

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, 2018

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 1-13602

**Veru Inc.**

(Name of registrant as specified in its charter)

Wisconsin (State of Incorporation)	39-1144397 (I.R.S. Employer Identification No.)
4400 Biscayne Boulevard, Suite 888 Miami, FL (Address of principal executive offices)	33137 (Zip Code)
305-509-6897 (Registrant's telephone number, including area code)	

N/A

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/>	Smaller reporting company <input checked="" type="checkbox"/>
(Do not check if smaller reporting company)	Emerging growth company <input type="checkbox"/>

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 10, 2018, the registrant had 55,284,956 shares of \$0.01 par value common stock outstanding.

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## FORWARD LOOKING STATEMENTS

Certain statements included in this quarterly report on Form 10-Q which are not statements of historical fact are intended to be, and are hereby identified as, "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about future financial and operating results, plans, objectives, expectations and intentions, costs and expenses, outcome of contingencies, financial condition, results of operations, liquidity, cost savings, objectives of management, business strategies, clinical trial timing and plans, the achievement of clinical and commercial milestones, the advancement of our technologies and our products and drug candidates, and other statements that are not historical facts. Forward-looking statements can be identified by the use of forward-looking words or phrases such as "anticipate," "believe," "could," "expect," "intend," "may," "opportunity," "plan," "predict," "potential," "estimate," "should," "will," "would" or the negative of these terms or other words of similar meaning. These statements are based upon the Company's current plans and strategies and reflect the Company's current assessment of the risks and uncertainties related to its business, and are made as of the date of this report. The Company cautions readers that forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievement expressed or implied by such forward-looking statements. Such factors include, among others, 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 relating to the Company's ability to secure adequate financing on acceptable terms when needed to fund product development and the Company's operations;
- risks related to the development of the Company's product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market;
- product demand and market acceptance;
- some of the Company's products are in development and the Company may fail to successfully commercialize such products;
- risks related to intellectual property, including the uncertainty of obtaining intellectual property protections and in enforcing them, the possibility of infringing a third party's intellectual property, and licensing risks;
- competition from existing and new competitors including the potential for reduced sales, pressure on pricing and increased spending on marketing;
- risks relating to compliance and regulatory matters, including costs and delays resulting from extensive government regulation and reimbursement and coverage under healthcare insurance and regulation;
- risk inherent in doing business on an international level;
- the disruption of production at the Company's manufacturing facilities due to raw material shortages, labor shortages and/or physical damage to the Company's facilities;
- the Company's reliance on its major customers and risks relating to delays in payment of accounts receivable by major customers;
- the Company's growth strategy;
- the costs and other effects of litigation, governmental investigations, legal and administrative cases and proceedings, settlements and investigations;
- government contracting risks, including the risk that government tenders and contracts may be subject to cancellation, delay, restructuring or substantial delayed payments;
- the Company's ability to identify, successfully negotiate and complete suitable acquisitions or other strategic initiatives; and
- the Company's ability to successfully integrate acquired businesses, technologies or products.

Such uncertainties and other risks that may affect the Company's performance are discussed further in Part I, Item 1A, "Risk Factors," in the Company's Form 10-K for the year ended September 30, 2017 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.

## PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements

VERU INC.  
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

	<u>June 30,</u> <u>2018</u>	<u>September 30,</u> <u>2017</u>
<b>ASSETS</b>		
Current Assets:		
Cash	\$ 5,577,440	\$ 3,277,602
Accounts receivable, net	3,668,673	3,555,350
Inventory, net	2,653,887	2,767,924
Prepaid expenses and other current assets	958,481	697,097
<b>TOTAL CURRENT ASSETS</b>	<b>12,858,481</b>	<b>10,297,973</b>
LONG-TERM ASSETS		
<b>PLANT AND EQUIPMENT</b>		
Equipment, furniture and fixtures	4,067,448	4,067,896
Leasehold improvements	287,686	287,686
Less: accumulated depreciation and amortization	<u>(3,889,345)</u>	<u>(3,800,043)</u>
Plant and equipment, net	465,789	555,539
Other trade receivables (Note 4)	—	7,837,500
Other assets	527,249	156,431
Deferred income taxes	12,194,000	8,827,000
Intangible assets, net	20,546,544	20,752,991
Goodwill	6,878,932	6,878,932
<b>TOTAL ASSETS</b>	<b>\$ 53,470,995</b>	<b>\$ 55,306,366</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 3,461,641	\$ 2,685,718
Accrued expenses and other current liabilities	1,713,143	1,441,359
Credit agreement, short-term portion (Note 7)	6,428,567	—
Unearned revenue	760,981	1,014,517
Accrued compensation	<u>355,800</u>	<u>345,987</u>
<b>TOTAL CURRENT LIABILITIES</b>	<b>12,720,132</b>	<b>5,487,581</b>
LONG-TERM LIABILITIES		
Credit agreement, long-term portion (Note 7)	4,274,428	—
Residual royalty agreement (Note 7)	517,314	—
Other liabilities (Note 4)	—	1,233,750
Deferred rent	89,093	131,830
<b>TOTAL LIABILITIES</b>	<b>17,600,967</b>	<b>6,853,161</b>
Commitments and contingencies (Note 10)		
<b>STOCKHOLDERS' EQUITY</b>		
Common stock	569,281	553,922
Additional paid-in-capital	93,971,011	90,550,669
Accumulated other comprehensive loss	(581,519)	(581,519)
Accumulated deficit	(50,282,140)	(34,263,262)
Treasury stock, at cost	<u>(7,806,605)</u>	<u>(7,806,605)</u>
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>35,870,028</b>	<b>48,453,205</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 53,470,995</b>	<b>\$ 55,306,366</b>

See notes to unaudited condensed consolidated financial statements.

VERU INC.  
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Nine Months Ended	
	June 30,		June 30,	
	2018	2017	2018	2017
Net revenues	\$ 5,501,730	\$ 4,314,068	\$ 10,661,215	\$ 9,963,186
Cost of sales	2,424,235	2,019,154	5,069,804	4,738,333
Gross profit	3,077,495	2,294,914	5,591,411	5,224,853
Operating expenses:				
Research and development	3,787,562	302,071	7,822,724	1,677,029
Selling, general and administrative	4,027,453	3,184,484	10,875,201	8,259,003
Loss on settlement of accounts receivable	227,208	—	3,991,346	—
Business acquisition	—	74,495	—	1,008,880
Total operating expenses	8,042,223	3,561,050	22,689,271	10,944,912
Operating loss	(4,964,728)	(1,266,136)	(17,097,860)	(5,720,059)
Non-operating expenses:				
Interest expense	(1,380,122)	—	(1,730,717)	—
Other income (expense), net	64	(13,323)	(15,516)	(35,630)
Change in fair value of derivative liabilities	(378,000)	—	(399,000)	—
Foreign currency transaction loss	(1,591)	(20,143)	(118,124)	(40,838)
Total non-operating expenses	(1,759,649)	(33,466)	(2,263,357)	(76,468)
Loss before income taxes	(6,724,377)	(1,299,602)	(19,361,217)	(5,796,527)
Income tax expense (benefit)	1,206,131	(509,713)	(3,342,339)	(1,863,815)
Net loss	\$ (7,930,508)	\$ (789,889)	\$ (16,018,878)	\$ (3,932,712)
Net loss per basic and diluted common share outstanding	\$ (0.15)	\$ (0.03)	\$ (0.30)	\$ (0.13)
Basic and diluted weighted average common shares outstanding	53,789,409	30,991,247	53,432,404	30,983,271

See notes to unaudited condensed consolidated financial statements.

VERU INC.  
UNAUDITED CONDENSED CONSOLIDATED STATEMENT 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, 2017	\$ —	55,392,193	\$553,922	\$90,550,669	\$ (581,519)	\$(34,263,262)	\$(7,806,605)	\$ 48,453,205
Share-based compensation	—	—	—	1,079,276	—	—	—	1,079,276
Shares issued in connection with common stock purchase agreement	—	304,457	3,045	344,036	—	—	—	347,081
Sale of shares under common stock purchase agreement	—	1,176,470	11,764	1,988,236	—	—	—	2,000,000
Amortization of deferred costs	—	—	—	(56,656)	—	—	—	(56,656)
Shares issued upon exercise of stock options	—	55,000	550	65,450	—	—	—	66,000
Net loss	—	—	—	—	—	(16,018,878)	—	(16,018,878)
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

	<b>Nine Months Ended</b>	
	<b>June 30,</b>	
	<b>2018</b>	<b>2017</b>
<b>OPERATING ACTIVITIES</b>		
Net loss	\$ (16,018,878)	\$ (3,932,712)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	131,920	267,193
Amortization of intangible assets	206,447	106,916
Noncash interest expense	1,730,717	—
Share-based compensation	1,079,276	527,785
Warrants issued	—	542,930
Deferred income taxes	(3,367,000)	(1,989,399)
Loss on settlement of accounts receivable	3,991,346	—
Change in fair value of derivative liabilities	399,000	—
Other	(39,155)	9,973
Changes in current assets and liabilities, net of effects of acquisition of a business:		
Decrease in accounts receivable	2,328,298	5,022,028
Decrease (increase) in inventory	114,037	(131,684)
Increase in prepaid expenses and other assets	(263,937)	(194,702)
Increase in accounts payable	775,923	127,525
Decrease (increase) in unearned revenue	(253,536)	964,382
Increase (decrease) in accrued expenses and other current liabilities	454,324	(914,763)
Net cash (used in) provided by operating activities	<u>(8,731,218)</u>	<u>405,472</u>
<b>INVESTING ACTIVITIES</b>		
Capital expenditures, net	(47,696)	(119,422)
Net cash used in investing activities	<u>(47,696)</u>	<u>(119,422)</u>
<b>FINANCING ACTIVITIES</b>		
Proceeds from SWK credit agreement	10,000,000	—
Payment of debt issuance costs	(266,923)	—
Installment payment on SWK credit agreement	(642,485)	—
Net proceeds from sale of shares under common stock purchase agreement	1,922,160	—
Proceeds from stock option exercises	66,000	—
Net cash provided by financing activities	<u>11,078,752</u>	<u>—</u>
Net increase in cash	2,299,838	286,050
CASH AT BEGINNING OF PERIOD	<u>3,277,602</u>	<u>2,385,082</u>
CASH AT END OF PERIOD	<u>\$ 5,577,440</u>	<u>\$ 2,671,132</u>
<b>Schedule of noncash investing and financing activities:</b>		
Issuance of common stock in connection with the APP Acquisition	\$ —	\$ 1,826,097
Issuance of Series 4 Preferred Stock in connection with the APP Acquisition	\$ —	\$ 17,981,883
Reduction of accrued expense upon issuance of shares	\$ —	\$ 22,176
Shares issued in connection with common stock purchase agreement	\$ 347,081	\$ —

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, 2017. The accompanying condensed consolidated balance sheet as of September 30, 2017 has been derived from our audited financial statements. The unaudited condensed consolidated statements of operations for the three and nine months ended June 30, 2018 and cash flows for the nine months ended June 30, 2018 are not necessarily indicative of the results to be expected for any future period or for the fiscal year ending September 30, 2018.

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

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, and The Female Health Company (UK) plc’s wholly owned subsidiary, The Female Health Company (M) SDN.BHD. All significant intercompany transactions and accounts have been eliminated in consolidation. Prior to the completion of the acquisition (the “APP Acquisition”) of APP through the merger of a wholly owned subsidiary of the Company into APP, the Company had been a single product company engaged in marketing, manufacturing and distributing a consumer health care product, the FC2 Female Condom® (“FC2”). The completion of the APP Acquisition transitioned the Company into a biopharmaceutical company with multiple drug products under clinical development focused on urology and oncology. Nearly all of the Company’s net revenues during the three and nine months ended June 30, 2018 and 2017 were derived from sales of FC2. The Female Health Company Limited is the holding company of The Female Health Company (UK) plc, which is located in London, England (collectively the “U.K. subsidiary”). The Female Health Company (M) SDN.BHD leases a manufacturing facility located in Selangor D.E., Malaysia (the “Malaysia subsidiary”). The Company’s headquarters are located in Miami, Florida in a leased office facility.

FC2 has been distributed in either or both commercial (private sector) and public health sector markets in 49 countries. It is marketed to consumers in 25 countries through distributors, public health programs, and/or retailers and in the U.S. by prescription.

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, respectively.

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



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security has been extended infrequently and only on occasions where it has been a contract term expressly stipulated as an absolute requirement by the customer or its provider of funds. The expiration of the bond is defined by the completion of the event such as, but not limited to, a period of time after the product has been distributed or expiration of the product shelf life. Restricted cash was approximately \$137,000 and \$139,000 at June 30, 2018 and September 30, 2017, respectively, and is included in cash on the accompanying unaudited condensed consolidated balance sheets.

Accounts receivable and concentration of credit risk: Accounts receivable are carried at original invoice amount less an estimate made for doubtful receivables based on a review of all outstanding amounts on a periodic basis.

The Company's standard credit terms vary from 30 to 120 days, depending on the class of trade and customary terms within a territory, so accounts receivable is affected by the mix of purchasers within the period. As is typical in the Company's business, extended credit terms may occasionally be offered as a sales promotion or for certain sales. The Company has agreed to credit terms of up to 150 days with our distributor in the Republic of South Africa. For the order of 15 million units under the Brazil tender in 2014, the Company agreed to up to 360 days credit terms with our distributor in Brazil subject to earlier payment upon receipt of payment by the distributor from the Brazilian Government. See discussion of receivables in Note 4. For the past twelve months, the Company's average days' sales outstanding was approximately 133 days.

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.

Equipment, furniture and fixtures: Depreciation and amortization are computed using primarily 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

Depreciation on leased assets is computed over the lesser of the remaining lease term or the estimated useful lives of the assets. Depreciation on leased assets is included with depreciation on owned assets.

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

Intangible assets: Our intangible assets arose from the APP Acquisition on October 31, 2016. 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. In-process research and development ("IPR&D") is required to be tested at least annually until the underlying projects are completed or abandoned.

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Assets acquired and liabilities assumed in business combinations, licensing and other transactions are generally recognized at the date of acquisition at their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is recognized as goodwill. We determined the fair value of intangible assets, including IPR&D, using the “income method.” This method starts with a forecast of net cash flows, risk adjusted for estimated probabilities of technical and regulatory success and adjusted to present value using an appropriate discount rate that reflects the risk associated with the cash flow streams. All assets are valued from a market participant view which might be different than our specific views. The valuation process is very complex and requires significant input and judgment using internal and external sources. Although a valuation is required to be finalized within a one-year period, it must consider all and only those facts and evidence which existed at the acquisition date. The most complex and judgmental matters applicable to the valuation process are summarized below:

- Unit of account – Most intangible assets are valued as single global assets rather than multiple assets for each jurisdiction or indication after considering the development stage, expected levels of incremental costs to obtain additional approvals, risks associated with further development, amount and timing of benefits expected to be derived in the future, expected patent lives in various jurisdictions and the intention to promote the asset as a global brand.
- Estimated useful life – The asset life expected to contribute meaningful cash flows is determined after considering all pertinent matters associated with the asset, including expected regulatory approval dates (if unapproved), exclusivity periods and other legal, regulatory or contractual provisions as well as the effects of any obsolescence, demand, competition, and other economic factors, including barriers to entry.
- Probability of Technical and Regulatory Success (“PTRS”) Rate – PTRS rates are determined based upon industry averages considering the respective project’s development stage and disease indication and adjusted for specific information or data known at the acquisition date. Subsequent clinical results or other internal or external data obtained could alter the PTRS rate and materially impact the estimated fair value of the intangible asset in subsequent periods leading to impairment charges.
- Projections – Future revenues are estimated after considering many factors such as initial market opportunity, pricing, sales trajectories to peak sales levels, competitive environment and product evolution. Future costs and expenses are estimated after considering historical market trends, market participant synergies and the timing and level of additional development costs to obtain the initial or additional regulatory approvals, maintain or further enhance the product. We generally assume initial positive cash flows to commence shortly after the receipt of expected regulatory approvals which typically may not occur for a number of years. Actual cash flows attributed to the project are likely to be different than those assumed since projections are subjected to multiple factors including trial results and regulatory matters which could materially change the ultimate commercial success of the asset as well as significantly alter the costs to develop the respective asset into commercially viable products.
- Tax rates – The expected future income is tax effected using a market participant tax rate. In determining the tax rate, we consider the jurisdiction in which the intellectual property is held and location of research and manufacturing infrastructure. We also consider that any repatriation of earnings would likely have U.S. tax consequences.
- Discount rate – Discount rates are selected after considering the risks inherent in the future cash flows; the assessment of the asset’s life cycle and the competitive trends impacting the asset, including consideration of any technical, legal, regulatory, or economic barriers to entry, as well as expected changes in standards of practice for indications addressed by the asset.

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 and additional development costs, inability to achieve expected synergies, higher operating costs, changes in tax laws and other macro-economic changes. The complexity in estimating the fair value of intangible assets in connection with an impairment test is similar to the initial valuation. Considering the high-risk nature of research and development and the industry’s success rate of bringing developmental compounds to market, IPR&D impairment charges are likely to occur in future periods.

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**Goodwill:** Goodwill represents the difference between the purchase price and the estimated fair value of the net assets acquired in connection with the APP Acquisition. All goodwill resides in the Company's Research and Development reporting unit.

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

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

**Deferred Financing Costs:** Costs incurred in connection with the common stock purchase agreement discussed in Note 8 have been included in other assets on the accompanying unaudited condensed consolidated balance sheet at June 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.

Costs incurred in connection with the issuance of debt discussed in Note 7 are presented as a reduction of the debt on the accompanying unaudited condensed consolidated balance sheet at June 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 first quarter of fiscal 2021. The amount of amortization was approximately \$30,000 and \$36,000 for the three and nine months ended June 30, 2018, respectively.

**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.

**Unearned revenue:** FC2 is distributed in the U.S. prescription channel principally through large pharmaceutical distributors. These distributors then sell principally to retail pharmacies. Unearned revenue as of June 30, 2018 and September 30, 2017 was approximately \$761,000 and \$1.0 million, respectively, and was comprised mainly of sales made to a large distributor. We lack the experiential data which would allow us to estimate returns for product sold to this distributor. Therefore, as of June 30, 2018 and September 30, 2017, we determined that we do not yet meet the criteria for the recognition of revenue at the time of shipment to this distributor as returns cannot be reasonably estimated. Accordingly, the Company deferred recognition of revenue on prescription product sold to this particular distributor until the right of return no longer exists, which occurs at the earlier of the time the prescription products were dispensed through patient prescriptions or expiration of the right of return.

**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.

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**Revenue recognition:** The Company recognizes revenue from product sales when each of the following conditions has been met: an arrangement exists, delivery has occurred, there is a fixed price, and collectability is reasonably assured.

**Research and development costs:** Research and development costs are expensed as they are incurred and include salaries and benefits, clinical trials costs and contract services. Nonrefundable advance payments made for goods or services to be used in research and development activities are deferred and capitalized until the goods have been delivered or the related services have been performed. If the goods are no longer expected to be delivered or the services are no longer expected to be performed, the Company would be required to expense the related capitalized advance payments. The Company had no capitalized nonrefundable advance payments as of June 30, 2018 or September 30, 2017.

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 accounts for share-based compensation expense for equity awards exchanged for services over the vesting period based on the grant-date fair value. In many instances, the equity awards are issued upon the grant date subject to vesting periods. In certain instances, the equity awards provide for future issuance contingent on future continued employment or performance of services as of the issuance date.

**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, 2018 and 2017.

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

**Foreign currency translation and operations:** Effective October 1, 2009, the Company determined that there were significant changes in facts and circumstances, triggering an evaluation of its subsidiaries' functional currency. The evaluation indicated that the U.S. dollar is the currency with the most significant influence upon the subsidiaries. Because all of the U.K. subsidiary's future sales and cash flows would be denominated in U.S. dollars following the October 2009 cessation of production of the Company's first-generation product, FC1, the U.K. subsidiary adopted the U.S. dollar as its functional currency effective October 1, 2009. As the Malaysia subsidiary is a direct and integral component of the U.K. parent's operations, it, too, adopted the U.S. dollar as its functional currency as of October 1, 2009. The consistent use of the U.S. dollar as the functional currency across the Company reduces its foreign currency risk and stabilizes its operating results. The cumulative foreign currency translation loss included in accumulated other comprehensive loss was \$0.6 million as of June 30, 2018 and September 30, 2017. Assets located outside of the U.S. totaled approximately \$6.9 million and \$5.6 million at June 30, 2018 and September 30, 2017, 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 condensed consolidated balance sheets, these items, along with net loss, are components of other comprehensive loss.

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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. In the three and nine months ended June 30, 2018 and 2017, comprehensive loss is equivalent to the reported net loss.

### Recently Issued Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09 *Revenue from Contracts with Customers (Topic 606)*. This new accounting guidance on revenue recognition provides for a single five-step model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations, and recognizing revenue when, or as, an entity satisfies a performance obligation. This new guidance is to be applied to all revenue contracts with customers. The new standard 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. ASU 2014-09 will be effective for the Company beginning on October 1, 2018. ASU 2014-09 allows for either full retrospective or modified retrospective adoption. We have not yet selected a transition method, and we are currently evaluating the effect that ASU 2014-09 will have on our consolidated financial statements and related disclosures.

In July 2015, the FASB issued ASU 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*. This new accounting guidance more clearly articulates the requirements for the measurement and disclosure of inventory. Topic 330, Inventory, currently requires an entity to measure inventory at the lower of cost or market. Market could be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. This new accounting guidance requires the measurement of inventory at the lower of cost or net realizable value. ASU 2015-11 was effective for the Company beginning on October 1, 2017, and the adoption did not have a material effect on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. The amendments in this Update increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. ASU 2016-02 will be effective for the Company beginning on October 1, 2019. Early adoption is permitted. We are currently evaluating the effect of the new guidance on our consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU 2016-09, *Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. The amendments in this Update simplify the income tax effects, minimum statutory tax withholding requirements and impact of forfeitures related to how share-based payments are accounted for and presented in the financial statements. ASU 2016-09 was effective for the Company beginning on October 1, 2017, and the adoption did not have a material effect on our consolidated financial statements.

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. ASU 2016-18 will be effective for annual periods beginning after December 15, 2017, including interim reporting periods within those annual periods. Early adoption is permitted. The adoption of ASU 2016-18 is not expected to have a material effect on the presentation of our consolidated statements of cash flows.

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 Update No. 2017-04 to have a material effect on our financial position or results of operations.

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In January 2017, the FASB issued ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*. The purpose of ASU 2017-01 is to change the definition of a business to assist entities with evaluating when a set of transferred assets and activities is a business. Update No. 2017-01 will be effective for annual periods beginning after December 15, 2017, including interim periods within those annual periods. Early adoption is permitted as of the beginning of an annual or interim period for which financial statements have not been issued or made available for issuance. The adoption of ASU 2017-01 is not expected 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. ASU 2017-09 will be effective for annual periods beginning after December 15, 2017, including interim periods within those annual periods. Early adoption is permitted as of the beginning of an annual or interim period for which financial statements have not been issued or made available for issuance. The adoption of ASU 2017-09 is not expected to 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.

### **Note 2 - APP Acquisition**

On October 31, 2016, as part of the Company's strategy to diversify its product line to mitigate the risks of being a single product company, the Company completed the APP Acquisition through the merger of a wholly owned subsidiary of the Company into APP. The completion of the APP Acquisition transitioned the Company from a single product company selling only FC2 to a biopharmaceutical company with multiple drug products under clinical development focused on urology and oncology.

The Company incurred acquisition-related costs of approximately \$74,000 and \$1.0 million in the three and nine months ended June 30, 2017, respectively, which are presented on a separate line item in the accompanying unaudited condensed consolidated statements of operations. The Company did not incur acquisition-related costs in the three and nine months ended June 30, 2018.

As of the date of the APP Acquisition, APP had developed technology consisting of PREBOOST® medicated wipes for prevention of premature ejaculation. IPR&D represents incomplete research and development projects at APP as of the date of the APP Acquisition. The fair value of the developed technology and IPR&D were determined using the income approach, which was prepared based on forecasts by management.

Purchase price in excess of assets acquired and liabilities assumed was recorded as goodwill. 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 Research and Development reporting unit.

In connection with the APP Acquisition, a consolidated complaint has been filed against the Company and its directors alleging breach of fiduciary duty. The Company intends to vigorously defend this lawsuit. See Note 10 for additional detail.

**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, 2018.

As of June 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 did not have any financial assets or liabilities measured at fair value on a recurring basis as of September 30, 2017.

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

The following table provides a reconciliation of the beginning and ending liability balance associated with embedded derivatives measured at fair value using significant unobservable inputs (Level 3) for the nine months ended June 30, 2018:

Beginning balance at October 1, 2017	\$	—
Additions		3,319,000
Change in fair value of derivative liabilities		399,000
Ending balance at June 30, 2018	\$	<u>3,718,000</u>

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

The liabilities associated with embedded derivatives represent the fair value of the change of control provisions in the SWK Credit Agreement and Residual Royalty Agreement. See Note 7 for additional information. There is no current observable market for these types of derivatives. The Company determined the fair value of the embedded derivatives using a Monte Carlo simulation model to value the financial liabilities at inception and on subsequent valuation dates. This valuation model incorporates transaction details such as the contractual terms, expected cash outflows, expected repayment dates, probability of a change of control, expected volatility, and risk-free interest rates. A significant acceleration of the estimated repayment date or a significant decrease in the probability of a change of control event prior to repayment of the SWK Credit Agreement, in isolation, would result in a significantly lower fair value measurement of the liabilities associated with the embedded derivatives.

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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, 2018:

Valuation Methodology	Significant Unobservable Input	Weighted Average (range, if applicable)
Monte Carlo Simulation	Estimated change of control dates	December 2018 to March 2020
	Discount rate	10.5% to 11.9%
	Probability of change of control	50% to 95%

*Assets That Are Measured at Fair Value on a Nonrecurring Basis*

Non-financial assets such as identified intangibles and goodwill that arose from the APP Acquisition are measured at fair value using Level 3 inputs, which include discounted cash flow methodologies, or similar techniques, when there is limited market activity and the determination of fair value requires significant judgment or estimation

**Note 4 - Accounts Receivable and Concentration of Credit Risk**

The components of accounts receivable consist of the following at June 30, 2018 and September 30, 2017:

	June 30, 2018	September 30, 2017
Trade receivables	\$ 3,586,566	\$ 11,330,814
Other receivables	118,268	100,139
Accounts receivable, gross	3,704,834	11,430,953
Less: allowance for doubtful accounts	(36,161)	(38,103)
Accounts receivable, net	3,668,673	11,392,850
Less: long-term trade receivables	—	(7,837,500)
Current accounts receivable, net	\$ 3,668,673	\$ 3,555,350

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. 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 amounts owed to us relate to outstanding accounts receivable for sales to Semina for the 2014 Brazil tender totaling \$8.9 million, \$7.8 million of which was classified as a long-term trade receivable and \$1.1 million as a current account receivable on the accompanying condensed consolidated balance sheet as of September 30, 2017. These receivables were net of payables owed to Semina by us totaling \$1.4 million, \$1.2 million of which was classified as a long-term liability and \$0.2 million was classified as a current liability on the accompanying condensed consolidated balance sheet as of September 30, 2017. The settlement was not related to our belief in the ultimate collectability of the receivables or in the creditworthiness of Semina. The result of the settlement was a net loss of approximately \$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, 2018 and September 30, 2017, Semina's accounts receivable balance represented 10% and 11% of current assets, respectively. No other single customer's accounts receivable balance accounted for more than 10% of current assets at those dates. At June 30, 2018, Semina's accounts receivable balance represented 35% of the Company's accounts receivable. At September 30, 2017, Semina's accounts receivable and long-term other receivables balance represented 78% of the Company's total accounts receivable and long-term other receivables. For the three months ended June 30, 2018, there was one customer who exceeded 10% of net revenues. For the three months ended June 30, 2017, there were two customers who exceeded 10% of net revenues. For the nine months ended June 30, 2018 and 2017, there were two customers who each exceeded 10% of net revenues.



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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, 2018 and 2017:

	<b>Nine Months Ended June 30,</b>	
	<b>2018</b>	<b>2017</b>
Beginning balance	\$ 38,103	\$ 38,103
Charges (reversals) to expense	(1,942)	—
Charge-offs	—	—
Ending balance	<u>\$ 36,161</u>	<u>\$ 38,103</u>

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 the female condom for use in HIV/AIDS prevention and family planning programs.

**Note 5 - Inventory**

Inventory at June 30, 2018 and September 30, 2017 consists of:

	<b>June 30, 2018</b>	<b>September 30, 2017</b>
FC2		
Raw material	\$ 644,210	\$ 530,384
Work in process	40,218	90,164
Finished goods	<u>2,304,828</u>	<u>2,427,386</u>
Inventory, gross	2,989,256	3,047,934
Less: inventory reserves	<u>(353,376)</u>	<u>(312,997)</u>
FC2, net	2,635,880	2,734,937
PREBOOST®		
Finished goods	18,007	32,987
Inventory, net	<u>\$ 2,653,887</u>	<u>\$ 2,767,924</u>

**Note 6 – Goodwill and Intangible Assets**Goodwill

The carrying amount of goodwill and the change in the balance for the nine months ended June 30, 2018 and 2017 is as follows:

	<b>2018</b>	<b>2017</b>
Beginning balance	\$ 6,878,932	\$ —
Goodwill arising from APP Acquisition	—	6,878,932
Ending balance	<u>\$ 6,878,932</u>	<u>\$ 6,878,932</u>

[Table of Contents](#)[Intangible Assets](#)

Intangible assets acquired in the APP Acquisition included IPR&D, developed technology consisting of PREBOOST® medicated wipes for prevention of premature ejaculation, and covenants not-to-compete.

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

	<u>Gross Carrying Amount</u>	<u>Accumulated Amortization</u>	<u>Net Book Value</u>
Intangible assets with finite lives:			
Developed technology - PREBOOST®	\$ 2,400,000	\$ 234,408	\$ 2,165,592
Covenants not-to-compete	500,000	119,048	380,952
Total intangible assets with finite lives	2,900,000	353,456	2,546,544
Acquired in-process research and development assets	18,000,000	—	18,000,000
Total intangible assets	<u>\$ 20,900,000</u>	<u>\$ 353,456</u>	<u>\$ 20,546,544</u>

The gross carrying amounts and net book value of intangible assets are as follows at September 30, 2017:

	<u>Gross Carrying Amount</u>	<u>Accumulated Amortization</u>	<u>Net Book Value</u>
Intangible assets with finite lives:			
Developed technology - PREBOOST®	\$ 2,400,000	\$ 81,533	\$ 2,318,467
Covenants not-to-compete	500,000	65,476	434,524
Total intangible assets with finite lives	2,900,000	147,009	2,752,991
Acquired in-process research and development assets	18,000,000	—	18,000,000
Total intangible assets	<u>\$ 20,900,000</u>	<u>\$ 147,009</u>	<u>\$ 20,752,991</u>

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

Amortization expense was approximately \$69,000 and \$40,000, for the three months ended June 30, 2018 and 2017, respectively. Amortization expense was approximately \$206,000 and \$107,000, for the nine months ended June 30, 2018 and 2017, respectively. Based on finite-lived intangible assets recorded as of June 30, 2018, the estimated future amortization expense is as follows:

Year Ending September 30,	<u>Estimated Amortization Expense</u>
2018	\$ 68,815
2019	309,234
2020	316,368
2021	323,706
2022	331,316
Thereafter	1,197,105
Total	<u>\$ 2,546,544</u>

SWK Credit Agreement

On March 5, 2018, the Company entered into a Credit Agreement (the “Credit Agreement”) with the financial institutions party thereto from time to time (the “Lenders”) and SWK Funding LLC, as agent for the Lenders (the “Agent”), for a synthetic royalty financing transaction. On and subject to the terms of the Credit Agreement, the Lenders agreed to provide the Company with a multi-draw term loan of up to \$12.0 million, with \$10.0 million advanced to the Company on the date of the Credit Agreement. The Company may draw up to an additional \$1.0 million if the Company enters into an agreement to distribute at least 47.5 million units of FC2 in Brazil upon the terms described in the Credit Agreement and up to an additional \$1.0 million if the Company enters into an agreement to distribute at least 30 million units of FC2 in South Africa upon the terms described in the Credit Agreement.

The Lenders will be entitled to receive quarterly payments on the term loan based on the Company’s product revenue from net sales of FC2 as provided in the Credit Agreement until the Company has paid 175% of the aggregate amount advanced to the Company under the Credit Agreement. If product revenue from net sales of FC2 for the twelve-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 twelve-month period ended as of the last day of the respective quarterly payment period is equal to or greater than \$10.0 million, the quarterly payments are calculated as the sum of 25% of product revenue from net sales of FC2 up to and including \$12.5 million in the Elapsed Period (as defined in the Credit Agreement), plus 10% of product revenue from net sales of FC2 greater than \$12.5 million in the Elapsed Period. Upon the Credit Agreement’s termination date of March 5, 2025, the Company must pay 175% of the aggregate amount advanced to the Company under the Credit Agreement less the amounts previously paid by the Company from product revenue. 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 (a) if the change of control or sale of the FC2 business occurs prior to September 5, 2018, an amount equal to 165% of the aggregate amount actually advanced to the Company under the Credit Agreement less the amounts previously paid by the Company from product revenue, or (b) if the change of control or sale of the FC2 business occurs on or after September 5, 2018, an amount equal to (i) 175% of the aggregate amount advanced to the Company under the Credit Agreement less the amounts previously paid by the Company from product revenue, plus (ii) the greater of (A) \$2.0 million or (B) the product of (x) 5% of the product revenue from net sales of FC2 for the most recently completed 12-month period multiplied by (y) five. A “change of control” under the Credit Agreement includes (i) an acquisition by any person of direct or indirect ownership of more than 50% of the Company’s issued and outstanding voting equity, (ii) a change of control or similar event in the Company’s articles of incorporation or bylaws, (iii) certain Key Persons as defined in the Credit Agreement cease to serve in their current executive capacities unless replaced within 90 days by a person reasonably acceptable to the Agent, which acceptance not to be unreasonably withheld, or (iv) the sale of all or substantially all of the Company’s assets.

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

In connection with the Credit Agreement, the Company and the Agent also entered into a Residual Royalty Agreement, dated as of March 5, 2018 (the “Residual Royalty Agreement”), which provides for an ongoing royalty payment of 5% of product revenue from net sales of FC2 commencing upon the payment in full by the Company of the required amount pursuant to the Credit Agreement. The Residual Royalty Agreement will terminate upon (i) a change of control or sale of the FC2 business and the payment by the Company of the amount due in connection therewith pursuant to the Credit Agreement, or (ii) mutual agreement of the parties. If a change of control occurs prior to payment in full of the Credit Agreement, there will be no payment due with respect to the Residual Royalty Agreement. If a change of control occurs after the payment in full of the Credit Agreement, the Agent will receive a payment that is the greater of (A) \$2.0 million or (B) the product of (x) 5% of the product revenue from net sales of FC2 for the most recently completed 12-month period multiplied by (y) five.

Pursuant to a Guarantee and Collateral Agreement dated as of March 5, 2018 (the “Collateral Agreement”) and an Intellectual Property Security Agreement dated as of March 5, 2018 (the “IP Security Agreement”), the Company’s obligations under the Credit Agreement are secured by a lien against substantially all of the assets of the Company

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that relate to or arise from FC2. In addition, pursuant to a Pledge Agreement dated as of March 5, 2018 (the "Pledge Agreement"), the Company's obligations under the Credit Agreement are secured by a pledge of up to 65% of the outstanding shares of The Female Health Company Limited, a wholly owned U.K. subsidiary.

After payment by the Company of certain fees and expenses of the Agent and the Lenders as required in the Credit Agreement, the Company received net proceeds of approximately \$9.9 million from the initial \$10.0 million advance under the Credit Agreement.

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

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

	<u>June 30, 2018</u>
Aggregate repayment obligation	\$ 17,500,000
Less: Payments	(642,485)
Less: Unamortized discounts	(9,587,369)
Less: Unamortized deferred issuance costs	(231,151)
Credit agreement, net	7,038,995
Add: Embedded derivative liability at fair value (see Note 3)	3,664,000
	<u>10,702,995</u>
Credit agreement, short-term portion	(6,428,567)
Credit agreement, long-term portion	<u>\$ 4,274,428</u>

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The fair value of the Residual Royalty Agreement at inception of \$346,000 was calculated using a Monte Carlo simulation model utilizing significant unobservable inputs including future revenue projections to determine when payments would commence under the Residual Royalty Agreement, the probability of a change of control event as defined in the Residual Royalty Agreement and an estimated discount rate commensurate with the risks of the expected cash flows attributable to the Residual Royalty Agreement. The payment commencement dates varied between the simulated Credit Agreement payoff dates (which the earliest date was September 30, 2019 per the simulation) and the Credit Agreement termination date of March 5, 2025. The change of control probabilities ranged from 50% to 95%. The discount rates ranged from approximately 10.5% to approximately 12.0%. Material changes in any of these inputs would have resulted in a significantly higher or lower fair value measurement and commensurate changes to this liability.

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

	<b>June 30, 2018</b>	
Residual Royalty Agreement liability, fair value at inception	\$	346,000
Less: Unamortized discounts		(4,822)
Add: Accretion of liability using effective interest rate		122,136
Residual Royalty Agreement liability, net		463,314
Add: Embedded derivative liability at fair value (see Note 3)		54,000
Residual Royalty Agreement liability	\$	517,314

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

	<b>Three Months Ended June 30, 2018</b>	<b>Nine Months Ended June 30, 2018</b>
Amortization of Credit Agreement and Residual Royalty Agreement discounts	\$ 1,255,062	\$ 1,572,809
Accretion of Residual Royalty Agreement liability	94,858	122,136
Amortization of deferred issuance costs	30,202	35,772
	\$ 1,380,122	\$ 1,730,717

## Revolving Line of Credit

The Company's Credit Agreement with BMO Harris Bank N.A. expired on December 29, 2017. No amounts were outstanding under the Credit Agreement at September 30, 2017 or when it expired on December 29, 2017.

## **Note 8 - Stockholders' Equity**

### Preferred Stock

The Company has 5,000,000 shares designated as Class A Preferred Stock with a par value of \$.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. In connection with the completion of the APP Acquisition (see Note 2), a total of 546,756 shares of Series 4 Preferred Stock were issued to the former APP stockholders as of October 31, 2016, and all of the outstanding shares of Series 4 Preferred automatically converted into shares of the Company's common stock effective July 31, 2017. There were no shares of Class A Preferred Stock of any series issued and outstanding at June 30, 2018 or September 30, 2017. 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, 2018 or September 30, 2017.

### Common Stock Purchase Warrants

In connection with the closing of the APP Acquisition, the Company issued a warrant to purchase up to 2,585,379 shares of the Company's common stock to Torrey Capital, the Company's financial advisor (the "Financial Advisor Warrant"). The Financial Advisor Warrant has a five-year term, a cashless exercise feature and a strike price equal

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to \$1.93 per share, the average price of the Company's common stock for the ten-day period preceding the original announcement of the APP Acquisition on April 6, 2016. The fair value of the Financial Advisor Warrant of \$542,930 was estimated at the October 31, 2016 date of grant using the Black-Scholes option pricing model assuming expected volatility of 47.2%, a risk-free interest rate of 1.31%, an expected life of five years, no dividend yield, and the closing price of the Company's common stock on October 31, 2016 of \$0.95. The Financial Advisor Warrant vested upon issuance. Half of the shares subject to the Financial Advisor Warrant, or 1,292,690 shares, were locked-up for a period of 18 months from the issuance date. The Financial Advisor Warrant was recorded as a component of additional paid-in-capital and the related expense is included in business acquisition expenses in the accompanying unaudited condensed consolidated statement of operations for the nine months ended June 30, 2017.

In May 2018, the Company issued two warrants to purchase a total of up to 750,000 shares of the Company's common stock in connection with a consulting services agreement. The first warrant allows the consultant to purchase up to 300,000 shares of the Company's common stock at \$2.31 per share subject to achievement of specified performance goals that will be measured at March 31, 2019. The second warrant allows the consultant to purchase up to 450,000 shares of the Company's common stock at \$2.31 per share subject to achievement of specified performance goals that will be measured at March 31, 2020. The warrants provide for early exercisability if certain events occur related to the Company's FC2 business. If the warrants become exercisable, they will expire to the extent not exercised on or before April 2, 2023. The warrants have a cashless exercise feature. If the performance goals defined in the warrant agreements are not achieved, the warrants will be forfeited. For measurement and recognition purposes, the Company utilized the lowest aggregate amount within the range of potential values, which was zero. Therefore, at June 30, 2018, the Company has determined the fair value of these warrants to be zero and has not recognized any compensation expense related to these warrants for the three and nine months ended June 30, 2018.

### Aspire Capital Purchase Agreement

On December 29, 2017, the Company entered into a common stock purchase agreement (the "Purchase Agreement") with Aspire Capital Fund, LLC ("Aspire Capital") which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right, from time to time in its sole discretion during the 36-month term of the Purchase Agreement, to direct Aspire Capital to purchase up to \$15.0 million of the Company's common stock in the aggregate. Concurrently with entering into the Purchase Agreement, the Company also entered into a registration rights agreement with Aspire Capital (the "Registration Rights Agreement"), in which the Company agreed to prepare and file under the Securities Act of 1933 and under its current registration statement on Form S-3 (File No. 333-221120), 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 deferred. 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

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above to additional paid-in capital. The unamortized amount of deferred costs of approximately \$368,000 is included in other assets on the accompanying unaudited condensed consolidated balance sheet at June 30, 2018. In July 2018, we sold an additional 540,540 shares of common stock to Aspire Capital under the Purchase Agreement resulting in proceeds to the Company of \$1.0 million.

**Note 9 – Share-based Compensation**

We allocate share-based compensation expense to cost of sales, selling, general and administrative expense and research and development expense based on the award holder's employment function. For the three and nine months ended June 30, 2018 and 2017, we recorded share-based compensation expenses as follows:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2018	2017	2018	2017
Cost of sales	\$ 2,867	\$ —	\$ 5,570	\$ —
Selling, general and administrative	379,814	105,316	919,516	527,785
Research and development	77,293	—	154,190	—
	<u>\$ 459,974</u>	<u>\$ 105,316</u>	<u>\$ 1,079,276</u>	<u>\$ 527,785</u>

Equity Plans

In March 2018, the Company's stockholders approved the Company's 2018 Equity Incentive Plan (the "2018 Plan"). A total of 2.0 million shares are authorized for issuance under the 2018 Plan. As of June 30, 2018, 907,900 shares remain available for issuance under the 2018 Plan.

In July 2017, the Company's stockholders approved the Company's 2017 Equity Incentive Plan (the "2017 Plan"). A total of 4.7 million shares are authorized for issuance under the 2017 Plan. As of June 30, 2018, 90,288 shares remain available for issuance under the 2017 Plan. The 2017 Plan replaced the Company's 2008 Stock Incentive Plan (the "2008 Plan"), and no further awards will be made under the 2008 Plan.

Stock Options

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

The following table outlines the weighted average assumptions for options granted during the three and nine months ended June 30, 2018 and 2017:

Weighted Average Assumptions:	Three Months Ended June 30,		Nine Months Ended June 30,	
	2018	2017	2018	2017
Expected Volatility	60.56%	43.76%	61.00%	43.76%
Expected Dividend Yield	0.00%	0.00%	0.00%	0.00%
Risk-free Interest Rate	2.86%	1.62%	2.63%	1.62%
Expected Term (in years)	6.0	6.0	5.9	6.0
Fair Value of Options Granted	<u>\$ 1.10</u>	<u>\$ 0.41</u>	<u>\$ 1.00</u>	<u>\$ 0.41</u>

During the three and nine months ended June 30, 2018 and 2017, the Company used historical volatility of our common stock over a period equal to the expected life of the options to estimate their fair value. The dividend yield assumption is based on the Company's history and expectation of future dividend payouts on the common stock. The risk-free interest rate is based on the implied yield available on U.S. treasury zero-coupon issues with an equivalent remaining term.

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The following table summarizes the stock options outstanding and exercisable at June 30, 2018:

	Number of Shares	Weighted Average		Aggregate Intrinsic Value
		Exercise Price Per Share	Remaining Contractual Term (years)	
Outstanding at September 30, 2017	2,830,805	\$ 1.27		
Granted	3,650,151	1.72		
Exercised	(55,000)	1.20		
Forfeited	(861,644)	1.19		
Outstanding at June 30, 2018	5,564,312	\$ 1.58	8.78	\$ 2,750,554
Exercisable at June 30, 2018	514,167	\$ 1.67	3.74	\$ 349,967

The aggregate intrinsic value in the table above is before income taxes, based on the Company's closing stock price of \$2.02 on the last day of business for the nine months ended June 30, 2018. As of June 30, 2018, the Company had unrecognized compensation expense of approximately \$3.6 million related to unvested stock options. This expense is expected to be recognized over approximately 3 years.

During fiscal 2018, the Company modified stock options held by certain optionees upon termination of their employment by the Company, retirement from the board of directors or resignation from the board of directors. The aggregate amount of expense recognized in connection with these modifications in the three and nine months ended June 30, 2018 was approximately \$123,000 and \$287,000, respectively.

Restricted Stock

The Company has issued restricted stock to employees, directors and consultants. Such issuances had vesting periods that range from one to three years. All such shares of restricted stock vest and all such shares must be issued pursuant to the vesting period noted, provided the grantee has not voluntarily terminated service or been terminated for cause prior to the vesting date.

A summary of the non-vested stock activity for the nine months ended June 30, 2018 is presented in the table below:

	Shares	Weighted Average		Vesting Period
		Grant Date Fair Value		
Outstanding at September 30, 2017	198,750	\$ 0.99		
Granted	—			
Vested	(198,750)			
Forfeited	—			
Outstanding at June 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 vest on October 31, 2018. The restricted stock units will be settled in common stock issued under the 2017 Plan. As of June 30, 2018, there was approximately \$41,000 of unrecognized compensation cost related to non-vested restricted stock units, which is expected to be recognized by October 31, 2018.

Stock Appreciation Rights

In connection with the closing of the APP Acquisition, the Company issued stock appreciation rights based on 50,000 and 140,000 shares of the Company's common stock to an employee and an outside director, respectively, that vest 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 of a share of the Company's common stock as quoted on NASDAQ on the trading day immediately preceding the date of the completion of the APP Acquisition. The stock appreciation rights will be settled in common stock issued under the 2017 Plan. As of June 30, 2018, there was approximately \$22,000



of unrecognized compensation cost related to non-vested stock appreciation rights, which is expected to be recognized by October 31, 2018.

#### **Note 10 - Contingent Liabilities**

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

##### Litigation

In connection with the APP Acquisition, two purported derivative and class action lawsuits were filed against the Company in the Circuit Court of Cook County, Illinois, which were 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. 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 alleges, among other things, that our 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 alleges that Mitchell S. Steiner, a director and the President and Chief Executive Officer of Veru and a co-founder of APP, and Harry Fisch, a director 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. Based on these allegations, the 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 Dr. Fisch, and costs and expenses of the litigation, including attorneys' fees. 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 the pre-acquisition directors 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, and the action is continuing as to those claims. The parties are currently engaged in discovery. Veru believes that this action is without merit and is vigorously defending itself. No amount has been accrued for possible losses relating to this litigation as any such losses are not both probable and reasonably estimable.

##### License and Purchase Agreements

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

In connection with the Company's acquisition of intellectual property rights associated with Solifenacin DRG and Tadalafil/Finasteride combination capsules in December 2017, the Company was obligated to make upfront payments totaling \$500,000 by March 2018, as well as future installment payments and milestone payments. Of the \$500,000, \$250,000 was paid in May 2018 and the remaining \$250,000 is included in accounts payable on the accompanying condensed consolidated balance sheet as of June 30, 2018. The Company expects to pay this amount in the fourth quarter of fiscal 2018. The Company has met the initial milestones for these two product candidates, which will result in additional payments totaling \$700,000. These amounts owed, which total \$950,000, are included in accounts payable on the accompanying unaudited condensed consolidated balance sheet at June 30, 2018.

**Note 11 - Income Taxes**

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

On December 22, 2017, significant changes were enacted to the U.S. tax law pursuant to H.R.1. “An Act to Provide for Reconciliation Pursuant to Titles II and V of the Concurrent Resolution on the Budget for Fiscal Year 2018” (the “Tax Act”) (previously known as “The Tax Cuts and Jobs Act”). The Tax Act included a permanent reduction to the U.S. federal corporate income tax rate from 35% to 21%, a one-time repatriation tax on deferred foreign income, deductions, credits and business-related exclusions.

On December 22, 2017, the SEC issued guidance under Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (“SAB 118”), directing registrants to consider the impact of the Tax Act as “provisional” when it does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete its accounting for the change in tax law.

In accordance with SAB 118, the Company’s income tax provision as of June 30, 2018 reflects (i) the current year impacts of the Tax Act on the estimated annual effective tax rate and (ii) the following discreet items resulting directly from the enactment of the Tax Act based on the information available, prepared or analyzed (including computations) in reasonable detail.

- (i) The Tax Act reduces the federal corporate tax rate from 35% to 21%. The impact from the permanent reduction to the U.S. federal corporate income tax rate from 35% to 21% is effective January 1, 2018 (the “Effective Date”). When a U.S. federal tax rate change occurs during a fiscal year, tax payers are required to compute a weighted daily average rate for the fiscal year of enactment. However, as the Company is in a net loss carry forward position, it is using the U.S. federal statutory income tax rate of 21% that will be in effect when the net loss is utilized.
- (ii) The Company determined the impact of the U.S. federal corporate income tax rate change, net of the related state income tax impact on the U.S. deferred tax assets and liabilities, to be a benefit of approximately \$1.2 million as of October 1, 2017.

The Tax Act imposes a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred and creates new taxes on certain foreign-sourced earnings. The one-time transition tax is based on total post-1986 foreign earnings and profits (“E&P”) which a tax payer has previously deferred from U.S. income taxes. The Company has no post-1986 foreign E&P which it has previously deferred.

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 completes a detailed analysis of its deferred income tax valuation allowances on an annual basis or more frequently if information comes to our attention that would indicate that a revision to our 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, forecast 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 2016, the Company has annually generated taxable income on a consolidated basis. In management’s analysis to determine the amount of the deferred tax asset to recognize, management projected future taxable income for each tax jurisdiction.

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As of June 30, 2018, the Company had U.S. federal and state net operating loss carryforwards of approximately \$10.5 million and \$15.5 million, respectively, for income tax purposes expiring in years 2022 to 2037. The Company's U.K. subsidiary has U.K. net operating loss carryforwards of approximately \$62.2 million as of June 30, 2018, which can be carried forward indefinitely to be used to offset future U.K. taxable income.

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		Nine Months Ended	
	June 30,		June 30,	
	2018	2017	2018	2017
Income tax benefit at statutory rates	\$ (1,412,119)	\$ (442,000)	\$ (5,040,855)	\$ (1,971,000)
Effect of change in U.S. tax rate	190,319	—	3,319	—
State income tax benefit, net of federal benefits	(15,213)	(66,000)	(963,608)	(295,000)
Non-deductible business acquisition expenses	—	29,000	—	182,000
Non-deductible expenses - other	862	10,000	13,564	14,000
Effect of change to state income tax rate	—	(12,955)	—	189,422
Effect of lower foreign income tax rates	(67,765)	(27,758)	12,621	16,763
Recharacterization of foreign tax credits to net operating loss	1,311,429	—	1,311,429	—
Increase in valuation allowance	933,000	—	933,000	—
Other	265,618	—	388,191	—
Income tax expense (benefit)	\$ 1,206,131	\$ (509,713)	\$ (3,342,339)	\$ (1,863,815)

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

	June 30, 2018	September 30, 2017
<b>Deferred tax assets:</b>		
Federal net operating loss carryforwards	\$ 6,770,000	\$ 4,075,000
State net operating loss carryforwards	2,052,000	963,000
AMT credit carryforward	533,000	533,000
Foreign net operating loss carryforwards – U.K.	10,583,000	10,578,000
Foreign capital allowance – U.K.	108,000	108,000
U.K. bad debts	2,000	2,000
Restricted stock – U.K.	1,000	1,000
U.S. unearned revenue	—	409,000
U.S. deferred rent	21,000	76,000
Share-based compensation	487,000	447,000
Foreign tax credits	—	1,797,000
Other, net – U.S.	58,000	82,000
Gross deferred tax assets	20,615,000	19,071,000
Valuation allowance for deferred tax assets	(3,077,000)	(2,144,000)
Net deferred tax assets	17,538,000	16,927,000
<b>Deferred tax liabilities:</b>		
In process research and development	(4,676,000)	(7,000,000)
Developed technology	(563,000)	(900,000)
Covenant not-to-compete	(99,000)	(200,000)
Other	(6,000)	—
Net deferred tax liabilities	(5,344,000)	(8,100,000)
<b>Net deferred tax asset</b>	<b>\$ 12,194,000</b>	<b>\$ 8,827,000</b>

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

	June 30, 2018	September 30, 2017
Long-term deferred tax asset – U.S.	\$ 3,644,000	\$ 282,000
Long-term deferred tax asset – U.K.	8,550,000	8,545,000
<b>Total long-term deferred tax asset</b>	<b>\$ 12,194,000</b>	<b>\$ 8,827,000</b>

**Note 12 – Net Loss Per Share**

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing net income by the weighted average number of common shares outstanding during the period after giving effect to all dilutive potential common shares that were outstanding during the period. Dilutive potential common shares consist of the incremental common shares issuable upon the exercise of stock options, stock appreciation rights and warrants, and the vesting of unvested restricted stock and restricted stock units. Due to our net loss for the periods presented, all potentially dilutive instruments were excluded because their inclusion would have been anti-dilutive. See Notes 8 and 9 for a discussion of our dilutive potential common shares.

**Note 13 - Industry Segments and Financial Information about Foreign and Domestic Operations**

The Company currently operates in two reporting segments: Commercial and Research and Development. 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 Steiner, M.D., our President and Chief Executive Officer.

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

	For the three months ended June 30,		For the nine months ended June 30,	
	2018	2017	2018	2017
<b>Operating (loss) income:</b>	<b>(In thousands)</b>		<b>(In thousands)</b>	
Commercial	\$ 1,328	\$ 1,099	\$ 1,309	\$ 2,531
Research and Development	(3,787)	(421)	(7,780)	(1,735)
Corporate	(2,506)	(1,944)	(10,627)	(6,516)
	<u>\$ (4,965)</u>	<u>\$ (1,266)</u>	<u>\$ (17,098)</u>	<u>\$ (5,720)</u>
<b>Revenues:</b>				
United States	\$ 641	\$ 53	\$ 2,616	\$ 790
South Africa	1,791	199	2,824	955
Zimbabwe	372	240	1,050	1,271
Mozambique	127	1,430	127	1,430
Other	2,571	2,392	4,044	5,517
	<u>\$ 5,502</u>	<u>\$ 4,314</u>	<u>\$ 10,661</u>	<u>\$ 9,963</u>

All of our revenues are attributed to our Commercial reporting segment. Depreciation and amortization related to long-lived assets are not reported as part of the reporting segments or reviewed by the CODM. These amounts are included in Corporate in the reconciliations above.

**Note 14 - Subsequent Events**

On August 10, 2018, the Company entered into an amendment (the “Credit Agreement Amendment”) to the Credit Agreement with SWK. The Credit Agreement Amendment defers until November 15, 2018 the due date for the quarterly revenue-based payment that would otherwise be due in August 2018.

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 and prostate cancer supportive care as well as near term specialty pharmaceuticals to address significant unmet needs in urology.

The Company's prostate cancer pipeline includes zuclomiphene citrate (VERU-944; cis-clomiphene) and VERU-111 (bisindole). Zuclomiphene is an estrogen receptor agonist being evaluated in a Phase 2 trial to treat hot flashes, a common side effect caused by hormone treatment for men who have advanced prostate cancer. VERU-111 is an oral, next-generation, first-in-class, antitubulin agent targeting alpha and beta tubulin of microtubules to treat metastatic castration and novel androgen blocking agent (enzalutamide or abiraterone) resistant prostate cancer that the Company expects to enter Phase 1/2 development in late 2018. VERU-111 is also being evaluated for a variety of other malignancies.

The Company is advancing four new drug formulations in our specialty pharmaceutical pipeline. Tamsulosin DRS granules and XR capsules are formulations of a super selective alpha-1 adrenergic receptor antagonist for the treatment of benign prostatic hyperplasia (BPH or enlarged prostate) without a food effect, allowing for potentially safer administration and improved drug compliance (NDA filing expected in 2018). Tadalafil/finasteride combination tablets are for inhibition of both phosphodiesterase type 5 (PDE5) and 5-alpha-reductase enzymes to shrink an enlarged prostate, treat symptoms of BPH and treat erectile dysfunction (NDA filing expected in 2019). Solifenacin DRG slow release granules are a formulation of a selective M3 muscarinic receptor antagonist for the treatment of overactive bladder in patients who have difficulty with swallowing tablets (NDA filing expected in 2019).

The Company also owns and maintains intellectual property around VERU-722 (fixed ratio trans- and cis- clomiphene citrate) for male infertility. While the Company remains optimistic about advancing VERU-722 into a Phase 2 clinical trial in men with testicular dysfunction (oligospermia (low sperm count) and secondary hypogonadism) as a cause of male factor infertility in the future, the clinical trial requirements of other Company drug candidates are taking priority at the current time.

The Company markets and sells the PREBOOST® medicated individual wipe, which is a male genital desensitizing drug product for the prevention of premature ejaculation being co-promoted with Timm Medical Technologies, Inc. The Company also markets and sells the FC2 Female Condom® ("FC2") in the U.S. market by prescription and other sales channels and through The Female Health Company Division in the global public health sector. The Female Health Company Division markets 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.

On October 31, 2016, as part of the Company's strategy to diversify its product line to mitigate the risks of being a single product company, the Company completed its acquisition (the "APP Acquisition") of Aspen Park Pharmaceuticals, Inc. ("APP") through the merger of a wholly owned subsidiary of the Company into APP. The completion of the APP Acquisition transitioned us from a single product company selling only FC2 to a biopharmaceutical company with multiple drug products under clinical development focused on urology and oncology.

On August 12, 2016, the FDA agreed that the Company's Tamsulosin DRS medication qualifies for the expedited 505(b)(2) regulatory approval pathway. In March 2017, the Company initiated a bioequivalence clinical study for Tamsulosin DRS and in April 2017 announced the successful completion of Stage 1 of the bioequivalence clinical study, which selected the optimal formulation of our proprietary Tamsulosin DRS product. In October 2017, the Company initiated Stage 2 of the bioequivalence clinical study of Tamsulosin DRS and in November 2017 announced the results of Stage 2 of the bioequivalence clinical study. During the Stage 2 bioequivalence clinical study, dosing with Tamsulosin DRS fasted and Tamsulosin DRS fed were successfully shown to be bioequivalent with FLOMAX fed based on AUC, which is the key determinant of drug exposure over time. The Tamsulosin DRS formulation still needs to meet the remaining bioequivalence criterion for peak value (Cmax). The Company intends to initiate a new bioequivalence study after adjusting the formulation to address Cmax and expects this study to be

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completed in 2018. The Company plans to develop Tamsulosin XR (extended release) capsules (tamsulosin HCl extended release capsules) as well.

On May 13, 2017, the Company announced positive results of a clinical study of its novel PREBOOST® product. The PREBOOST® clinical study enrolled 26 men aged 18 years or older in a heterosexual, monogamous relationship, with premature ejaculation, defined as reported poor control over ejaculation, personal distress related to ejaculation and average intravaginal ejaculation latency time (IELT) of two minutes or less on stopwatch measurement. After treatment with PREBOOST®, 82% of men were no longer considered to have premature ejaculation with an increase on average of 5 minutes. Results showed that treatment was well tolerated. Therefore, the results of the study showed that PREBOOST® prolonged time to ejaculation, supporting the clinical validity of PREBOOST® for the prevention of premature ejaculation. The Company launched the product in the U.S. in January 2017 and in October 2017 entered into a co-promotion and distribution agreement with Timm Medical Technologies, Inc.

On May 24, 2017, the Company announced that, following a Pre-IND meeting with the FDA, it plans to advance zuclomiphene citrate, an oral agent being evaluated for the treatment of hot flashes in men receiving hormone therapy, androgen deprivation therapy (“ADT”), for advanced prostate cancer into Phase 2 clinical trial utilizing the 505(b)(2) regulatory pathway. Approximately 80% of men receiving one of the common forms of ADT, including LUPRON® (Leuprolide), ELIGARD® (Leuprolide), and FIRMAGON® (degarelix), experience hot flashes and 30-40% will suffer from moderate to severe hot flashes.

On December 11, 2017, the Company announced that it has acquired world-wide rights to a novel, proprietary oral granule formulation for solifenacin from Camargo Pharmaceuticals Services, LLC. Solifenacin is the active ingredient in a leading drug VESicare® for the treatment of overactive bladder in men and women. Solifenacin Delayed Release Granule (“DRG”) formulation addresses the large population of men and women who have overactive bladder (“OAB”) and who have dysphagia, or difficulty swallowing tablets. In a Pre-IND meeting, the FDA confirmed that a single bioequivalence study and that no additional nonclinical, clinical efficacy and/or safety studies will be required to support the approval of Solifenacin DRG product for the treatment of overactive bladder. The Company plans to complete the Solifenacin DRG bioequivalence study in 2018 and to file the NDA in 2019.

On December 15, 2017, the Company acquired world-wide rights to Tadalafil-Finasteride combination tablet formulation from Camargo Pharmaceuticals Services, LLC. Tadalafil-Finasteride combination tablet (tadalafil 5mg and finasteride 5mg) is a new, proprietary formulation that addresses the large population of men who have lower urinary tract symptoms and restricted urinary stream because of an enlarged prostate. Tadalafil 5mg is a phosphodiesterase 5 (PDE5) inhibitor marketed under CIALIS® for benign prostatic hyperplasia and erectile dysfunction and finasteride 5mg is a Type 2, 5-alpha reductase inhibitor marketed under PROSCAR® to decrease the size of the prostate, prevent urinary retention and the need for prostate surgery in men who have an enlarged prostate. In a Pre-IND meeting held in November 2017, the FDA agreed that a single bioequivalence study and no additional nonclinical, clinical efficacy and safety studies will be required to support the approval of Tadalafil-Finasteride combination tablet via a 505(b)(2) regulatory pathway. The Company plans to complete the bioequivalence study in 2018 and to file the NDA in 2019.

The Company presented data from a preclinical study of VERU-111 at the 2018 American Society of Clinical Oncology (“ASCO”) Genitourinary Cancers Symposium on February 6, 2018 and at the 2018 European Association of Urology (“EAU”) 33<sup>rd</sup> Annual Congress on March 16, 2018. The data showed potent activity against paclitaxel sensitive and resistant prostate cancer models.

On March 22, 2018, the Company announced that the FDA granted its application for a small business waiver of the drug application fee of approximately \$2.4 million for the Company’s NDA for Tamsulosin DRS. FDA’s grant of the fee waiver frees up resources to further advance the Company’s drug development programs.

On May 17, 2018, the Company announced publication of data on oral VERU-111 in prostate cancer in connection with the 2018 ASCO Annual Meeting. The data showed greater efficacy of oral VERU-111 in highly resistant prostate cancer with less toxicity than docetaxel.

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On May 17, 2018, the Company also announced publication of data from three cancer studies as part of the ASCO Annual Meeting. The data showed efficacy of oral VERU-111 in human taxane-resistant triple negative breast cancer, pancreatic cancer and ovarian cancer.

On June 11, 2018, the Company filed an investigational new drug application (“IND”) with the FDA regarding a Phase 2 clinical trial for zuclomiphene citrate. The Company announced on June 12, 2018 that the U.S. Patent and Trademark Office had issued Patent No. 9,913,815 with expiry in 2035, providing intellectual property protection for the use of zuclomiphene citrate in men with prostate cancer as a method of treating and preventing side effects caused by ADT, including hot flashes, bone loss and bone fractures.

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. FC2 is the only currently available female-controlled product approved for market by the FDA and cleared by the World Health Organization (“WHO”) for purchase by U.N. agencies that provides dual protection against unintended pregnancy and sexually transmitted infections (“STIs”). The Centers for Disease Control and Prevention has referenced the use of condoms, including the female condom, as a means to reduce the risk of transmitting STI’s, including HIV/AIDS and the transmission of Zika by sex. Nearly all of the Company’s net revenues for the three and nine months ended June 30, 2018 and 2017 were derived from sales of FC2.

FC2’s primary use is for disease prevention and family planning, and the public health sector is the Company’s main market. Within the 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 149 countries. A significant number of countries with the highest demand potential are in the developing world. The incidence of HIV/AIDS, other STIs and unwanted pregnancy in these countries represents a remarkable potential for significant sales of a product that benefits some of the world’s most underprivileged people. However, conditions in these countries can be volatile and result in unpredictable delays in program development, tender applications and processing orders.

FC2 has a relatively small customer base, with a limited number of customers who generally purchase in large quantities. Over the past few years, major 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 NGOs.

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

In April 2017, the Company launched a small-scale marketing and sales program to support the promotion of FC2 in the U.S. market. The commercial team developed a plan to confirm the “proof of concept” that FC2 represented a significant business opportunity. This required changes in the distribution process for FC2 in the U.S. As part of this reorganization the Company announced new distribution agreements with three of the country’s largest distributors that support the pharmaceutical industry. This newly developed network now allows up to 98% of major retail



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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, utilizing the telemedicine “HeyDoctor” App, through 340B covered entities, college and universities and our patient assistance program. We continue to increase healthcare provider awareness, education and acceptance which has resulted in more women utilizing FC2 in the U.S. We believe that the initial results from these efforts support the U.S. market opportunity and that we will continue to see increased utilization of FC2.

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

<b>Period</b>	<b>2018</b>	<b>2017</b>	<b>2016</b>	<b>2015</b>	<b>2014</b>
October 1 — December 31	4,399,932	6,389,320	15,380,240	12,154,570	11,832,666
January 1 — March 31	4,125,032	4,549,020	9,163,855	20,760,519	7,298,968
April 1 — June 30	10,021,188	8,466,004	10,749,860	14,413,032	13,693,652
July 1 — September 30		6,854,868	6,690,080	13,687,462	9,697,341
<b>Total</b>	<b>18,546,152</b>	<b>26,259,212</b>	<b>41,984,035</b>	<b>61,015,583</b>	<b>42,522,627</b>

*Revenues.* The Company's revenues are primarily derived from sales of FC2 in the public sector and are recognized upon shipment of the product to its customers. Other sales are from FC2 into the prescription channel in the U.S. and sales of PREBOOST; however, these sales were not material to our results for the three and nine months ended June 30, 2018.

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

The Company's most significant customers have been either global public health sector agencies or those who facilitate their purchases and/or distribution of FC2 for use in HIV/AIDS prevention and/or family planning. The Company's four largest customers currently are UNFPA, USAID, Barrs Medical (PTY) Ltd and Semina. We sell to the Brazil Ministry of Health either through UNFPA or Semina.

In 2017, the Company began expanding access to FC2 in the U.S. by making it available by prescription. With a prescription, FC2 is covered by most insurance companies with no copay. The Company retained an independent sales organization to help educate doctors, pharmacists, clinics and student health centers on the benefits of FC2 and how to prescribe it. In the U.S., FC2 is sold to major distributors and sold direct 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. For the remainder of fiscal 2018 and into fiscal 2019, we expect to increase our expenses relating to research and development due to advancement of multiple drug candidates.

Results of Operations

THREE MONTHS ENDED JUNE 30, 2018 COMPARED TO THREE MONTHS ENDED JUNE 30 2017

The Company generated 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, compared to net revenues of \$4.3 million and net loss of \$0.8 million, or \$(0.03) per basic and diluted common share, for the three months ended June 30, 2017.

Net revenues increased 28%, which consisted of an 18% increase in unit sales and an increase in average sales price per unit of 8%. The principal factors for the increase in the FC2 average sales price per unit compared to the same period last year were changes in sales mix and unit price increases for customers in the U.S.

Cost of sales increased to \$2.4 million in the three months ended June 30, 2018 from \$2.0 million for the same period last year. The increase is primarily due to the increase in unit sales.

Gross profit increased to \$3.1 million for the three months ended June 30, 2018 from \$2.3 million, for the three months ended June 30, 2017. Gross profit margin for the three months ended June 30, 2018 was 56% of net revenues, compared to 53% of net revenues for the same period in 2017.

Significant quarter-to-quarter variations 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 female condoms. The Company is also currently seeing pressure on spending for FC2 by large global agencies and donor governments in the developed world. As a result, the Company may continue to experience challenges for unit sales of FC2 in the global public sector.

Research and development expenses increased to \$3.8 million for the three months ended June 30, 2018 from \$0.3 million in the prior year period. The increase is primarily due to increased research and development costs associated with the in-process research and development projects acquired pursuant to the APP Acquisition and increased personnel costs associated with the research and development.

Selling, general and administrative expenses increased to \$4.0 million for the three months ended June 30, 2018 from \$3.2 million in the prior year period. The increase primarily relates to salaries for our U.S. Commercial team, part of our Commercial reporting segment, and additional corporate personnel, severance, investor relations and shared-based compensation expenses. In the third quarter of fiscal 2018, the Company changed its U.S. sales strategy for FC2 by principally relying on an independent sales organization, which change resulted in severance payments of \$0.5 million. This amount was substantially paid in the three months ended June 30, 2018.

The Company incurred a loss on net accounts receivable of approximately \$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.

Business acquisition expenses for the three months ended June 30, 2018 decreased to zero from approximately \$74,000 in the prior year period for expenses representing costs related to the APP Acquisition.

Interest expense was approximately \$1.4 million for the three months ended June 30, 2018 which included \$1.3 million of amortization of the discounts on the SWK Credit Agreement, \$95,000 of accretion of the liability for the SWK Residual Royalty Agreement and approximately \$30,000 of amortization of the deferred issuance costs related to the SWK Credit Agreement.

The Company realized a foreign currency transaction loss of approximately \$2,000 in the most recent quarter, compared to approximately \$20,000 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 period.

The income tax expense for the three months ended June 30, 2018 was \$1.2 million, compared to an income tax benefit of \$0.5 million for the same period in fiscal 2017. The increase in income tax expense is primarily due to the write-off of approximately \$1.3 million of deferred tax assets related to foreign tax credits that were treated as a tax deduction, a valuation allowance recorded against the Illinois net operating loss carryforwards of \$0.9 million and

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an expense of \$0.2 million due to the decrease in the state income tax rate, net of an increase in the income tax benefit of \$1.0 million due to the change in the U.S. federal corporate income tax rate from 35% to 21% under the Tax Act and the increase in the loss before income taxes.

NINE MONTHS ENDED JUNE 30, 2018 COMPARED TO NINE MONTHS ENDED JUNE 30 2017

The Company generated 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, compared to net revenues of \$10.0 million and net loss of \$3.9 million, or \$(0.13) per basic and diluted common share, for the nine months ended June 30, 2017.

Net revenues increased 7% on an increase in average sales price per unit of 12%, which was partially offset by a 4% decrease in unit sales. The FC2 average sales price per unit increased due to changes in sales mix and unit price increases for customers in the U.S.

Cost of sales increased to \$5.1 million in the nine months ended June 30, 2018 from \$4.7 million for the same period last year. The increase is primarily due to the mix of units sold with higher costs per unit and partially impacted by the unfavorable impact of currency exchange rates on costs of goods, which was partially offset by lower unit sales.

Gross profit increased to \$5.6 million for the nine months ended June 30, 2018 from \$5.2 million for the nine months ended June 30, 2017. Gross profit margin for the nine months ended June 30, 2018 was 52% of net revenues, which was consistent with the same period in 2017.

Significant quarter-to-quarter variations 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 female condoms. The Company is also currently seeing pressure on spending for FC2 by large global agencies and donor governments in the developed world. As a result, the Company may continue to experience challenges for unit sales of FC2 in the global public sector.

Research and development expenses increased to \$7.8 million for the nine months ended June 30, 2018 from \$1.7 million in the prior year period. The increase is primarily due to increased research and development costs associated with the in-process research and development projects acquired pursuant to the APP Acquisition and increased personnel costs associated with the research and development.

Selling, general and administrative expenses increased to \$10.9 million for the nine months ended June 30, 2018 from \$8.3 million in the prior year period. The increase primarily relates to salaries for our U.S. Commercial team, part of our Commercial reporting segment, and additional corporate personnel, severance, investor relations, shared-based compensation, and legal and patent costs. In the third quarter of fiscal 2018, the Company changed its U.S. sales strategy for FC2 by principally relying on an independent sales organization, which change resulted in severance payments of approximately \$0.5 million. This amount was substantially paid in the three months ended June 30, 2018.

The Company incurred a loss on net accounts receivable of approximately \$4.0 million, which consists of \$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.

Business acquisition expenses for the nine months ended June 30, 2018 decreased to zero from \$1.0 million in the prior year period for expenses representing costs related to the APP Acquisition.

Interest expense was \$1.7 million for the nine months ended June 30, 2018 which included approximately \$1.6 million of amortization of the discounts on the SWK Credit Agreement, \$0.1 million of accretion of the liability for the SWK Residual Royalty Agreement and approximately \$36,000 of amortization of the deferred issuance costs related to the SWK Credit Agreement.

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The Company realized a foreign currency transaction loss of approximately \$118,000 for the nine months ended June 30, 2018, compared to approximately \$40,000 for the same period in fiscal 2017. This foreign currency transaction loss was primarily due to the adverse movement of the U.S. dollar against the Malaysian Ringgit during the period.

The income tax benefit for the nine months ended June 30, 2018 was \$3.3 million, compared to income tax benefit of \$1.9 million for the same period in fiscal 2017. The increase in the income tax benefit of \$1.5 million is primarily due to an increase of \$3.7 million due to the change in the U.S. federal corporate income tax rate from 35% to 21% under the Tax Act and the increase in the loss before income taxes, a decrease in income tax expense of \$0.2 million due to a reduction in non-deductible business acquisition expenses, a decrease in income tax expense of \$0.2 million from the effect of a lower foreign tax rate, net of the write-off of approximately \$1.3 million of deferred tax assets related to foreign tax credits that were treated as a tax deduction and a valuation allowance recorded against the Illinois net operating loss carryforwards of \$0.9 million.

Liquidity and Sources of Capital

*Liquidity*

Our cash on hand (including restricted cash) at June 30, 2018 was approximately \$5.6 million, compared to \$3.3 million at September 30, 2017. At June 30, 2018, the Company had working capital of \$0.1 million and stockholders' equity of \$35.9 million compared to working capital of \$4.8 million and stockholders' equity of \$48.5 million as of September 30, 2017. The reduction in working capital is primarily due to estimated amounts payable under the SWK Credit Agreement over the next twelve months.

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 product 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 Form 10-K for the year ended September 30, 2017, 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, convertible debt or other equity-linked securities and may include financings under the Company's current registration statement on Form S-3 (File No. 333-221120). The Company's intention is to be opportunistic when pursuing equity financing which could include selling common stock under the Purchase Agreement with Aspire Capital and/or a marketed deal with an investment bank. The Company's ability to raise capital through equity financing may be limited by the number of authorized shares of the Company's common stock, which is currently 77 million shares. The Company may need to seek stockholder approval to amend our Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock, and any such amendment would require the approval of the holders of at least two-thirds of the outstanding shares of the Company's common stock. See Part I, Item 1A, "Risk Factors - Risks Related to Our Financial Position and Need for Capital" in the Company's Form 10-K for the year ended September 30, 2017, for a description of certain risks related to our ability to raise capital on acceptable terms.

*Operating activities*

Our operating activities used cash of approximately \$8.7 million in the first nine months of fiscal 2018. Cash used in operating activities included a net loss of approximately \$(16.0) million, adjustments for non-cash items totaling \$4.1 million and cash from changes in working capital of \$3.2 million. Adjustments for non-cash items primarily consisted of \$4.0 million for the loss on settlement of accounts receivable, \$3.4 million related to deferred income taxes, \$1.7 million of non-cash interest expense related to the SWK Credit 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 SWK Credit Agreement. The increase in cash from changes in working capital included a decrease in net accounts receivable and long-term other receivables of \$2.3 million and increases in trade accounts payable of \$0.8 million.

Our operating activities provided cash of approximately \$0.4 million in the first nine months of fiscal 2017. Cash provided by operating activities included a net loss of approximately \$(3.9) million, adjustments for non-cash items totaling \$0.5 million and cash from changes in working capital of \$4.9 million. Adjustments for non-cash items primarily consisted of \$2.0 million related to deferred income taxes, \$0.5 million of share-based compensation and \$0.5 million for the fair value of a warrant issued to the Company financial advisor for the APP Acquisition. The increase in cash from changes in working capital primarily consisted of a decrease in accounts receivable of \$5.0 million and an increase in unearned revenue of \$1.0 million, which were partially offset by a decrease in accrued expenses and other current liabilities of \$0.9 million.

On December 27, 2017, we entered into a settlement agreement with Semina pursuant to which Semina made 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 2014 Brazil tender. 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 \$1.3 million was received by us on July 26, 2018. The settlement

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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 approximately \$4.0 million, which is presented as a separate line item in the accompanying unaudited condensed consolidated statement of operations for the nine months ended June 30, 2018.

In connection with the Company's acquisition of intellectual property rights associated with Solifenacin DRG and Tadalafil/ Finasteride combination capsules, the Company was obligated to make upfront payments totaling \$500,000 by March 2018, as well as future installment payments and milestone payments. Of the \$500,000, \$250,000 was paid in May 2018 and the Company expects to pay the remaining \$250,000 in the fourth quarter of fiscal 2018. The Company has met the initial milestones for these two product candidates, which will result in additional payments totaling \$700,000. These amounts owed, which total \$950,000, are included in accounts payable on the accompanying unaudited condensed consolidated balance sheet at June 30, 2018.

### *Investing activities*

Net cash used in investing activities during the first nine months of fiscal 2018 was approximately \$48,000 and was primarily associated with capital expenditures at our UK location. Net cash used in investing activities during the first nine months of fiscal 2017 was approximately \$119,000 and was primarily related to office furniture and equipment purchases at our Chicago and Miami locations.

### *Financing activities*

Net cash provided by financing activities during the nine months ended June 30, 2018 was approximately \$11.1 million and primarily consists of the net proceeds from the SWK Credit Agreement (see discussion below) and the net proceeds from the sale of shares under the Purchase Agreement with Aspire Capital (see discussion below).

### **Sources of Capital**

#### *SWK Credit Agreement*

On March 5, 2018, the Company entered into a Credit Agreement (the "Credit Agreement") with the financial institutions party thereto from time to time (the "Lenders") and SWK Funding LLC, as agent for the Lenders (the "Agent"), for a synthetic royalty financing transaction. On and subject to the terms of the Credit Agreement, the Lenders agreed to provide the Company with a multi-draw term loan of up to \$12.0 million, with \$10.0 million advanced to the Company on the date of the Credit Agreement. The Company may draw up to an additional \$1.0 million if the Company enters into an agreement to distribute at least 47.5 million units of FC2 in Brazil upon the terms described in the Credit Agreement and up to an additional \$1.0 million if the Company enters into an agreement to distribute at least 30 million units of FC2 in South Africa upon the terms described in the Credit Agreement. Under the Credit Agreement, the Company is required to make quarterly payments on the term loan based on the Company's product revenue from net sales of FC2 until the earlier of receipt by the Lenders of a return premium specified in the Credit Agreement or a required payment upon termination of the Credit Agreement on March 5, 2025 or an earlier change of control of the Company or sale of the FC2 business. The recourse of the Lenders and the Agent for obligations under the Credit Agreement is limited to assets relating to FC2.

In connection with the Credit Agreement, Veru and the Agent also entered into a Residual Royalty Agreement, dated as of March 5, 2018 (the "Residual Royalty Agreement"), which provides for an ongoing royalty payment of 5% of product revenue from net sales of FC2 commencing upon the payment in full by the Company of the required amount pursuant to the Credit Agreement. The Residual Royalty Agreement will terminate upon (i) a change of control or sale of the FC2 business and the payment by the Company of the amount due in connection therewith pursuant to the Credit Agreement, or (ii) mutual agreement of the parties.

After payment by the Company of certain fees and expenses of the Agent and the Lenders as required in the Credit Agreement, the Company received net proceeds of approximately \$9.9 million from the initial \$10.0 million advance under the Credit Agreement. The first quarterly payment on the loan of \$0.6 million was made in May 2018.

*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 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. In July 2018, we sold an additional 540,540 shares of common stock to Aspire Capital under the Purchase Agreement resulting in proceeds to the Company of \$1.0 million.

*BMO Line of Credit*

The Company's Credit Agreement with BMO Harris Bank N.A. expired on December 29, 2017. No amounts were outstanding under the Credit Agreement during the three and nine months ended June 30, 2018 or 2017.

Fair Value Measurements

As of June 30, 2018, the Company's financial liabilities measured at fair value on a recurring basis, which consisted of embedded derivatives, represent the fair value of the change of control provisions in the SWK Credit Agreement and Residual Royalty Agreement. See Note 7 for additional information.

The fair values of these liabilities were estimated based on unobservable inputs (Level 3 measurement). See Note 3 for additional information. 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. 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. The change in the fair value of the embedded derivatives is included on a separate line item on our condensed consolidated statements of operations.



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

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

There was no change 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 has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

In connection with the APP Acquisition, two purported derivative and class action lawsuits were filed against the Company in the Circuit Court of Cook County, Illinois, which were 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. 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 alleges, among other things, that our 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 alleges that Mitchell S. Steiner, a director and the President and Chief Executive Officer of Veru and a co-founder of APP, and Harry Fisch, a director 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. Based on these allegations, the 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 Dr. Fisch, and costs and expenses of the litigation, including attorneys' fees. 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 the pre-acquisition directors 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, and the action is continuing as to those claims. The parties are currently engaged in discovery. Veru believes that this action is without merit and is vigorously defending itself.

Item 1A. Risk Factors

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the risks and uncertainties relating to the Company's business disclosed in Part I, Item 1A, "Risk Factors," of the Company's Form 10-K for the year ended September 30, 2017. 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, 2017, except for the following additional risk factor:

***The recently passed Tax Cuts and Jobs Act may have a significant impact on our financial condition and results of operations.***

On December 22, 2017, significant changes were enacted to the U.S. tax law pursuant to H.R.1. "An Act to Provide for Reconciliation Pursuant to Titles II and V of the Concurrent Resolution on the Budget for Fiscal Year 2018" (the "Tax Act") (previously known as "The Tax Cuts and Jobs Act"). The Tax Act makes broad and complex changes to the U.S. tax code that could materially affect us. The Tax Act includes a permanent reduction in the U.S. federal corporate income tax rate from 35% to 21%, requires companies to pay a one-time transition tax on the previously untaxed earnings of certain foreign subsidiaries, generally eliminates the corporate alternative minimum tax, adds an anti-base erosion tax and makes other changes to deductions, credits and business-related exclusions.

While we have reflected the impact of the Tax Act on the accounting treatment of certain discrete items, we are still evaluating the full potential impact of the Tax Act on our tax provision and deferred tax assets. It is possible that the changes contained in the Tax Act could result in a write down of deferred tax assets or otherwise have an adverse impact on our effective tax rate, tax payments, financial condition or results of operations. The Tax Act is complex and additional interpretative guidance may be issued that could affect interpretations and assumptions we have made, as well as actions we may take as a result of the Tax Act.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

In May 2018, the Company issued two warrants to purchase a total of up to 750,000 shares of the Company's common stock in connection with a consulting services agreement. The first warrant allows the consultant to purchase up to 300,000 shares of the Company's common stock at \$2.31 per share subject to achievement of specified performance goals that will be measured at March 31, 2019. The second warrant allows the consultant to purchase up to 450,000 shares of the Company's common stock at \$2.31 per share subject to achievement of specified performance goals that will be measured at March 31, 2020. The warrants provide for early exercisability if certain events occur related to the Company's FC2 business. If the warrants become exercisable, they will expire to the extent not exercised on or before April 2, 2023. The warrants have a cashless exercise feature. The Company believes that the issuance of the warrants in connection with the performance of services to the Company were exempt from registration under Section 4(a)(2) of the Securities Act of 1933 and/or Regulation D promulgated under the Securities Act of 1933 because such issuance was made to an entity which is an accredited investor. Restrictive legends were placed on the warrants.

Item 5. Other Information

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

On August 10, 2018, the Company entered into an amendment (the "Credit Agreement Amendment") to the Credit Agreement with SWK. The Credit Agreement Amendment defers until November 15, 2018 the due date for the quarterly revenue-based payment that would otherwise be due in August 2018.

The foregoing description of the Credit Agreement Amendment is qualified in its entirety by reference to the full text of the Credit Agreement Amendment, which is filed as Exhibit 10.2 to this Quarterly Report on Form 10-Q and is incorporated herein by reference.

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Item 6. Exhibits\_

<u>Exhibit Number</u>	<u>Description</u>
3.1	<a href="#">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).</a>
3.2	<a href="#">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).</a>
3.3	<a href="#">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).</a>
3.4	<a href="#">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).</a>
3.5	<a href="#">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).</a>
3.6	<a href="#">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).</a>
3.7	<a href="#">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).</a>
3.8	<a href="#">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).</a>
4.1	Amended and Restated Articles of Incorporation, as amended (same as Exhibits <a href="#">3.1</a> , <a href="#">3.2</a> , <a href="#">3.3</a> , <a href="#">3.4</a> , <a href="#">3.5</a> , <a href="#">3.6</a> and <a href="#">3.7</a> ).
4.2	<a href="#">Articles II, VII and XI of the Amended and Restated By-Laws (included in Exhibit 3.8).</a>
10.1	<a href="#">Separation Agreement and General Release, effective as of April 16, 2018, between the Company and Brian Groch (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on April 20, 2018).</a> (1)
10.2	<a href="#">First Amendment to Credit Agreement, dated as of August 10, 2018, among the Company, SWK Funding LLC and the financial institutions party to the Credit Agreement from time to time.</a> (2)

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31.1	<a href="#">Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a> (2)
31.2	<a href="#">Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a> (2)
32.1	<a href="#">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).</a> (2) (3)
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, formatted in XBRL (Extensible Business Reporting Language): (1) the Unaudited Condensed Consolidated Balance Sheets, (2) the Unaudited Condensed Consolidated Statements of Operations, (3) the Unaudited Condensed Consolidated Statement of Stockholders' Equity, (4) the Unaudited Condensed Consolidated Statements of Cash Flows and (5) the Notes to the Unaudited Condensed Consolidated Financial Statements.
(1)	Management contract or compensatory plan or arrangement
(2)	Filed herewith
(3)	This certification is not "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

**SIGNATURES**

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

**VERU INC.**

DATE: August 14, 2018

/s/ Mitchell S. Steiner

Mitchell S. Steiner

Chairman, Chief Executive Officer and President

DATE: August 14, 2018

/s/ Michele Greco

Michele Greco

Chief Financial Officer and Chief Administrative Officer

**FIRST AMENDMENT TO CREDIT AGREEMENT**

THIS FIRST AMENDMENT TO CREDIT AGREEMENT (this "**Amendment**"), dated as of August 10, 2018 is entered into by and among VERU INC., a Wisconsin corporation ("**Borrower**"), each of the undersigned financial institutions (individually each a "**Lender**" and collectively "**Lenders**") and SWK FUNDING LLC, a Delaware limited liability company, in its capacity as Agent for all Lenders (in such capacity, "**Agent**").

**RECITALS**

WHEREAS, Borrower, Agent and Lenders entered into that certain Credit Agreement dated as of March 5, 2018, (as the same may be further amended, modified or restated from time to time, being hereinafter referred to as the "**Credit Agreement**"); capitalized terms used in this Amendment are defined in the Credit Agreement unless otherwise stated);

WHEREAS, Borrower has requested that, and the Lenders have agreed to, amend certain provisions of the Credit Agreement as more fully set forth herein.

**AGREEMENT**

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

**ARTICLE I****Amendments to Credit Agreement**

**1.1 Amendment to Section 2.9.1 of the Credit Agreement.** Effective as of the date hereof, Section 2.9.1 of the Credit Agreement is hereby amended to add a new subsection (e) thereto to read as follows:

"(e) Notwithstanding the foregoing, the Revenue-Based Payment that would otherwise be due and owing on the Payment Date in August 2018 shall be deferred until the November 2018 Payment Date without the need for any further action by Agent, Lenders or Borrower."

**ARTICLE II****Conditions Precedent**

**2.1** The effectiveness of the Amendments set forth in Article I above are subject to the satisfaction of the following conditions precedent in a manner satisfactory to Agent, unless specifically waived in writing by Agent in its sole discretion:

A. Agent shall have received this Amendment duly executed by all parties hereto.

B. Agent shall have received an amendment fee of \$10,000, which shall be deemed fully earned and non-refundable on the date hereof and which amount includes the reimbursement in full of Agent's out-of-pocket costs and expenses in connection with this Amendment as provided in the Credit Agreement.

C. The representations and warranties contained herein and in the Credit Agreement and the other Loan Documents, as each is amended hereby, shall be true and correct in all material respects as of the date hereof, as if made on the date hereof, except for such representations and warranties as are by their

[Veru] First Amendment to Credit Agreement

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express terms limited to a specific date, which shall be true and correct in all material respects as of such earlier date.

D. All corporate proceedings taken in connection with the transactions contemplated by this Amendment and all documents, instruments and other legal matters incident thereto shall be satisfactory to Agent.

### ARTICLE III

#### **Ratifications, Representations and Warranties**

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

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

### ARTICLE IV

#### **Miscellaneous Provisions**

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

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

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

**4.4 Successors and Assigns.** This Amendment is binding upon and shall inure to the benefit of Agent and each Lender and Borrower and their respective successors and assigns, except that Borrower may not assign or transfer any of its rights or obligations hereunder without the prior written consent of Agent.



**4.5 Counterparts.** This Amendment may be executed in one or more counterparts, each of which when so executed shall be deemed to be an original, but all of which when taken together shall constitute one and the same instrument. This Amendment may be executed by facsimile or electronic (.pdf) transmission, which facsimile or electronic (.pdf) signatures shall be considered original executed counterparts for purposes of this Section 4.5, and each party to this Amendment agrees that it will be bound by its own facsimile or electronic (.pdf) signature and that it accepts the facsimile or electronic (.pdf) signature of each other party to this Amendment.

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

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

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

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

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

**BORROWER:**

**VERU INC.,**  
a Wisconsin corporation

By: /s/ Mitchell Steiner  
Name: Mitchell Steiner, M.D.  
Title: Chairman, CEO and President

[Veru] First Amendment to Credit Agreement

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**AGENT AND LENDER:**

SWK FUNDING LLC,  
as Agent and a Lender

By: SWK Holdings Corporation,  
its sole Manager

By: /s/ Winston Black  
Name: Winston Black  
Title: Chief Executive Officer

[Veru] First Amendment to Credit Agreement

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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 14, 2018

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

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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 14, 2018

/s/Michele Greco

Michele Greco  
Chief Financial Officer and Chief Administrative Officer

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**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, 2018 fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934 and information contained in that Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2018

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

Date: August 14, 2018

/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.

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