VERU INC.
Form 10-K/A
January 05, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A

(Amendment No. 1)

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended September 30, 2017

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission file number 1-13602

Veru Inc.

(Name of registrant as specified in its charter)

Wisconsin	39-1144397
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
4400 Biscayne Boulevard, Suite 888, Miami, Florida	33137
(Address of principal executive offices)	(Zip Code)

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

Securities registered under Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common stock, $.01 par value	NASDAQ Stock Market

Securities registered under Section 12(g) of the Act:

None

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) 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 defined in Rule 12b-2 of the Act). Yes No

The aggregate market value of the voting stock held by non-affiliates of the registrant as of March 31, 2017, was approximately $28.5 million based on the per share closing price as of March 31, 2017 quoted on the NASDAQ Capital Market for the registrant s common stock, which was $1.01.

There were 53,208,489 shares of the registrant s common stock, $0.01 par value per share outstanding at December 21, 2017.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Proxy Statement for the 2018 Annual Meeting of the Shareholders of the Registrant are incorporated by reference into Part III of this report.

As used in this report, the terms we, us, our, Veru and the Company mean Veru Inc. and its subsidiaries collectiv including Aspen Park Pharmaceuticals, Inc. from and after October 31, 2016, unless the context indicates another meaning, and the term common stock means shares of our common stock, par value of $0.01 per share.

EXPLANATORY NOTE

This Amendment No. 1 to the Annual Report on Form 10-K (the Form 10-K) of Veru Inc. (the Company) for the fiscal year ended September 30, 2017 filed on January 2, 2018 is being filed solely for the purpose of correcting an error contained in Part II, Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Sources of Capital in the amounts of cash, net trade accounts receivable and current trade accounts payable as of December 6, 2017. There was an inadvertent failure to update these amounts in the original Form 10-K filed on January 2, 2018 from the amounts reported in the prior year s Form 10-K as of December 9, 2016. This Amendment No. 1 also changes the reference to net loss for the year ended September 30, 2017 to net loss attributable to common shareholders. In accordance with Rule 12b-15 under the Securities and Exchange Act of 1934, as amended, Exhibits 31.1 and 31.2 have also been filed with this Amendment No. 1. In addition, in connection with the filing of this Amendment No. 1 and pursuant to Rule 12b-15, the Company has updated the dates of the certifications contained therein. The remainder of the Form 10-K is unchanged and is not reproduced in this Amendment No. 1. This Amendment No. 1 speaks as of the original filing date of the Form 10-K and does not reflect events occurring after the fling date of the original Form 10-K, or modify or update the disclosures therein in any way other than as required to reflect the amendment set forth below.

Item 7. 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 Healthcare 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 (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 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 drug product candidates for benign prostatic hyperplasia (BPH or enlarged prostate), overactive bladder (urge incontinence, urgency, or frequency of urination), hot flashes in men associated with prostate cancer hormone treatment, erectile dysfunction, male infertility and novel oral therapy (alpha & beta tubulin inhibitor) for a variety of malignancies, including metastatic prostate, breast, endometrial, ovarian, and other cancers.

To help support these clinical development programs, the Company markets and sells the FC2 Female Condom® (FC2) into the U.S. market by prescription and other sales channels and through The Female Health Company Division in the global public health sector (ministries of health, government health agencies, U.N. agencies, and nonprofit organizations). In addition, the Company markets and sells the PREBOOST® (4% benzocaine medicated individual wipes) which is a male genital desensitizing drug product for the prevention of premature ejaculation (PE) that is being co-promoted and distributed with Timm Medical Technologies, Inc.

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 (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 (tamsulosin HCl delayed release sachet) medication, a proprietary slow release granule formulation for the treatment of lower urinary tract symptoms of an enlarged prostate called benign prostatic hyperplasia (BPH), a $3.5 billion market, 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 quarter of 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 the first half of 2018.

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 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 FDA in the first quarter of 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 PreIND meeting, 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 PreIND meeting held in November 2017, 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.

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 fiscal 2017 were derived from sales of FC2.

FC2 s primary use is for disease prevention and family planning, and the public health sector is the Company s main market. Within the public health sector, various organizations supply critical products such as FC2, at no cost or low cost, to those who need but cannot afford to buy such products for themselves.

FC2 has been distributed in 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 October 2014, the Company announced that Semina was awarded an exclusive contract under a public tender. The contract was valid through August 20, 2015, allowing the Brazil Ministry of Health to place orders against this tender at its discretion. Through the end of the contract, the Company received orders for 40 million units of FC2 in fulfillment of the tender, 28 million of which were shipped during the year ended September 30, 2015 and 12 million of which were shipped during the year ended September 30, 2016.

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 U.S. We believe that the initial results from these efforts support the U.S. market opportunity and that we will continue to see increased utilization of FC2.

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

Period	**2017**	**2016**	**2015**	**2014**	**2013**
October 1 December 31	6,389,320	15,380,240	12,154,570	11,832,666	17,114,630
January 1 March 31	4,549,020	9,163,855	20,760,519	7,298,968	16,675,035
April 1 June 30	8,466,004	10,749,860	14,413,032	13,693,652	12,583,460
July 1 September 30	6,854,868	6,690,080	13,687,462	9,697,341	8,386,800
Total	26,259,212	41,984,035	61,015,583	42,522,627	54,759,925

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 revenues include the sales from FC2 into the prescription channel in the U.S. and sales of PREBOOST; however these sales were not material to our fiscal 2017 results.

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. USAID accounted for 44 percent of unit sales in fiscal 2017, 24 percent of unit sales in fiscal 2016, and 16 percent of unit sales in fiscal 2015. UNFPA accounted for 25 percent of unit sales in fiscal 2017, 25 percent of unit sales in fiscal 2016, and 18 percent of unit sales in fiscal 2015. Semina accounted for 27 percent of unit sales in fiscal 2016 and 47 percent of unit sales in fiscal 2015. No other single customer accounted for more than 10 percent of unit sales in fiscal 2017, 2016, or 2015. We sell to the Brazil Ministry of Health either through UNFPA or Semina. In the U.S., FC2 is sold to city and state public health clinics as well as to not-for-profit organizations such as Planned Parenthood.

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.

On April 1, 2015, a tariff exemption in Brazil for condoms was eliminated subjecting all shipments of FC2 clearing customs in Brazil on or after that date to a tariff. The Company agreed to share 50 percent of these tariff costs with Semina and recognized the expense as the units were shipped.

Fiscal Year Ended September 30, 2017 Compared to Fiscal Year Ended September 30, 2016.

Results of Operations. The Company had net revenues of $13,655,592 and net loss attributable to common shareholders of $8,602,818, or $(0.25) per diluted share, in fiscal 2017, compared to net revenues of $22,127,342 and net income attributable to common shareholders of $344,725, or $0.01 per diluted share, in fiscal 2016. Net revenues decreased $8,471,750, or 38 percent, in fiscal 2017 compared to the prior fiscal year. The Company s fiscal 2017 unit sales were 15.7 million units, or 37 percent, lower than fiscal 2016. The decrease in unit sales and net revenues is primarily due to 11.5 million units shipped during fiscal 2016 under the 2014 Brazilian tender, with no comparable sales in the fiscal 2017 period.

Cost of sales decreased $2,141,778, or 24 percent, to $6,636,080 in fiscal 2017 from $8,777,858 in fiscal 2016, and cost per unit increased 20 percent from $0.21 per unit in fiscal 2016 to $0.25 per unit in fiscal 2017. The reduction in cost of sales is due to the lower unit sales, reduction of certain costs, and the favorable impact of currency exchange rates. The increase in cost per unit was most heavily impacted by reduced unit sales, which results in higher per-unit allocations of fixed overhead costs.

Gross profit decreased $6,329,972, or 47 percent, to $7,019,512 in fiscal 2017 from $13,349,484 in fiscal 2016. Gross profit as a percentage of net revenues decreased to 51 percent in fiscal 2017 from 60 percent in fiscal 2016. The decrease in the gross profit margin is primarily due to higher cost of sales on a per-unit basis as noted above.

Overall, total operating expenses increased $5,182,652, or 50 percent, to $15,513,624 in fiscal 2017 from $10,330,972 in fiscal 2016.

Selling, general and administrative expenses increased $2,358,917, or 27 percent, to $11,019,091 in fiscal 2017 from $8,660,174 in fiscal 2016. The increase was a result of $1.2 million in costs related to additional headcount from the APP Acquisition, $1.2 million related to the prescription launch of FC2 in the US which includes additional personnel and other selling and marketing costs, and $1.3 million related to increased administrative costs such as litigation fees, investor relations, and general office costs. The increases are net of a reduction in expenses of $1.5 million related to marketing and management fees incurred for fiscal 2016, deliveries on the Brazil tender, and lower business development costs. No diversification expenses were incurred in fiscal 2017 compared to $548,077 of diversification expenses in fiscal 2016.

Business acquisition expenses decreased $546,758, or 37 percent, to $935,781 in fiscal 2017 from $1,482,539 in fiscal 2016. These expenses represent costs related to the APP Acquisition.

Research and development expenses increased $3,405,089 to $3,504,482 in fiscal 2017 from $99,393 in fiscal 2016. Research and development expenses were primarily due to development of Tamsulosin DRS as well as the advancement of other drug candidates.

The Company s operating loss was $8,494,112 in fiscal 2017 compared to operating income of $3,018,512 in fiscal 2016 due to the factors noted above.

Income tax benefit was $1,990,443 in fiscal 2017 compared to income tax expense of $2,469,191 in fiscal 2016. The effective tax rate for fiscal 2017 and 2016 was 23.1 percent and 87.7 percent, respectively. The $1.9 million tax benefit in fiscal 2017 is primarily due to losses of $8.6 million generating a tax benefit of $3.1 million at a 40% effective US tax rate, net of $0.9 million related to a deemed dividend from Malaysia, $0.6 million reduction in UK deferred tax assets due to a 1% tax rate decrease from 18% to 17% on $60 million of net operating losses, and $0.5 million of disallowed acquisition expenses at 40%. The 87% effective rate in fiscal 2016 is due to the mix of tax jurisdictions in which the Company recognized income before income taxes, the non-deductible business acquisition expenses related to the APP Acquisition, and the reduction in the UK income tax rate from 20% to 18%. The Company s net operating loss (NOL) carryforwards will be utilized to reduce cash payments for income taxes based on the statutory rate in effect at the time of such utilization. Actual income taxes paid are reflected on the Company s

consolidated statements of cash flows.

Fiscal Year Ended September 30, 2016 Compared to Fiscal Year Ended September 30, 2015

Operating Highlights. The Company had net revenues of $22,127,342 during fiscal 2016, compared to $32,604,865 in fiscal 2015. The Company s fiscal 2016 unit sales were 19 million units, or 31 percent, lower than fiscal 2015. The decrease in unit sales and net revenues is primarily due to 28 million units shipped during fiscal 2015 under the 2014 Brazilian tender, versus 12 million units shipped during fiscal 2016. The average sales price of FC2 decreased 1.4 percent in fiscal 2016 from fiscal 2015. Effective April 1, 2016, the unit price has been reduced for major public sector purchasers.

The Company used cash in operations of $1,714,358 in fiscal 2016 compared to $1,548,697 in fiscal 2015. The Company had net income attributable to common shareholders of $344,725, or $0.01 per diluted share, in fiscal 2016 compared to net income attributable to common shareholders of $4,346,036, or $0.15 per diluted share, in fiscal 2015.

Results of Operations. The Company had net revenues of $22,127,342 and net income attributable to common shareholders of $344,725, or $0.01 per diluted share, in fiscal 2016, compared to net revenues of $32,604,865 and net income attributable to common shareholders of $4,346,036, or $0.15 per diluted share, in fiscal 2015. Net revenues decreased $10,477,523, or 32 percent, in fiscal 2016 compared to the prior fiscal year. The reduction in net revenues is due to the lower unit sales, change in sales mix, and public sector price adjustment.

Cost of sales decreased $4,857,048, or 36 percent, to $8,777,858 in fiscal 2016 from $13,634,906 in fiscal 2015. The reduction in cost of sales is due to the lower unit sales, reduction of certain costs, and the favorable impact of currency exchange rates.

Gross profit decreased $5,620,475, or 30 percent, to $13,349,484 in fiscal 2016 from $18,969,959 in fiscal 2015. Gross profit as a percentage of net revenues increased to 60 percent in fiscal 2016 from 58 percent in fiscal 2015. The increase in the gross profit margin is primarily due to the reduction of certain costs and the favorable impact of currency exchange rates on cost of sales.

Selling, general and administrative expenses decreased $3,471,563, or 29 percent, to $8,660,174 in fiscal 2016 from $12,131,737 in fiscal 2015. The decrease was a result of a reduction in payments due to our Brazilian distributor for marketing and management fees for the 2014 tender, a reduction in employee compensation expense, a reduction in expenses related to a study regarding a potential FC2 consumer program in the U.S., and a reduction in diversification expenses. The diversification expenses were $548,077 in fiscal 2016 compared to $709,462 in fiscal 2015.

Business acquisition expense of $1,482,539 in fiscal 2016 represents costs related to the APP Acquisition.

Research and development expenses decreased $120,422 to $99,393 in fiscal 2016 from $219,815 in fiscal 2015.

Total operating expenses decreased $2,020,580 to $10,330,972 in fiscal 2016 from $12,351,552 in fiscal 2015.

The Company s operating income decreased $3,599,895 to $3,018,512 in fiscal 2016 from $6,618,407 in fiscal 2015. The decrease is primarily due to decreased net revenues, partially offset by lower operating expenses and improved gross margins.

The Company recorded non-operating expense of $204,596 in fiscal 2016 compared to non-operating income of $68,633 in fiscal 2015. The impact of the foreign currency transactions was a loss of $147,540 in fiscal 2016 compared to a gain of $58,483 in fiscal 2015.

Income tax expense increased $128,187 to $2,469,191 in fiscal 2016 compared to income tax expense of $2,341,004 in fiscal 2015. The effective tax rate for fiscal 2016 and 2015 was 87.7 percent and 35.0 percent, respectively. The increase in the effective tax rate is due to the mix of tax jurisdictions in which the Company recognized income before income taxes, the non-deductible business acquisition expenses related to the APP Acquisition, and the reduction in the UK income tax rate from 20% to 18%. The Company s net operating loss (NOL) carryforwards will be utilized to reduce cash payments for income taxes based on the statutory rate in effect at the time of such utilization. Actual income taxes paid are reflected on the Company s consolidated statements of cash flows. In fiscal 2016 the Company recorded income tax expense of $2,469,191, while due to the use of NOL carryforwards the Company made cash payments of $352,856 for income taxes.

Liquidity and Sources of Capital

We have generally funded our operations and working capital needs through cash generated from operations. Our operating activities generated cash of $1.0 million in fiscal 2017, used cash of $1.7 million in fiscal 2016, and used cash of $1.5 million in fiscal 2015. Accounts receivable and long-term other receivables decreased from $18.6 million at September 30, 2016 to $11.4 million at September 30, 2017. Semina s accounts receivable and long-term other receivables balance represents 78 percent of the Company s accounts receivable and long-term other receivables balance at September 30, 2017. Semina normally pays upon payment from the Brazilian Government; however due to economic issues in Brazil the government has been slower in paying vendors. In addition, total current liabilities increased $2.1 million, primarily due to $1.0 million of unearned revenue related to prescription sales of FC2, and timing related to the recurring vendor payments.

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 outstanding receivables for sales to Semina for the 2014 Brazil Tender. The settlement is 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 uncertainty regarding the timing of payment by the Brazilian Government and, ultimately to us, on the remaining amounts due. In connection with the settlement agreement with Semina, on December 27, 2017, the Company s management concluded that a material impairment charge of $3.75 million will be required to the receivables for sales to Semina relating to the 2014 Brazil Tender, which will be reflected in our results for the fiscal quarter ending December 31, 2017.

At September 30, 2017, the Company had working capital of $4.8 million and stockholders equity of $48.5 million compared to working capital of $12.9 million and stockholders equity of $33.9 million as of September 30, 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. will expire on December 29, 2017 and will not be renewed. No amounts were outstanding under the Credit Agreement at September 30, 2017 and none will be outstanding when the Credit Agreement expires.

As described in more detail in Item 9B below, on December 29, 2017, the Company entered into a common stock purchase agreement (the Purchase Agreement) with Aspire Capital Fund, LLC, an Illinois limited liability company (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 to purchase up to $15.0 million of the Company s common stock in the aggregate. Other than 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.

The Company believes that its current cash position and its ability to secure other financing alternatives to equity financing are expected to be 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, 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 equity under the Aspire Capital Purchase and/or a marketed deal through an investment bank. See Item 1A., Risk Factors Risks Related to Our Financial Position and Need for Capital for a description of certain risks relating to our ability to raise capital on acceptable terms.

As of December 6, 2017, the Company had approximately $2.0 million in cash, net trade accounts receivable of $10.1 million and current trade accounts payable of $1.9 million. Presently, the Company has no required debt service obligations.

Critical Accounting Estimates

The preparation of financial statements requires management to make estimates and use assumptions that affect certain reported amounts and disclosures. Critical accounting estimates include the deferred income tax valuation allowance. Actual results may differ from those estimates.

The Company files separate income tax returns for its foreign subsidiaries. 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.

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 assets and liabilities, and for net operating loss and tax credit carryforwards.

The Company completes a detailed analysis of its deferred income tax valuation allowance on an annual basis or more frequently if information comes to our attention that would indicate that a revision to its estimates is necessary. In evaluating the Company s ability to realize its deferred tax assets, management considers all available positive and negative evidence on a country by country basis, including past operating results and forecast of future taxable income. 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. Since fiscal 2006, the Company has consistently generated taxable income on a consolidated basis, providing a reasonable future period in which the Company can reasonably expect to generate taxable income. In management s analysis to determine the amount of the deferred tax asset to recognize, management projected future taxable income for each tax jurisdiction.

Although management uses the best information available, it is reasonably possible that the estimates used by the Company will be materially different from the actual results. These differences could have a material effect on the Company s future results of operations and financial condition.

Our effective tax rates have differed from the statutory rate primarily due to the tax impact of foreign operations, state taxes and reversal of the valuation allowance against the NOL carryforwards. Our future effective tax rates could be adversely affected by earnings being lower than anticipated in countries where we have lower statutory rates and higher than anticipated in countries where we have higher statutory rates, changes in the valuation of our deferred tax assets or liabilities, or changes in tax laws, regulations, and accounting principles. In addition, we are subject to the continuous examination of our income tax returns by the IRS and other tax authorities. We regularly assess the likelihood of adverse outcomes resulting from these examinations to determine the adequacy of our provision for income taxes.

Impact of Inflation and Changing Prices

Although the Company cannot accurately determine the precise effect of inflation, the Company has experienced increased costs of product, supplies, salaries and benefits, and increased general and administrative expenses. The Company has, where possible, increased selling prices to offset such increases in costs.

Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K.

Item 15. Exhibits and Financial Statement Schedules.

Exhibits

2.1	Amended and Restated Agreement and Plan of Merger, dated as of October 31, 2016, among the Company, Blue Hen Acquisition, Inc. and APP (incorporated by reference to Exhibit 2.1 to the Company s Form 8-K (File No. 1-13602) filed with the SEC on November 2, 2016).
3.1	Amended and Restated Articles of Incorporation of the Company (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 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 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 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 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 Amended and Restated Articles of Incorporation 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 of the Company (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 of the Company (included in Exhibit 3.8).

5.1 Opinion of Reinhart Boerner Van Deuren s.c.**

10.1 Form of Lock-Up Agreement, dated as of October 31, 2016, between the Company and each of Mitchell S. Steiner M.D., Harry Fisch, M.D. and K&H Fisch Family Partners LLC (incorporated by reference to Exhibit 10.1 to the Company s Form 8-K (File No. 1-13602) filed with the SEC on November 2, 2016).

10.2	Registration Rights Agreement, dated as of October 31, 2016, among the Company and the former stockholders of APP (incorporated by reference to Exhibit 10.2 to the Company s Form 8-K (File No. 1-13602) filed with the SEC on November 2, 2016).
10.3	Escrow Agreement, dated as of October 31, 2016, among the Company, O.B. Parrish, David R. Bethune and Mary Margaret Frank, Ph.D., acting as the committee representing the interests of the Company, Mitchell S. Steiner, M.D., in his capacity as nominee for the stockholders of the Company identified on Exhibit A thereto, and Computershare Trust Company, N.A., as escrow agent (incorporated by reference to Exhibit 10.3 to the Company s Form 8-K (File No. 1-13602) filed with the SEC on November 2, 2016).
10.4	Warrant to Purchase Common Stock, dated October 31, 2016, issued by the Company to Torreya Capital, a division of Financial West Investment Group (incorporated by reference to Exhibit 10.4 to the Company s Form 8-K (File No. 1-13602) filed with the SEC on November 2, 2016).
10.5	Employment Agreement, dated April 5, 2016, between the Company and Mitchell S. Steiner, M.D. (incorporated by reference to Exhibit 10.1 to the Company s Form 8-K (File No. 1-13602) filed with the SEC on April 6, 2016).*
10.6	First Amendment to Employment Agreement, dated as of July 18, 2016, between the Company and Mitchell S. Steiner, M.D. (incorporated by reference to Exhibit 10.7 to the Company s Form 10-K (File No. 1-13602) filed with the SEC on December 12, 2016).*
10.7	Second Amendment to Employment Agreement, dated as of November 4, 2016, between the Company and Mitchell S. Steiner, M.D. (incorporated by reference to Exhibit 10.6 to the Company s Form 10-Q (File No. 1-13602) filed with the SEC on February 9, 2017).*
10.8	Employment Agreement, dated as of December 20, 2016, between the Company and Brian J. Groch (incorporated by reference to Exhibit 10.7 to the Company s Form 10-Q (File No. 1-13602) filed with the SEC on February 9, 2017).
10.9	Consulting Agreement, dated as of January 1, 2017, between the Company and Harry Fisch, M.D.**
10.10	Employment Agreement, dated April 5, 2016, between the Company and Michele Greco (incorporated by reference to Exhibit 10.2 to the Company s Form 8-K (File No. 1-13602) filed with the SEC on April 6, 2016).*
10.11	First Amendment to Employment Agreement, dated as of July 18, 2016, between the Company and Michele Greco (incorporated by reference to Exhibit 10.9 to the Company s Form 10-K (File No. 1-13602) filed with the SEC on December 12, 2016).*
10.12	Employment Agreement, dated April 5, 2016, between the Company and Martin Tayler (incorporated by reference to Exhibit 10.3 to the Company s Form 8-K (File No. 1-13602) filed with the SEC on April 6, 2016).*
10.13	First Amendment to Employment Agreement, dated as of July 18, 2016, between the Company and Martin Tayler (incorporated by reference to Exhibit 10.11 to the Company s Form 10-K (File No. 1-13602) filed with the SEC on December 12, 2016).*
10.14	The Female Health Company 2008 Stock Incentive Plan (incorporated by reference to Exhibit 99.1 to the Company s Form 8-K (File No. 1-13602) filed with the SEC on March 31, 2008).*
10.15	Form of Nonstatutory Stock Option Grant Agreement for The Female Health Company 2008 Stock Incentive Plan (incorporated by reference to Exhibit 10.13 to the Company s Form 10-K (File No. 1-13602) filed with the SEC on December 17, 2009).*
10.16	Form of Restricted Stock Grant Agreement for The Female Health Company 2008 Stock Incentive Plan (incorporated by reference to Exhibit 10.14 to the Company s Form 10-K (File No. 1-13602) filed with the

SEC on December 3, 2013).*

10.17 Veru Inc. 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company s Form 8-K (File No. 1-13602) filed with the SEC on August 1, 2017).*

10.18 Form of Nonstatutory Stock Option Grant Agreement for Veru Inc. 2017 Equity Incentive Plan.**

10.19 Restricted Stock Unit Agreement, dated as of October 31, 2016, between the Company and David R. Bethune (incorporated by reference to Exhibit 10.8 to the Company s Form 10-Q (File No. 1-13602) filed with the SEC on February 9, 2017).

10.20	Stock Appreciation Rights Agreement, dated as of October 31, 2016, between the Company and David R. Bethune (incorporated by reference to Exhibit 10.9 to the Company s Form 10-Q (File No. 1-13602) filed with the SEC on February 9, 2017).
10.21	Credit Agreement, dated as of December 29, 2015, between the Company and BMO Harris Bank N.A. (incorporated by reference to Exhibit 99.1 to the Company s Form 8-K (File No. 1-13602) filed with the SEC on January 4, 2016).
10.22	First Amendment and Waiver to Credit Agreement and Security Agreement, dated as of January 4, 2016, between the Company and BMO Harris Bank N.A. (incorporated by reference to Exhibit 10.16 to the Company s Form 10-K (File No. 1-13602) filed with the SEC on December 12, 2016).
10.23	Consent and Amendment to Credit Agreement, dated as of March 31, 2016, between the Company and BMO Harris Bank N.A. (incorporated by reference to Exhibit 10.1 to the Company s Form 10-Q (File No. 1-13602) filed with the SEC on July 28, 2016).
10.24	Security Agreement, dated as of December 29, 2015, between the Company and BMO Harris Bank N.A. (incorporated by reference to Exhibit 99.3 to the Company s Form 8-K (File No. 1-13602) filed with the SEC on January 4, 2016).
10.25	Charge Over Shares Agreement, dated as of December 29, 2015, between The Female Health Company and BMO Harris Bank N.A. (incorporated by reference to Exhibit 99.4 to the Company s Form 8-K (File No. 1-13602) filed with the SEC on January 4, 2016).
10.26	Second Amendment to Security Agreement and First Amendment to Subsidiary Security Agreement, dated as of September 29, 2016, between the Company and BMO Harris Bank N.A. (incorporated by reference to Exhibit 10.21 to the Company s Form 10-K (File No. 1-13602) filed with the SEC on December 12, 2016).
10.27	Third Amendment to Credit Agreement, dated as of November 28, 2016, among the Company, APP, Badger Acquisition Sub, Inc. and BMO Harris Bank, N.A. (incorporated by reference to Exhibit 99.1 to the Company s Form 8-K (File No. 1-13602) filed with the SEC on December 1, 2016).
10.28	Amended and Restated Revolving Note, dated November 28, 2016, from the Company and APP to BMO Harris Bank, N.A. (incorporated by reference to Exhibit 99.2 to the Company s Form 8-K (File No. 1-13602) filed with the SEC on December 1, 2016).
10.29	General Security Agreement, dated as of November 28, 2016, between APP and BMO Harris Bank, N.A. (incorporated by reference to Exhibit 99.3 to the Company s Form 8-K (File No. 1-13602) filed with the SEC on December 1, 2016).
10.30	Intellectual Property Security Agreement, dated as of November 28, 2016, between APP and BMO Harris Bank, N.A. (incorporated by reference to Exhibit 99.4 to the Company s Form 8-K (File No. 1-13602) filed with the SEC on December 1, 2016).
10.31	Stock Pledge Agreement, dated as of November 28, 2016, between the Company and BMO Harris Bank, N.A. (incorporated by reference to Exhibit 99.5 to the Company s Form 8-K (File No. 1-13602) filed with the SEC on December 1, 2016).
10.32	Fourth Amendment to Credit Agreement, dated as of November 28, 2016, among the Company, APP, Badger Acquisition Sub, Inc. and BMO Harris Bank, N.A. (incorporated by reference to Exhibit 99.1 to the Company s Form 8-K (File No. 1-13602) filed with the SEC on May 19, 2017).
10.33	Common Stock Purchase Agreement, dated as of December 29, 2017, between the Company and Aspire Capital Fund, LLC.**
10.34	Registration Rights Agreement, dated as of December 29, 2017, between the Company and Aspire Capital Fund, LLC.**

21	Subsidiaries of Registrant.**
23.1	Consent of RSM US LLP.**
23.2	Consent of Reinhart Boerner Van Deuren s.c. (included in Exhibit 5.1).**
24.1	Power of Attorney.**

31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002. (15)**
101	The following materials from the Company s Annual Report on Form 10-K for the year ended September 30, 2017, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Income, (iii) Consolidated Statements of Stockholders Equity, (iv) Consolidated Statements of Cash Flows, and (v) the Notes to Consolidated Financial Statements. **

* Indicates management contract or compensatory plan.
** Previously filed with the Annual Report on Form 10-K filed on January 2, 2018.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Date: January 5, 2018

VERU INC.

BY: /s/ Mitchell Steiner
Mitchell Steiner, President and
Chief Executive Officer

BY: /s/ Michele Greco
Michele Greco, Executive Vice President of Finance

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the date indicated.

Signature	Title	Date
/s/ Mitchell Steiner Mitchell Steiner	President, Chief Executive Officer and Director (Principal Executive Officer)	January 5, 2018
/s/ Michele Greco Michele Greco	Executive Vice President of Finance (Principal Accounting and Financial Officer)	January 5, 2018
* Elgar Peerschke	Chairman of the Board	January 5, 2018
* O.B. Parrish	Vice Chairman of the Board	January 5, 2018
* David R. Bethune	Director	January 5, 2018
* Mario Eisenberger	Director	January 5, 2018
* Harry Fisch	Director	January 5, 2018

*	Director	January 5, 2018
Mary Margaret Frank		
*	Director	January 5, 2018
Lucy Lu		
*	Director	January 5, 2018
Georges Makhoul		
*	Director	January 5, 2018
Jesus Socorro		
*/s/ Mitchell Steiner		January 5, 2018
Mitchell Steiner Pursuant to the Powers of Attorney filed with the Annual Report on Form 10-K		