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 March 31, 2019

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

Commission File Number 1-13602

Veru Inc.

(Exact Name of Registrant as Specified in its Charter)

Wisconsin	**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, Former Address and Former Fiscal Year, 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 ☒

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value per share	VERU	NASDAQ Capital Market

As of May 10, 2019, the registrant had62,790,208 shares of $0.01 par value common stock outstanding.

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FORWARD LOOKING STATEMENTS

Certain statements included in this quarterly report on Form 10-Q which are not statements of historical fact are intended to be, and are hereby identified as, "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about future financial and operating results, plans, objectives, expectations and intentions, costs and expenses, 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 and/or of our ability to supply product due to raw material shortages, labor shortages, physical damage to our facilities, product testing, transportation delays or regulatory actions;
- our reliance on major customers and risks related to delays in payment of accounts receivable by major customers;
- risks related to our growth strategy;
- our continued ability to attract and retain highly skilled and qualified personnel;
- the costs and other effects of litigation, governmental investigations, legal and administrative cases and proceedings, settlements and investigations;
- government contracting risks;
- 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

	March 31, 2019	September 30, 2018
Assets		
Current assets:		
Cash	$ 5,896,536	$ 3,759,509
Accounts receivable, net	4,027,235	3,972,632
Inventory, net	2,998,201	2,302,030
Prepaid expenses and other current assets	1,220,908	1,148,345
Total current assets	14,142,880	11,182,516
Plant and equipment, net	320,802	404,552
Deferred income taxes	8,570,150	8,543,758
Intangible assets, net	20,323,112	20,477,729
Goodwill	6,878,932	6,878,932
Other assets	776,178	965,152
Total assets	$ 51,012,054	$ 48,452,639
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,525,162	$ 3,226,036
Accrued research and development costs	437,928	981,357
Accrued expenses and other current liabilities	2,472,422	2,465,657
Credit agreement, short-term portion (Note 7)	5,836,615	6,692,718
Unearned revenue	—	187,159
Total current liabilities	11,272,127	13,552,927
Credit agreement, long-term portion (Note 7)	2,717,934	2,701,570
Residual royalty agreement (Note 7)	2,341,522	1,753,805
Deferred income taxes	895,860	844,758
Deferred rent	210,594	88,161
Other liabilities	30,000	30,000
Total liabilities	17,468,037	18,971,221
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock; no shares issued and outstanding at March 31, 2019 and September 30, 2018	—	—
Common stock, par value $0.01 per share; 154,000,000 and 77,000,000 shares authorized, 64,968,184 and 57,468,660 shares issued and 62,784,480 and 55,284,956 shares outstanding at March 31, 2019 and September 30, 2018, respectively	649,682	574,687
Additional paid-in-capital	105,666,943	95,496,506
Accumulated other comprehensive loss	(581,519)	(581,519)
Accumulated deficit	(64,384,484)	(58,201,651)
Treasury stock, 2,183,704 shares, at cost	(7,806,605)	(7,806,605)
Total stockholders' equity	33,544,017	29,481,418
Total liabilities and stockholders' equity	$ 51,012,054	$ 48,452,639

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended March 31,		Six Months Ended March 31,	
	2019	2018	2019	2018
Net revenues	$ 6,976,115	$ 2,572,872	$ 13,347,924	$ 5,159,485
Cost of sales	2,367,264	1,374,936	4,094,993	2,647,928
Gross profit	4,608,851	1,197,936	9,252,931	2,511,557
Operating expenses:				
Research and development	2,910,587	2,076,794	5,272,410	4,035,162
Selling, general and administrative	3,822,854	3,817,692	7,116,838	6,845,390
Loss on settlement of accounts receivable	—	—	—	3,764,137
Total operating expenses	6,733,441	5,894,486	12,389,248	14,644,689
Operating loss	(2,124,590)	(4,696,550)	(3,136,317)	(12,133,132)
Non-operating (expenses) income:				
Interest expense	(1,258,272)	(350,595)	(2,536,695)	(350,595)
Other income (expense), net	25,637	(2,412)	52,031	(15,580)
Change in fair value of derivative liabilities	(628,000)	(21,000)	(403,000)	(21,000)
Foreign currency transaction loss	(23,643)	(63,077)	(41,187)	(116,532)
Total non-operating expenses	(1,884,278)	(437,084)	(2,928,851)	(503,707)
Loss before income taxes	(4,008,868)	(5,133,634)	(6,065,168)	(12,636,839)
Income tax expense (benefit)	25,167	(1,302,416)	117,665	(4,548,469)
Net loss	$ (4,034,035)	$ (3,831,218)	$ (6,182,833)	$ (8,088,370)
Net loss per basic and diluted common share outstanding	$ (0.06)	$ (0.07)	$ (0.10)	$ (0.15)
Basic and diluted weighted average common shares outstanding	62,767,258	53,355,944	62,659,352	53,253,901

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Preferred Stock	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Treasury Stock, at Cost	Total
		Shares	Amount					
Balance at September 30, 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
Share-based compensation	—	—	—	496,209	—	—	—	496,209
Issuance of shares pursuant to share-based awards	—	166,667	1,667	198,333	—	—	—	200,000
Net loss	—	—	—	—	—	(4,034,035)	—	(4,034,035)
Balance at March 31, 2019	$ —	64,968,184	$649,682	$105,666,943	$ (581,519)	$(64,384,484)	$(7,806,605)	$33,544,017
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
Share-based compensation	—	—	—	411,848	—	—	—	411,848
Net loss	—	—	—	—	—	(3,831,218)	—	(3,831,218)
Balance at March 31, 2018	$ —	55,696,650	$556,967	$ 91,514,007	$ (581,519)	$(42,351,632)	$(7,806,605)	$41,331,218

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Six Months Ended March 31,	
	2019	2018
OPERATING ACTIVITIES		
Net loss	$ (6,182,833)	$ (8,088,370)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	84,394	88,239
Amortization of intangible assets	154,617	137,631
Noncash interest expense	2,536,695	350,595
Share-based compensation	913,465	619,302
Deferred income taxes	24,710	(4,653,558)
Loss on settlement of accounts receivable	—	3,764,137
Change in fair value of derivative liabilities	403,000	21,000
Other	174,357	(1,942)
Changes in current assets and liabilities:		
(Increase) decrease in accounts receivable	(54,603)	3,250,664
Increase in inventory	(748,095)	(821,133)
(Increase) decrease in prepaid expenses and other assets	(73,589)	62,485
(Decrease) increase in accounts payable	(656,527)	853,949
Decrease in unearned revenue	(187,159)	(142,147)
x(Decrease) increase in accrued expenses and other current liabilities	(391,011)	375,957
Net cash used in operating activities	(4,002,579)	(4,183,191)
INVESTING ACTIVITIES		
Capital expenditures	(644)	(1,913)
Net cash used in investing activities	(644)	(1,913)
FINANCING ACTIVITIES		
Proceeds from sale of shares in public offering, net of fees and costs	9,131,967	—
Installment payments on SWK credit agreement	(3,191,717)	—
Proceeds from stock option exercises	200,000	—
Proceeds from SWK credit agreement	—	10,000,000
Payment of debt issuance costs	—	(120,000)
Net cash provided by financing activities	6,140,250	9,880,000
Net increase in cash	2,137,027	5,694,896
CASH AT BEGINNING OF PERIOD	3,759,509	3,277,602
CASH AT END OF PERIOD	$ 5,896,536	$ 8,972,498
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	$ —	$ 77,840
Debt issuance costs in accounts payable and accrued expenses	$ —	$ 143,943

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 for the three and six months ended March 31, 2019 and cash flows for the six months ended March 31, 2019 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. Most of the Company's net revenues during the three and six months ended March 31, 2019 and 2018 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. The Company had no restricted cash at March 31, 2019. Restricted cash was approximately $135,000 at September 30, 2018 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 March 31, 2019 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 six months ended March 31, 2019 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 March 31, 2019 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 third quarter of fiscal 2021. The amortization 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. The Company had no unearned revenue at March 31, 2019. Unearned revenue at September 30, 2018 was approximately $187,000 and was comprised 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 trial 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 March 31, 2019 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 and six months ended March 31, 2019 and 2018.

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 March 31, 2019 and September 30, 2018. Assets

located outside of the U.S. totaled approximately $5.0 million and $5.2 million at March 31, 2019 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 and six months ended March 31, 2019 and 2018, 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)*, which requires that lessees recognize a right-of-use asset and a lease liability for all leases with lease terms greater than twelve months in the balance sheet. ASU 2016-02 distinguishes leases as either a finance lease or an operating lease, which affects how the leases are measured and presented in the statement of operations and statement of cash flows, and requires disclosure of key information about leasing arrangements. 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. In March 2019, the FASB issued ASU 2019-01,*Leases (Topic 842): Codification Improvements* to address, among other things, certain transition disclosure requirements subsequent to the adoption of ASU 2016-02. The Company 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 ofevaluating 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 ASU 2017-09 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 8) and/or a marketed deal with an investment bank.

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 six months ended March 31, 2019 and 2018.

As of March 31, 2019 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) as of March 31, 2019 and 2018:

	Six Months Ended March 31,	
	2019	**2018**
Beginning balance	$ 2,426,000	$ —
Additions	—	3,319,000
Change in fair value of derivative liabilities	403,000	21,000
Ending balance	$ 2,829,000	$ 3,340,000

The expense 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 usinga 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 March 31, 2019:

Valuation Methodology	Significant Unobservable Input	Weighted Average (range, if applicable)
Monte Carlo Simulation	Estimated change of control dates	December 2019 to December 2021
	Discount rate	15.3% to 17.3%
	Probability of change of control	0% 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.

The components of accounts receivable consist of the following at March 31, 2019 and September 30, 2018:

	March 31, 2019	September 30, 2018
Accounts receivable	$ 4,076,745	$ 4,046,733
Less: allowance for doubtful accounts	(36,201)	(36,201)
Less: allowance for sales and payment term discounts	(13,309)	(37,900)
Accounts receivable, net	$ 4,027,235	$ 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 six months ended March 31, 2018, 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 March 31, 2019, one customer had an accounts receivable balance that represented 11% of current assets. At September 30, 2018, one customer had an accounts receivable balance that represented 15% of current assets.

At March 31, 2019, 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 March 31, 2019, there were four customers whose individual net revenue to the Company exceeded 10% of the Company’s net revenues, representing 82% of the Company’s net revenues in the aggregate. For the three months ended March 31, 2018, there were two customers whose individual net revenue to the Company exceeded 10% of the Company’s net revenues, representing 44% of the Company’s net revenues in the aggregate.

For the six months ended March 31, 2019, there were three customers whose individual net revenue to the Company exceeded 10% of the Company’s net revenues, representing 66% of the Company’s net revenues in the aggregate.

For the six months ended March 31, 2018, there werethree customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 50% 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 six months ended March 31, 2019 and 2018.

	Six Months Ended March 31,	
	2019	2018
Beginning balance	$ 36,201	$ 38,103
Charges to expense	—	3,058
Charge-offs	—	(5,000)
Ending balance	$ 36,201	$ 36,161

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 March 31, 2019 and September 30, 2018:

	March 31, 2019	September 30, 2018
FC2		
Raw material	$ 599,772	$ 366,220
Work in process	62,710	77,669
Finished goods	2,786,083	2,232,864
Inventory, gross	3,448,565	2,676,753
Less: inventory reserves	(451,041)	(391,861)
FC2, net	2,997,524	2,284,892
PREBOOST®		
Finished goods	677	17,138
Inventory, net	$ 2,998,201	$ 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 March 31, 2019 and September 30, 2018:

	March 31, 2019	September 30, 2018
Equipment, furniture and fixtures	$ 4,018,333	$ 4,018,284
Leasehold improvements	287,686	287,686
	4,306,019	4,305,970
Less: accumulated depreciation and amortization	(3,985,217)	(3,901,418)
Plant and equipment, net	$ 320,802	$ 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 March 31, 2019:

	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Intangible assets with finite lives:			
Developed technology - PREBOOST®	$ 2,400,000	$ 404,269	$ 1,995,731
Covenants not-to-compete	500,000	172,619	327,381
Total intangible assets with finite lives	2,900,000	576,888	2,323,112
Acquired in-process research and development assets	18,000,000	—	18,000,000
Total intangible assets	$ 20,900,000	$ 576,888	$ 20,323,112

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 over10 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.

For the three months ended March 31, 2019 and 2018, amortization expense was approximately$77,000 and $69,000, respectively. For the six months ended March 31, 2019 and 2018, amortization expense was approximately $155,000 and $138,000, respectively.

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 macroeconomic 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 March 31, 2019 and September 30, 2018 was $6.9 million. There was no change in the balance during the six months ended March 31, 2019 and 2018. 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 Company's sole reporting unit in the Company's Research and Development reporting segment, 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, and 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 least47.5 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 the12-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), plus10% 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$0.6 million 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. On February 15, 2019, the Company paid approximately $0.6 million for the quarterly revenue-based payment due on that date.

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

In connection with the Credit Agreement, the Company and the Agent also entered into a Residual Royalty Agreement, dated as of March 5, 2018 (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 completed12-month period multiplied by (y) five.

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

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 allocatedbetween the Credit Agreement and the Residual Royalty Agreement on a relative fair value basis. A portion of the amount allocated to the Credit Agreement and a portion of the amount allocated to the Residual Royalty Agreement, in both cases equal to the fair value of the respective change of control provisions, was allocated to the embedded derivative liabilities. The derivative liabilities 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 March 31, 2019 and September 30, 2018, the Credit Agreement consisted of the following:

	March 31, 2019	September 30, 2018
Aggregate repayment obligation	$ 17,500,000	$ 17,500,000
Less: Cumulative payments	(3,834,202)	(642,485)
Less: Unamortized discounts	(6,212,466)	(8,475,874)
Less: Unamortized deferred issuance costs	(149,783)	(204,353)
Credit agreement, net	7,303,549	8,177,288
Add: Embedded derivative liability at fair value (see Note 3)	1,251,000	1,217,000
	8,554,549	9,394,288
Credit agreement, short-term portion	(5,836,615)	(6,692,718)
Credit agreement, long-term portion	$ 2,717,934	$ 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 March 31, 2019 and September 30, 2018, respectively.

At March 31, 2019 and September 30, 2018, the Residual Royalty Agreement liability consisted of the following:

	March 31, 2019	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	417,522	201,225
Residual Royalty Agreement liability, net	763,522	544,805
Add: Embedded derivative liability at fair value (see Note 3)	1,578,000	1,209,000
Residual Royalty Agreement liability	$ 2,341,522	$ 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 and six months ended March 31, 2019, interest expense related to the Credit Agreement and Residual Royalty Agreement was as follows:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2019	2018	2019	2018
Amortization of Credit Agreement and Residual Royalty Agreement discounts	$ 1,107,622	$ 317,747	$ 2,265,828	$ 317,747
Accretion of Residual Royalty Agreement liability	123,946	27,278	216,297	27,278
Amortization of deferred issuance costs	26,704	5,570	54,570	5,570
	$ 1,258,272	$ 350,595	$ 2,536,695	$ 350,595

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 March 31, 2019 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 March 31, 2019 and September 30, 2018.

Common Stock

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

Common Stock Offering

On October 1, 2018, we completed an underwritten public offering of7,142,857 shares of our common stock, at a public offering price of $1.40 per share. Net proceeds to the Company from this offering were $9.1 million after deducting underwriting discounts and commissions and costs paid by the Company. All of the shares sold in the offering were by the Company. The offering was made pursuant to the Shelf Registration Statement.

Common Stock Purchase Warrants

In connection with the closing of the APP Acquisition, the Company issued a warrant to purchase up to 2,585,379 shares of the Company's common stock to Torreya Capital, the Company's financial advisor (the "Financial Advisor Warrant"). The Financial Advisor Warrant has a five-year term expiring October 31, 2021, a cashless exercise feature and a strike price equal to $1.93 per share. The Financial Advisor Warrant vested upon issuance and remains outstanding at March 31, 2019.

In May 2018, the Company issued two warrants to purchase a total of up to 750,000 shares of the Company's common stock at $2.31 per share in connection with a services agreement. The services agreement was terminated in March 2019 and the warrants were cancelled at the same time. Prior to termination of the services agreement, for measurement and recognition purposes, the Company utilized the lowest aggregate amount within the range of potential values, which was zero. Therefore, in prior periods, the Company had determined the fair value of these warrants to be zero and had not recognized any compensation expense related to these warrants.

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 March 31, 2019 and September 30, 2018. As of March 31, 2019, the amount remaining under the Purchase Agreement was $12.0 million.

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 and six months ended March 31, 2019 and 2018, we recorded share-based compensation expenses as follows:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2019	2018	2019	2018
Cost of sales	$ 7,778	$ 1,797	$ 15,730	$ 5,061
Selling, general and administrative	407,426	362,006	734,435	537,344
Research and development	81,005	48,045	163,300	76,897
	$ 496,209	$ 411,848	$ 913,465	$ 619,302

Equity Plans

In March 2018, the Company's stockholders approved the Company's 2018 Equity Incentive Plan (the "2018 Plan").On March 26, 2019, the Company's stockholders approved an increase in the number of shares that may be issued under the 2018 Plan to 6.0 million. As of March 31, 2019, 4,117,272 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 of4.7 million shares are authorized for issuance under the 2017 Plan. As of March 31, 2019, 190,868 shares remain available for issuance under the 2017 Plan. The 2017 Plan replaced the Company's 2008 Stock Incentive Plan (the "2008 Plan"), andno further awards will be made under the 2008 Plan.

Stock Options

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

The following table outlines the weighted average assumptions for options granted during thethree and six months ended March 31, 2019 and 2018:

	Three Months Ended March 31,		Six Months Ended March 31,	
Weighted Average Assumptions:	2019	2018	2019	2018
Expected volatility	65.45%	62.34%	66.88%	61.38%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%
Risk-free interest rate	2.27%	2.76%	2.59%	2.47%
Expected term (in years)	5.9	6.0	5.7	5.8
Fair value of options granted	$ 0.90	$ 1.28	$ 0.85	$ 0.93

During the three and six months ended March 31, 2019 and 2018, the Company used historical volatility of our common stock over a period equal to the expected life of the options to estimate their fair value. The dividend yield assumption is based on the Company's recent history and expectation of future dividend payouts on the common stock. The risk-free interest rate is based on the implied yield available on U.S. treasury zero-coupon issues with an equivalent remaining term.

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

	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	880,882	1.42		
Exercised	(166,667)	1.20		
Forfeited	(301,834)	1.52		
Outstanding at March 31, 2019	6,057,693	$ 1.57	7.83	$ 785,435
Exercisable at March 31, 2019	2,042,285	$ 1.46	6.51	$ 436,840

The aggregate intrinsic values in the table above are before income taxes andrepresent the number of in-the-money options outstanding or exercisable multiplied by the closing price per share of the Company's common stock on the last trading day of the quarter ended March 31, 2019 of $1.46, less the respective weighted average exercise price per share at period end

The total intrinsic value of options exercised during the six months ended March 31, 2019 was approximately$48,000. Cash received from options exercised during the six months ended March 31, 2019 was approximately $200,000. No stock options were exercised during the six months ended March 31, 2018.

As of March 31, 2019, the Company had unrecognized compensation expense of approximately$2.7 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 March 31, 2019 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 March 31, 2019, 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 on50,000 and 140,000 shares of the Company's common stock to an employee and an outside director, respectively, that vested on October 31, 2018. The stock appreciation rights have a ten-year term and an exercise price per share of$0.95, which was the closing price per share of the Company's common stock as quoted on NASDAQ on the trading day immediately preceding the date of the completion of the APP Acquisition. The stock appreciation rights will be settled in common stock issued under the 2017 Plan. As of March 31, 2019, 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, which was previously dismissed in part, 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. On May 6, 2019, the Court granted plaintiffs' motion and certified a class consisting of "All holders of common stock of the Female Health Company as of October 31, 2016 and their successors in interest, excluding the named defendants to the Action and any person, firm, trust, corporation or other entity related to or affiliated with any of the Defendants." The parties filed cross-motions for summary judgment on April 15, 2019 which are set for hearing on July 11, 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 March 31, 2019. An additional valuation allowance has been recorded against the U.S. deferred tax assets and net operating loss carryforwards as of March 31, 2019 of $1.6 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 March 31,		Six Months Ended March 31,	
	2019	2018	2019	2018
Income tax benefit at statutory rates	$ (841,862)	$ (1,077,736)	$ (1,273,685)	$ (3,628,736)
State income tax benefit, net of federal benefits	(199,521)	(385,395)	(301,863)	(948,395)
Effect of change in U.S. tax rate	—	—	—	(187,000)
Non-deductible expenses – other	2,364	8,702	4,783	12,702
Effect of lower foreign income tax rates	4,830	50,981	(3,527)	80,386
Effect of deemed dividend	32,318	—	63,627	—
Other	(1,025)	101,032	(22,863)	122,574
Change in valuation allowance	1,028,063	—	1,651,193	—
Income tax expense (benefit)	$ 25,167	$ (1,302,416)	$ 117,665	$ (4,548,469)

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

Deferred tax assets:	March 31, 2019	September 30, 2018
Federal net operating loss carryforwards	$ 8,057,926	$ 6,973,047
State net operating loss carryforwards	2,468,061	2,195,865
Foreign net operating loss carryforwards – U.K.	10,621,438	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	54,706	22,902
Share-based compensation	759,875	622,442
Other, net – U.S.	125,508	91,419
Other, net – Malaysia	34,314	33,843
Gross deferred tax assets	22,243,212	20,656,420
Valuation allowance for deferred tax assets	(9,282,271)	(7,631,078)
Net deferred tax assets	12,960,941	13,025,342
Deferred tax liabilities:		
In process research and development	(4,675,860)	(4,675,860)
Developed technology	(518,431)	(549,318)
Covenant not-to-compete	(85,044)	(94,321)
Other	(7,316)	(6,843)
Net deferred tax liabilities	(5,286,651)	(5,326,342)
Net deferred tax asset	$ 7,674,290	$ 7,699,000

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

	March 31, 2019	September 30, 2018
Long-term deferred tax asset – U.K.	8,535,836	8,509,915
Long-term deferred tax asset – Malaysia	34,314	33,843
Total long-term deferred tax asset	$ 8,570,150	$ 8,543,758
Long-term deferred tax liability – U.S.	(895,860)	(844,758)
Total long-term deferred tax liability	$ (895,860)	$ (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 March 31,		For the six months ended March 31,	
	2019	2018	2019	2018
Operating (loss) income:	(In thousands)		(In thousands)	
Commercial	$ 3,204	$ (163)	$ 6,872	$ (19)
Research and Development	(2,889)	(1,960)	(5,250)	(3,992)
Corporate	(2,440)	(2,574)	(4,758)	(8,122)
	$ (2,125)	$ (4,697)	$ (3,136)	$ (12,133)
Revenues:				
United States	$ 2,596	$ 981	$ 5,646	$ 1,975
Brazil	1,098	—	1,098	—
United Arab Emirates	677	278	677	278
South Africa	24	715	233	1,033
Zimbabwe	590	378	1,948	678
Other	1,991	221	3,746	1,195
	$ 6,976	$ 2,573	$ 13,348	$ 5,159

All of our net revenues, which are primarily derived from the sale of FC2, are attributed to our Commercial reporting segment. The loss on settlement of accounts receivable and depreciation and amortization related to long-lived assets that are not utilized in the production of FC2 are not reported as part of the reporting segments or reviewed by the CODM. These amounts are included in Corporate in the reconciliations above. Total assets are not presented by reporting segment as they are not reviewed by the CODM when evaluating the reporting segments' performance.

Note 14 – Subsequent Events

On May 13, 2019, the Company entered into an amendment (the "Second Amendment") to the Credit Agreement discussed in Note 7. The Second Amendment provides for reduced percentages to be used to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar 2019, a return to the current percentages used to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar 2020 and increased percentages to be used to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar 2021 and thereafter until the loan has been repaid. The Second Amendment also provides for an increase in the repayment amount from 175% to 176.5% of the aggregate amount advanced. In addition, the Second Amendment provides for payments under the Residual Royalty Agreement to commence at the same time as they would have commenced prior to the Second Amendment. The Second Amendment also eliminates the Company's option to draw up to an additional $2.0 million under the Credit Agreement depending on the Company entering into agreements to distribute FC2 in Brazil and South Africa as the Company has determined that it would not make such draws. As a result of the Second Amendment, the Company's quarterly revenue-based payment due May 15, 2019 will decrease from approximately $1.7 million to approximately $0.9 million. At this time, the Company is unable to determine all of the financial effects of the Second Amendment, which will likely result in the Company recording an extinguishment loss due to the modification of the terms of the Credit Agreement in the quarter ending June 30, 2019. An estimate of the loss amount cannot be made at this time as the Company is currently analyzing the accounting for the transaction, which includes fair value determinations.

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 prostate cancer treatment and prostate cancer supportive care as well as urology specialty pharmaceuticals.

The Company's prostate cancer pipeline includes zuclomiphene citrate (which is also known as VERU-944, cis-clomiphene) and VERU-111 (bisindole). Zuclomiphene citrate is an estrogen receptor agonist being evaluated in a Phase 2 clinical trial to treat hot flashes, a common side effect caused by hormone treatment in 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 tubulin subunits of microtubules in cells to treat metastatic prostate cancer patients whose disease is resistant to both castration and novel androgen-blocking agents (abiraterone or enzalutamide). VERU-111 is being evaluated in men with metastatic castration and androgen-blocking agent resistant prostate cancer in an open label Phase 1b/2 clinical trial. The 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 the 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 is currently approved for treatment of BPH (finasteride 5mg PROSCAR®) and male pattern hair loss (finasteride 1mg PROPECIA®). The co-administration of tadalafil and finasteride has been shown to be more effective for the treatment of BPH than by finasteride alone. The Company anticipates submitting an NDA for its TADFIN™ tablet under the 505(b)(2) regulatory pathway between the fourth quarter of calendar year 2019 and first quarter of calendar year 2020. The Company is also developing Tamsulosin DRS (Delayed Release Sachet) granules and Tamsulosin 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® (also marketed as Roman Swipes) 4% benzocaine 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 and over-the-counter 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 website getroman.com.

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 the Zika virus by sex. Most 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 150 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 in the global public sector 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 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. primarily through telemedicine distribution partners.

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. As of March 31, 2019, the Company has not shipped any units under this tender award and expects to begin shipping units under the tender award in the third quarter of fiscal 2019.

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	9,792,584	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	17,175,108	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 and six months ended March 31, 2019 or 2018.

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

The Company’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 $2.9 million and $2.1 million for the three months ended March 31, 2019 and 2018, respectively. Our research and development expenses were $5.3 million and $4.0 million for the six months ended March 31, 2019 and 2018, respectively. For the remainder of fiscal 2019, we expect to continue this trend of increased expenses relating to research and development due to advancement of multiple drug candidates.

THREE MONTHS ENDED MARCH 31, 2019 COMPARED TO THREE MONTHS ENDED MARCH 31, 2018

The Company generated net revenues of $7.0 million and net loss of $4.0 million, or $(0.06) per basic and diluted common share, for the three months ended March 31, 2019, compared to net revenues of $2.6 million and net loss of $3.8 million, or $(0.07) per basic and diluted common share, for the three months ended March 31, 2018.

Net revenues increased 171%, of which 166% relate to FC2. The Company experienced an increase in FC2 net revenues in both the public sector and the U.S. prescription channels. There was a 137% increase in FC2 unit sales and an increase in FC2 average sales price per unit of 12%. 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 $2.4 million in the three months ended March 31, 2019 from $1.4 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 March 31, 2019 from $1.2 million for the three months ended March 31, 2018. Gross profit margin for the three months ended March 31, 2019 was 66% of net revenues, compared to 47% of net revenues for the same period in 2018. In the three months ended March 31, 2019, 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 in the U.S., which should help smooth quarter to quarter and year to year revenue fluctuations.

Research and development expenses increased to $2.9 million for the three months ended March 31, 2019 from $2.1 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 were $3.8 million for the three months ended March 31, 2019, which was comparable to the $3.8 million in the prior year period.

Interest expense, which consists of items related to the SWK Credit Agreement and the SWK Residual Royalty Agreement, was approximately $1.3 million for the three months ended March 31, 2019 compared to $0.4 million for the three months ended March 31, 2018. These agreements, which were entered into in March 2018, were outstanding for the entire fiscal 2019 period, but outstanding for only one month in the fiscal 2018 period.

Expense associated with the change in fair value of the embedded derivatives was $0.6 million for the three months ended March 31, 2019 compared to expense of $21,000 for the three months ended March 31, 2018. The liabilities associated with embedded derivatives represent the fair value of the change of control provisions in the SWK Credit Agreement and Residual Royalty Agreement. See Note 3 and Note 7 to the financial statements included in this report for additional information.

The Company realized a foreign currency transaction loss of approximately $24,000 in the most recent quarter, compared to approximately $63,000 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 March 31, 2019 was $25,000, compared to an income tax benefit of $1.3 million for the same period in fiscal 2018. The increase in income tax expense of $1.3 million is primarily due to a valuation allowance recorded against the U.S. net deferred tax assets of $1.0 million and a decrease in the income tax benefit of $0.4 million due to the decrease in the loss before income taxes in addition to a decrease of $0.1 million in income tax expense for the effect of change in the U.S. and foreign tax rates.

SIX MONTHS ENDED MARCH 31, 2019 COMPARED TO SIX MONTHS ENDED MARCH 31, 2018

The Company generated net revenues of $13.3 million and net loss of $6.2 million, or $(0.10) per basic and diluted common share, for the six months ended March 31, 2019, compared to net revenues of $5.2 million and net loss of $8.1 million, or $(0.15) per basic and diluted common share, for the six months ended March 31, 2018.

Net revenues increased 159%, of which 155% relate to FC2. The Company experienced an increase in FC2 net revenues in both the public sector and the U.S. prescription channels. There was a 101% increase in FC2 unit sales and an increase in FC2 average sales price per unit of 27%. 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 $4.1 million in the six months ended March 31, 2019 from $2.6 million for the same period last year. The increase is primarily due to the increase in unit sales.

Gross profit increased to $9.3 million for the six months ended March 31, 2019 from $2.5 million for the six months ended March 31, 2018. Gross profit margin for the six months ended March 31, 2019 was 69% of net revenues, compared to 49% of net revenues for the same period in 2018. In the six months ended March 31, 2019, 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 in the U.S., which should help smooth quarter to quarter and year to year revenue fluctuations.

Research and development expenses increased to $5.3 million for the six months ended March 31, 2019 from $4.0 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 by $0.3 million to $7.1 million for the six months ended March 31, 2019 from $6.8 million in the prior year period.

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 six months ended March 31, 2018.

Interest expense, which consists of items related to the SWK Credit Agreement and the SWK Residual Royalty Agreement, was approximately $2.5 million for the six months ended March 31, 2019 compared to $0.4 million for the six months ended March 31, 2018. These agreements, which were entered into in March 2018, were outstanding for the entire fiscal 2019 period, but outstanding for only one month in the fiscal 2018 period.

Expense associated with the change in fair value of the embedded derivatives related to the SWK Credit Agreement and the SWK Residual Royalty Agreement was $0.4 million for the six months ended March 31, 2019 compared to expense of $21,000 for the six months ended March 31, 2018.

The Company realized a foreign currency transaction loss of approximately $41,000 in the six months ended March 31, 2019, compared to approximately $0.1 million 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 six months ended March 31, 2019 was $0.1 million, compared to an income tax benefit of $4.5 million for the same period in fiscal 2018. The increase in income tax expense of $4.6 million is primarily due to a valuation allowance recorded against the U.S. net deferred tax assets of $1.6 million and the decrease in the income taxes benefit of $3.0 million due to the decrease in the loss before income taxes.

Liquidity

Our cash on hand at March 31, 2019 was $5.9 million, compared to $3.8 million (including restricted cash) at September 30, 2018.At March 31, 2019, the Company had working capital of $2.9 million and stockholders' equity of $33.5 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. 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 $4.0 million in the six months ended March 31, 2019. Cash used in operating activities included a net loss of $6.2 million, adjustments for non-cash items totaling $4.3 million and changes in operating assets and liabilities of $2.1 million. Adjustments for non-cash items primarily consisted of $2.5 million of interest expense and $0.4 million of expense due to the increase in fair value of the embedded derivatives related to the SWK Credit Agreement and the SWK Residual Royalty Agreement, and $0.9 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 $1.0 million and an increase in inventories of $0.7 million.

Our operating activities used cash of $4.2 million in the six months ended March 31, 2018. Cash used in operating activities included a net loss of $8.1 million, adjustments for non-cash items totaling $0.3 million and cash from changes in operating assets and liabilities of $3.6 million. Adjustments for non-cash items primarily consisted of a $3.8 million loss on the settlement of net accounts receivable, $0.6 million of share-based compensation, and $0.4 million of interest expense related to the SWK Credit Agreement and the SWK Residual Royalty Agreement. These amounts were mostly offset by a $4.7 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 $3.3 million and increases in accounts payable and accrued expenses of $1.2 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 and six months ended March 31, 2018, 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.

Financing activities

Net cash provided by financing activities in the six months ended March 31, 2019 was $6.1 million and primarily consisted of the net proceeds from the underwritten public offering of the Company's common stock of $9.1 million (see discussion below), proceeds from stock option exercises of $0.2 million, less payments on the SWK Credit Agreement (see discussion below) totaling $3.2 million.

Sources of Capital

Common Stock Offering

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

SWK Credit Agreement

On March 5, 2018, the Company entered into a Credit Agreement (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 $0.6 million 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. On February 15, 2019, the Company paid approximately $0.6 million for the quarterly revenue-based payment due on that date.

On May 13, 2019, the Company entered into an amendment (the "Second Amendment") to the Credit Agreement. The Second Amendment provides for reduced percentages to be used to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar 2019, a return to the current percentages to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar 2020 and increased percentages to be used to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar 2021 and thereafter until the loan has been repaid. The Second Amendment also provides for an increase in the repayment amount from 175% to 176.5% of the aggregate amount advanced. In addition, the Second Amendment provides for payments under the Residual Royalty Agreement to commence at the same time as they would have commenced prior to the Second Amendment. The Second Amendment also eliminates the Company's option to draw up to an additional $2.0 million under the Credit Agreement depending on the Company entering into agreements to distribute FC2 in Brazil and South Africa as the Company has determined that it would not make such draws. As a result of the Second Amendment, the Company currently estimates the aggregate amount of quarterly revenue-based payments payable during the 12-month period subsequent to March 31, 2019 will be approximately $2.9 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 March 31, 2019, the amount remaining under the Purchase Agreement was $12.0 million. During fiscal 2019 to date, we have not sold any shares of common stock to Aspire Capital under the Purchase Agreement.

Fair Value Measurements

As of March 31, 2019 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 thesupervision and with the participation of the Company's management, including the Company's Chief Executive Officer and the Company's Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Based on this evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective. It should be noted that in designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. The Company has designed its disclosure controls and procedures to reach a level of reasonable assurance of achieving desired control objectives and, based on the evaluation described above, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective at reaching that level of reasonable assurance.

Changes in Internal Control over Financial Reporting

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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, which was previously dismissed in part, 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. On May 6, 2019, the Court granted plaintiffs' motion and certified a class consisting of "All holders of common stock of the Female Health Company as of October 31, 2016 and their successors in interest, excluding the named defendants to the Action and any person, firm, trust, corporation or other entity related to or affiliated with any of the Defendants." The parties filed cross-motions for summary judgment on April 15, 2019 which are set for hearing on July 11, 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 5. Other Infor mation

Disclosure Pursuant to Item 1.01 of Form 8-K - Entry into a Material Definitive Agreement

On May 13, 2019, the Company entered into the Second Amendment to theCredit Agreement. The Second Amendment provides for reduced percentages to be used to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar 2019, a return to the current percentages to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar 2020 and increased percentages to be used to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar 2021 and thereafter until the loan has been repaid. The Second Amendment also provides for an increase in the repayment amount from 175% to 176.5% of the aggregate amount advanced. In addition, the Second Amendment provides for payments under the Residual Royalty Agreement to commence at the same time as they would have commenced prior to the Second Amendment. The Second Amendment also eliminates the Company’s option to draw up to an additional $2.0 million under the Credit Agreement depending on the Company entering into agreements to distribute FC2 in Brazil and South Africa as the Company has determined that it would not make such draws.

The foregoing is a summary description of certain terms of the Second Amendment and, by its nature, is incomplete. A copy of the Second Amendment is filed herewith as Exhibit 10.3 to this Quarterly Report on Form 10-Q and is incorporated herein by reference. All readers are encouraged to read the entire text of the Second Amendment.

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	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 154,000,000 shares (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on March 29, 2019).
3.9	Amended and Restated By-Laws (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on May 4, 2018).
4.1	Amended and Restated Articles of Incorporation, as amended (same as Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7 and 3.8).
4.2	Articles II, VII and XI of the Amended and Restated By-Laws (included in Exhibit 3.9).
10.1	Separation Agreement and General Release, dated as of March 27, 2019, between the Company and Charles T. Todd, Jr. (1) (2)

10.2	Veru Inc. 2018 Equity Incentive Plan (as amended and restated effective March 26, 2019) (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on March 29, 2019. (1)
10.3	Second Amendment to Credit Agreement & Amendment to Residual Royalty Agreement, dated as of May 13, 2019, among the Company, SWK Funding LLC and the financial institutions party thereto from time to time. (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 March 31, 2019, formatted in XBRL (Extensible Business Reporting Language): (1) the Unaudited Condensed Consolidated Balance Sheets, (2) the Unaudited Condensed Consolidated Statements of Operations, (3) the Unaudited Condensed Consolidated Statements of Stockholders' Equity, (4) the Unaudited Condensed Consolidated Statements of Cash Flows and (5) the Notes to the Unaudited Condensed Consolidated Financial Statements.

(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: May 15, 2019

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

DATE: May 15, 2019

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

Exhibit 10.1

SEPARATION AGREEMENT
AND GENERAL RELEASE

THIS SEPARATION AGREEMENT AND GENERAL RELEASE ("Agreement") is between Veru Inc. ("Company") and Charles T. Todd, Jr. ("Employee").

RECITALS

The Company and Employee desire to effect a final resolution and settlement of all matters and issues relating directly or indirectly to Employee's employment with the Company and Employee's March 27, 2019 resignation from that employment (the "Resignation Date"), and have arrived at a compromise of all such matters in this Agreement.

AGREEMENTS

1. Acknowledgment of Full Compensation. Employee acknowledges and agrees that, with the payment on March 29, 2019 by the Company to Employee of $11,995.83, gross, less ordinary tax withholding and all required deductions, and the payment on April 15, 2019 by the Company to Employee of $2,796.66, gross, less ordinary tax withholding and all required deductions, Employee has received from the Company all salary, fringe benefits (including without limitation by enumeration vacation pay, bonuses, and retirement plan contributions) and all other compensation and benefits owed by the Company to Employee through and including the Resignation Date, except for the reimbursement for outstanding business-related expenses Employee incurred on behalf of the Company, which shall be handled and reimbursed in accordance with the Company's expense reimbursement practices.

2. Consideration. Conditioned upon (i) Employee's signing of this Agreement and Employee's return of this Agreement to the Company, (ii) expiration of the seven day revocation period without revocation, (iii) Employee's properly executing and returning the attached acknowledgment form to the Company (Exhibit A) indicating Employee's decision not to revoke this Agreement and (iv) Employee's compliance with Employee's obligations under this Agreement, the Company shall:

(a) pay Employee a total gross separation payment of $143,950.00, less ordinary tax withholding and all required deductions, an amount representing the approximate equivalent of six (6) months' base salary, which shall be paid in twenty-four substantially equal installments. The first installment payment shall be made payable on the Company's next regularly scheduled payroll date following Employee's satisfaction of the above conditions and subsequent installments shall continue to be made on each of the next 23 regularly scheduled payroll dates;

(b) not contest any claim for unemployment insurance benefits filed by Employee after the Resignation Date; provided, however, that nothing in this Agreement shall prohibit the Company from responding truthfully to any inquiries from the unemployment insurance division of the pertinent state unemployment insurance agency. Employee acknowledges and agrees that it is the parties' intent that Employee shall not be eligible for unemployment insurance benefits during the twelve (12) month period following Employee's satisfaction of the conditions specified in this paragraph 2 because Employee will be receiving separation pay allocated to that

period of time. The Company reserves the right to challenge any application seeking benefits for any portion of the aforementioned twelve (12) month period; and

(c) permit (i) the part of the non-qualified stock option to purchase 280,000 shares of common stock issued to Employee on March 20, 2018 (the "March 2018 Stock Option") under the Company's 2017 Equity Incentive Plan that vested on March 20, 2019 (93,333 shares) to be exercised in accordance with the terms of the Company's 2017 Equity Incentive Plan and the applicable stock option grant agreement through March 20, 2020, (ii) the part of the March 2018 Stock Option that is scheduled to vest on March 20, 2020 (93,333 shares) to vest on such vesting date conditioned on Employee being available to provide transition consulting assistance pursuant to paragraph 17 of this Agreement through such vesting date and permit such part of such stock option, if it so vests, to be exercised in accordance with the terms of the Company's 2017 Equity Incentive Plan and the applicable stock option grant agreement through March 20, 2021, and (iii) the part of the non-qualified stock option to purchase 42,226 shares of common stock issued to Employee on January 2, 2019 (the "January 2019 Stock Option") under the Company's 2018 Equity Incentive Plan that is scheduled to vest on January 2, 2020 (42,226 shares) to vest on such vesting date conditioned on Employee being available to provide transition consulting assistance pursuant to paragraph 17 of this Agreement through such vesting date and permit such part of such stock option, if it so vests, to be exercised in accordance with the terms of the Company's 2018 Equity Incentive Plan and the applicable stock option grant agreement through January 2, 2021. Employee acknowledges and agrees that all other stock options issued to Employee under the Company's 2017 Equity Incentive Plan or the Company’s 2018 Equity Incentive Plan, including the remainder of the March 2018 Stock Option that is scheduled to vest and March 20, 2021 (93,334 shares total) are unvested, shall terminate as of the Resignation Date and may not be exercised.

The consideration specified in paragraph 2(a) shall be subject to ordinary tax withholding and all required deductions. The consideration specified in this paragraph 2 shall not be deemed "compensation" for purposes of any of the Company's qualified retirement plans or other benefit programs, and payment of this separation pay does not entitle Employee to any retirement plan contributions by the Company for Employee's benefit or account. This consideration is not an amount to which Employee is otherwise entitled, and constitutes additional consideration for Employee's release and waiver of potential claims identified in paragraph 5 below, including without limitation a potential claim for age discrimination under the Age Discrimination in Employment Act, and for the promises contained in paragraphs 13 and 17.

3. Confidentiality and Non-Disclosure. Employee agrees that this Agreement, and its terms and provisions, are strictly confidential and shall not be divulged or disclosed in any way to any person other than Employee's spouse, legal counsel, or tax advisor. Should Employee choose to divulge the terms and conditions of this Agreement to Employee's spouse, legal counsel, or tax advisor, Employee shall ensure that they will be similarly bound to keep the same confidential. A breach of this paragraph by Employee's spouse, legal counsel, or tax advisor shall be considered a breach of this paragraph by Employee.

4. Non-Admission of Liability. Neither this Agreement nor any action taken by the Company or Employee pursuant to it shall in any way be construed as an admission by the Company or Employee of any liability, wrongdoing, or violation of law, regulation, contract or

policy regarding any of the Company's or Employee's decisions and actions regarding the employment or separation from employment of Employee.

5. Release. For valuable consideration from the Company as stated above, Employee, for Employee and Employee's heirs, personal representatives, successors and assigns, hereby releases all claims of whatever nature that Employee may have against the Company, its affiliates, subsidiaries, predecessors, successors and assigns and its and their present, former or later insurers, agents, representatives, officers, administrators, directors, shareholders and employees (collectively "Releasees"), which arise out of or are in any manner based upon or related to the employment relationship between Employee and the Company, and the end of that relationship, and from all other claims or liabilities of any nature whatsoever which have arisen from any occurrence, transaction, omission or communication which transpired or occurred at any time before or on the date of this Agreement; provided, however, that this Agreement will not affect any existing obligations that the Company may have to indemnify Employee and will not prevent any party from asserting a claim against the other party for breach of this Agreement.

Without limitation to the foregoing, Employee specifically releases, waives and forever discharges the Releasees from and against all liabilities, claims, actions, demands, damages and costs of every nature, whether known or unknown, asserted or unasserted, which arise under the New Hampshire Protective Legislation Law; New Hampshire Unemployment Compensation Law; New Hampshire Uniform Trade Secrets Act; New Hampshire Whistleblowers' Protection Act; New Hampshire Minimum Wage Act; New Hampshire Public Employee Labor Relations Act; New Hampshire Safety and Health of Employees Law; New Hampshire Law Against Discrimination; Florida Civil Rights Act; Florida Whistleblower Protection Act; Florida Workers' Compensation Retaliation provision, Florida Minimum Wage Act; Article X, Section 24 of the Florida Constitution; Title VII of the Civil Rights Act of 1964, as amended; the Genetic Information Nondiscrimination Act; the Age Discrimination in Employment Act (29 U.S.C. § 621 et seq.); the Americans With Disabilities Act, as amended; Section 1981 of U.S.C. Title 42; National Labor Relations Act; Employee Retirement Income Security Act of 1974; the Equal Pay Act; state or federal parental, family and medical leave acts; the Uniformed Services Employment and Reemployment Rights Act (USERRA), or any other local, state, or federal military and/or veterans rights act, or any other claim based on veteran status; or arising under any other local, state or federal statute, ordinance, regulation or order, or which involve a claim or action for wrongful discharge, breach of contract (express or implied) and/or any other tort or common law cause of action.

6. No Limitation of Rights. The waiver and release in paragraph 5 does not affect those rights or claims that arise after the execution of this Agreement. Nor does the waiver and release affect those rights or claims that cannot be waived by law. While nothing contained in this Agreement shall be interpreted to prevent the United States Equal Employment Opportunity Commission ("EEOC") or equivalent state or local agency, the United States Securities and Exchange Commission ("SEC"), the National Labor Relations Board ("NLRB"), the Occupational Safety and Health Administration ("OSHA"), or any other federal, state or local agency or commission from investigating and pursuing any matter which it deems appropriate, Employee understands and agrees that, by signing this Agreement, Employee is waiving any and all rights Employee may have to reinstatement, damages, remedies, costs, attorney's fees or other relief as to any claims Employee has released and any rights Employee has waived as a result of Employee's execution of this Agreement. Nothing contained in this Agreement is intended to limit Employee's

right or ability to file a charge with the EEOC or equivalent state or local agency, SEC, NLRB, OSHA, or any other federal, state or local agency or commission, or to receive an award for providing information to these agencies. The EEOC or equivalent state or local agency, SEC, NLRB, OSHA, and any other federal, state or local agency or commission have the authority to carry out their statutory duties by investigating the charge, issuing a determination, filing a lawsuit in court in their own name, or taking any other action authorized under law. Employee retains the right to testify, assist or participate in any such action. Employee retains the right to communicate with the EEOC or equivalent state or local agency, SEC, NLRB, OSHA, or any other federal, state or local agency or commission and such communication can be initiated by Employee or in response to the government and is not limited by the confidentiality or non-disparagement obligations contained in paragraphs 3, 11, 12, 22 and 27 of this Agreement.

7. No Reinstatement, Reemployment or Rehire. Employee expressly declines reinstatement, reemployment or rehire by the Company and waives all rights to claim such relief. If Employee should apply for employment with the Company or with any of its related entities in the future, Employee agrees that Employee has no entitlement to such employment and may be denied employment on the basis of this Agreement.

8. No Representations as Employee. After the Resignation Date, Employee agrees that Employee will not represent Employee as being a current employee, officer, attorney, agent or representative of Company for any purpose. Within five business days of the Resignation Date, Employee specifically agrees to update any and all social media accounts the Employee accesses, uses or maintains to remove any reference to Employee being a current employee of the Company. For purposes of this paragraph 8, social media accounts include, without limitation, Facebook, LinkedIn and Twitter.

9. No Pending Matters. Employee warrants and represents that Employee has not filed any pending complaint, charge, claim or grievance concerning Employee's compensation, separation from employment or terms and conditions of employment against the Company with any local, state or federal agency, court or commission, and that if any agency, commission or court assumes jurisdiction of any such complaint or charge on behalf of Employee, Employee will immediately request that agency, commission, or court to dismiss such proceeding with prejudice.

10. No Injuries. Employee acknowledges and agrees that Employee has reported to Company management any and all workplace injuries (if any) sustained by Employee during Employee's employment with the Company and that Employee is not aware of any facts that would give rise to a worker's compensation claim that has not already been properly reported.

11. Non-Disparagement. Employee agrees to maintain a positive and constructive attitude and demeanor towards the Company, its directors, officers, shareholders, employees and agents, and agrees to refrain from making derogatory comments or statements of a negative nature about the Company, its directors, officers, shareholders, employees and agents, to anyone, including, but not limited to, current and former Company customers, employees, suppliers, vendors, and referral sources. Nothing contained in this paragraph shall be construed to prohibit Employee from providing truthful testimony in any administrative, state or federal proceeding or cooperating in an investigation conducted by the EEOC or equivalent state or local agency, SEC, NLRB, OSHA, or any other federal, state or local agency or commission. The Company agrees to

cause its officers to maintain a positive and constructive attitude and demeanor towards Employee and to refrain from making derogatory comments or statements of a negative nature about Employee.

12. Restrictive Covenant Obligations. Employee reaffirms that Employee will abide by the confidentiality obligations in Section 7 of the Executive Employment Agreement between the parties dated as of January 2, 2019 (the "Employment Agreement"); the non-competition, non-solicitation and non-interference obligations in Section 8 of the Employment Agreement; the intellectual property obligations in Section 13 of the Employment Agreement; and the security and exit obligations in Section 14 of the Employment Agreement (collectively, the "Restrictive Covenant Obligations"). Employee agrees that the Restrictive Covenant Obligations are reasonable as to their terms and are fully enforceable against him. Employee represents and agrees that Employee has not to-date breached any of the Restrictive Covenant Obligations.

13. Trade Secrets.

(a) Protection of Trade Secrets. Notwithstanding the provisions of Section 7 of the Employment Agreement, the parties agree that nothing in this Agreement nor in Section 7 of the Employment Agreement shall be construed to limit or negate any statutory or common law of torts or trade secrets, where such law provides Company with broader protection than that provided in this Agreement or in Section 7 of the Employment Agreement. After termination of employment, Employee shall not use or disclose the trade secrets of Company as long as they remain trade secrets.

(b) Notification of Trade Secret Rights. Employee will be immune from criminal and civil liability under any federal or state trade secret law for any disclosure of the Company's trade secret(s) that is made (i) in confidence to an attorney or to a federal, state or local government official solely for the purpose of reporting or investigating a suspected violation of law and/or (ii) in a complaint or other document filed in a lawsuit or other proceeding, provided such filing is made under seal. If Employee files a lawsuit alleging retaliation by the Company for reporting a suspected violation of law, Employee may disclose the relevant trade secret to Employee's attorney, and may use the trade secret information in the court proceeding provided (i) any filing containing the trade secret is made under seal; and (ii) Employee does not disclose the trade secret, except pursuant to a court order.

14. Specific Performance. Employee acknowledges and agrees that irreparable injury to Company may result in the event that Employee breaches any covenant in this Agreement, and that the remedy at law for the breach of any such covenant will be inadequate. If Employee engages in any act in violation of any provision of paragraph 13, Employee agrees that Company shall be entitled, in addition to such other remedies and damages that may be available to it by law or under this Agreement, to injunctive relief to enforce such provisions without the necessity of posting a bond.

15. Return of Company Property. Employee represents and agrees that Employee has returned any and all Company records and files and any copies thereof (whether in electronic or paper form), keys, keyless entry cards, documents, confidential or proprietary information, computer equipment, CDs, computer software programs, vehicles, credit cards and any other

property owned by or belonging to the Company in Employee's possession or under Employee's control on or after the Resignation Date without any originals or copies being kept by Employee or conveyed to any other person or entity. Employee acknowledges and agrees that Employee will use reasonable care to properly ship any Company property back to the Company via a shipment method that does not cause damage or destruction to Company property. Employee also agrees to cooperate with any request by the Company to review the Employee's personal electronic device(s) for purposes of removing any Company data. Employee acknowledges that, to the extent permitted by law, Employee will be liable to Company for the Company's costs incurred in enforcing its rights under this paragraph 15, including Company's reasonable attorneys' fees.

16. Waiver of Reimbursement of COBRA Premiums. Employee waives any right to receive reimbursement by the Company for any and all COBRA premiums paid by Employee, as stated under section 5.2(a)(iv) of the Employment Agreement, should Employee elect to continue Employee's healthcare coverage.

17. Transition Consulting Assistance. As a precondition for receiving certain benefit(s) specified in paragraph 2(c) above, following execution of this Agreement, Employee agrees that Employee will make himself available at reasonable times and use his best efforts to answer any of the Company's questions or to otherwise assist the Company in making an orderly transition. Without limitation to the foregoing, Employee acknowledges and agrees that he will use his best efforts to answer any of the Company's inquiries concerning matters for which he was responsible during his active employment with the Company. Employee further acknowledges and agrees that he shall receive no additional consideration for time spent answering the Company's questions or otherwise providing such assistance as described in this paragraph 17, as the consideration referenced in paragraph 2(c) above represents adequate consideration for his answering such questions and otherwise providing such assistance.

18. Binding Agreement. This Agreement shall be binding upon Employee and upon Employee's heirs, administrators, representatives, executors, successors and assigns and shall inure to the benefit of the Releasees and to their heirs, administrators, representatives, executors, successors and assigns.

19. Jurisdiction and Venue. This Agreement shall be governed by and construed in accordance with the laws of the State of Florida. Any controversy between Company and Employee arising under or relating to this Agreement shall be determined by the Circuit Court of Miami-Dade County, Florida, and the parties agree not to present any such controversy to any other court or forum. The parties expressly consent to the exclusive jurisdiction of the Circuit Court of Miami-Dade County, Florida.

20. Severability. It is understood and agreed that the provisions of this Agreement shall be deemed severable, and the invalidity or unenforceability of any one or more of the provisions herein shall not affect the validity and enforceability of the other provisions herein.

21. Complete and Exclusive Agreement. The parties understand and agree that this Agreement is final and binding and constitutes the complete and exclusive statement of the terms and conditions of settlement, that no representations or commitments were made by the parties to induce this Agreement other than as expressly set forth herein and that this Agreement is fully

understood by the parties. This Agreement may not be modified or supplemented except by a subsequent written agreement signed by the party against whom enforcement is sought.

22. Effect of Termination. Employee acknowledges and agrees that the Employment Agreement has terminated and that all obligations imposed on either party under the Employment Agreement have ceased effective the date of Employee's termination from employment, except as otherwise expressly provided in the Employment Agreement. Notwithstanding the foregoing, Employee agrees that Sections 5.8(a), 5.8(b), 6, 7, 7.1(a), 7.1(b), 7.1(c), 7.1(d), 8.1, 8.2, 8.3, 8.4, 8.5, 8.6, 8.7, 9, 10, 11, 13.1, 13.2, 13.3, 13.4, 14.1, 14.2, 15, 16, 17, 18, 19, 20, 21, 22.1, 22.2, 22.3, 22.4, 22.5, 23, 24, 26, 27, 28, and 29 of the Employment Agreement shall continue in full force and effect notwithstanding the termination of Employee's employment with the Company and the termination of the Employment Agreement.

23. Acknowledgement of Resignation. By signing this Agreement, Employee acknowledges that Employee has resigned from the position of Chief Executive Officer of The Female Health Company Division of the Company, and all other positions Employee holds with respect to the Company or any subsidiary thereof, effective as of the Resignation Date.

24. Complete and Exclusive Agreement. The parties understand and agree that this Agreement (with Exhibit A attached hereto) is final and binding and, excepting solely the Restrictive Covenant Obligations referenced in paragraph 12 and the provisions of the Employment Agreement referenced in paragraph 22, constitutes the complete and exclusive statement of the terms and conditions of settlement, that no representations or commitments were made by the parties to induce this Agreement other than as expressly set forth herein and that this Agreement is fully understood by the parties. This Agreement may not be modified or supplemented except by a subsequent written agreement signed by the party against whom enforcement is sought.

25. Consideration Period. Employee represents and agrees that Employee has had the opportunity and time to consult with legal counsel concerning the provisions of this Agreement, and that the Company has given Employee up to twenty-one (21) days to consider this Agreement. Any changes made to this Agreement before Employee signs it, whether material or immaterial, will not restart the 21-day consideration period. Employee understands and agrees that if Employee does not return the signed Agreement by the close of business on the 22nd day after Employee receives this Agreement, this Agreement will be automatically revoked by the Company and amounts payable hereunder shall be forfeited. Employee further understands and agrees that if Employee does not return the signed Exhibit A by the close of business on the 10th day after the date on which Employee signs the Agreement, this Agreement will be automatically revoked by the Company and amounts payable hereunder shall be forfeited.

26. Employee Right to Revoke. Employee may revoke the Agreement within seven (7) calendar days of Employee's signing of the Agreement. For this revocation to be effective, written notice must be received by Philip R. Greenberg, Executive Vice President – Legal, Veru Inc., 4400 Biscayne Boulevard, Suite 888, Miami, Florida 33137, no later than the seventh calendar day after Employee signs the Agreement.

27. Company Right to Revoke. The parties understand and agree that this Agreement will not be effective until the Company's signing of this Agreement, and that the Company has the

right to revoke its offer at any time prior to the Company's signing of this Agreement, which revocation may be made for any reason including, without limitation, Employee's making of derogatory comments or statements of a negative nature about the Company, its directors, officers, shareholders, employees and agents to anyone, including, but not limited to, current and former Company customers, employees, suppliers, vendors, and referral sources.

28. Counterparts. This Agreement may be executed in one or more counterparts, all of which shall be considered one and the same agreement. Signatures to this Agreement transmitted by facsimile, by electronic mail in portable document format (.pdf) form, or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document will have the same effect as physical delivery of the paper document bearing the original signature.

29. Code Section 409A. This Agreement is intended to satisfy the requirements for the deferral of compensation under section 409A of the Internal Revenue Code of 1986, as amended (the "Code") or an exemption thereunder. All terms used in this Agreement shall be interpreted to the maximum extent possible to satisfy Code section 409A. Notwithstanding anything herein to the contrary, payments provided under this Agreement may be made upon a permissible payment event in a manner that complies with Code section 409A or an applicable exemption. Any right to a series of installment payments pursuant to this Agreement is to be treated as a right to a series of separate payments. Any separate payment or benefit under this Agreement or otherwise that may be excluded from Code section 409A as separation pay, a short-term deferral or any other applicable exemption or provision of Code section 409A shall be excluded from Code section 409A to the maximum extent possible. Notwithstanding anything herein to the contrary, the Company may amend this Agreement without the consent of Employee to add, alter or remove any provision that the Company deems necessary, appropriate or advisable to comply with Code section 409A. If there is more than one way to add, alter or remove a provision to comply with Code section 409A, the Company shall have the discretion to choose the alternative it believes to be in the best interest of Employee and the Company.

30. Acknowledgment. The undersigned parties acknowledge and agree that they have carefully read the foregoing document, that a copy of the document was available to them prior to execution, that they understand its contents including its release of claims, that they have been given the opportunity to ask any questions concerning the Agreement and its contents, and have signed this Agreement as their free and voluntary act.

IN WITNESS WHEREOF, the parties herein executed this Separation Agreement and General Release as of the date appearing next to their signatures.

Veru Inc.

Date: April 18, 2019

By: /s/ Mitchell S. Steiner

Its: Chief Executive Officer and President

CAUTION: THIS IS A RELEASE. THE COMPANY HEREBY ADVISES EMPLOYEE TO CONSULT WITH AN ATTORNEY AND READ IT BEFORE SIGNING. THIS AGREEMENT MAY BE REVOKED IN WRITING BY EMPLOYEE WITHIN SEVEN (7) CALENDAR DAYS OF EMPLOYEE'S EXECUTION OF THE DOCUMENT.

Date: April 18, 2019

/s/ Charles T. Todd, Jr.

Charles T. Todd, Jr.

Exhibit 10.3

SECOND AMENDMENT TO
CREDIT AGREEMENT & AMENDMENT TO RESIDUAL ROYALTY AGREEMENT

THIS SECOND AMENDMENT TO CREDIT AGREEMENT AND AMENDMENT TO RESIDUAL ROYALTY AGREEMENT (this " **Amendment**"), dated as of May 13, 2019, is entered into by and among **VERU INC.**, a Wisconsin corporation ("**Borrower**"), each of the undersigned financial institutions (individually each a "**Lender**" and collectively "**Lenders**") and **SWK FUNDING LLC,** a Delaware limited liability company, in its capacity as administrative agent for the other Lenders (in such capacity, "**Agent**").

RECITALS

WHEREAS, Borrower, Agent and Lenders entered into that certain Credit Agreement dated as March 5, 2018 (as the same may be amended, modified or restated from time to time, being hereinafter referred to as the "**Credit Agreement**");

WHEREAS, Borrower and Agent entered into that certain Residual Royalty Agreement dated as of March 5, 2018, (as the same may be amended, modified or restated from time to time, being hereinafter referred to as the "**Royalty Agreement**"); and

WHEREAS, Borrower, Agent and Lenders, desire to amend the Credit Agreement and the Royalty Agreement as set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the premises herein contained and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties, intending to be legally bound, agree as follows:

ARTICLE I

Definitions

1.1 Capitalized terms used in this Amendment are defined in the Credit Agreement or the Royalty Agreement, as applicable, as each is amended hereby, unless otherwise stated.

ARTICLE II

Amendments

2.1 **Amendments to Credit Agreement**.

2.1.1 **Amendments to Section 1.1**. Effective as of the date hereof, Section 1.1 of the Credit Agreement is hereby amended as follows:

(a) The definition of "Revenue-Based Cap" is amended and restated to read as follows:

"Revenue-Based Cap means, as of any date of determination, an amount equal to (i) 1.765 multiplied by (ii) the aggregate amount of the Term Loan actually advanced by Lenders pursuant to Section 2.2 hereof on or prior to such date."

(b) The definitions of "Subsequent Term Loan A" and "Subsequent Term Loan B" are deleted in their entirety, and any reference to such terms in the Credit Agreement or any other Loan Document shall be deemed to be a reference to the Term Loan as made on the Closing Date.

(c) The definition of "Term Loan" is amended and restated to read as follows:

"Term Loan has the meaning set forth in Section 2.1."

(d) The definition of "Term Loan Commitment" is amended and restated to read as follows:

"Term Loan Commitment means $10,000,000."

2.1.2 Amendment to Section 2.1. Effective as of the date hereof, Section 2.1 of the Credit Agreement is amended and restated in its entirety to read as follows:

"2.1 Term Loan Commitments.

On and subject to the terms and conditions of this Agreement, each Lender, severally and for itself alone, agrees to make a multi-draw term loan to Borrower (each such loan, individually and collectively, a "Term Loan") in an amount equal to such Lender's applicable Pro Rata Term Loan Share of the Term Loan Commitment. The Commitments of Lenders to make any portion of the Term Loan shall terminate concurrently with the making of such portion of the Term Loan, such portion terminated to equal the amount of such Term Loan. The Loan is not a revolving credit facility, and therefore any amount thereof that is repaid or prepaid by Borrower, in whole or in part, may not be re-borrowed."

2.1.3 Amendment to Section 2.2. Effective as of the date hereof, Section 2.2 of the Credit Agreement is amended and restated in its entirety to read as follows:

"2.2 Loan Procedures

On the Closing Date, Lenders advanced to Borrower an amount equal to Ten Million and No/100 Dollars ($10,000,000). Pursuant to that certain Second Amendment to Credit Agreement and Amendment to Residual Royalty Agreement, dated as of May 13, 2019, Agent, Lenders and Borrower agreed to terminate the availability of the "Subsequent Term Loan A" and "Subsequent Term Loan B" (as such terms were defined in this Agreement prior to giving effect to such Amendment)."

2.1.4 **Amendment to Section 2.3**. Effective as of the date hereof, Section 2.3 of the Credit Agreement is amended and restated in its entirety to read as follows:

"2.3 Commitments Several.

The failure of any Lender to make the initial Term Loan on the Closing Date shall not relieve any other Lender of its obligation (if any) to make a Loan on the applicable date, but no Lender shall be responsible for the failure of any other Lender to make any Term Loan to be made by such other Lender."

2.1.5 **Amendment to Section 2.9.1(a)**. Effective as of the date hereof, Section 2.9.1(a)(i) of the Credit Agreement is amended and restated in its entirety to read as follows:

"(i) the aggregate Revenue-Based Payments payable during the period commencing as of January 1 of the calendar year of which such Fiscal Quarter is part, through the end of such Fiscal Quarter (such elapsed portion of the Fiscal Year, the "Elapsed Period"), calculated as,

(A) if the Product Revenue for the twelve (12) month period ended as of the last day of such Fiscal Quarter is less than $10,000,000, then thirty-two and one-half of one percent (32.50%) of Product Revenue during the Elapsed Period; or

(B) if the Product Revenue for the twelve (12) month period ended as of the last day of such Fiscal Quarter is equal to or greater than $10,000,000, then:

(1) as it relates to each Fiscal Quarter in the 2019 calendar year, the sum of:

(aa) Twelve and one-half of one percent (12.50%) of Product Revenue during the Elapsed Period up to and including $12,500,000; plus

(bb) Five percent (5.00%) of Product Revenue during the Elapsed Period greater than $12,500,000; minus;

(2) as it relates to each Fiscal Quarter in the 2020 calendar year, the sum of:

(aa) Twenty-five percent (25.00%) of Product Revenue during the Elapsed Period up to and including $12,500,000; plus

(bb) Ten percent (10.00%) of Product Revenue during the Elapsed Period greater than $12,500,000; minus; or

(3) as it relates to the Fiscal Quarter ending March 31, 2021 and for each Fiscal Quarter thereafter, the sum of:

(aa) Thirty percent (30.00%) of Product Revenue during the Elapsed Period up to and including $12,500,000; plus

(bb) Twenty percent (20.00%) of Product Revenue during the Elapsed Period greater than $12,500,000; minus"

2.1.6 Amendment to Section 5. Effective as of the date hereof, the introductory sentence in Section 5 of the Credit Agreement is amended and restated to read as follows:

"To induce Agent and Lenders to enter into this Agreement and to induce Lenders to make the Loan hereunder, Borrower represents and warrants to Agent and Lenders, as of the Closing Date that:"

2.1.7 Amendment to Annex I. Effective as of the date hereof, Annex I to the Credit Agreement is amended and restated to read as follows:

ANNEX I

Commitments and Pro Rata Term Loan Shares

Lender	Commitment	Pro Rata Term Loan Share
SWK Funding LLC	$10,000,000	100%

2.2 Amendments to Royalty Agreement.

2.2.1 Amendment to Section 1.1. Effective as of the date hereof, the definition of "Residual Royalty Commencement Date" in Section 1.1 of the Royalty Agreement is hereby amended and restated to read as follows:

"'Residual Royalty Commencement Date" means, the date on which Product Revenue received by the Company would have otherwise resulted in the payment in full of the Deemed Residual Royalty Return Premium (as defined herein) pursuant to the payment mechanics set forth in Section 2.9.1 of the Credit Agreement without taking into account the amendments to such Section 2.9.1 as set forth in that certain Second Amendment to Credit Agreement and Amendment to Residual Royalty Agreement dated as of May 13, 2019. For the avoidance of doubt, because the Deemed Residual Royalty Return Premium will be calculated without giving effect to the amendments to Section 2.9.1 as set forth in that certain Second Amendment to Credit Agreement and Amendment to Residual Royalty

Agreement dated as of May 13, 2019, SWK may not have actually received an amount equal to the Deemed Residual Royalty Return Premium on such date pursuant to Section 2.9.1 as of the Residual Royalty Commencement Date."

2.2.2 Addition to Section 1.1. Effective as of the date hereof, the following definitions are hereby added to Section 1.1 of the Royalty Agreement:

"'Deemed Residual Royalty Return Premium' means, as of any date of determination, an amount equal to the sum (if positive) of: (a) Residual Royalty Revenue-Based Cap, minus (b) all Revenue-Based Payments that would have been paid to Agent, for the benefit of Lenders, on or prior to such date pursuant to the payment mechanics set forth in Section 2.9.1 of the Credit Agreement without taking into account the amendments to such Section 2.9.1 as set forth in that certain Second Amendment to Credit Agreement and Amendment to Residual Royalty Agreement dated as of May 13, 2019, minus (c) the outstanding principal amount of the Loans as of such date."

"'Residual Royalty Revenue-Based Cap' means, as of any date of determination, an amount equal to (i) 1.75 multiplied by (ii) the aggregate amount of the Term Loan actually advanced by Lenders pursuant to Section 2.2 of the Credit Agreement on or prior to such date."

2.2.3 Amendment to Section 2.1(a). Effective as of the date hereof, Section 2.1(a) of the Royalty Agreement is amended and restated in its entirety to read as follows:

"(a) Commencing as of the Residual Royalty Commencement Date, the Company promises to pay to SWK an amount based on a percentage of the aggregate of (without duplication) the Net Sales, Royalties and any other income or revenue realized by the Company solely related to or arising from the FC2 Product, calculated in accordance with GAAP (collectively, the "Product Revenue") in each Fiscal Quarter (or, in the case of the initial Fiscal Quarter in which the Residual Royalty Commencement Date occurs, partial Fiscal Quarter) (the "Revenue-Based Payment"). The Revenue-Based Payment with respect to each Fiscal Quarter shall be payable on the Payment Date next following the end of such Fiscal Quarter. The Revenue-Based Payment with respect to each Fiscal Quarter shall be calculated as, five percent (5.00%) of Product Revenue during the applicable Fiscal Quarter (or portion thereof during the first Fiscal Quarter). For purposes of clarity, (i) Product Revenue pertaining to any Fiscal Quarter (or portion thereof with respect to the Fiscal Quarter containing the Residual Royalty Commencement Date) arising prior to the Residual Royalty Commencement Date, and all payments relating thereto, shall be payable in accordance with the terms of the Credit Agreement, (ii) all Product Revenue pertaining to the portion of the Fiscal Quarter containing the Residual Royalty Commencement Date occurring after the Residual Royalty Commencement Date and all Product Revenue pertaining to any Fiscal Quarters thereafter until the date on which the Obligations under the Credit Agreement are Paid in Full (the "Payoff Date"), and all payments

relating thereto, shall be payable in accordance with the terms of both the Credit Agreement and this Agreement, on a separate basis, and (iii) all Product Revenue pertaining to the portion of the Fiscal Quarter containing the Payoff Date occurring after the Payoff Date and all Product Revenue pertaining to any Fiscal Quarters thereafter, and all payments relating thereto, shall be payable in accordance with the terms of this Agreement. For further clarity, (i) each dollar of Product Revenue pertaining to the period between the Residual Royalty Commencement Date and the Payoff Date, will be subject to both the obligation to pay a percentage thereof to the Agent under the Credit Agreement and the obligation to pay a percentage thereof to SWK as a Revenue-Based Payment hereunder, and (ii) in no event will any amounts paid under the Credit Agreement satisfy any portion of the Company's obligations under this Agreement nor shall any amounts paid under this Agreement satisfy any portion of the Company's obligations under the Credit Agreement."

Article III

Conditions Precedent

3.1 Conditions Precedent. The effectiveness of this Amendment is subject to the satisfaction of the following conditions precedent in a manner satisfactory to Agent, unless specifically waived in writing by Agent in its sole discretion:

(A) Agent shall have received this Amendment duly executed by Borrower.

(B) The representations and warranties contained herein and in the Credit Agreement and the other Loan Documents, as each is amended hereby, shall be true and correct as of the date hereof, as if made on the date hereof, except for such representations and warranties as are by their express terms limited to a specific date.

(C) No Default or Event of Default under the Credit Agreement, as amended hereby, shall have occurred and be continuing, unless such Default or Event of Default has been otherwise specifically waived in writing by Agent.

(D) All corporate proceedings taken in connection with the transactions contemplated by this Amendment and all documents, instruments and other legal matters incident thereto shall be satisfactory to Agent; and Borrower shall provide to Agent an officer's certificate with resolutions in form and substance acceptable to Agent.

Article IV

No Waiver, Ratifications, Representations and Warranties

4.1 No Waiver. Nothing contained in this Amendment or any other communication between Agent, any Lender, Borrower or any other Loan Party shall be a waiver of any past, present or future violation, Default or Event of Default of Borrower under the Credit Agreement or any Loan Document. Agent and each Lender hereby expressly reserves any rights, privileges and remedies under the Credit Agreement and each Loan Document that Lender may have with respect to any violation, Default or Event of Default, and any failure by Agent or any Lender to

exercise any right, privilege or remedy as a result of the violations set forth above shall not directly or indirectly in any way whatsoever either (i) impair, prejudice or otherwise adversely affect the rights of Agent or any Lender, except as set forth herein, at any time to exercise any right, privilege or remedy in connection with the Credit Agreement or any Loan Document, (ii) amend or alter any provision of the Credit Agreement or any Loan Document or any other contract or instrument or (iii) constitute any course of dealing or other basis for altering any obligation of Borrower or any other Loan Party or any rights, privilege or remedy of Agent or any Lender under the Credit Agreement or any Loan Document or any other contract or instrument. Nothing in this Amendment shall be construed to be a consent by Agent or any Lender to any prior, existing or future violations of the Credit Agreement or any Loan Document.

4.2 **Ratifications.** The terms and provisions set forth in this Amendment shall modify and supersede all inconsistent terms and provisions set forth in the Credit Agreement and the other Loan Documents, and, except as expressly modified and superseded by this Amendment, the terms and provisions of the Credit Agreement and the other Loan Documents are ratified and confirmed and shall continue in full force and effect. Borrower, the other Loan Parties, Lenders and Agent agree that the Credit Agreement and the other Loan Documents, as amended hereby, shall continue to be legal, valid, binding and enforceable in accordance with their respective terms. Borrower and the other Loan Parties agrees that this Amendment is not intended to and shall not cause a novation with respect to any or all of the Obligations.

4.3 **Representations and Warranties.** Borrower hereby represents and warrants to Agent and Lenders that (a) the execution, delivery and performance of this Amendment, any and all other Loan Documents executed and/or delivered in connection herewith have been authorized by all requisite action (as applicable) on the part of Borrower and will not violate the organizational documents of Borrower or such Loan Parties; (b) Borrower's directors have authorized the execution, delivery and performance of this Amendment any and all other Loan Documents executed and/or delivered in connection herewith; (c) the representations and warranties contained in the Credit Agreement, as amended hereby, and any other Loan Document are true and correct on and as of the date hereof and on and as of the date of execution hereof as though made on and as of each such date (except to the extent such representations and warranties expressly relate to an earlier date); (d) no Default or Event of Default under the Credit Agreement, as amended hereby, has occurred and is continuing; (e) Loan Parties are in full compliance in all material respects with all covenants and agreements contained in the Credit Agreement and the other Loan Documents, as amended hereby; and (f) except as disclosed to Agent, Borrower has not amended its organizational documents since the date of the Credit Agreement.

Article V

Miscellaneous Provisions

5.1 **Survival of Representations and Warranties.** All representations and warranties made in the Credit Agreement or any other Loan Document, including, without limitation, any document furnished in connection with this Amendment, shall survive the execution and delivery of this Amendment and the other Loan Documents, and no investigation by Agent or any Lender or any closing shall affect the representations and warranties or the right of Agent and each Lender to rely upon them.

5.2 Reference to Credit Agreement. Each of the Credit Agreement and the other Loan Documents, and any and all other Loan Documents, documents or instruments now or hereafter executed and delivered pursuant to the terms hereof or pursuant to the terms of the Credit Agreement, as amended hereby, are hereby amended so that any reference in the Credit Agreement and such other Loan Documents to the Credit Agreement shall mean a reference to the Credit Agreement, as amended hereby.

5.3 Expenses of Agent. As provided in the Credit Agreement, Borrower agrees to pay on demand all costs and expenses incurred by Agent, or its Affiliates, in connection with the preparation, negotiation, and execution of this Amendment and the other Loan Documents executed pursuant hereto and any and all amendments, modifications, and supplements thereto, including, without limitation, the reasonable costs and fees of legal counsel, and all costs and expenses incurred by Agent and each Lender in connection with the enforcement or preservation of any rights under the Credit Agreement, as amended hereby, or any other Loan Documents, including, without, limitation, the reasonable costs and fees of legal counsel.

5.4 Severability. Any provision of this Amendment held by a court of competent jurisdiction to be invalid or unenforceable shall not impair or invalidate the remainder of this Amendment and the effect thereof shall be confined to the provision so held to be invalid or unenforceable.

5.5 Successors and Assigns. This Amendment is binding upon and shall inure to the benefit of Agent and each Lender and Borrower and their respective successors and assigns, except that no Loan Party may assign or transfer any of its rights or obligations hereunder without the prior written consent of Agent.

5.6 Counterparts. This Amendment may be executed in one or more counterparts, each of which when so executed shall be deemed to be an original, but all of which when taken together shall constitute one and the same instrument. This Amendment may be executed by facsimile or electronic (.pdf) transmission, which facsimile or electronic (.pdf) signatures shall be considered original executed counterparts for purposes of this Section 5.6, and each party to this Amendment agrees that it will be bound by its own facsimile or electronic (.pdf) signature and that it accepts the facsimile or electronic (.pdf) signature of each other party to this Amendment.

5.7 Effect of Waiver. No consent or waiver, express or implied, by Agent to or for any breach of or deviation from any covenant or condition by Borrower shall be deemed a consent to or waiver of any other breach of the same or any other covenant, condition or duty.

5.8 Headings. The headings, captions, and arrangements used in this Amendment are for convenience only and shall not affect the interpretation of this Amendment.

5.9 Applicable Law. THE TERMS AND PROVISIONS OF SECTIONS 10.17 (GOVERNING LAW) AND 10.18 (FORUM SELECTION; CONSENT TO JURISDICTION) OF THE CREDIT AGREEMENT ARE HEREBY INCORPORATED HEREIN BY REFERENCE, AND SHALL APPLY TO THIS AMENDMENT *MUTATIS MUTANDIS* AS IF FULLY SET FORTH HEREIN.

5.10 **Final Agreement.** THE CREDIT AGREEMENT AND THE OTHER LOAN DOCUMENTS, EACH AS AMENDED HEREBY, REPRESENT THE ENTIRE EXPRESSION OF THE PARTIES WITH RESPECT TO THE SUBJECT MATTER HEREOF ON THE DATE THIS AMENDMENT IS EXECUTED. THE CREDIT AGREEMENT AND THE OTHER LOAN DOCUMENTS, AS AMENDED HEREBY, MAY NOT BE CONTRADICTED BY EVIDENCE OF PRIOR, CONTEMPORANEOUS OR SUBSEQUENT ORAL AGREEMENTS OF THE PARTIES. THERE ARE NO UNWRITTEN ORAL AGREEMENTS BETWEEN THE PARTIES. NO MODIFICATION, RESCISSION, WAIVER, RELEASE OR AMENDMENT OF ANY PROVISION OF THIS AMENDMENT SHALL BE MADE, EXCEPT BY A WRITTEN AGREEMENT SIGNED BY BORROWER AND AGENT.

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Part 1.

IN WITNESS WHEREOF, this Amendment has been executed and is effective as of the date first written above.

BORROWER:

VERU INC.,
a Wisconsin corporation

By:
Name:
Title: _____

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: May 15, 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: May 15, 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 March 31, 2019 fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934 and information contained in that Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 15, 2019

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

Date: May 15, 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.