the terms of this Agreement or any other plan, arrangement or agreement, or otherwise) (all such payments collectively referred to herein as the "280G Payments") constitute "parachute payments" within the meaning of Section 280G of the Code and would, but for this Section 5.8, be subject to the excise tax imposed under Section 4999 of the Code (the "Excise Tax"), then prior to making the 280G Payments, a calculation shall be made comparing (i) the Net Benefit (as defined below) to the Executive of the 280G Payments after payment of the Excise Tax to (ii) the Net Benefit to the Executive if the 280G Payments are limited to the extent necessary to avoid being subject to the Excise Tax. Only if the amount calculated under (i) above is less than the amount under (ii) above will the 280G Payments be reduced to the minimum extent necessary to ensure that no portion of the 280G Payments is subject to the Excise Tax. **"Net Benefit"** shall mean the present value of the 280G Payments net of all federal, state, local, foreign income, employment and excise taxes. Any reduction made pursuant to this Section 5.8 shall be made in a manner determined by the Company that is consistent with the requirements of Section 409A.

(b) Unless the Company and the Executive otherwise agree, all calculations and determinations under this Section 5.8 shall be made by an independent accounting firm whose determinations shall be conclusive and binding on the Company and the Executive for all purposes. For purposes of making the calculations and determinations required by this Section 5.8, the accounting firm may rely on reasonable, good faith assumptions and approximations concerning the application of Section 280G and Section 4999 of the Code. The Company and the Executive shall furnish the accounting firm with such information and documents as the accounting firm may reasonably request in order to make its determinations under this Section 5.8. The Company shall bear all costs the accounting firm may reasonably incur in connection with its services as contemplated by this provision.

6**. Cooperation**. The parties agree that certain matters in which the Executive will be involved during his employment with the Company may necessitate the Executive's cooperation in the future. Accordingly, following the termination of the Executive's employment for any reason, to the extent reasonably requested by the Company's CEO, the Executive shall cooperate with the Company in connection with matters arising out of the Executive's service to the Company; provided that, the Company shall make reasonable efforts to minimize disruption of the Executive's other activities. The Company shall reimburse the Executive for reasonable expenses incurred in connection with such cooperation and, to the extent that the Executive is required to spend substantial time on such matters, the Company shall compensate the Executive at an hourly rate based on the Executive's Base Salary on the Termination Date.

7. **Confidential Information**. The Executive understands and acknowledges that during his employment with the Company, he will have access to and learn about Confidential Information, as defined below.

7.1 **Confidential Information Defined; Restrictions**.

(a) **Definition**.

For purposes of this Agreement, **"Confidential Information"** includes, but is not limited to, all information not known to the public, in spoken, printed, electronic or any other form or medium, relating directly or indirectly to: business processes, methods, policies, plans, publications, documents, research, operations, strategies, techniques, contracts, transactions, potential transactions, negotiations, pending negotiations, know-how, trade secrets, computer programs, computer software, applications, operating systems, software design, web design, work-in-process, databases, manuals, records, articles, systems, material, sources of material, supplier information, vendor information, financial information, accounting information, accounting records, legal information, marketing information, advertising information, pricing information, design information, payroll information and staffing information, personnel information, employee lists, supplier lists, vendor lists, developments, reports, internal controls, security procedures, graphics, drawings, sketches, market studies, sales information, revenue, costs, formulae, product plans, designs, models, ideas, inventions, unpublished patent applications, discoveries, experimental processes, experimental results, specifications, customer or client information or lists, manufacturing information, distributor lists, and buyer lists of the Company, and any information about or from any existing or prospective customer, supplier, investor or other associated third party, or of any other person or entity that has entrusted information to the Company in confidence.

The Executive understands that the above list is not exhaustive, and that Confidential Information also includes other information that is marked or otherwise identified as confidential or proprietary, or that would otherwise appear to a reasonable person to be confidential or proprietary in the context and circumstances in which the information is known or used.

The Executive understands and agrees that Confidential Information includes information developed by him in the course of his employment by the Company as if the Company furnished the same Confidential Information to the Executive in the first instance. Confidential Information shall not include (i) information that is or becomes publicly known to others who are not under a confidentiality obligation to the Company, without breach by the Executive of Section 7.1(c) below or (ii) information provided to the Executive by a third party who is not under a confidentiality obligation benefitting the Company or others with respect to the information. The Executive understands and agrees that all Company Confidential Information constitutes trade secrets under Florida law and any other applicable law.

(b) **Company Creation and Use of Confidential Information**.

The Executive understands and acknowledges that the Company has invested, and continues to invest, substantial time, money and specialized knowledge into developing its resources, creating a customer base, generating customer and potential customer lists, training its employees (including the Executive), and improving its offerings in the field of diversified drugs, therapeutics and medical devices for men's and women's reproductive health, urology and oncology. The Executive understands and acknowledges that as a result of these efforts, the Company has created, and continues to use and create Confidential Information. This Confidential Information provides the Company with a competitive advantage over others in the marketplace.

(d) **Disclosure and Use Restrictions**.

The Executive agrees and covenants: (i) to treat all Confidential Information as strictly confidential; (ii) not to directly or indirectly disclose, publish, communicate or make available Confidential Information, or allow it to be disclosed, published, communicated or made available, in whole or part, to any entity or person whatsoever (including other employees of the Company) not having a need to know and authority to

know and use the Confidential Information in connection with the business of the Company and, in any event, not to anyone outside of the direct employ of the Company except as required in the performance of the Executive's authorized employment duties to the Company or with the prior consent of the CEO acting on behalf of the Company in each instance (and then, such disclosure shall be made only within the limits and to the extent of such duties or consent); and (iii) not to access or use any Confidential Information, and not to copy any documents, records, files, media or other resources containing any Confidential Information, or remove any such documents, records, files, media or other resources from the premises or control of the Company, except as required in the performance of the Executive's authorized employment duties to the Company or with the prior consent of the CEO acting on behalf of the Company in each instance (and then, such disclosure shall be made only within the limits and to the extent of such duties or consent). Nothing herein shall be construed to prevent disclosure of Confidential Information as may be required by applicable law or regulation, or pursuant to the valid order of a court of competent jurisdiction or an authorized government agency, provided that the disclosure does not exceed the extent of disclosure required by such law, regulation or order. The Executive shall promptly provide written notice of any such order to Company's Executive Vice President-Legal. While complying with this Section 7.1 to the greatest extent possible, nothing herein prohibits the Executive from reporting possible violations of federal law or regulation to any governmental agency or from making disclosures under the whistleblower provisions of federal or state law or regulation. Executive is not required to notify the Company if Executive makes such reports or disclosures.

The Executive understands and acknowledges that his obligations under this Agreement with regard to any particular Confidential Information shall commence immediately upon the Executive first having access to such Confidential Information (whether before or after he begins employment by the Company) and shall continue during and after his employment by the Company until such time as such Confidential Information has become public knowledge other than as a result of the Executive's breach of this Agreement or breach by those acting in concert with the Executive or on the Executive's behalf.

(e) **Defend Trade Secrets Act Notice**

Executive is hereby notified in accordance with the Defend Trade Secrets Act of 2016 that he will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (i) is made in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or (ii) is made in a complaint or other document that is filed under seal in a lawsuit or other proceeding. Executive is further notified that if Executive files a lawsuit for retaliation by an employer for reporting a suspected violation of law, Executive may disclose the employer's trade secrets to Executive's attorney and use the trade secret information in the court proceeding if Executive: (i) files any document containing the trade secret under seal; and (ii) does not disclose the trade secret, except pursuant to court order.

8. **Restrictive Covenants**.

8.1 **Acknowledgement**. The Executive understands that the nature of the Executive's position gives him access to and knowledge of Confidential Information and places him in a position of trust and confidence with the Company. The Executive understands and acknowledges that the intellectual services he provides to the Company are unique, special or extraordinary because of his knowledge, experience, training and expertise in the areas and disciplines for which the Company has chosen to employ him.

The Executive further understands and acknowledges that the Company's ability to reserve these for the exclusive knowledge and use of the Company is of great competitive importance and commercial value to the Company, and that improper use or disclosure by the Executive is likely to result in unfair or unlawful competitive activity.

8.2 **Non-competition**. Because of the Company's legitimate business interest as described herein and the good and valuable consideration offered to the Executive, during the Executive's employment with the Company and for the period of two (2) years beginning on the last day of the Executive's employment with the Company (the "Restricted Period"), whether employment is terminated at the option of the Executive or the Company, the Executive agrees and covenants not to engage in Prohibited Activity that is, or is expected to be, competitive with the Company's drug products, female condom, diversified drugs, and therapeutics and medical device businesses in the fields of men's and women's reproductive health, urology and oncology (collectively the "Prohibited Field"). For purposes of this Agreement, the Prohibited Field is limited to products and/or services for which the Executive participated in the development, planning, testing, sale, marketing or evaluation of on behalf of the Company in or during any part of the last 24 months of the Executive's employment with the Company or for which the Executive supervised one of or more of the Company's employees, units, divisions, or departments in doing so.

8.3 **Prohibited Activity.** For purposes of this Section 8, **"Prohibited Activity"** is activity in which the Executive contributes his knowledge, services and/or financial support, directly or indirectly, in whole or in part, as an owner, operator, manager, advisor, lender, investor, consultant, agent, employee, partner, director, stockholder, officer, volunteer, intern or any other similar capacity to an entity or person engaged in the same or similar business as the Company, including those engaged in the Prohibited Field, within the United States and any other countries in which the Company sells, markets and/or develops its products and/or services. Prohibited Activity also includes activity that may require or inevitably requires disclosure of Company trade secrets or other Confidential Information. Nothing herein shall prohibit the Executive from purchasing or owning less than five percent (5%) of the publicly traded securities of any corporation, provided that such ownership represents a passive investment and that the Executive is not a controlling person of, or a member of a group that controls, such corporation.

8.4 **Non-solicitation of Employees**. The Executive agrees that the Company has made a substantial investment in its employees in order to retain their services and valuable contribution to its business, and to minimize turnover and recruitment training time and cost. Therefore, to protect this legitimate interest of the Company, the Executive agrees and covenants not to directly or indirectly, on Executive's own behalf or on behalf of any other person or entity, solicit, hire, recruit, attempt to hire or recruit, or induce the termination of employment of any employee of the Company during the Restricted Period.

8.5 **Non-solicitation of Customers**. The Executive agrees that the Company has made a substantial investment in order to develop and maintain valuable relationships with its customers and prospective customers. The Executive further agrees that the Company has long-standing relationships with its customers and that but for the Executive's employment with the Company, the Executive would not have had access to or

Confidential Information about its customers. Executive understands and acknowledges that because of the Executive's experience with and relationship to the Company he will have access to the Company's customers and prospective customers and learn about much or all of the Company's customer information which is confidential and/or compiled in a confidential manner. **"Customer Information"** includes, but is not limited to, names, phone numbers, addresses, e-mail addresses, order history, order preferences, chain of command, pricing information, profitability, sales and marketing strategy, and other information identifying facts and circumstances specific to the customer or prospective customer and relevant to sales or services provided by the Company, whether Confidential Information or otherwise.

The Executive understands and acknowledges that loss of customer or prospective customer relationships and/or goodwill will cause significant and irreparable harm to the Company.

Therefore, to protect these legitimate interests of the Company, Executive agrees and covenants, during Restricted Period, not to directly or indirectly, on Executive's own behalf or on behalf of any other person or entity, solicit, contact (including but not limited to e-mail, regular mail, express mail, telephone, fax, and instant message), attempt to contact or meet with or provide any products or services to the Company's customers or prospective customers for purposes of offering or providing goods or services similar to or competitive with those offered by the Company.

The restrictions in this Section 8.5 shall only apply to:

(a) Customers or prospective customers the Executive contacted in any way during the past one (1) year prior to the Executive's last day of employment with the Company; or

(b) Customers or prospective customers about whom the Executive has or had access to trade secret or other Confidential Information; or

(c) Customers under the Executive's supervisory or sales purview who became customers during the Executive's employment with the Company.

8.6 **Non-interference with Other Business Relationships**. The Executive agrees and covenants, during the Restricted Period, not to directly or indirectly, on Executive's own behalf or on behalf of any other person, interfere with or cause disruption in any way to the Company's contracts or relationships with its business partners, including, but not limited to, vendors, suppliers, manufacturing sources, and IT consultants.

8.7 **Extension of Restricted Period**. The Executive agrees that should he breach any of his covenants in this Section 8, the Restricted Period shall be extended by the length of any period of such breach.

9. **Non-disparagement**. The Executive agrees and covenants that he will not at any time make, publish or communicate to any person or entity or in any public forum any defamatory or disparaging remarks, comments or statements concerning the Company or its businesses, or any of its employees, officers, directors, and existing and prospective customers, suppliers, investors and other associated third parties.

This Section 9 does not, in any way, restrict or impede the Executive from exercising protected rights to the extent that such rights cannot be waived by agreement or from complying with any applicable law or regulation or a valid order of a court of competent jurisdiction or an authorized government agency, provided that such compliance does not exceed that required by the law, regulation or order. The Executive shall promptly provide written notice of any such order to Company's EVP Legal.

10. **Acknowledgement**. The Executive acknowledges and agrees that the services to be rendered by him to the Company are of a special and unique character; that the Executive will obtain knowledge and skill relevant to the Company's industry, methods of doing business and marketing strategies by virtue of the Executive's employment; and that the restrictive covenants and other terms and conditions of this Agreement are reasonable and reasonably necessary to protect the legitimate business interests of the Company.

The Executive further acknowledges and agrees that the amount of his compensation hereunder reflects, in part, substantial consideration for his obligations and the Company's rights under Sections 7 through 9 of this Agreement; that he has no expectation of any additional compensation, royalties or other payment of any kind not otherwise referenced herein in connection herewith; that he will not be subject to undue hardship by reason of his full compliance with the terms and conditions of Sections 7 through 9 of this Agreement or the Company's enforcement thereof.

11. **Remedies**. In the event of a breach or threatened breach by the Executive of any of Sections 7 through 9 of this Agreement, the Executive hereby consents and agrees that the Company shall be entitled to seek, in addition to other available remedies, a temporary or permanent injunction or other equitable relief against such breach or threatened breach from any court of competent jurisdiction, without the necessity of posting any bond or other security or of showing any actual damages or that money damages would not afford an adequate remedy. The aforementioned equitable relief shall be in addition to, not in lieu of, legal remedies, monetary damages or other available forms of relief. In the event the Executive breaches any of his obligations contained in any of Sections 7 through 9, the Company shall be entitled to an award of its costs, reasonable attorneys' and expert witness fees, and out-of-pocket expenses incurred in obtaining a judgment or order against the Executive in addition to any to other relief awarded to the Company.

12. Intentionally Omitted.

13. **Work Product and Intellectual Property Protection**.

13.1 **Work Product.** The Executive acknowledges and agrees that all right, title and interest in and to all writings, works of authorship, technology, inventions, discoveries, processes, techniques, methods, ideas, concepts, research, proposals, materials and all other work product of any nature whatsoever, that are created, prepared, produced, authored, edited, amended, conceived or reduced to practice by the Executive individually or jointly with others during the period of his employment by the Company and relate in any way to the business or contemplated business, products, activities, research or development of the Company or result from any work performed by the Executive for the Company (in each case, regardless of when or where prepared or whose equipment or other resources is used in preparing the same) all rights and claims related to the foregoing, and all printed, physical and electronic copies, and other tangible embodiments thereof (collectively, **"Work Product"),** as well as any and all rights in and to US and foreign (a) patents, patent disclosures and inventions (whether patentable or not), (b) trademarks, service marks, trade dress, trade names, logos, corporate names and domain names, and other similar designations of source or origin, together with the goodwill symbolized by any of the foregoing, (c) copyrights and copyrightable works (including computer programs), and rights in data and databases, (d) trade secrets, know-how and other confidential information, and (e) all other intellectual property rights, in each case whether registered or unregistered and including all registrations and applications for, and renewals and extensions of, such rights, all improvements thereto and all similar or equivalent rights or forms of protection in any part of the world (collectively, **"Intellectual Property Rights"),** shall be the sole and exclusive property of the Company.

13.2 **Work Made for Hire; Assignment**. The Executive acknowledges that, by reason of being employed by the Company at the relevant times, to the extent permitted by law, all of the Work Product consisting of copyrightable subject matter is "work made for hire" as defined in 17 U.S.C. § 101 and such copyrights are therefore owned by the Company. To the extent that the foregoing does not apply, the Executive hereby irrevocably assigns to the Company, for no additional consideration, the Executive's entire right, title and interest in and to all Work Product and Intellectual Property Rights therein, including the right to sue, counterclaim and recover for all past, present and future infringement, misappropriation or dilution thereof, and all rights corresponding thereto throughout the world. The Company's rights under this Section 13.2 are in addition to, and not in lieu of, any substantive protections the Company may have under any law.

13.3 **Further Assurances; Power of Attorney**. During and after his employment, the Executive agrees to reasonably cooperate with the Company to (a) apply for, obtain, perfect and transfer to the Company the Work Product as well as any and all Intellectual Property Rights in the Work Product in any jurisdiction in the world; and (b) maintain, protect and enforce the same, including, without limitation, giving testimony and executing and delivering to the Company any and all applications, oaths, declarations, affidavits, waivers, assignments and other documents and instruments as shall be requested by the Company. The Executive hereby irrevocably grants the Company power of attorney to execute and deliver any such documents on the Executive's behalf in his name and to do all other lawfully permitted acts to transfer the Work Product to the Company and further the transfer, prosecution, issuance and maintenance of all Intellectual Property Rights therein, to the full extent permitted by law, if the Executive does not promptly cooperate with the Company's request (without limiting the rights the Company shall have in such circumstances by operation of law). The power of attorney is coupled with an interest and shall not be affected by the Executive's subsequent incapacity.

13.4 **No License**. The Executive understands that this Agreement does not, and shall not be construed to grant the Executive any license or right of any nature with respect to any Work Product or Intellectual Property Rights or any Confidential Information, materials, software or other tools made available to him by the Company.

14. **Security**.

14.1 **Security and Access**. The Executive agrees and covenants (a) to comply with all Company security policies and procedures as in force from time to time including without limitation those regarding computer equipment, telephone systems, facilities access, key cards, access codes, Company intranet, internet, social media and instant messaging systems, computer systems, e-mail systems, computer networks, document storage systems, software, data security, encryption, firewalls, passwords and any and all other Company IT resources and communication technologies (collectively, **"Facilities and Information Technology Resources");** (b) not to access or use any Facilities and Information Technology Resources except as authorized by the Company; and (iii) not to access or use any Facilities and Information Technology Resources in any manner after the termination of the Executive's employment by the Company, whether termination is voluntary or involuntary. The Executive agrees to notify the Company promptly in the event he learns of any violation of the foregoing by others, or of any other misappropriation or unauthorized access, use, reproduction or reverse engineering of, or tampering with any Facilities and Information Technology Resources or other Company property or materials by others.

14.2 **Exit Obligations**. Upon (a) voluntary or involuntary termination of the Executive's employment or (b) the Company's request at any time during the Executive's employment, the Executive shall (i) provide or return to the Company any and all Company property, including but limited to, keys, access cards, identification cards, Company credit cards, computers smartphones, equipment, manuals, reports, files, books, compilations,

work product, e-mail messages, thumb drives and other removable information storage devices, hard drives, and data and all Company documents and materials belonging to the Company and stored in any fashion, including but not limited to those that constitute or contain any Confidential Information or Work Product, that are in the possession or control of the Executive, whether they were provided to the Executive by the Company or any of its business associates or created by the Executive in connection with his employment by the Company; and (ii) delete or destroy all copies of any such documents and materials not returned to the Company that remain in the Executive's possession or control, including those stored on any non-Company devices, networks, storage locations and media in the Executive's possession or control.

15. **Publicity**. The Executive hereby irrevocably consents to any and all uses and displays, by the Company and its agents, representatives and licensees, of the Executive's name, voice, likeness, image, appearance and biographical information in, on or in connection with any pictures, photographs, audio and video recordings, digital images, websites, television programs and advertising, other advertising and publicity, sales and marketing brochures, books, magazines, other publications, CDs, DVDs, tapes and all other printed and electronic forms and media throughout the world, at any time during or after the period of his employment by the Company, for all legitimate commercial and business purposes of the Company (**"Permitted Uses"**) without further consent from or royalty, payment or other compensation to the Executive. The Executive hereby forever waives and releases the Company and its directors, officers, employees and agents from any and all claims, actions, damages, losses, costs, expenses and liability of any kind, arising under any legal or equitable theory whatsoever at any time during or after the period of his employment by the Company, arising directly or indirectly from the Company's and its agents', representatives' and licensees' exercise of their rights in connection with any Permitted Uses.

16. **Governing Law; Jurisdiction and Venue**. This Agreement, for all purposes, shall be construed in accordance with the laws of the State of Florida without regard to conflicts of law principles. Any action or proceeding by either of the parties to enforce this Agreement shall be brought only in a state or federal court located in the state of Florida, county of Miami-Dade. The parties hereby irrevocably submit to the exclusive jurisdiction of such courts and waive any defenses relating to personal jurisdiction, improper venue or inconvenient forum with respect to any such action or proceeding.

17. **Entire Agreement**. Unless specifically provided herein, this Agreement contains all of the understandings and representations between the Executive and the Company pertaining to the subject matter hereof and supersedes all prior and contemporaneous understandings, agreements, representations and warranties, both written and oral, with respect to such subject matter, including the Consulting Agreement, dated as of April 26, 2018, between the Executive and the Company and the Mutual Nondisclosure Agreement, dated as of April 25, 2018, between the Executive and the Company, each of which is terminated as of the Effective Date. The Stock Option shall continue to be governed by the terms of the grant agreement relating thereto and the Plan. The parties mutually agree that the Agreement can be specifically enforced in court and can be cited as evidence in legal proceedings alleging breach of the Agreement.

18. **Modification and Waiver**. No provision of this Agreement may be amended or modified unless such amendment or modification is agreed to in writing and signed by the Executive and by the CEO of the Company. No waiver by either of the parties of any breach by the other party hereto of any condition or provision of this Agreement to be performed by the other party hereto shall be deemed a waiver of any similar or dissimilar provision or condition at the same or any prior or subsequent time, nor shall the failure of or delay by either of the parties in exercising any right, power or privilege hereunder operate as a waiver thereof to preclude any other or further exercise thereof or the exercise of any other such right, power or privilege.

19. **Severability**. Should any provision of this Agreement be held by a court of competent jurisdiction to be enforceable only if modified, or if any portion of this Agreement shall be held as unenforceable and thus stricken, such holding shall not affect the validity of the remainder of this Agreement, the balance of which

shall continue to be binding upon the parties with any such modification to become a part hereof and treated as though originally set forth in this Agreement.

The parties further agree that any such court is expressly authorized and shall modify any such unenforceable provision of this Agreement in lieu of severing such unenforceable provision from this Agreement in its entirety, whether by rewriting the offending provision, deleting any or all of the offending provision, adding additional language to this Agreement or by making such other modifications as it deems warranted to carry out the intent and agreement of the parties as embodied herein to the maximum extent permitted by law.

The parties expressly agree that this Agreement as so modified by the court shall be binding upon and enforceable against each of them. In any event, should one or more of the provisions of this Agreement be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions hereof, and if such provision or provisions are not modified as provided above, this Agreement shall be construed as if such invalid, illegal or unenforceable provisions had not been set forth herein.

20. **Captions**. Captions and headings of the sections and paragraphs of this Agreement are intended solely for convenience and no provision of this Agreement is to be construed by reference to the caption or heading of any section or paragraph.

21. **Counterparts**. This Agreement may be executed in separate counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument.

22. **Section 409A**.

22.1 **The Parties' Intent**. The intent of the Parties is that payments and benefits under this Agreement comply with or be exempt for Section 409A of the Code and the regulations and guidance promulgated thereunder (collectively, "Code Section 409A"), and this Agreement and any associated documents shall be interpreted and construed in a manner the establishes an exemption from (or compliance with Code Section 409A). Any terms of this Agreement that are undefined or ambiguous shall be interpreted in a manner that complies with Code Section 409A to the extent necessary to comply with Code Section 409A. If for any reason, such imprecision in drafting any provision of this Agreement (or any award of compensation, including, without limitation, equity compensation or benefits) does not accurately reflect its intended establishment as an exemption from (or compliance with Code Section 409A), as demonstrated by consistent interpretations or other evidence of intent, such provision shall be considered ambiguous as to its exemption from (or compliance with) Code Section 409A and shall be interpreted in a manner consistent with such intent, as determined in the discretion of the Company.

22.2 **Separation from Service**. A termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for any payment of any amounts or benefits that the Company determines may be considered nonqualified deferred compensation under Code Section 409A upon or following termination of employment unless such termination is a "Separation of Service" with the meaning of Code Section 409A, and, for purposes of any such provision of this Agreement, references to a "termination," "termination of employment" or the like shall mean a separation of service. The determination of whether and when a separation of service has occurred for purposes of this Agreement shall be made in in accordance with the presumptions set forth in Section 1.409A-1(h) of the Treasury Regulations.

22.3 **Reimbursements**. Any reimbursements and in-kind benefits provided under this Agreement that constitute deferred compensation within the meaning of Code Section 409A shall be made or provided in accordance with the requirements of Code Section 409A, including, without limitation, that in no event shall any fees, expenses or other amounts eligible to be reimbursed by the Company under this Agreement be paid later that the last day of the calendar year next following the calendar year in which the applicable fees, expenses or other amounts were incurred.

22.4 **Payments**. For purposes of Code Section 409A, the Executive's right to receive any installment payments shall be treated as a right to receive a series of separate and distinct payments. Whenever a payment under this Agreement specifies a payment period with reference to a number of days (for example, "payment shall be made within thirty (30) days following the date of termination), the actual date of payment within the specified period shall be within the sole discretion of the Company. In no event may the Executive, directly or indirectly, designate the calendar year of any payment to be made under this Agreement, to the extent that such payment is subject to Code Section 409A.

22.5 **No Company Warranties**. The Company makes no representation or warranty and shall have no liability to the Executive or any other person if any provisions in this Agreement are determined to constitute deferred compensation subject to Code Section 409A but do not satisfy an exemption from, or the conditions of, Code Section 409A.

23. **Notification to Subsequent Employer**. When the Executive's employment with the Company terminates, the Executive agrees to notify any subsequent employer of the restrictive covenants sections contained in this Agreement. The Executive will also deliver a copy of such notice to the Company before the Executive commences employment with any subsequent employer. In addition, the Executive authorizes the Company to provide a copy of sections 7 to 11 of this Agreement to third parties, including but not limited to, the Executive's subsequent, anticipated or possible future employer.

24. **Successors and Assigns**. This Agreement is personal to the Executive and shall not be assigned by the Executive. Any purported assignment by the Executive shall be null and void from the initial date of the purported assignment. The Company may assign this Agreement to any successor or assign (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company. This Agreement shall inure to the benefit of the Company and permitted successors and assigns.

25. **Notice**. Notices and all other communications provided for in this Agreement shall be in writing and shall be delivered personally or sent by registered or certified mail, return receipt requested, or by overnight carrier to the parties at the addresses set forth below (or such other addresses as specified by the parties by like notice):

If to the Company:
Veru Inc.
4400 Biscayne Blvd
Suite 888
Miami, FL 33137
Attention: EVP Legal

If to the Executive:
Charles T. Todd, Jr.
Newport Drive
New Durham, NH 03855

26. **Representations of the Executive**. The Executive represents and warrants to the Company that:

(a) The Executive's acceptance of employment with the Company and the performance of his duties hereunder will not conflict with or result in a violation of, a breach of, or a default under any contract, agreement or understanding to which he is a party or is otherwise bound; and

(b) The Executive's acceptance of employment with the Company and the performance of his duties hereunder will not violate any non-solicitation, non-competition or other similar covenant or agreement of a prior employer.

27. **Withholding**. The Company shall have the right to withhold from any amount payable hereunder any federal, state and/or local taxes in order for the Company to satisfy any withholding tax obligation it may have under any applicable law or regulation.

28. **Survival**. Upon the termination of this Agreement, the respective rights and obligations of the parties hereto shall survive such termination to the extent necessary to carry out the intentions of the parties under this Agreement.

29. **Acknowledgement of Full Understanding**. THE EXECUTIVE ACKNOWLEDGES AND AGREES THAT HE HAS FULLY READ, UNDERSTANDS AND VOLUNTARILY ENTERS INTO THIS AGREEMENT. THE EXECUTIVE ACKNOWLEDGES AND AGREES THAT HE HAS HAD AN OPPORTUNITY TO ASK QUESTIONS AND CONSULT WITH AN ATTORNEY OF HIS CHOICE BEFORE SIGNING THIS AGREEMENT.

IN WITNESS WHEREOF, the parties hereto have entered into this Agreement in Miami, Florida as of the date first written above.

VERU INC.

/s/ Mitchell Steiner
Mitchell S. Steiner, MD, FACS
Chairman, President and CEO

Charles T. Todd, Jr.

/s/ Charles T. Todd, Jr.
Executive

Exhibit 31.1

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

I, Mitchell S. Steiner, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: February 13, 2019

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

Exhibit 31.2

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

I, Michele Greco, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: February 13, 2019

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

Exhibit 32.1

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

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned officers of Veru Inc. (the "Company") certifies that the Quarterly Report on Form 10-Q of the Company for the quarter ended December 31, 2018 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 13, 2019

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

Date: February 13, 2019

/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.