**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 June 30, 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**<br>**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)

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

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

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

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

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

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

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

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

As of August 5, 2019, the registrant had 65,038,247 shares of $0.01 par value common stock outstanding.

VERU INC.
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## FORWARD LOOKING STATEMENTS

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

- potential delays in the timing of and results from clinical trials and studies and the risk that such results will not support marketing approval and commercialization;
- potential delays in the timing of any submission to the U.S. Food and Drug Administration (the “FDA”) and in regulatory approval of products under development;
- risks related to our ability to obtain sufficient financing on acceptable terms when needed to fund product development and our operations;
- risks related to the development of our product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market;
- product demand and market acceptance;
- some of our products are in development and we may fail to successfully commercialize such products;
- risks related to intellectual property, including the uncertainty of obtaining intellectual property protections and in enforcing them, the possibility of infringing a third party’s intellectual property, and licensing risks;
- competition from existing and new competitors including the potential for reduced sales, pressure on pricing and increased spending on marketing;
- risks related to compliance and regulatory matters, including costs and delays resulting from extensive government regulation and reimbursement and coverage under healthcare insurance and regulation;
- risks inherent in doing business on an international level, including currency risks, regulatory requirements, political risks, export restrictions and other trade barriers;
- the disruption of production at our manufacturing facilities and/or of our ability to supply product due to raw 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, and the risk that we may not prevail in any appeal of the summary judgment for the Company in the class action litigation relating to our acquisition of Aspen Park Pharmaceuticals, Inc.;
- government contracting risks, including the appropriations process and funding priorities, potential bureaucratic delays in awarding contracts, process errors, politics or other pressures, and the risk that government tenders and contracts may be subject to cancellation, delay, restructuring or substantial delayed payments;
- a governmental tender award, including our 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

| | June 30, 2019 | September 30, 2018 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash | $ 8,039,116 | $ 3,759,509 |
| Accounts receivable, net | 4,766,962 | 3,972,632 |
| Inventory, net | 3,130,720 | 2,302,030 |
| Prepaid expenses and other current assets | 1,206,003 | 1,148,345 |
| Total current assets | 17,142,801 | 11,182,516 |
| Plant and equipment, net | 314,690 | 404,552 |
| Deferred income taxes | 8,574,448 | 8,543,758 |
| Intangible assets, net | 20,245,803 | 20,477,729 |
| Goodwill | 6,878,932 | 6,878,932 |
| Other assets | 684,091 | 965,152 |
| Total assets | $ 53,840,765 | $ 48,452,639 |
| | | |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 3,134,795 | $ 3,226,036 |
| Accrued research and development costs | 1,464,298 | 981,357 |
| Accrued expenses and other current liabilities | 2,403,620 | 2,465,657 |
| Credit agreement, short-term portion (Note 8) | 4,660,572 | 6,692,718 |
| Unearned revenue | — | 187,159 |
| Total current liabilities | 11,663,285 | 13,552,927 |
| Credit agreement, long-term portion (Note 8) | 4,489,540 | 2,701,570 |
| Residual royalty agreement (Note 8) | 1,824,745 | 1,753,805 |
| Deferred income taxes | 895,861 | 844,758 |
| Deferred rent | 201,167 | 88,161 |
| Other liabilities | 30,000 | 30,000 |
| Total liabilities | 19,104,598 | 18,971,221 |
| | | |
| Commitments and contingencies (Note 11) | | |
| | | |
| Stockholders' equity: | | |
| Preferred stock; no shares issued and outstanding at June 30, 2019 and September 30, 2018 | — | — |
| Common stock, par value $0.01 per share; 154,000,000 and 77,000,000 shares authorized, 67,002,483 and 57,468,660 shares issued and 64,818,779 and 55,284,956 shares outstanding at June 30, 2019 and September 30, 2018, respectively | 670,025 | 574,687 |
| Additional paid-in-capital | 109,612,826 | 95,496,506 |
| Accumulated other comprehensive loss | (581,519) | (581,519) |
| Accumulated deficit | (67,158,560) | (58,201,651) |
| Treasury stock, 2,183,704 shares, at cost | (7,806,605) | (7,806,605) |
| Total stockholders' equity | 34,736,167 | 29,481,418 |
| Total liabilities and stockholders' equity | $ 53,840,765 | $ 48,452,639 |

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

| | Three Months Ended June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Net revenues | $ 9,727,060 | $ 5,501,730 | $ 23,074,984 | $ 10,661,215 |
| Cost of sales | 3,155,902 | 2,427,542 | 7,250,895 | 5,075,470 |
| Gross profit | 6,571,158 | 3,074,188 | 15,824,089 | 5,585,745 |
| Operating expenses: | | | | |
| Research and development | 4,866,114 | 3,787,562 | 10,138,524 | 7,822,724 |
| Selling, general and administrative | 3,547,046 | 4,024,146 | 10,663,884 | 10,869,535 |
| Loss on settlement of accounts receivable | — | 227,208 | — | 3,991,346 |
| Total operating expenses | 8,413,160 | 8,038,916 | 20,802,408 | 22,683,605 |
| Operating loss | (1,842,002) | (4,964,728) | (4,978,319) | (17,097,860) |
| Non-operating (expenses) income: | | | | |
| Interest expense | (1,091,276) | (1,380,122) | (3,627,971) | (1,730,717) |
| Other income (expense), net | 18,345 | 64 | 70,376 | (15,516) |
| Change in fair value of derivative liabilities | 157,000 | (378,000) | (246,000) | (399,000) |
| Foreign currency transaction loss | (16,601) | (1,591) | (57,788) | (118,124) |
| Total non-operating expenses | (932,532) | (1,759,649) | (3,861,383) | (2,263,357) |
| Loss before income taxes | (2,774,534) | (6,724,377) | (8,839,702) | (19,361,217) |
| Income tax (benefit) expense | (458) | 1,206,131 | 117,207 | (3,342,339) |
| Net loss | $ (2,774,076) | $ (7,930,508) | $ (8,956,909) | $ (16,018,878) |
| Net loss per basic and diluted common share outstanding | $ (0.04) | $ (0.15) | $ (0.14) | $ (0.30) |
| Basic and diluted weighted average common shares outstanding | 62,917,362 | 53,789,409 | 62,745,355 | 53,432,404 |

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

| | Preferred Stock | Common Stock Shares | Common Stock Amount | Additional Paid-in Capital | Accumulated Other Comprehensive Loss | Accumulated Deficit | Treasury Stock, at Cost | Total |
|---|---|---|---|---|---|---|---|---|
| Balance at September 30, 2018 | $ — | 57,468,660 | $ 574,687 | $ 95,496,506 | $ (581,519) | $ (58,201,651) | $ (7,806,605) | $ 29,481,418 |
| Share-based compensation | — | — | — | 417,256 | — | — | — | 417,256 |
| Shares issued in connection with public offering of common stock, net of fees and costs | — | 7,142,857 | 71,428 | 9,060,539 | — | — | — | 9,131,967 |
| Issuance of shares pursuant to share-based awards | — | 190,000 | 1,900 | (1,900) | — | — | — | — |
| Net loss | — | — | — | — | — | (2,148,798) | — | (2,148,798) |
| Balance at December 31, 2018 | — | 64,801,517 | 648,015 | 104,972,401 | (581,519) | (60,350,449) | (7,806,605) | 36,881,843 |
| 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 |
| Share-based compensation | — | — | — | 468,207 | — | — | — | 468,207 |
| Shares issued in connection with common stock purchase agreement | — | 2,000,000 | 20,000 | 3,580,000 | — | — | — | 3,600,000 |
| Amortization of deferred costs | — | — | — | (101,981) | — | — | — | (101,981) |
| Issuance of shares pursuant to share-based awards | — | 34,299 | 343 | (343) | — | — | — | — |
| Net loss | — | — | — | — | — | (2,774,076) | — | (2,774,076) |
| Balance at June 30, 2019 | $ — | 67,002,483 | $ 670,025 | $ 109,612,826 | $ (581,519) | $ (67,158,560) | $ (7,806,605) | $ 34,736,167 |
| | | | | | | | | |
| 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 |
| Share-based compensation | — | — | — | 459,974 | — | — | — | 459,974 |
| Shares issued in connection with common stock purchase agreement | — | 1,176,470 | 11,764 | 1,988,236 | — | — | — | 2,000,000 |
| Amortization of deferred costs | — | — | — | (56,656) | — | — | — | (56,656) |
| Issuance of shares pursuant to share-based awards | — | 55,000 | 550 | 65,450 | — | — | — | 66,000 |
| Net loss | — | — | — | — | — | (7,930,508) | — | (7,930,508) |
| Balance at June 30, 2018 | $ — | 56,928,120 | $ 569,281 | $ 93,971,011 | $ (581,519) | $ (50,282,140) | $ (7,806,605) | $ 35,870,028 |

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

| | Nine Months Ended June 30, | |
|---|---|---|
| | 2019 | 2018 |
| OPERATING ACTIVITIES | | |
| Net loss | $ (8,956,909) | $ (16,018,878) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 126,084 | 131,920 |
| Amortization of intangible assets | 231,926 | 206,447 |
| Noncash interest expense | 3,627,971 | 1,730,717 |
| Share-based compensation | 1,381,672 | 1,079,276 |
| Deferred income taxes | 20,413 | (3,367,000) |
| Loss on settlement of accounts receivable | — | 3,991,346 |
| Change in fair value of derivative liabilities | 246,000 | 399,000 |
| Other | 261,172 | (39,155) |
| Changes in current assets and liabilities: | | |
| (Increase) decrease in accounts receivable | (791,272) | 2,339,947 |
| (Increase) decrease in inventory | (941,188) | 114,037 |
| Increase in prepaid expenses and other assets | (68,578) | (275,586) |
| (Decrease) increase in accounts payable | (46,894) | 775,923 |
| Decrease in unearned revenue | (187,159) | (253,536) |
| Increase in accrued expenses and other current liabilities | 566,557 | 454,324 |
| Net cash used in operating activities | (4,530,205) | (8,731,218) |
| | | |
| INVESTING ACTIVITIES | | |
| Capital expenditures | (74,948) | (47,696) |
| Net cash used in investing activities | (74,948) | (47,696) |
| | | |
| FINANCING ACTIVITIES | | |
| Proceeds from sale of shares in public offering, net of fees and costs | 9,131,967 | — |
| Installment payments on SWK credit agreement | (4,047,207) | (642,485) |
| Proceeds from stock option exercises | 200,000 | 66,000 |
| Net proceeds from sale of shares under common stock purchase agreement | 3,600,000 | 1,922,160 |
| Proceeds from SWK credit agreement | — | 10,000,000 |
| Payment of debt issuance costs | — | (266,923) |
| Net cash provided by financing activities | 8,884,760 | 11,078,752 |
| | | |
| Net increase in cash | 4,279,607 | 2,299,838 |
| CASH AT BEGINNING OF PERIOD | 3,759,509 | 3,277,602 |
| CASH AT END OF PERIOD | $ 8,039,116 | $ 5,577,440 |
| | | |
| Schedule of noncash investing and financing activities: | | |
| Shares issued in connection with common stock purchase agreement | $ — | $ 347,081 |
| Amortization of deferred costs related to common stock purchase agreement | $ 101,981 | $ 56,656 |

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 nine months ended June 30, 2019 and cash flows for the nine months ended June 30, 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 healthcare product, the FC2 Female Condom/FC2 Internal Condom® ("FC2"). The completion of the APP Acquisition transitioned the Company into a biopharmaceutical company focused on oncology and urology with multiple drug products under clinical development. Most of the Company's net revenues during the three and nine months ended June 30, 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 June 30, 2019. Restricted cash was $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 9have been included in other assets on the accompanying unaudited condensed consolidated balance sheets at June 30, 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 9, in connection with thecommon stock offering that closed on October 1, 2018, we incurred costs of approximately $190,000 through September 30, 2018. This amount was included inother assets on the accompanying unaudited condensed consolidated balance sheet at September 30, 2018. These costs were charged to additional paid-in capital in the nine months ended June 30, 2019 after the common stock offering was closed.

Costs incurred in connection with the issuance of debt discussed in Note 8 are presented as a reduction of the debt on the accompanying unaudited condensed consolidated balance sheets at June 30, 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 fourth 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.

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 8.

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. See Note 4 for further discussion on revenue.

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 June 30, 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 nine months ended June 30, 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 June 30, 2019 and September 30, 2018. Assets located outside of the U.S. totaled approximately $6.1 million and $5.2 million at June 30, 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 nine months ended June 30, 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 Note 4 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 are evaluating the effect of the new guidance on our consolidated financial statements and related disclosures. The primary effect of adoption will be recording right-of-use assets and corresponding lease obligations for current operating leases. The adoption is expected to have a material impact on the Company's consolidated balance sheets, but not on the consolidated statements of operations or cash flows. The Company is reviewing current accounting policies and related disclosures, and evaluating changes to business processes and controls to support adoption of the new standard.

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 operationsas 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 9) 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 nine months ended June 30, 2019 and 2018.

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

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 June 30, 2019 and 2018:

| | Nine Months Ended June 30, | |
|---|---|---|
| | **2019** | **2018** |
| Beginning balance | $ 2,426,000 | $ — |
| Additions | — | 3,319,000 |
| Change in fair value of derivative liabilities | 246,000 | 399,000 |
| Ending balance | $ 2,672,000 | $ 3,718,000 |

The expense associated with the change in fair value of the embedded derivatives is included as 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 Credit Agreement and Residual Royalty Agreement. See Note 8 for additional information. There is no current observable market for these types of derivatives. The Company determined the fair value of the embedded derivatives 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 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 June 30, 2019:

| Valuation Methodology | Significant Unobservable Input | Weighted Average (range, if applicable) |
|---|---|---|
| Monte Carlo Simulation | Estimated change of control dates | March 2020 to December 2021 |
| | Discount rate | 16.3% to 19.7% |
| | Probability of change of control | 0% to 90% |

**Note 4 – Revenue from Contracts with Customers**

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

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

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

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

| | Three Months Ended June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| FC2 | | | | |
| Public sector | $ 4,905,874 | $ 5,126,434 | $ 13,039,878 | $ 9,823,793 |
| U.S. prescription channel | 4,377,862 | 372,981 | 9,412,177 | 830,525 |
| Total FC2 | 9,283,736 | 5,499,415 | 22,452,055 | 10,654,318 |
| PREBOOST® | 443,324 | 2,315 | 622,929 | 6,897 |
| Net revenues | $ 9,727,060 | $ 5,501,730 | $ 23,074,984 | $ 10,661,215 |

The following table presents net revenue by geographic area:

| | Three Months Ended June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| United States | $ 5,548,987 | $ 640,313 | $ 11,234,870 | $ 2,615,652 |
| South Africa | 260,644 | 1,791,100 | 494,136 | 2,823,970 |
| Zimbabwe | 610,004 | 372,000 | 2,558,308 | 1,049,500 |
| Other | 3,307,425 | 2,698,317 | 8,787,670 | 4,172,093 |
| Net revenues | $ 9,727,060 | $ 5,501,730 | $ 23,074,984 | $ 10,661,215 |

The Company's performance obligations consist mainly of transferring control of products identified in the contracts which occurs either when: i) the product is made available to the customer for shipment; ii) the product is shipped via common carrier; or iii) the product is delivered to the customer or distributor, in accordance with the terms of the agreement. Some of the Company's contracts require the customer to make advanced payments prior to transferring control of the products. These advanced payments create a contract liability for the Company. The balances of the Company's contract liability, included in accrued expenses and other current liabilities on the accompanying unaudited condensed consolidated balances sheets, was approximately $106,000 and $4,000 at June 30, 2019 and September 30, 2018, respectively.

The Company records an unearned revenue liability if a customer pays consideration for product that was shipped by the Company but revenue recognition criteria have not been met under the terms of a contract. Unearned revenue is recognized as revenue after control of the product is transferred to the customer and all revenue recognition criteria have been met. The Company had no unearned revenue at June 30, 2019. Unearned revenue at September 30, 2018 was approximately $187,000 and was comprised of sales made to a large distributor who had the right to return product under certain conditions.

**Note 5 – Accounts Receivable and Concentration of Credit Risk**

The Company's standard credit terms vary from 30 to 120 days, depending on the class of trade and customary terms within a territory, so accounts receivable is affected by the mix of purchasers within the period. As is typical in the Company's business, extended credit terms may occasionally be offered as a sales promotion or for certain sales. The Company has agreed to credit terms of up to 150 days with its distributor in the Republic of South Africa and up to 180 days with its distributor in Brazil.

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

| | June 30, 2019 | September 30, 2018 |
|---|---|---|
| Accounts receivable | $ 4,838,665 | $ 4,046,733 |
| Less: allowance for doubtful accounts | (33,143) | (36,201) |
| Less: allowance for sales and payment term discounts | (38,560) | (37,900) |
| Accounts receivable, net | $ 4,766,962 | $ 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. 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. 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 $0.2 million and $4.0 million in the three and nine months ended June 30, 2018, respectively, which is presented as a separate line item in the accompanying unaudited condensed consolidated statements of operations.

At June 30, 2019, no customer had an accounts receivable balance that represented greater than 10% of current assets. At September 30, 2018, one customer had an accounts receivable balance that represented 15% of current assets.

At June 30, 2019, three customers had an accounts receivable balance greater than 10% of net accounts receivable, representing 76% 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 June 30, 2019, there were three customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 63% of the Company's net revenues in the aggregate. For the three months ended June 30, 2018, there were two customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 78% of the Company's net revenues in the aggregate.

For the nine months ended June 30, 2019, there werethree customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 64% of the Company's net revenues in the aggregate. For the nine months ended June 30, 2018, there were three customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing65% 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 nine months ended June 30, 2019 and 2018.

| | Nine Months Ended June 30, | |
|---|---|---|
| | **2019** | **2018** |
| Beginning balance | $ 36,201 | $ 38,103 |
| Charges to expense | — | 3,058 |
| Charge-offs | (3,058) | (5,000) |
| Ending balance | $ 33,143 | $ 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 6 – Balance Sheet Information**

Inventory

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

Inventory consisted of the following at June 30, 2019and September 30, 2018:

| | **June 30, 2019** | **September 30, 2018** |
|---|---|---|
| FC2 | | |
| Raw material | $ 701,344 | $ 366,220 |
| Work in process | 126,550 | 77,669 |
| Finished goods | 2,752,787 | 2,232,864 |
| Inventory, gross | 3,580,681 | 2,676,753 |
| Less: inventory reserves | (450,367) | (391,861) |
| FC2, net | 3,130,314 | 2,284,892 |
| PREBOOST® | | |
| Finished goods | 406 | 17,138 |
| Inventory, net | $ 3,130,720 | $ 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 June 30, 2019 and September 30, 2018:

| | June 30, 2019 | September 30, 2018 |
|---|---|---|
| Equipment, furniture and fixtures | $ 3,535,560 | $ 4,018,284 |
| Leasehold improvements | 287,686 | 287,686 |
| | 3,823,246 | 4,305,970 |
| Less: accumulated depreciation and amortization | (3,508,556) | (3,901,418) |
| Plant and equipment, net | $ 314,690 | $ 404,552 |

**Note 7 – 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 June 30, 2019:

| | Gross Carrying Amount | Accumulated Amortization | Net Book Value |
|---|---|---|---|
| Intangible assets with finite lives: | | | |
| Developed technology - PREBOOST® | $ 2,400,000 | $ 463,721 | $ 1,936,279 |
| Covenants not-to-compete | 500,000 | 190,476 | 309,524 |
| Total intangible assets with finite lives | 2,900,000 | 654,197 | 2,245,803 |
| Acquired in-process research and development assets | 18,000,000 | — | 18,000,000 |
| Total intangible assets | $ 20,900,000 | $ 654,197 | $ 20,245,803 |

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 June 30, 2019 and 2018, amortization expense was approximately$77,000 and $69,000, respectively. For the nine months ended June 30, 2019 and 2018, amortization expense was approximately $232,000 and $206,000, 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 June 30, 2019 and September 30, 2018 was $6.9 million. There was no change in the balance during the nine months ended June 30, 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 the 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 8 – Debt**

SWK Credit Agreement

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

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

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

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

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

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

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

At June 30, 2019 and September 30, 2018, the Credit Agreement consisted of the following:

| | June 30, 2019 | September 30, 2018 |
|---|---|---|
| Aggregate repayment obligation | $ 17,650,000 | $ 17,500,000 |
| Less: Cumulative payments | (4,689,692) | (642,485) |
| Less: Unamortized discounts | (5,440,322) | (8,475,874) |
| Less: Unamortized deferred issuance costs | (127,874) | (204,353) |
| Credit agreement, net | 7,392,112 | 8,177,288 |
| Add: Embedded derivative liability at fair value (see Note 3) | 1,758,000 | 1,217,000 |
| | 9,150,112 | 9,394,288 |
| Credit agreement, short-term portion | (4,660,572) | (6,692,718) |
| Credit agreement, long-term portion | $ 4,489,540 | $ 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 June 30, 2019 and September 30, 2018, respectively.

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

| | June 30, 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 | 564,745 | 201,225 |
| Residual Royalty Agreement liability, net | 910,745 | 544,805 |
| Add: Embedded derivative liability at fair value (see Note 3) | 914,000 | 1,209,000 |
| Residual Royalty Agreement liability | $ 1,824,745 | $ 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 nine months ended June 30, 2019 and 2018, interest expense related to the Credit Agreement and Residual Royalty Agreement was as follows:

| | Three Months Ended June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Amortization of Credit Agreement and Residual Royalty Agreement discounts | $ 922,144 | $ 1,255,062 | $ 3,187,972 | $ 1,572,809 |
| Accretion of Residual Royalty Agreement liability | 147,223 | 94,858 | 363,520 | 122,136 |
| Amortization of deferred issuance costs | 21,909 | 30,202 | 76,479 | 35,772 |
| | $ 1,091,276 | $ 1,380,122 | $ 3,627,971 | $ 1,730,717 |

**Note 9 – Stockholders' Equity**

Preferred Stock

The Company has 5,000,000 shares designated as Class A Preferred Stock with a par value of $0.01 per share. There are 1,040,000 shares of Class A Preferred Stock – Series 1 authorized; 1,500,000 shares of Class A Preferred Stock – Series 2 authorized; 700,000 shares of Class A Preferred Stock – Series 3 authorized; and 548,000 shares of Class A Preferred Stock – Series 4 (the "Series 4 Preferred Stock") authorized. There were no shares of Class A Preferred Stock of any series issued and outstanding at June 30, 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 June 30, 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 June 30, 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 the third quarter of fiscal 2019, we sold 2,000,000 shares of common stock to Aspire Capital under the Purchase Agreement resulting in proceeds to the Company of $3.6 million. As a result of this sale, we recorded approximately $102,000 of the deferred costs noted above to additional paid-in capital. During the third quarter of fiscal 2018, we sold 1,176,470 shares of common stock to Aspire Capital under the Purchase Agreement resulting in proceeds to the Company of $2.0 million. As a result of this sale, we recorded approximately $57,000 of the deferred costs noted above to additional paid-in capital. The unamortized amount of deferred costs of approximately $238,000 and $340,000 at June 30, 2019 and September 30, 2018, respectively, is included in other assets on the accompanying unaudited condensed consolidated balance sheets. As of June 30, 2019, the amount remaining under the Purchase Agreement was $8.4 million.

**Note 10 – Share-based Compensation**

We allocate share-based compensation expense to cost of sales, selling, general and administrative expense and research and development expense based on the award holder's employment function. For the three and nine months ended June 30, 2019 and 2018, we recorded share-based compensation expenses as follows:

| | Three Months Ended June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Cost of sales | $ 9,998 | $ 6,174 | $ 25,728 | $ 11,235 |
| Selling, general and administrative | 347,165 | 376,507 | 1,081,600 | 913,851 |
| Research and development | 111,044 | 77,293 | 274,344 | 154,190 |
| | $ 468,207 | $ 459,974 | $ 1,381,672 | $ 1,079,276 |

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 June 30, 2019, 3,006,239 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 June 30, 2019, 46,514 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 nine months ended June 30, 2019 and 2018:

| | Three Months Ended June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Weighted Average Assumptions: | | | | |
| Expected volatility | 65.29% | 60.56% | 65.91% | 61.00% |
| Expected dividend yield | 0.00% | 0.00% | 0.00% | 0.00% |
| Risk-free interest rate | 2.23% | 2.86% | 2.37% | 2.63% |
| Expected term (in years) | 6.0 | 6.0 | 5.9 | 5.9 |
| Fair value of options granted | $ 0.97 | $ 1.10 | $ 0.92 | $ 1.00 |

During the three and nine months ended June 30, 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 June 30, 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 | 2,255,282 | $ 1.53 | | |
| Exercised | (283,333) | $ 1.19 | | |
| Forfeited | (480,847) | $ 1.89 | | |
| Outstanding at June 30, 2019 | 7,136,414 | $ 1.56 | 8.17 | $ 4,082,982 |
| Exercisable at June 30, 2019 | 2,240,384 | $ 1.48 | 7.10 | $ 1,460,499 |

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 June 30, 2019 of $2.13, less the respective weighted average exercise price per share at period end

The total intrinsic value of options exercised during the nine months ended June 30, 2019 and 2018 was approximately$105,000 and $44,000, respectively. Cash received from options exercised during the nine months ended June 30, 2019 and 2018 was approximately $200,000 and $66,000, respectively.

As of June 30, 2019, the Company had unrecognized compensation expense of approximately$3.5 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 fromone 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 June 30, 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 June 30, 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. Upon exercise, the stock appreciation rights will be settled in common stock issued under the 2017 Plan. As of June 30, 2019, these vested stock appreciation rights remain outstanding.

**Note 11 – 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. On July 10, 2019, the Court denied plaintiffs' motion for summary judgment, granted defendants' motion for summary judgment on all counts, dismissed the Amended Consolidated Complaint, and entered final judgment in favor of all defendants. Plaintiffs have a right to appeal the final judgment. Veru will continue vigorously defending itself on appeal if necessary. 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 12 – 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 June 30, 2019. An additional valuation allowance has been recorded against the U.S. deferred tax assets and net operating loss carryforwards as of June 30, 2019 of $2.4 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$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 $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 June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Income tax benefit at statutory rates | $ (582,652) | $ (1,412,119) | $ (1,856,337) | $ (5,040,855) |
| State income tax benefit, net of federal benefits | (138,089) | (15,213) | (439,952) | (963,608) |
| Effect of change in U.S. tax rate | — | 190,319 | — | 3,319 |
| Non-deductible expenses – other | 2,269 | 862 | 7,052 | 13,564 |
| Effect of lower foreign income tax rates | 43 | (67,765) | (3,484) | 12,621 |
| Recharacterization of foreign tax credits to net operating loss | — | 1,311,429 | — | 1,311,429 |
| Effect of deemed dividend | 2,554 | — | 66,182 | — |
| Increase in valuation allowance | 716,442 | 933,000 | 2,367,633 | 933,000 |
| Other | (1,025) | 265,618 | (23,887) | 388,191 |
| Income tax (benefit) expense | $ (458) | $ 1,206,131 | $ 117,207 | $ (3,342,339) |

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

| | June 30, 2019 | September 30, 2018 |
|---|---|---|
| **Deferred tax assets:** | | |
| Federal net operating loss carryforwards | $ 8,527,304 | $ 6,973,047 |
| State net operating loss carryforwards | 2,579,909 | 2,195,865 |
| Foreign net operating loss carryforwards – U.K. | 10,626,155 | 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 | 52,257 | 22,902 |
| Share-based compensation | 843,466 | 622,442 |
| Other, net – U.S. | 159,497 | 91,419 |
| Other, net – Malaysia | 33,896 | 33,843 |
| Gross deferred tax assets | 22,943,868 | 20,656,420 |
| Valuation allowance for deferred tax assets | (9,998,711) | (7,631,078) |
| Net deferred tax assets | 12,945,157 | 13,025,342 |
| **Deferred tax liabilities:** | | |
| In process research and development | (4,675,860) | (4,675,860) |
| Developed technology | (502,987) | (549,318) |
| Covenant not-to-compete | (80,405) | (94,321) |
| Other | (7,318) | (6,843) |
| Net deferred tax liabilities | (5,266,570) | (5,326,342) |
| **Net deferred tax asset** | $ 7,678,587 | $ 7,699,000 |

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

| | June 30, 2019 | September 30, 2018 |
|---|---|---|
| Deferred tax asset – U.K. | $ 8,540,552 | $ 8,509,915 |
| Deferred tax asset – Malaysia | 33,896 | 33,843 |
| Total deferred tax asset | $ 8,574,448 | $ 8,543,758 |
| | | |
| Deferred tax liability – U.S. | (895,861) | (844,758) |
| Total deferred tax liability | $ (895,861) | $ (844,758) |

**Note 13 – Net Loss Per Share**

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

**Note 14 – Industry Segments**

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.

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

| | Three Months Ended June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| | (In thousands) | | (In thousands) | |
| Commercial | $ 5,621 | $ 1,328 | $ 12,493 | $ 1,309 |
| Research and development | (4,853) | (3,787) | (10,104) | (7,780) |
| Corporate | (2,610) | (2,506) | (7,367) | (10,627) |
| Operating loss | $ (1,842) | $ (4,965) | $ (4,978) | $ (17,098) |

All of our net revenues, which are primarily derived from the sale of FC2, are attributed to our Commercial reporting segment. See Note 4 for additional information regarding our net revenues. 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.

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 VERU-111, zuclomiphene citrate, and VERU-100. 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. Zuclomiphene citrate is an oral estrogen receptor agonist being evaluated in a Phase 2 trial to treat hot flashes, a common side effect caused by hormone treatment for men with advanced prostate cancer. VERU-100 is a novel, proprietary peptide formulation for androgen deprivation therapy with multiple beneficial clinical attributes addressing the shortfalls of current FDA-approved androgen deprivation therapy formulations for advanced prostate cancer. VERU-100 is a long-acting gonadotropin-releasing hormone (GnRH) antagonist designed to be administered as a small volume subcutaneous 3-month depot injection without a loading dose. VERU-100 will immediately suppress testosterone with no testosterone surge upon initial or repeated administration --- a problem which occurs with currently approved LHRH agonists. Currently, there are no GnRH antagonists commercially approved beyond 1 month. VERU-100 is anticipated to enter a Phase 2 dose-finding study in early 2020.

The Company is also advancing new drug formulations in its specialty pharmaceutical pipeline addressing unmet medical needs in urology such as the Tadalafil and Finasteride Combination (TADFIN®) for the administration of tadalafil 5mg and finasteride 5mg combination formulation dosed daily for benign prostatic hyperplasia (BPH). Tadalafil (CIALIS®) is currently approved for treatment of BPH and erectile dysfunction and finasteride is currently approved for treatment of BPH (finasteride 5mg PROSCAR®) and male pattern hair loss (finasteride 1mg PROPECIA®). The co-administration of tadalafil and finasteride has been shown to be more effective for the treatment of BPH than by finasteride alone. The Company had a successful preNDA meeting with the FDA and the expected submission of the NDA for TADFIN is summer of 2020. The Company is also developing Tamsulosin DRS granules and Tamsulosin XR 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, and the PREBOOST® 4% benzocaine medicated individual wipe for the prevention of premature ejaculation (also marketed as Roman Swipes). 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 OTC in the U.S. at www.fc2.us.com. In the global public health sector, the Company markets FC2 to entities, including ministries of health, government health agencies, U.N. agencies, nonprofit organizations and commercial partners, that work to support and improve the lives, health and well-being of women around the world. For our premature ejaculation product, marketed as "Roman Swipes," the Company has 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 www.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. Most of the Company's net revenues are currently derived from sales of FC2 in the public and commercial sectors.

*FC2 Public Sector.* FC2's primary use is for sexual 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 sexually transmitted infections and unwanted pregnancy in these countries represents a remarkable potential for significant sales of a product that

benefits some of the world's most underprivileged people. However, conditions in these countries can be volatile and result in unpredictable delays in program development, tender applications and processing orders.

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

On August 27, 2018, the Company announced that through six of its distributors in the Republic of South Africa, the Company had received a tender award to supply 75% of a tender covering up to 120 million female condoms over three years, which includes an award to the Company of up to 29.8 million units of the 40 million total units for the first year. The Company began shipping units under this tender award in the third quarter of fiscal 2019.

*FC2 Commercial Sector.* In April 2017, the Company launched a small-scale marketing and sales program to support the promotion of FC2 in the U.S. market. The commercial team developed a plan to confirm the "proof of concept" that FC2 represented a significant business opportunity. This required changes in the distribution process for FC2 in the U.S. As part of this 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, 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 a significant increase in revenue from sales in the U.S. prescription channel primarily through telemedicine distribution partners.

*FC2 Unit Sales.* 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 | 10,876,704 | 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 | 28,051,812 | 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 U.S. prescription channel. Generally, these sales are recognized upon shipment of the product to the customers. Other revenues are from sales of PREBOOST® (Roman Swipes).

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. 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 $4.9 million and $3.8 million for the three months ended June 30, 2019 and 2018, respectively. Our research and development expenses were $10.1 million and $7.8 million for the nine months ended June 30, 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 JUNE 30, 2019 COMPARED TO THREE MONTHS ENDED JUNE 30, 2018

The Company generated net revenues of $9.7 million and net loss of $2.8 million, or $(0.04) per basic and diluted common share, for the three months ended June 30, 2019, compared to net revenues of $5.5 million and net loss of $7.9 million, or $(0.15) per basic and diluted common share, for the three months ended June 30, 2018. Net revenues increased 77% for the period.

FC2 net revenues represented 95% of total net revenues. FC2 net revenuesincreased 69% for the period. There was a 9% increase in total FC2 unit sales and an increase in FC2 average sales price per unit of 56%.The increase in the FC2 average sales price per unit compared to the same period last year was due to the increase in sales in the U.S. prescription channel. The Company experienced an increase in FC2 net revenues of 1,074% in the U.S. prescription channel and a slight decrease in global public sector net revenues of 4%.

Cost of sales increased to $3.2 million in the three months ended June 30, 2019 from $2.4 million for the same period last yearprimarily due to the increase in unit sales in the U.S. prescription channel.

Gross profit increased to $6.6 million for the three months ended June 30, 2019 from $3.1 million for the three months ended June 30, 2018. Gross profit margin for the three months ended June 30, 2019 was 68% of net revenues, compared to 56% of net revenues for the same period in 2018. These increases were due to the increase in sales in the U.S. prescription channel, which have a higher profit margin.

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

Research and development expenses increased to $4.9 million for the three months ended June 30, 2019 from $3.8 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 decreased to $3.5 million for the three months ended June 30, 2019 from $4.0 million in the prior year period. The decrease is primarily due to the Company's change in its U.S. sales strategy, which eliminated our internal sales team thereby resulting in a reduction of personnel and marketing expenses.

The Company incurred a loss on net accounts receivable of $0.2 million in the third quarter of fiscal 2018 to settle the remaining account receivable balance outstanding from Semina, our distributor in Brazil. This amount is presented as a separate line item in the accompanying unaudited condensed consolidated statement of operations for the three months ended June 30, 2018.

Interest expense, which consists of items related to the Credit Agreement and Residual Royalty Agreement discussed in Note 8 to the financial statements included in this report, was $1.1 million for the three months ended June 30, 2019 compared to $1.4 million for the three months ended June 30, 2018. The decrease in interest expense was a result of the amendment to the Credit Agreement that was executed on May 13, 2019, which resulted in a reduction in the effective interest rate.

Income associated with the change in fair value of the embedded derivatives was $0.2 million for the three months ended June 30, 2019 compared to expense of $0.4 million for the three months ended June 30, 2018. The liabilities associated with embedded derivatives represent the fair value of the change of control provisions in the Credit Agreement and Residual Royalty Agreement. See Note 3 and Note 8 to the financial statements included in this report for additional information.

The income tax benefit for the three months ended June 30, 2019 was $458, compared to an income tax expense of $1.2 million for the same period in fiscal 2018. The change in income tax expense of $1.2 million is primarily due to a decrease of $1.3 million for the recharacterization of foreign tax credits to net operating loss in the prior period.

NINE MONTHS ENDED JUNE 30, 2019 COMPARED TO NINE MONTHS ENDED JUNE 30, 2018

The Company generated net revenues of $23.1 million and net loss of $9.0 million, or $(0.14) per basic and diluted common share, for the nine months ended June 30, 2019, compared to net revenues of $10.7 million and net loss of $16.0 million, or $(0.30) per basic and diluted common share, for the nine months ended June 30, 2018. Net revenues increased 116% for the period.

FC2 net revenues represented 97% of total net revenues. FC2 net revenues increased 111% for the period. There was a 51% increase in total FC2 unit sales and an increase in FC2 average sales price per unit of 39%. The principal factors for the increase in the FC2 average sales price per unit compared to the same period last year were the increase in net revenues in the U.S. prescription channel and the unit price increases for customers in the U.S. public sector. The Company experienced an increase in FC2 net revenues in both the global public sector and the U.S. prescription channels. The global public sector net revenues increased 33% and the U.S. prescription channel net revenues increased 1,033%.

Cost of sales increased to $7.3 million in the nine months ended June 30, 2019 from $5.1 million for the same period last year primarily due to the increase in unit sales.

Gross profit increased to $15.8 million for the nine months ended June 30, 2019 from $5.6 million for the nine months ended June 30, 2018. Gross profit margin for the nine months ended June 30, 2019 was 69% of net revenues, compared to 52% of net revenues for the same period in 2018. In the nine months ended June 30, 2019, the Company experienced an increase in FC2 sales into the U.S. prescription channel with higher profit margins, contributing to the increase in overall gross profit margin.

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

Research and development expenses increased to $10.1 million for the nine months ended June 30, 2019 from $7.8 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 $10.7 million for the nine months ended June 30, 2019, which was comparable to the $10.9 million in the prior year period.

The Company incurred a loss on net accounts receivable of $4.0 million in the nine months ended June 30, 2018, which includes $3.8 million incurred in the first quarter of fiscal 2018 as a result of a settlement agreement we entered with Semina, our distributor in Brazil, in December 2017. The Company recorded an additional charge of $0.2 million in the third quarter of fiscal 2018 as a result of the Company's decision in July 2018 to accept a reduced final payment in order to settle the remaining account receivable balance outstanding. This loss is presented as a separate line item in the accompanying unaudited condensed consolidated statement of operations for the nine months ended June 30, 2018.

Interest expense, which consists of items related to the Credit Agreement and Residual Royalty Agreement, was $3.6 million for the nine months ended June 30, 2019 compared to $1.7 million for the nine months ended June 30, 2018. These agreements, which were entered into in March 2018, were outstanding for the entire fiscal 2019 period, but outstanding for only four months in the fiscal 2018 period.

Expense associated with the change in fair value of the embedded derivatives related to the Credit Agreement and Residual Royalty Agreement was $0.2 million for the nine months ended June 30, 2019 compared to expense of $0.4 million for the nine months ended June 30, 2018.

The Company realized a foreign currency transaction loss of $58,000 in the nine months ended June 30, 2019, compared to $118,000 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 nine months ended June 30, 2019 was $0.1 million, compared to an income tax benefit of $3.3 million for the same period in fiscal 2018. The change in income tax expense of $3.4 million is primarily due to a decrease in the federal and state income tax benefit of $3.7 million related to the decrease in the loss before income taxes during the current period. This amount was partially offset by the increase in the valuation allowance recorded against the U.S. net deferred tax assets of $1.4 million in the current period and a decrease of $1.3 million related to the recharacterization of foreign tax credits to net operating loss, which occurred in the prior period.

Liquidity and Sources of Capital

***Liquidity***

Our cash on hand at June 30, 2019 was $8.0 million, compared to $3.8 million (including restricted cash) at September 30, 2018. At June 30, 2019, the Company had working capital of $5.5 million and stockholders' equity of $34.7 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 in October 2018 and the sale of shares of common stock under the Purchase Agreement 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 $4.5 million in the nine months ended June 30, 2019. Cash used in operating activities included a net loss of $9.0 million, adjustments for noncash items totaling $5.9 million and changes in operating assets and liabilities of $15 million. Adjustments for noncash items primarily consisted of $3.6 million of noncash interest expense and $1.4 million of share-based compensation. The decrease in cash from changes in operating assets and liabilities included an increase in accounts receivable of $0.8 million and an increase in inventories of $0.9 million. These were partially offset by an increase in accrued expenses and other current liabilities of $0.6 million.

Our operating activities used cash of $8.7 million in the nine months ended June 30, 2018. Cash used in operating activities included a net loss of $16.0 million, adjustments for noncash items totaling $4.1 million and cash from changes in operating assets and liabilities of $3.2 million. Adjustments for noncash items primarily consisted of a $4.0 million loss on the settlement of net accounts receivable, $3.4 million related to deferred income taxes, $1.7 million of noncash interest expense related to the Credit Agreement and Residual Royalty Agreement, $1.1 million of share-based compensation and $0.4 million for the increase in the fair value of derivative liabilities related to the Credit Agreement and Residual Royalty Agreement. The increase in cash from changes in operating assets and liabilities included a decrease in net accounts receivable and long-term other receivables of $2.3 million and an increase in trade accounts payable of $0.8 million.

On December 27, 2017, we entered into a settlement agreement with Semina, our distributor in Brazil, pursuant to which Semina made a payment of $2.2 million and was obligated to make a second payment of $1.5 million by February 28, 2018, to settle net amounts due to us totaling $7.5 million relating to the Brazil tender in 2014. 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. 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 $4.0 million, which is presented as a separate line item in the accompanying unaudited condensed consolidated statements of operations for the nine months ended June 30, 2018.

*Investing activities*

Net cash used in investing activities was $75,000 and $48,000 in the nine months ended June 30, 2019 and 2018, respectively, and was primarily associated with capital expenditures at our UK location.

*Financing activities*

Net cash provided by financing activities in the nine months ended June 30, 2019was $8.9 million and primarily consisted of net proceeds from the underwritten public offering of the Company's common stock of $9.1 million (see discussion below) and $3.6 million from the sale of shares under the Purchase Agreement with Aspire Capital (see discussion below), less payments on the Credit Agreement (see discussion below) totaling $4.0 million.

Net cash provided by financing activities in the nine months ended June 30, 2018 was $11.1 million and primarily consists of net proceeds from the Credit Agreement of $9.7 million and net proceeds from the sale of shares under the Purchase Agreement with Aspire Capital of $1.9 million, less payments on the Credit Agreement of $0.6 million.

***Sources of Capital***

*Common Stock Offering*

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

*SWK Credit Agreement*

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

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

The Company made total payments under the Credit Agreement of $4.0 million and $0.6 million during the nine months ended June 30, 2019 and 2018, respectively. As a result of the Second Amendment, the Company currently estimates the aggregate amount of quarterly revenue-based payments payable during the 12-month period subsequent to June 30, 2019 will be approximately $4.7 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 the third quarter of fiscal 2019, we sold 2,000,000 shares of common stock to Aspire Capital under the Purchase Agreement resulting in proceeds to the Company of $3.6 million. 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 June 30, 2019, the amount remaining under the Purchase Agreement was $8.4 million.

Fair Value Measurements

As of June 30, 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 Credit Agreement and Residual Royalty Agreement. See Note 8 to the financial statements included in this report for additional information.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The Company's exposure to market risk 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. On July 10, 2019, the Court denied plaintiffs' motion for summary judgment, granted defendants' motion for summary judgment on all counts, dismissed the Amended Consolidated Complaint, and entered final judgment in favor of all defendants. Plaintiffs have a right to appeal the final judgment. Veru will continue vigorously defending itself on appeal if necessary.

Item 1A. Risk Factors

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the risks and uncertainties relating to the Company's business disclosed in Part I, Item 1A, "Risk Factors," of the Company's Form 10-K for the year ended September 30, 2018. There have been no material changes from the risk factors previously disclosed in Part I, Item 1A, "Risk Factors," of the Company's Form 10-K for the year ended September 30, 2018, except for the following additional risk factor.

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

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

Item 6. Exhibits

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

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|---|---|
| 31.2 | Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. * |
| 32.1 | Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002). *, ** |
| 101 | The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, formatted in XBRL (Extensible Business Reporting Language): (1) the Unaudited Condensed Consolidated Balance Sheets, (2) the Unaudited Condensed Consolidated Statements of Operations, (3) the Unaudited Condensed Consolidated Statements of Stockholders' Equity, (4) the Unaudited Condensed Consolidated Statements of Cash Flows and (5) the Notes to the Unaudited Condensed Consolidated Financial Statements. |

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

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**VERU INC.**

DATE: August 8, 2019

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

DATE: August 8, 2019

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

**Exhibit 31.1**

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

I, Mitchell S. Steiner, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 8, 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: August 8, 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 June 30, 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: August 8, 2019

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

Date: August 8, 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.