VERU INC.
Form 10-Q
February 14, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended December 31, 2017

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	Accelerated filer
Non-accelerated filer	Smaller reporting company
(Do not check if smaller reporting company)	Emerging growth company

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

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

As of February 13, 2018, the registrant had 53,512,946 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:

- the Company's ability to secure adequate capital to fund product development, working capital requirements, advertising and promotional expenditures and strategic initiatives;
- 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;
- many of the Company's products are at an early stage of development and the Company may fail to successfully commercialize such products;
- risks related to intellectual property, including licensing risks;
- increased competition from existing and new competitors including the potential for reduced sales, pressure on pricing and increased spending on marketing;
- 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;
- 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.

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Item 1. Financial Statements

VERU INC.

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2017	September 30, 2017
ASSETS		
Current Assets:		
Cash	$ 3,572,350	$ 3,277,602
Accounts receivable, net	3,000,308	3,555,350
Inventory, net	3,067,036	2,767,924
Prepaid expenses and other current assets	625,497	697,097
TOTAL CURRENT ASSETS	10,265,191	10,297,973
LONG-TERM ASSETS		
PLANT AND EQUIPMENT		
Equipment, furniture and fixtures	4,069,810	4,067,896
Leasehold improvements	287,686	287,686
Less: accumulated depreciation and amortization	(3,844,272)	(3,800,043)
Plant and equipment, net	513,224	555,539
Other trade receivables (Note 5)	—	7,837,500
Other assets	159,662	156,431
Deferred assets	423,001	—
Deferred income taxes	12,124,000	8,827,000
Intangible assets, net	20,684,175	20,752,991
Goodwill	6,878,932	6,878,932
TOTAL ASSETS	$ 51,048,185	$ 55,306,366
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,517,371	$ 2,685,718
Accrued expenses and other current liabilities	2,383,628	1,441,359
Unearned revenue	990,016	1,014,517
Accrued compensation	338,136	345,987
TOTAL CURRENT LIABILITIES	6,229,151	5,487,581
LONG-TERM LIABILITIES		
Other liabilities (Note 5)	—	1,233,750
Deferred rent	68,446	131,830

TOTAL LIABILITIES	6,297,597	6,853,161
Commitments and contingencies (Note 10)		
STOCKHOLDERS' EQUITY		
Preferred stock	—	—
Common stock	556,967	553,922
Additional paid-in-capital	91,102,159	90,550,669
Accumulated other comprehensive loss	(581,519)	(581,519)
Accumulated deficit	(38,520,414)	(34,263,262)
Treasury stock, at cost	(7,806,605)	(7,806,605)
TOTAL STOCKHOLDERS' EQUITY	44,750,588	48,453,205
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 51,048,185	$ 55,306,366

See notes to unaudited condensed consolidated financial statements.

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VERU INC.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended December 31,	
	2017	2016
Net revenues	$ 2,586,613	$ 3,243,599
Cost of sales	1,272,574	1,591,315
Gross profit	1,314,039	1,652,284
Operating expenses:		
Research and development	2,038,786	171,100
Selling, general and administrative	2,947,697	2,529,504
Loss on settlement of accounts receivable	3,764,137	—
Business acquisition	—	826,370
Total operating expenses	8,750,620	3,526,974
Operating loss	(7,436,581)	(1,874,690)
Non-operating expenses:		
Interest and other expense, net	(13,169)	(9,621)
Foreign currency transaction loss	(53,455)	(11,939)
Total non-operating expenses	(66,624)	(21,560)
Loss before income taxes	(7,503,205)	(1,896,250)
Income tax benefit	(3,246,053)	(530,069)
Net loss	$ (4,257,152)	$ (1,366,181)
Net loss per basic and diluted common share outstanding	$ (0.08)	$ (0.04)
Basic and diluted weighted average common shares outstanding	53,154,076	30,976,140

See notes to unaudited condensed consolidated financial statements.

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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)	$ 48,453,20
Share-based compensation	—	—	—	207,454	—	—	—	207,454
Shares issued in connection with common stock purchase agreement	—	304,457	3,045	344,036	—	—	—	347,081
Net loss	—	—	—	—	—	(4,257,152)	—	(4,257,15
Balance at December 31, 2017	$ —	55,696,650	$ 556,967	$ 91,102,159	$ (581,519)	$ (38,520,414)	$ (7,806,605)	$ 44,750,58

See notes to unaudited condensed consolidated financial statements.

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VERU INC.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Three Months Ended December 31,	
	2017	2016
OPERATING ACTIVITIES		
Net loss	$ (4,257,152)	$ (1,366,181)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	44,229	89,284
Amortization of intangible assets	68,816	26,729
Share-based compensation	207,454	317,311
Warrants issued	—	542,930
Deferred income taxes	(3,297,000)	(591,573)
Loss on settlement of accounts receivable	3,764,137	—
Other	(5,000)	4,469
Changes in current assets and liabilities, net of effects of acquisition of a business:		
Decrease in accounts receivable	3,226,930	2,391,226
Decrease in income tax receivable	—	191
(Increase) decrease in inventory	(299,112)	111,404
Decrease (increase) in prepaid expenses and other assets	68,369	(75,378)
Decrease in accounts payable	(168,347)	(522,125)
Decrease in unearned revenue	(24,501)	—
Increase in accrued expenses and other current liabilities	967,839	237,678
Net cash provided by operating activities	296,662	1,165,965
INVESTING ACTIVITIES		
Capital expenditures	(1,914)	(65,623)
Net cash used in investing activities	(1,914)	(65,623)
Net increase in cash	294,748	1,100,342
CASH AT BEGINNING OF PERIOD	3,277,602	2,385,082
CASH AT END OF PERIOD	$ 3,572,350	$ 3,485,424
Schedule of noncash investing and financing activities:		
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	$ —

Increase in deferred assets from accrued expenses	$ 75,920	$ —

See notes to unaudited condensed consolidated financial statements.

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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 and cash flows for the three months ended December 31, 2017 are not necessarily indicative of the results to be expected for any future period or for the 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 subsidiaries, The Female Health Company (UK) plc and 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. The completion of the APP Acquisition transitioned the Company into a biopharmaceutical company with multiple drug products under clinical development and commercialization focused in urology and oncology. Nearly all of the Company's net revenues during the three months ended December 31, 2017 and 2016 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 headquarters is 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 144 countries. It is marketed to consumers in 25 countries through distributors, public health programs, and/or retailers and in the U.S. by prescription.

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

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

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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 most recent order of 15 million units under the Brazil tender, the Company has agreed to up to 360 day 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 from our distributor in Brazil in Note 5. For the past twelve months, the Company's average days' sales outstanding was approximately 303 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.

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 $581,519 as of December 31, 2017 and September 30, 2017. Assets located outside of the U.S. totaled approximately $4,640,000 and $5,600,000 at December 31, 2017 and September 30, 2017, respectively.

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.

Financial instruments: 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.

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 Company currently does not have any assets or liabilities measured at fair value on a recurring basis as of December 31, 2017. Substantially all of the Company's cash, as well as restricted cash, are held in demand deposits with three financial institutions. The Company has no financial instruments for which the carrying value is materially different than fair value.

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Non-financial assets such as intangible assets, goodwill and property, plant, and equipment are evaluated for impairment annually or when indicators of impairment exist and are measured at fair value only if an impairment charge is recorded. Non-financial assets such as identified intangible assets acquired in connection with 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.

Research and development costs: Research and development expenses include salaries and benefits, clinical trials costs and contract services. Research and development expenses are charged to operations as they are incurred.

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. Research and development costs are expensed as incurred.

The Company follows the provisions of FASB ASC Topic 730, Research and Development, which requires the Company to defer and capitalize nonrefundable advance payments made for goods or services to be used in research and development activities 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 December 31, 2017 or September 30, 2017, and had no refundable advance payments as of December 31, 2017 and September 30, 2017.

Restricted cash: Restricted cash relates to security provided to one of the Company's U.K. banks for performance bonds issued in favor of customers. The Company has a facility of $250,000 for such performance bonds. Such security has been extended infrequently and only on occasions where it has been a contract term expressly stipulated as an absolute requirement by the customer or its provider of funds. The expiration of the bond is defined by the completion of the event such as, but not limited to, a period of time after the product has been distributed or expiration of the product shelf life. Restricted cash was approximately $140,000 at December 31, 2017 and September 30, 2017,

and is included in cash on the accompanying unaudited condensed consolidated balance sheets.

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.

Unearned revenue: FC2 is distributed in the U.S. prescription channel principally through the retail pharmacy, which initiates through large pharmaceutical wholesalers in the U.S. Unearned revenue as of December 31, 2017 and September 30, 2017 was $990,016 and $1,014,517, respectively, and was comprised mainly of sales made to wholesalers. We lack the experiential data which would allow us to estimate returns; therefore, as of December 31, 2017 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 certain wholesalers as allowances for returns cannot be reasonably estimated. Accordingly, the Company deferred recognition of revenue on prescription products sold to wholesale distributors 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.

Intangible Assets: Our intangible assets arose from the APP Acquisition on October 31, 2016. These intangible assets are carried at cost less accumulated amortization and are tested for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable.

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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 in-process research and development ("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 program'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 tested for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable, although IPR&D is required to be tested at least annually until the project is completed or abandoned. Upon obtaining regulatory approval, the IPR&D asset is then accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life. If the project is abandoned, the IPR&D asset is charged to expense.

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,

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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. IPR&D is closely monitored and assessed each period for impairment.

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.

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 $23,640 and $17,941 for the three months ended December 31, 2017 and 2016, respectively.

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.

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 months ended December 31, 2017 and 2016, 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 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. We are in the process of determining the effect the adoption will have on 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.

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 us from a single product company selling only the FC2 Female Condom® to a biopharmaceutical company with multiple drug products under clinical development and commercialization.

The Company incurred $826,370 in acquisition-related costs in the three months ended December 31, 2016, which are presented on a separate line item in the accompanying unaudited condensed consolidated statement of operations.

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 segment.

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 - Earnings 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 7 and 8 for a discussion of our dilutive potential common shares.

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Note 4 - Inventory

Inventory consists of the following components at December 31, 2017 and September 30, 2017:

	December 31, 2017	September 30, 2017
FC2		
Raw material	$ 554,737	$ 530,384
Work in process	121,137	90,164
Finished goods	2,631,155	2,427,386
Inventory, gross	3,307,029	3,047,934
Less: inventory reserves	(272,980)	(312,997)
FC2, net	3,034,049	2,734,937
PREBOOST®		
Finished goods	32,987	32,987
Inventory, net	$ 3,067,036	$ 2,767,924

Note 5 - Accounts Receivable and Concentration of Credit Risk

The components of accounts receivable consist of the following at December 31, 2017 and September 30, 2017:

	December 31, 2017	September 30, 2017
Trade receivables	$ 2,905,094	$ 11,330,814
Other receivables	128,317	100,139
Accounts receivable, gross	3,033,411	11,430,953
Less: allowance for doubtful accounts	(33,103)	(38,103)
Accounts receivable, net	3,000,308	11,392,850

Less: long-term trade receivables	—	(7,837,500)
Current accounts receivable, net	$ 3,000,308	$ 3,555,350

On December 27, 2017, we entered into a settlement agreement with Semina, our distributor in Brazil, pursuant to which Semina has made a payment of $2.25 million and is 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. 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 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 $3.76 million, which is presented as a separate line item in the accompanying unaudited condensed consolidated statement of operations for the three months ended December 31, 2017.

At December 31, 2017 and September 30, 2017, Semina’s accounts receivable balance represented 15 percent and 11 percent of current assets, respectively. No other single customer’s accounts receivable balance accounted for more than 10 percent of current assets at the end of those periods. At December 31, 2017, Semina’s accounts receivable balance represented 50 percent of the Company’s accounts receivable balance. At September 30, 2017, Semina’s accounts receivable and long-term other receivables balance represented 78 percent of the Company’s accounts receivable and long-term other receivables balance. For the three months ended December 31, 2017 and 2016, there were four and three customers who each exceeded 10 percent of net revenues, respectively.

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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 written-off when deemed uncollectible. The table below sets forth the components of the allowance for doubtful accounts at December 31, 2017 and 2016:

Fiscal Year	Balance at October 1	Provision Charges to Expenses	Write offs/ Recoveries	Balance at December 31
2017	$ 38,103	$ —	$ —	$ 38,103
2018	$ 38,103	$ —	$ (5,000)	$ 33,103

Recoveries of accounts receivable previously written-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 6 - 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 7 - 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 other shares of Class A Preferred Stock of any series issued and outstanding at December 31, 2017 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 December 31, 2017 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 Torreya Capital, the Company's financial advisor (the Financial Advisor Warrant). The Financial Advisor Warrant has a five-year term, a cashless exercise feature and a strike price equal to $1.93 per share, the 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 percent, a risk-free interest rate of 1.31 percent, 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, are locked-up for a period of 18 months from the issuance date. The Financial Advisor Warrant is 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 three months ended December 31, 2016.

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Aspire Capital Purchase Agreement

On December 29, 2017, the Company entered into a common stock purchase agreement (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 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 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 $347,081. This amount and related expenses of $75,920 have been included in deferred assets on the accompanying unaudited condensed consolidated balance sheet at December 31, 2017. As of the date of filing this Quarterly Report with the SEC, no shares of the Company's common stock have been sold to Aspire Capital under the Purchase Agreement.

Note 8 – Share-based Compensation

We allocate share-based compensation expense to cost of sales, selling, general and administrative expense and research and development expense based on the award holder's employment function. For the three months ended December 31, 2017 and 2016, we recorded share-based compensation expenses as follows:

	2017	2016
Cost of sales	$ 2,373	$ —
Selling, general and administrative	176,229	317,311
Research and development	28,852	—
	$ 207,454	$ 317,311

Equity Plans

In July 2017, the Company's stockholders approved the Company's 2017 Equity Incentive Plan. A total of 4.7 million shares are available for issuance under the 2017 Equity Incentive Plan. As of December 31, 2017, a total of 4,096,356 shares had been granted under the 2017 Equity Incentive Plan and not forfeited or are subject to outstanding commitments to issue shares under the 2017 Equity Incentive Plan, of which 3,716,356 shares were in the form of stock options, 190,000 shares were in the form of stock appreciation rights and 190,000 shares were in the form of restricted stock units. The 2017 Equity Incentive Plan replaced the Company's 2008 Stock Incentive Plan, and no further awards will be made under the 2008 Stock Incentive Plan.

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Stock Options

The following table outlines the weighted average assumptions for options granted during the three months ended December 31, 2017 and 2016:

Weighted Average Assumptions:	2017	2016
Expected Volatility	60.60%	43.76%
Expected Dividend Yield	0.00%	0.00%
Risk-free Interest Rate	2.24%	1.62%
Expected Term (in years)	5.7	6.0
Fair Value of Options Granted	$ 0.65	$ 0.41

During the three months ended December 31, 2017 and 2016, 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.

The expected term of the options represents the estimated period of time until exercise and is based on the simplified method. To value options granted for actual share-based compensation, the Company used the Black-Scholes option valuation model. When the measurement date is certain, the fair value of each option grant is estimated on the date of grant and is based on the assumptions used for the expected stock price volatility, expected term, risk-free interest rates and future dividend payments.

The following table summarizes the stock options outstanding and exercisable at December 31, 2017:

	Number of Shares	Weighted Average Exercise Price Per Share	Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2017	2,830,805	$ 1.27		
Granted	1,183,051	1.15		
Exercised	—	—		
Forfeited	—	—		
Outstanding at December 31, 2017	4,013,856	$ 1.24	9.46	$ 76,680
Exercisable at December 31, 2017	288,750	$ 1.90	6.50	$ 36,100

The aggregate intrinsic value in the table above is before income taxes, based on the Company's closing stock price of $1.14 on the last day of business for the three months ended December 31, 2017. As of December 31, 2017, the Company had unrecognized compensation expense of approximately $2.0 million related to unvested stock options. This expense is expected to be recognized over approximately 3 years.

Restricted Stock

The Company has issued restricted stock to employees, directors and consultants. Such issuances may have 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.

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A summary of the non-vested stock activity for the three months ended December 31, 2017 is presented in the table below:

	Shares	Weighted Average Grant Date Fair Value	Vesting Period
Outstanding at September 30, 2017	198,750	$ 0.99	
Granted	—		
Vested	(190,000)		
Forfeited	—		
Outstanding at December 31, 2017	8,750	$ 1.82	April 2018

As of December 31, 2017, there was approximately $4,000 of total unrecognized compensation cost related to non-vested restricted stock, which is expected to be recognized over the next 0.3 years.

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 Equity Incentive Plan. As of December 31, 2017, there was approximately $100,000 of unrecognized compensation cost related to non-vested restricted stock units, which is expected to be recognized over the next 0.8 years.

Stock Appreciation Rights

In connection with the closing of the APP Acquisition, the Company issued stock appreciation rights based on 50,000 and 140,000 shares of the Company’s common stock to an employee and an outside director, respectively, that 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 Equity Incentive Plan. As of December 31, 2017, there was approximately $54,000 of unrecognized compensation cost related to non-vested stock appreciation rights, which is expected to be recognized over the next 0.8 years.

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Note 9 - 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 interest expense 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 December 31,	
	2017	2016
Operating (loss) income:	(In thousands)	
Commercial	$ 143	$ 948
Research and Development	(2,032)	(159)
Corporate	(5,548)	(2,664)
	$ (7,437)	$ (1,875)
Revenues:		
United States	$ 994	$ 358
South Africa	318	636
Zimbabwe	300	516
Peru	282	—
Cameroon	—	891
Other	693	843
	$ 2,587	$ 3,244

All of our revenues are attributed to our Commercial reporting segment. Amounts related to long-lived assets, depreciation and amortization, and income taxes 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 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 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

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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. 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, 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 will be obligated to make upfront payments totaling $500,000 by March 2018, as well as future installment payments and milestone payments. The $500,000 is included in accrued expenses on the accompanying condensed consolidated balance sheet as of December 31, 2017.

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 December 31, 2017 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 $1,162,000 as of October 1, 2017.

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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.

As of December 31, 2017, the Company had U.S. federal and state net operating loss carryforwards of approximately $12,100,000 and $15,351,000, 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 $62,223,000 as of December 31, 2017, 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 December 31,	
	2017	2016
Income tax benefit at statutory rates	$ (2,551,000)	$ (645,000)
Effect of change in U.S. tax rate	(187,000)	—
State income tax benefit, net of federal benefits	(563,000)	(96,000)
Non-deductible business acquisition expenses	—	111,000
Non-deductible expenses - other	4,000	1,000
Effect of lower foreign income tax rates	29,405	81,736
Other	21,542	17,195
Income tax benefit	$ (3,246,053)	$ (530,069)

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

Deferred tax assets:	December 31, 2017	September 30, 2017
Federal net operating loss carryforwards	$ 4,063,000	$ 4,075,000
State net operating loss carryforwards	1,703,000	963,000
AMT credit carryforward	533,000	533,000
Foreign net operating loss carryforwards – U.K.	10,578,000	10,578,000
Foreign capital allowance – U.K.	108,000	108,000
UK bad debts	2,000	2,000
Restricted stock – U.K.	1,000	1,000
US unearned revenue	282,000	409,000
US deferred rent	20,000	76,000
Share-based compensation	335,000	447,000
Foreign tax credits	1,820,000	1,797,000
Other, net - U.S.	71,000	82,000
Gross deferred tax assets	19,516,000	19,071,000
Valuation allowance for deferred tax assets	(2,144,000)	(2,144,000)
Net deferred tax assets	17,372,000	16,927,000
Deferred tax liabilities:		
In process research and development	(4,562,000)	(7,000,000)
Developed technology	(575,000)	(900,000)
Covenant not-to-compete	(106,000)	(200,000)
Other	(5,000)	
Net deferred tax liabilities	(5,248,000)	(8,100,000)
Net deferred tax asset	$ 12,124,000	$ 8,827,000

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

	December 31, 2017	September 30, 2017
Long-term deferred tax asset - U.S.	$ 3,579,000	$ 282,000

Long-term deferred tax asset - U.K.	8,545,000	8,545,000
Total long-term deferred tax asset	$ 12,124,000	$ 8,827,000

Note 12 - 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 December 31, 2017:

	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Intangible assets with finite lives:			
Developed technology - PREBOOST®	$ 2,400,000	$ 132,492	$ 2,267,508
Covenants not-to-compete	500,000	83,333	416,667
Total intangible assets with finite lives	2,900,000	215,825	2,684,175
Acquired in-process research and development assets	18,000,000	—	18,000,000
Total intangible assets	$ 20,900,000	$ 215,825	$ 20,684,175

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

	Gross Carrying Amount	Accumulated Amortization	Net Book Value
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	$ 20,900,000	$ 147,009	$ 20,752,991

Intangible assets are carried at cost less accumulated amortization. Amortization is recorded over the projected related revenue stream for the PREBOOST® developed technology over the next 10 years and 7 years for the covenants not-to-compete, and the amortization expense is recorded in selling, general and administrative expenses in the accompanying unaudited condensed consolidated statement of operations. The IPR&D assets will not be amortized until the underlying development programs are completed. Upon obtaining regulatory approval, the IPR&D assets will then be accounted for as finite-lived intangible assets and amortized on a straight-line basis over their respective estimated useful lives.

Amortization expense was $68,816 and $26,729 for the three months ended December 31, 2017 and 2016, respectively. Based on finite-lived intangible assets recorded as of December 31, 2017, the estimated future amortization expense is as follows:

Year Ending September 30,	Estimated Amortization Expense
2018	$ 206,446
2019	309,234
2020	316,368
2021	323,706
2022	331,316
Thereafter	1,197,105

Total	$ 2,684,175

Note 13 - Subsequent Events

We have evaluated events and transactions that occurred subsequent to December 31, 2017 through the date the financial statements were issued, for potential recognition or disclosure in the accompanying unaudited condensed consolidated financial statements. We did not identify any events or transactions that should be recognized or disclosed in the accompanying unaudited condensed consolidated financial statements.

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Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

Veru Inc. is a biopharmaceutical company focused on urology and oncology. The Company does business as both "Veru" and "The Female Health Company." On July 31, 2017, the Company changed its corporate name from The Female Health Company to Veru Inc.

Veru utilizes the U.S. Food and Drug Administration's (the FDA) 505(b)(2) regulatory approval pathway to develop and commercialize drug candidates. The FDA's 505(b)(2) regulatory approval pathway is designed to allow for potentially expedited, lower cost and lower risk regulatory approval based on previously established safety, efficacy, and manufacturing information on a drug that has been already approved by the FDA for the same or a different indication. Veru is developing drug candidates under the 505(b)(1) pathway as well, which is the traditional full new drug application (NDA) pathway that requires a complete preclinical, clinical, and manufacturing application. The Company is currently developing the following drug product candidates: Tamsulosin DRS slow release granules and Tamsulosin XR capsules for lower urinary tract symptoms of benign prostatic hyperplasia (BPH or enlarged prostate), Solifenacin DRG, slow release granules, for overactive bladder (urge incontinence, urgency, or frequency of urination), Tadalafil/finasteride combination capsule for restricted urination because of an enlarged prostate; VERU-944 (cis-clomiphene citrate) for hot flashes in men associated with prostate cancer hormone treatment, VERU-722 (fixed ratio clomiphene citrate) for male infertility and VERU-111 a novel oral anti-tubulin cancer therapy targeting alpha & beta tubulin for a variety of malignancies, including metastatic prostate, breast, endometrial and ovarian cancers.

To help support these clinical development programs, the Company markets and sells the PREBOOST® medicated individual wipe, which is a male genital desensitizing drug product for the prevention of premature ejaculation and is being co-promoted with Timm Medical Technologies, Inc., and also markets and sells the FC2 Female Condom® (FC2) in the US 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 the FC2 Female Condom® to a biopharmaceutical company with multiple drug products under clinical development and commercialization.

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 completed in the first half of calendar 2018. The Company plans to develop Tamsulosin XR (extended release) capsules (tamsulosin HCl extended release capsules) as well. The Company does not believe that the new bioequivalence study and capsule formulation development will affect the timing of its planned submission of an NDA for Tamsulosin DRS granules and Tamsulosin XR capsules and, if the new bioequivalence study is successful, plans to submit the NDA in 2018.

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On December 6, 2016, the Company presented an overview of its drug candidate for male infertility, VERU-722, at the meeting of the Bone, Reproductive and Urologic Drugs (BRUD) FDA Advisory Committee at the invitation of the FDA. At the meeting, the committee discussed appropriate clinical trial design features, including acceptable endpoints for demonstrating clinical benefit, for drugs intended to treat secondary hypogonadism (low testosterone levels) while preserving or improving testicular function, including spermatogenesis. At the meeting, the FDA Advisory Committee provided guidance for clinical trial design and endpoints, and agreed with the intended patient population to treat, recommended a short-term study, and supported the use of improvement of semen quality for such clinical endpoints as avoidance of aggressive assisted reproductive procedures such as in vitro fertilization or pregnancy. Based on this advice, the Company is considering advancing VERU-722 into Phase 2 clinical trial in men with testicular dysfunction (oligospermia (low sperm count) and secondary hypogonadism) as a cause of male factor infertility.

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 PE, defined as reported poor control over ejaculation, personal distress related to ejaculation and average IELT of two minutes or less on stopwatch measurement. After treatment with PREBOOST®, 82 percent 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 United States 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 VERU-944 (cis-clomiphene citrate), 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. An investigational new drug application (IND) is expected to be filed with the FDA in the first half of calendar 2018.

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 capsules formulation from Camargo Pharmaceuticals Services, LLC. Tadalafil-Finasteride combination capsules (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 size 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 a bioequivalence study and no additional nonclinical, clinical efficacy and safety studies will be required to support the approval of Tadalafil-Finasteride combination capsules via a 505(b)(2) regulatory pathway. The Company plans to complete the bioequivalence study in 2018 and to file the NDA in 2019.

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Prior to the completion of the APP Acquisition, the Company had been a single product company, focused on manufacturing, marketing and selling the Female Condom (FC2). 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), including HIV/AIDS and the Zika virus. Nearly all of the Company's net revenues for the three months ended December 31, 2017 and 2016 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 144 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 UNFPA and 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. 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 US 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 US. As part of this reorganization the Company announced new distribution agreements with three of the country's largest distributors that support the pharmaceutical industry. This newly developed network now allows up to 98% of major retail pharmacies the ability to make FC2 available to their customers. In addition to the distribution system, the Company expanded sales and market access efforts that resulted in FC2 now being available through the following access points: community-based organizations, by prescription, 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 US. We believe that the initial results from these efforts support the US market opportunity and that we will continue to see increased utilization of FC2.

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

Period	2018	2017	2016	2015	2014
October 1 – December 31	4,399,932	6,389,320	15,380,240	12,154,570	11,832,666
January 1 - March 31		4,549,020	9,163,855	20,760,519	7,298,968
April 1 - June 30		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
Total	4,399,932	26,259,212	41,984,035	61,015,583	42,522,627

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 US and sales of PREBOOST; however, these sales were not material to our results for the three months ended December 31, 2017.

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 $0 copay. The Company also hired a small sales force 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.

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. In fiscal 2018, we expect to increase our expenses relating to research and development due to advancement of multiple drug candidates.

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Results of Operations

THREE MONTHS ENDED DECEMBER 31, 2017 COMPARED TO THREE MONTHS ENDED DECEMBER 31, 2016

The Company generated net revenues of $2,586,613 and net loss of $4,257,152, or $(0.08) per basic and diluted common share, for the three months ended December 31, 2017, compared to net revenues of $3,243,599 and net loss of $1,366,181, or $(0.04) per basic and diluted common share, for the three months ended December 31, 2016.

Net revenues decreased $656,986, or 20 percent, on a 31 percent decrease in unit sales for the three months ended December 31, 2017, compared with the same period last year. The principal factor in the decrease is the period to period impact of the timing of shipments for key customers. The FC2 average sales price per unit increased 16 percent compared with the same period last year due to changes in sales mix and unit price increases for customers in the U.S.

Cost of sales decreased $318,741 to $1,272,574 in the three months ended December 31, 2017 from $1,591,315 for the same period last year. The reduction is due to the lower unit sales.

Gross profit decreased $338,245, or 20 percent, to $1,314,039 for the three months ended December 31, 2017 from $1,652,284 for the three months ended December 31, 2016. Gross profit margin for the three months ended December 31, 2017 and for the same period in 2016 was 51 percent of net revenues.

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 for the remainder of fiscal 2018.

Research and development expenses increased $1,867,686 to $2,038,786 for the three months ended December 31, 2017 from $171,100 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 $418,193, or 17 percent, to $2,947,697 for the three months ended December 31, 2017 from $2,529,504 in the prior year period. The increase primarily relates to salaries for our U.S. Commercial team, part of our Commercial reporting segment.

The Company incurred a loss on net accounts receivable of approximately $3.76 million for the three months ended December 31, 2017, as a result of a settlement agreement we entered with Semina, our distributor in Brazil. This amount is presented as a separate line item in the accompanying unaudited condensed consolidated statement of operations.

Business acquisition expenses for the three months ended December 31, 2017 decreased to zero from $826,370 in the prior year period for expenses representing costs related to the APP Acquisition.

Interest and other expense, net, for the three months ended December 31, 2017 was $13,169, compared to $9,621 for the same period in fiscal year 2017. The Company recorded a foreign currency transaction loss of $53,455 in the most recent quarter, compared to $11,939 for the same period last year.

The income tax benefit for the three months ended December 31, 2017 was $3,246,053, compared to income tax benefit of $530,069 for the same period in fiscal year 2017. The increase in the income tax benefit is 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.

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Liquidity and Sources of Capital

Our operating activities generated cash of $296,662 in the first quarter of fiscal 2018. Accounts receivable and long-term other receivables decreased from $11.4 million at September 30, 2017 to $3.0 million at December 31, 2017.

On December 27, 2017, we entered into a settlement agreement with Semina pursuant to which Semina has made a payment of $2.25 million and is 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. The settlement was not related to our belief in the ultimate collectability of the receivables or in the creditworthiness of Semina. We elected to settle these amounts due to the uncertainty regarding the timing of payment by the Brazilian Government and, ultimately to us, on the remaining amounts due. The result of the settlement was a net loss of approximately $3.76 million, which is included in selling, general and administrative expenses in our unaudited condensed consolidated statement of operations for the three months ended December 31, 2017.

At December 31, 2017, the Company had working capital of $4.0 million and stockholders’ equity of $44.8 million compared to working capital of $4.8 million and stockholders’ equity of $48.5 million as of December 31, 2016.

In connection with the Company's acquisition of intellectual property rights associated with Solifenacin DRG and Tadalafil/ Finasteride combination capsules, the Company will be obligated to make upfront payments totaling $500,000 by March 2018, as well as future installment payments and milestone payments.

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 months ended December 31, 2017 or 2016.

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. As of the date of filing this Quarterly Report with the SEC, no shares of the Company’s common stock have been sold to Aspire Capital under the Purchase Agreement.

The Company believes its current cash position and its ability to secure equity financing or other financing alternatives are adequate to fund 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. 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.

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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. The Company had a line of credit with BMO Harris Bank, consisting of a revolving note for up to $10 million. The line of credit expired on December 29, 2017.

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 Principal Executive Officer and the Company's Principal 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 Principal Executive Officer and Principal 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 Principal Executive Officer and Principal 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.

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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. 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.

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Item 6. Exhibits

Exhibit Number	Description
3.1	Amended and Restated Articles of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Form SB-2 Registration Statement (File No. 333-89273) filed with the SEC on October 19, 1999).
3.2	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 27,000,000 shares (incorporated by reference to Exhibit 3.2 to the Company's Form SB-2 Registration Statement (File No. 333-46314) filed with the SEC on September 21, 2000).
3.3	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 35,500,000 shares (incorporated by reference to Exhibit 3.3 to the Company's Form SB-2 Registration Statement (File No. 333-99285) filed with the SEC on September 6, 2002).
3.4	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 38,500,000 shares (incorporated by reference to Exhibit 3.4 to the Company's Form 10-QSB (File No. 1-13602) filed with the SEC on May 15, 2003).
3.5	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company designating the terms and preferences for the Class A Preferred Stock – Series 3 (incorporated by reference to Exhibit 3.5 to the Company's Form 10-QSB (File No. 1-13602) filed with the SEC on May 17, 2004).
3.6	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company designating the terms and preferences for the Class A Preferred Stock – Series 4 (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on November 2, 2016).
3.7	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company changing the corporate name to Veru Inc. and increasing the number of authorized shares of common stock to 77,000,000 shares (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on August 1, 2017).
3.8	Amended and Restated By-Laws (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on May 22, 2013).
4.1	Amended and Restated Articles of Incorporation, as amended (same as Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6 and 3.7).
4.2	Articles II, VII and XI of the Amended and Restated By-Laws (included in Exhibit 3.7).

10.1	Executive Employment Agreement, dated as of October 4, 2017, between the Company and Michele Greco (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on January 10, 2018). +
10.2	Separation Agreement and General Release, effective as of January 4, 2018, between the Company and Daniel Haines (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on January 10, 2018). +

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31.1 Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *

31.2 Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *

32.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002).**

101 The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended December 31, 2017, 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.

* Filed herewith

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

\+ Management contract or compensatory plan or arrangement

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SIGNATURES

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

VERU INC.

DATE: February 14, 2018

/s/ Mitchell Steiner

Mitchell Steiner, President and

Chief Executive Officer

DATE: February 14, 2018

/s/ Michele Greco

Michele Greco, Executive Vice President of Finance and

Chief Administrative Officer