veru

2017 ANNUAL REPORT

VERU INC.'S MISSION IS TO IMPROVE LIVES THROUGH INNOVATIVE SCIENCE AND MEDICINE AS A LEADING BIOPHARMACEUTICAL COMPANY FOCUSED ON UROLOGY AND ONCOLOGY, WHILE ENHANCING STAKEHOLDER VALUE.

DEAR SHAREHOLDERS,

It has been a very productive year for Veru building the foundation for growth. Veru is now well positioned to become a leading urology and oncology biopharmaceutical company. We are focused on low cost, near-term, and high reward pharmaceuticals using an expedited regulatory pathway known as 505(b)(2). Our goal is to have several near-term and mid-term products progressing at the same time to have "multiple shots" to ensure that we file and commercialize several drugs in urology and oncology putting our company on a trajectory of solid growth.

We are delivering on this goal. We have advanced Tamsulosin DRS, 0.4mg (Tamsulosin HCl extended release for oral suspension)—a new slow release granule formulation for the most popular medicine for symptoms of an enlarged prostate causing difficulty in urination (also called benign prostatic hyperplasia or BPH)—and currently marketed under the FLOMAX® brand name. As is stated in the FDA package insert, FLOMAX® capsules should not be crushed, chewed or opened, because it may lead to serious side effects of low blood pressure and dizziness. A slow release granule formulation will allow us to target up to the 60% of men in long-term care or nursing homes and the 15% of men in the general population over 60 years of age that have difficulty or cannot swallow tablets or capsules. On August 2016, FDA agreed that a single small bioequivalence study would be all that is required clinically for the new drug application (NDA).

When we conducted the bioequivalence studies, we discovered that this new granule formulation, unlike FLOMAX, does not have to be taken with meals. Because there appears to be no food requirement with our slow release granules compared to the existing FLOMAX formulation, we plan to put these proprietary granules into a capsule as Tamsulosin XR capsules. Tamsulosin XR capsules will allow us to target the broader urology and primary care markets including those men who can swallow tablets or capsules. The final bioequivalence study will be conducted in, and the NDA will be filed in, 2018.

We also purchased a proprietary Solifenacin DRG (delayed release granule) formulation which uses the same delivery technology platform used to create our Tamsulosin DRS slow release granule formulation. Solifenacin is the active ingredient in VESIcare®, a drug for treatment of overactive bladder (urgency, urge incontinence and frequency) in both men and women. Like FLOMAX, the FDA package insert states that solifenacin tablets must be swallowed whole. There are no granule formulations available for men and for women who have the common condition of overactive bladder and who have difficulty or cannot swallow tablets. In November 2017, FDA agreed that a single bioequivalence study would be acceptable for a 505(b)(2) NDA filing. We plan to conduct the bioequivalence study in 2018 and to file the NDA in early 2019. The overactive bladder market is a multi-billion dollar opportunity. The initial target population would be men and women in long-term care facilities that have difficulty or cannot swallow tablets and will utilize the same sales channel that would be in place for Tamsulosin DRS.

To further ensure we have multiple urology products progressing at the same time, we purchased another new proprietary formulation—Tadalafil/Finasteride combination capsules. This proprietary formulation contains the active ingredients of CIALIS® (tadalafil—approved for the treatment of symptoms BPH and erectile dysfunction) and PROSCAR® (finasteride—approved for shrinking enlarged prostates). The Tadalafil/Finasteride combination formulation will allow us to offer a family of BPH drugs that have different mechanisms to treat the symptoms and signs of BPH. Tamsulosin treats immediate symptoms of BPH in men with smaller prostates, whereas Tadalafil/Finasteride combination capsules treat symptoms and shrink the size of the prostate in men who have enlarged prostates. In November 2017, FDA agreed that a single bioequivalence study would be acceptable for a 505(b)(2) NDA filing for the Tadalafil/Finasteride combination tablet as well. We plan to conduct the bioequivalence study in 2018 and to file the NDA in early 2019.

We are well positioned to take advantage of the multi-billion dollar BPH and overactive bladder market opportunities. These four products, Tamsulosin DRS granules, Tamsulosin XR capsules, Solifenacin DRG granules, and Tadalafil/Finasteride combination capsules, should allow us to file, launch and partner, when and where appropriate, multiple urology drugs over the next two and a half years.

The next wave of urology or oncology pharmaceuticals will come from VERU-944 (cis-clomiphene citrate) for the treatment of hot flashes in men who are on hormone therapy to treat advanced prostate cancer. In May 2017, FDA agreed that we may advance into a Phase 2 dose finding clinical trial. We should file the IND and initiate the Phase 2 clinical trial in early 2018. Finally, an FDA Advisory Committee met to review VERU-722 (fixed clomiphene citrate ratio) for the treatment of male infertility in December 2016. Based on their feedback, VERU-722 is ready to advance into Phase 2 clinical studies. We will continue to be opportunistic in both internally developing and/or finding new pharmaceutical products to license in urology and oncology.

To further increase shareholder value, we are also developing a novel, new chemical entity for the treatment of metastatic prostate, breast, ovarian, endometrial, and other cancers called VERU-111. VERU-111 is an oral anti-tubulin therapy that targets alpha and beta tubulin of microtubules. We are completing the required preclinical studies and should be ready for initial trials in patients who have advanced cancer by the second half of 2018. We are working with The Johns Hopkins Cancer Center. We will initially target men with metastatic prostate cancer and women who have metastatic breast, ovarian, or endometrial cancers in a Phase 1/2 open label clinical trial. In the Phase 2 portion of the clinical study, we will target men with metastatic prostate cancer who have become resistant to, or who have failed, ZYTIGA® (abiraterone) or XTANDI® (enzalumatide). These are blockbuster hormone prostate cancer drugs that are generating several billion dollars in annual revenue today. In addition, VERU-111 can be developed as an oral drug (pill form) for other tumor types that are currently being treated by intravenously given anti-tubulin chemotherapies (with a pill form being highly preferable to intravenous administration), which is a large market opportunity as well at over $5 billion of annual revenue today. The initial investment for this program over the next 2 years would be relatively modest and would increase when VERU-111 enters into Phase 2 clinical trials.

We have accomplished quite a lot this past year. We were able to do this with our existing resources and without undertaking a separate debt or equity financing. We paid for these activities this past year in part by the revenue produced from our commercial products: the FC2 Female Condom® Business from The Female Health Company Division and PREBOOST®.

The Female Health Company Division has revenue from both the global public health sector and the US market. In the global public health sector, FC2 is the world's leading female condom. With growing international competition, now, more than ever, we need to protect our brand, beat our competition, and aggressively grow our product revenues in the global public sector. The global public sector is the channel where FC2 is purchased in bulk quantities by governments and non-governmental donor agencies for public health distribution. This past year we felt the impact of two of our largest customers, Brazil and South Africa, who did not place orders due to their normal procurement cycles. We believe fiscal year 2018 should be better as Brazil is awarding a 50 million unit tender for this year and South Africa is expected to award this year a 40 million unit tender per year for three years totaling 120 million units. We are confident that we will get orders from these tenders in 2018.

In the US market, FC2 is uniquely positioned as the only FDA approved female condom to prevent both unwanted pregnancies and the sexual transmission of STIs including HIV/AIDs and the Zika virus. Our challenge was to create the distribution and marketing in the US to serve this market and we are seeing traction in these new areas of market access. FC2 is reimbursable with a prescription by both public and private payers under the Affordable Care Act (ACA) and under the laws of numerous States prior to the ACA. We now have the pharmacy distribution, market access and reimbursement infrastructure in place so that FC2 is available and reimbursable in over 98% of retail pharmacies across the country. We have a small sales force that markets to OB/GYN and primary care physicians. We have eliminated the "middle men" FC2 distributors and we now sell directly to Departments of Health and community organizations with better margins. We have signed a master service agreement to sell directly to 340B covered entities (approximately 56,000 entities) such as HIV and STD clinics. We have partnered with the "HeyDoctor" telemedicine application so that an FC2 prescription can be obtained by the patient via an Apple or Android smartphone where the prescription is sent to their local pharmacy or shipped to their home by a specialty pharmacy. We have an Uninsured or Underinsured Assistance Program where an individual can purchase FC2 at a discount from our website. Finally, we have an active Colleges and Universities Program that continues to grow. We now have proof that revenue can be generated and is growing in the US market.

Our other revenue opportunity is PREBOOST (4% benzocaine wipes) for the prevention of premature ejaculation. We received positive final results from our Phase 4 PREBOOST clinical trial which was press released by the American Urological Association during their scientific meeting in May 2017. We launched PREBOOST via digital and social media marketing. We also entered into a co-promotion and distribution agreement with Timm Medical Technologies, Inc., a specialty urology sales organization.

Fiscal year 2017 has been a transformational year for Veru. We have established a foundation to make Veru the leading urology and oncology biopharmaceutical company. We have several near-term and mid-term products progressing at the same time to have "multiple shots" to have drugs filed and launched in urology and oncology. We aspire to file at least one NDA each year for the next 5 years. This will provide the engine for growth as we continue to develop and commercialize existing 505(b)(2) products in our portfolio or seek new, outside 505(b)(2) products. We are excited about VERU-111 as a novel targeted oral therapy for multiple types of cancer and look forward to partnering this drug at the right time. We will continue to drive value through lower cost and expedited clinical development for large market opportunities. We are committed to becoming the leading biopharmaceutical company focused on urology and oncology while enhancing stakeholder value.

Sincerely,

Mitchell Steiner, M.D., F.A.C.S.
President and Chief Executive Officer

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(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 collectively, 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.

VERU INC.

FORM 10-K

September 30, 2017

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FORWARD-LOOKING STATEMENTS

Certain statements included in this Annual Report on Form 10-K 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. You can identify forward-looking statements by words such as "anticipate," "believe," "could," "expect," "intend," "may," "opportunity," "plan," "predict," "potential," "estimate," "should," "will," "would" or the negative of those terms or other words of similar meaning. These statements are based upon the Company's current plans and strategies, and reflect the Company's current assessment of the risks and uncertainties related to its business, and are made as of the date of this report. These statements are inherently subject to known and unknown risks and uncertainties. You should read these statements carefully because they discuss our future expectations or state other "forward-looking" information. We believe that it is important to communicate our future expectations to our investors. However, there may be events in the future that we are not able to accurately predict or control and our actual results may differ materially from the expectations we describe in our forward-looking statements. Factors that could cause actual results to differ materially from those currently anticipated include the following.

- our 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 our product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market;
- product demand and market acceptance;
- many of our products are at an early stage of development and we 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;
- risks inherent in doing business on an international level;
- the disruption of production at our manufacturing facilities due to raw material shortages, labor shortages and/or physical damage;
- our reliance on major customers and risks relating to delays in payment of accounts receivable by major customers;
- our growth strategy;
- our continued ability to attract and retain highly-skilled and qualified personnel;
- the costs and other effects of litigation, governmental investigations, legal and administrative cases and proceedings, settlements and investigations;
- government contracting risks;
- our ability to identify, successfully negotiate and complete suitable acquisitions or other strategic initiatives; and
- our ability to successfully integrate acquired businesses, technologies or products.

All forward-looking statements in this report should be considered in the context of the risks and other factors described above and in "Risk Factors" in Item 1A. of this report. The Company undertakes no obligation to make any revisions to the forward-looking statements contained in this report or to update them to reflect events or circumstances occurring after the date of this report.

PART I

Item 1. Business

General

Veru Inc. is a urology and oncology biopharmaceutical company. 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 US 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 (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® into a biopharmaceutical company with multiple drug products under clinical development and commercialization focused in urology and oncology.

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 (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 May 13, 2017, the Company announced positive results of a clinical study of its novel PREBOOST®product. The PREBOOST® Phase 4 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 intravaginal ejaculatory latency time (IELT) of two minutes or less on stopwatch measurement. After treatment with PREBOOST®, 82 percent of men were no longer considered to have PE with an increase time to ejaculation 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 on January 6, 2017 and on October 3, 2017 entered a co-promotion and distribution agreement with Timm Medical Technologies, Inc.

The Company presented an overview of its drug candidate for male infertility, VERU-722 by invitation from the FDA to present at the meeting of the Bone, Reproductive and Urologic Drugs (BRUD) FDA Advisory Committee on December 6, 2016. The FDA uses advisory committees to obtain independent expert advice on scientific, technical and policy matters. 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. The committee agreed with the intended patient population to treat, 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 plans to consider 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 24, 2017, the Company announced that, following a Pre-Investigational New Drug Application 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®, ELIGARD® and FIRMAGON®, 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) in the public sector. FC2 is the only currently available female-controlled product approved for market by the FDA and cleared by the World Health Organization (WHO) for purchase by U.N. agencies that provides dual protection against unintended pregnancy and sexually transmitted infections (STIs), including HIV/AIDS and the Zika virus. In 2017, The Company established new commercial sales channels for US market to generate new revenue. Nearly all of the Company's net revenues for fiscal 2017 were derived from sales of FC2.

Company History

Veru Inc. is the successor to The Wisconsin Pharmacal Company, Inc. (Wisconsin Pharmacal), a company which manufactured and marketed disparate specialty chemical and branded consumer products. Wisconsin Pharmacal was originally incorporated in 1971.

The FDA approved the Company's first generation Female Condom, FC1, for distribution in the U.S. in 1993 and approved the Company's U.K. FC1 manufacturing facility in 1994. Prior to 1996, Wisconsin Pharmacal owned certain rights to the Female Condom in the U.S., Canada, and Mexico. In 1996, the Company completed a series of actions which resulted in the Company's acquisition of worldwide rights to FC1, the divestiture of Wisconsin Pharmacal's other businesses and the change of the Company's name to "The Female Health Company." As a result of these actions, the Company's sole business consisted of the manufacture, marketing, and sale of the FC1 Female Condom.

In 2005, the Company completed the development of its second generation Female Condom (FC2). FC2 was first marketed internationally in March 2007 and has been marketed in the U.S. since August 2009. FC2 was approved by the FDA as a Class III medical device on March 10, 2009. In addition to FDA approval, FC2 has been approved by other regulatory agencies, including the European Union, India, and Brazil. Based on a rigorous scientific review, WHO cleared FC2 for purchase by U.N. agencies in 2006.

On October 31, 2016, the Company completed the APP Acquisition. Pursuant to the APP Acquisition, the outstanding shares of APP common stock and preferred stock were converted into the right to receive in the aggregate 2,000,000 shares of our common stock and 546,756 shares of our Class A Convertible Preferred Stock - Series 4 (the Series 4 Preferred Stock). Effective as of July 31, 2017, the shares of Series 4 Preferred Stock converted into a total of 21,870,240 shares of common stock, resulting in the total issuance of 23,870,240 shares of common stock to the former stockholders of APP in the transaction. The total estimated purchase price of approximately $19,807,980 was based on the closing price of our common stock of $0.95 per share on October 31, 2016 and certain

discounts due to lack of liquidity and other factors. See Note 2 to the Consolidated Financial Statement for detail on how the purchase price was determined.

Strategy

Our goal is to be a leading biopharmaceutical company focused on urology and oncology by developing a portfolio of pharmaceutical products that address significant health needs in large potential markets. We have combined the revenue and cash flows from the market leading FC2 female condom with APP's deep pipeline of pharmaceutical and consumer health product candidates. Initially, we intend to focus on the three low-cost, near-term and potentially high-reward programs that are expected to qualify for the abbreviated 505(b)(2) FDA regulatory pathway: Tamsulosin DRS and Tamsulosin XR capsules for BPH and VERU-944 for hot flashes in men taking hormonal therapies for advanced prostate cancer. The 505(b)(2) regulatory pathway can result in a much less expensive and faster route to approval, compared with the traditional 505(b)(1) regulatory development path, while creating new, differentiated products with potentially high commercial value. The Company is also developing new chemical entities such as VERU-111 for the treatment of metastatic prostate, breast, endometrial, ovarian, and other cancers and VERU-111/112 for the prevention and treatment of gout and Familial Mediterranean Fever (FMF) via the traditional 505(b)(1) regulatory development pathway.

The key elements of our strategy are as follows:

- ***Obtain regulatory approvals of products in North America, Europe and Asia***. Assuming the successful completion of clinical trials, we expect to file, or a partner will file on our behalf, for regulatory approval of our pharmaceutical products in North America, Europe and Asia, including Tamsulosin DRS and Tamsulosin XR capsules for the treatment of BPH, Solifenacin DRG for the treatment of OAB, Tadalafil/Finasteride combination capsules for the initial treatment of BPH in men with enlarged prostate, VERU-722 for the treatment of male infertility, VERU-944 for the treatment of hot flashes in men on prostate cancer hormonal therapies, VERU-111 for the treatment of metastatic prostate, breast, endometrial, ovarian, and other cancers and VERU-111/112 for the prevention and treatment of gout and Familial Mediterranean Fever (FMF).

- ***Develop a portfolio of urology and oncology pharmaceutical products***. We have developed or acquired development and marketing rights to a portfolio of urology and oncology pharmaceutical products and intend to continue to acquire, in-license and develop new pharmaceutical products that we believe offer unique market opportunities and/or complement existing product lines. We have adopted a three-tier strategy with respect to licensing or acquiring new products and technologies designed to diversify the risks inherent in traditional new chemical entity pharmaceutical development: (i) license or acquire fully-developed, FDA-approved products that have development potential and offer certain market protection against competitors, such as patent rights, marketing exclusivity or orphan drug designation; (ii) create differentiated products with potentially high commercial value by selecting a new indication for or modifying existing FDA-approved products utilizing the 505(b)(2) FDA approval pathway; and (iii) identify and acquire products and technologies in late preclinical or early clinical stages of development to minimize the time and expense of development.

- ***Focus on products with significant potential commercial opportunities in urology and oncology markets***. We intend to focus on developing drugs that we believe have potential significant commercial opportunities in markets. The core areas of interest include BPH, overactive bladder, sexual dysfunction, erectile dysfunction, cancer treatments for prostate, breast, endometrial, ovarian and other cancers, amelioration of prostate cancer hormonal therapy side effects including hot flashes and bone loss, and male infertility. We believe that these areas of the pharmaceutical market are large, growth markets. Through continued specialization as a urology and oncology company and by continuing to refine its capabilities in clinical research and development and marketing, we believe we can develop a strong position to be a leader in these markets.

- ***Develop business and enhance research through strategic alliances***. A key component of our business strategy is to leverage the resources gained from each collaboration to expand our technology and operations base. In addition, we believe outsources functions to health science companies (CROs), collaborations with academic centers and small discovery innovative companies will supplement the scientific resources available to us and broaden access to rapidly emerging drug discovery candidates.

- ***Develop opportunities in the consumer and prescription markets***. The Company believes that there are opportunities to develop the prescription market for FC2, and that such marketing of FC2 will complement the consumer launch of PREBOOST®. The Company appointed a Chief Commercial Officer for Veru to oversee the implementation of its marketing plan for FC2 by prescription and PREBOOST®, as well as the future prelaunch and launch activities for Tamsulosin DRS, Tamsulosin XR capsules, Solifenacin DRG, and Tadalafil/Finasteride combination capsules.

- ***Continue efforts in the global public sector***. The Company intends to continue to develop global markets for FC2 for both contraception and STI prevention, including HIV/AIDS and the Zika virus. The Company has developed contacts and relationships with global public health sector organizations such as WHO, UNFPA, USAID, and the United Nations Joint Programme on HIV/AIDS (UNAIDS), country-specific health ministries, NGOs and commercial partners in various

countries. In November 2016, the Company appointed a President of The Female Health Company Division. The Company also has representatives in various locations around the world to provide technical and marketing support as well as assist with its customers' prevention and family planning education programs.

- ***Capitalize on expertise and reputation of our management team and scientific advisors***. Our management team has significant expertise and experience in urology and oncology as well as drug development, marketing and sales which will enable us to manage effectively the preclinical studies and clinical trials of drug candidates and product commercialization. In addition, we intend to capitalize on the strong reputations of the members of our management and board of directors with academic institutions, hospitals, physicians, pharmacists and distributors to expand its customer base and to introduce new products.

Products

The following table summarizes the current status of the Company's product portfolio:

PRODUCT	INDICATION	U.S. REGULATORY PATHWAY	DEVELOPMENT PHASE
Urology 505(b)(2) Drug Candidates			
Tamsulosin Delayed Release Sachet (DRS) (tamsulosin HCl 0.4mg for extended-release oral suspension) and Tamsulosin XR capsules (tamsulosin HCL 0.4mg extended release capsules)	Benign prostatic hyperplasia	505(b)(2)	Bioequivalence study
Solifenacin Delayed Release Granules (DRG)	Overactive bladder	505(b)(2)	Bioequivalence study
Tadalafil/Finasteride combination capsules (tadalafil 5mg/ finasteride 5mg)	Initial treatment of men with lower urinary tract symptoms and enlarged prostate	505(b)(2)	Bioequivalence study
VERU-944 (cis-clomiphene citrate)	Hot flashes in men on prostate cancer hormonal therapies	505(b)(2)	Phase 2
VERU-722 (fixed ratio of trans- and cis-clomiphene citrate isomers)	Male infertility caused by testicular dysfunction	505(b)(2)	Phase 2
Oncology Drug Candidate			
VERU-111- Novel oral alpha and beta tubulin inhibitor	Metastatic prostate, breast, endometrial, ovarian and other cancers	505(b)(1)	Preclinical
Other 505(b)(1) Drug Candidates			
VERU-111/VERU-112- Novel oral agent that targets colchicine binding site of tubulin	Gout and Familial Mediterranean Fever	505(b)(1)	Preclinical
Commercial Products			
FC2 Female Condom®	Unintended pregnancy and STIs	FDA approved	Marketed
PREBOOST® (4% benzocaine wipes)	Premature ejaculation	FDA monograph compliant	Marketed

Tamsulosin DRS (tamsulosin HCl 0.4mg for extended release oral suspension) and Tamsulosin 0.4mg XR capsules (tamsulosin HCl extended release capsules) for the treatment of lower urinary tract symptoms of BPH.

Scientific Overview. Tamsulosin DRS is a new slow release granule formulation containing the active pharmaceutical ingredient in FLOMAX® (tamsulosin HCl) capsules which is a commonly used medicine for the treatment of symptoms of BPH, also known as enlargement of the prostate. FLOMAX® is indicated for the treatment of symptoms of BPH. Tamsulosin is a selective alpha$_1$ adrenergic receptor blocking drug that is specific for the alpha$_1$ adrenergic receptors located in the smooth muscle of the prostate and bladder neck. Symptoms associated with BPH occur, at least in part, as a result of increased smooth muscle tone of the prostate and bladder which leads to constriction of urinary flow, urinary retention, urinary infection, kidney damage and life threatening blood infection called urosepsis. Blocking these alpha$_1$ adrenergic receptors relaxes the smooth muscles of the prostate and bladder neck resulting in the improvement of urinary flow rate and alleviation of the symptoms of BPH. As stated on the FDA approved package insert, FLOMAX® capsules should not be crushed, chewed or opened, because doing so changes the speed by which the drug is absorbed into the bloodstream. Further, FLOMAX® capsules can only be taken after a meal. It has a "food effect" such that, if FLOMAX ® is not taken with food, the drug gets in too fast and men are placed at higher risk for dizziness and postural hypotension (sudden drop in blood pressure upon standing that can lead to fainting). Tablets and capsules are problematic for 15% of men over the age of 60 in the general community and the up to 60% of men in long term facilities who have difficulty or cannot swallow tablets and capsules because of certain medical conditions, including degenerative neurological diseases like Parkinson's, having suffered a stroke, and Alzheimer's disease. Not being able to take an alpha blocker drug for BPH, like FLOMAX®, because of difficulty or not able to swallow tablets and capsules may lead to the increased risk of acute urinary retention, urinary catheterization, urosepsis and death. These men are currently managed with diapers, catheters, or surgery. Because Tamsulosin DRS is a new proprietary slow release granule formulation containing the active pharmaceutical ingredient in FLOMAX®, it would provide a more convenient and reliable way to deliver therapeutic levels of tamsulosin to men who have difficulty or cannot swallow tablets and capsules.

Development Plan. This new formulation called Tamsulosin DRS contains the same active pharmaceutical ingredient, tamsulosin, that is found in FLOMAX® (tamsulosin HCl 0.4mg) capsules and, as such, would be expected to have the same efficacy and safety as FLOMAX®. This information can be referenced under a 505(b)(2) NDA submission for Tamsulosin DRS. On August 12, 2016, the FDA agreed that the Company's Tamsulosin DRS medication, a proprietary slow release granules formulation for the treatment of lower urinary tract symptoms of BPH, a $3.5 billion market, qualifies for the expedited 505(b)(2) regulatory approval pathway. In March 2017, the Company initiated a Stage 1 (pilot) bioequivalence clinical study for Tamsulosin DRS, and in April 2017, announced the successful completion of Stage 1 of the bioequivalence clinical study, which demonstrated that the blood levels of the Tamsulosin DRS over time were bioequivalent to FLOMAX®. In August 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 did not 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 2018. Unlike FLOMAX®, the new tamsulosin granule formulation, based on the bioequivalence studies, does not appear to have a food effect which means that the new formulation may be administered without food. This difference may have a market advantage not only for men who cannot swallow capsules, but also for men who can swallow capsules. As a consequence, the Company is also developing Tamsulosin XR (extended release) capsules, which contain the new formulated granules, for the urology and primary care markets. The Company does not believe that the new bioequivalence study will affect the timing of its planned submission of an NDA for Tamsulosin DRS and Tamsulosin XR capsules and, if the new bioequivalence study is successful, plans to submit the NDA in the first half of 2018. In addition, the Company plans to meet with the European Medicines Agency (EMA) to discuss the requirements to file a Marketing Authorization Application (MAA) in EU in 2018.

Market. The initial commercialization plan for Tamsulosin DRS granule formulation is to target men in long term care facilities and men in the community who have difficulty or cannot swallow tablets and capsules. Currently, tamsulosin oral suspension is not currently available,and if approved, would be the only oral suspension formulation that would be available on formularies in long term care pharmacies. A sales force is not required for this product as pharmacists and physicians in long term care facilities would identify patients that would benefit from this formulation.. Tamsulosin XR capsules, however, will be marketed to urology and primary care physicians, and the Company will either commercialize itself or seek marketing and sales partnerships. Based on IMS data, FLOMAX® and generic tamsulosin sales from March 2014 to March 2015 were $3.5 billion in the U.S. The U.S. market for all alpha blockers for BPH is estimated to be $4.5 billion annually per IMS. Men in long term care or nursing homes have up to a 60% prevalence of swallowing difficulties and account for about 13% of total tamsulosin sales, whereas over 15% of men over 60 years of age in the general population have difficulty swallowing tablets and capsules. Tamsulosin DRS and Tamsulosin XR capsules, if approved, will be new branded, not generic products.

Solifenacin Delayed Release Granules (DRG) (solifenacin succinate for extended release oral suspension) for the treatment of overactive bladder.

Scientific Overview. Solifenacin DRS is a new proprietary granule formulation containing the active pharmaceutical ingredient in VESIcare® (Solifenacin 5mg or 10 mg tablets). Solifenacin is a competitive selective M_3 muscarinic receptor antagonist. Solifenacin is indicated for the treatment of overactive bladder (OAB) which are symptoms of urge urinary incontinence, urgency, and urinary frequency in men and women. Muscarinic receptors play a major role in mediating contractions of the urinary bladder.

Development Plan. In November 2017 PreIND meeting, FDA confirmed that Solifenacin DRG qualifies for a 505(b)(2) regulatory pathway. FDA also agreed that a single bioequivalence study will be sufficient to support the approval of Solifenacin DRG product for the treatment of overactive bladder and no additional nonclinical, clinical efficacy and/or safety studies will be required.. The Company plans to complete the Solifenacin DRG bioequivalence study in 2018 and to file the NDA in 2019.

Market. Solifenacin DRS (solifenacin succinate extended release for oral suspension) is a new proprietary oral extended release granule formulation being developed for men and women with overactive bladder and dysphagia, difficulty or cannot swallow pills or capsules. In the US, the prevalence of OAB was similar in women and men, at 16.9% and 16%, respectively. According to the US Department of Health and Human Services (2014), up to 36.7% of short-term residents and 70.3% of long-term nursing home residents were not in complete control of their bladder (2014). Annual sales for VESIcare® tablets (5 mg and 10 mg) were approximately $1.1 billion dollars according to IMS Health 2017 sales data and worldwide annual direct costs of OAB are expected to be greater than 10 billion dollars by 2018. Like OAB, dysphagia (swallowing difficulty) is also a growing health issue in our aging population. Up to 38% of elderly who live independently and up to 68% of elderly nursing home residents have difficulty swallowing. Swallowing difficulties are particularly prevalent in people who have Parkinson's Disease (80%), Alzheimer's Disease (40-70%) and Stroke (50%). These are the same conditions that are associated with OAB, and unfortunately, currently available selective M_3 muscarinic receptor antagonists, including solifenacin, are only available as tablets. According to FDA label, tablets should be swallowed whole and not chewed, crushed or broken. Currently, Solifenacin DRG oral suspension is not currently available, and if approved, would be the only oral suspension formulation of a M3 muscarinic antagonist that would be available on formularies in long term care pharmacies. A sales force is not required for this product as pharmacists and physicians in long term care facilities would identify patients that would benefit from this formulation.

Tadalafil-Finasteride combination capsules (tadalafil 5mg and finasteride 5mg) for the initial treatment of men with lower urinary tract symptoms and enlarged prostate

Scientific Overview. *Tadalafil-Finasteride combination capsule* is a new, proprietary formulation that addresses men who have lower urinary tract symptoms and restricted urinary stream because of an enlarged prostate. CIALIS® (tadalafil 5mg) and PROSCAR® (finasteride 5mg) co-administration is indicated for the initial treatment of BPH for up to 26 weeks. CIALIS® (Tadalafil 5mg) is a phosphodiesterase 5 (PDE5) inhibitor and PROSCAR® (finasteride 5mg) is a Type 2, 5 alpha reductase inhibitor. Tadalafil 5mg daily has been approved for the treatment of erectile dysfunction and BPH. Finasteride 5mg has been approved the treatment of BPH: to improve symptoms, to reduce risk of acute urinary retention and the need for prostate surgery, and to prevent progression of BPH.

Development plan. In a November 2017 PreIND meeting, FDA confirmed that Tadalafil/Finasteride combination capsules qualifies for a 505(b)(2) regulatory pathway. FDA also agreed that a single bioequivalence study and no additional nonclinical, clinical efficacy and/or safety studies will be required to support the approval of Tadalafil/Finasteride combination capsules for the initial treatment of lower urinary tract symptoms in men with enlarged prostates. The Company plans to complete the Tadalafil/Finasteride combination capsules bioequivalence study in 2018 and to file the NDA in 2019.

Market. The worldwide prevalence of BPH lower urinary symptoms is estimated to be 10-25% of the male population and will rise to 1.1 billion men by 2018. Currently, co-adminstration of CIALIS® and PROSCAR® is currently FDA approved for the initial treatment of signs and symptoms of BPH up to 26 weeks. According to Elkelany O et al. (Therapeutics and Clinical Risk Management 11:507-513, 2015), other men who may benefit from this co-administration include: 1) men who have a suboptimal response to 5 alpha reductase inhibitors alone (PROSCAR®(finasteride) or AVODART®(dutasteride)) 2) men who have a suboptimal response to an alpha blocker alone (FLOMAX® (tamsulosin), HYTRIN® (terazocin), UROXATRAL® (alfuzosin), CARDURA® (doxazosin), and RAPAFLO® (silodosin)) or in combination with a 5 alpha reductase inhibitor (JALYN® (dutasteride/tamsulosin combination)) and 3) men who have an optimal response to 5 alpha reductase inhibitors, but who also have erectile dysfunction. A Tadalafil 5mg / Finasteride 5mg combination capsule is not currently available. A combination capsule would increase convenience and drug compliance. Poor compliance with a BPH medicine could lead to increase chance of acute urinary retention, urosepsis, and death. The Company would consider marketing and sales efforts of this product to urology, but seek co-promotion partners for primary care physicians in US. The company would seek pharmaceutical partnerships in territories outside the US.

VERU-944 (cis-clomiphene citrate) for the treatment of hot flashes caused by prostate cancer hormonal therapies in men with advanced prostate cancer.

Scientific Overview. Prostate cancer is the most common noncutaneous cancer diagnosed in men, with over 161,000 new cases in the U.S. in 2017. The estimated prevalence of prostate cancer in the U.S. is 2.35 million cases for which over one-third will have received androgen deprivation therapy. Hot flashes, also known as vasomotor symptoms, are the most common and distressing side effect of prostate cancer hormonal therapies. Hormone therapies include androgen deprivation, like LUPRON® (leuprolide) or ZOLADEX® (goserelin), as well as the newer agents approved to treat advanced prostate cancer such as ZYTIGA® (abiraterone) and XTANDI® (enzalutamide). Up to 80% of men on androgen deprivation therapy complain of hot flashes and 30-40% will have moderate to severe hot flashes. Hot flashes are defined as intense heat sensation, flushing and profuse sweating and chills as well as anxiety and palpitations. Although episodes of hot flashes occur repeatedly and last a few minutes, some may last up to 20 minutes. Hot flashes associated with prostate cancer hormonal therapies tend to persist over time with the same frequency and intensity throughout therapy. Up to 50% of men continue to report hot flashes after five years on prostate cancer hormonal therapy. Patients on prostate cancer hormonal therapy report significant effects on daily functioning and quality of life. Hot flashes are one of the main reasons for patients to be noncompliant with their prostate cancer hormonal therapy. As prostate cancer patients with advanced and metastatic disease are living longer because of more effective hormonal therapies, hot flashes have become an even bigger concern and impact on quality of life.

Hormonal and nonhormonal therapies have been used off-label to treat hot flashes in men on prostate cancer hormonal therapies. In general, hormonal agents especially estrogens have been shown off-label to be helpful for treating hot flashes. However, estrogen treatment is complicated by lack of consistent dosing, dose dependent gynecomastia (breast enlargement), gynecodynia (painful breasts), and increase in thromboembolic events. Nonhormonal agents that have been also used off-label include anti-seizure agents and antidepressants that have serious side effects. Moreover, nonhormonal agents tend to be less effective than hormonal therapies for the treatment of hot flashes. There are no FDA-approved therapies for hot flashes caused by prostate cancer hormonal therapy in men with advanced prostate cancer. CLOMID® (clomiphene citrate), which contains 30-50% zuclomiphene, appears to be well-tolerated in 39 published studies in over 2,200 men with doses as high as 400 mg/day and up to three years of use. CLOMID® (clomiphene citrate) also contains the trans-isomer, enclomiphene which causes hot flashes as such CLOMID® (clomiphene citrate) and generics cannot substitute for VERU-944 as they will actually exacerbate hot flashes. VERU-944 is the pure cis-clomiphene. Cis-clomiphene is a potent nonsteroidal estrogen receptor agonist. We believe that a nonsteroidal hormone therapy like VERU-944 has the potential to be an effective and well tolerated treatment for hot flashes caused by prostate cancer hormonal therapies in men with advanced prostate cancer.

Development Plan. As VERU-944, cis-clomiphene, comprises 30-50% of CLOMID® (clomiphene citrate) which is approved for the treatment of ovulatory dysfunction in women desiring pregnancy, the Company believes that it will be able to reference parts of the nonclinical and clinical safety information from both the listed drug labeling and the published literature under the 505(b)(2) regulatory pathway. On May 24, 2017, the Company announced that, following a Pre-IND meeting with the FDA in which the Company received concurrence on the 505(b)(2) pathway, that FDA agreed with plan to advance the proprietary drug candidate, VERU-944 (cis-clomiphene), into a dose finding Phase 2 clinical trial for the treatment of hot flashes in men receiving hormone therapy (ADT) for prostate cancer. Approximately 80% of men receiving one of the common forms of ADT, including LUPRON® (leuprolide), ELIGARD®(leuprolide) and FIRMAGON®(degarelix), experience hot flashes. The Company expects to file an IND with the FDA and begin the Phase 2 dose finding clinical trial to evaluate VERU-944 for the treatment of hot flashes in men on androgen deprivation therapy in the first half of 2018.

Market. Hot flashes are the most common side effect of prostate cancer hormone therapy occurring in up to 80% of men, with about 30-40% having moderate to severe hot flashes. Approximately 700,000 men annually in the United States are on androgen deprivation therapy, abiraterone, or enzalutamide for advanced prostate cancer. There are currently no FDA-approved therapies for hot flashes associated with prostate cancer hormonal therapies. The annual U.S. market for the treatment of hot flashes in men on prostate cancer hormonal therapies is estimated to be $600 million.

VERU-722 (Fixed ratio of trans- and cis- clomiphene citrate isomers) for the treatment of male infertility related to testicular dysfunction.

Scientific Overview. Up to 10% of infertile men have an endocrine cause and 2% of infertile men have an adult onset form of idiopathic hypogonadotropic hypogonadism. Current FDA-approved treatments for this indication include Human Chorionic Gonadotropin (HCG) and Follicle Stimulating Hormone (FSH) injections. There are no FDA-approved oral therapies for male infertility. CLOMID® (clomiphene citrate) 50mg tablets are being used off-label as first line empiric therapy in 90% of idiopathic infertile men. CLOMID® is FDA-approved for the treatment of ovulatory dysfunction in women desiring pregnancy. CLOMID is a mixture of two geometric isomers cis-clomiphene (zuclomiphene) and trans-clomiphene (enclomiphene) containing between 30-50% of the cis-clomiphene isomer. Trans-clomiphene has antiestrogenic activity, while the cis-clomiphene has estrogenic activity. In men, clomiphene has the ability interact with the hypothalamus and pituitary gland to cause the secretion of Luteinizing Hormone (LH), and

the higher levels of LH will stimulate Leydig cells in the testes to produce testosterone, to promote spermatogenesis, and to improve sperm count and quality.

Based on the scientific literature, clomiphene has demonstrated the ability to improve sperm quality and sperm counts in infertile men and result in higher pregnancy rates. Based on 39 published studies, clomiphene appears to be well tolerated in men with doses as high as 400 mg/day and up to three years of use. However, the efficacy results for an individual patient have been inconsistent from study to study for several reasons: the form of clomiphene used contains varying ratios of the trans- and cis-clomiphene isomers, different doses were given, various dosing schedules were followed and different patient populations were studied. Clomiphene has not been formally studied for regulatory approval for the indication of male infertility; therefore, there is no established dose or schedule for efficacy or safety in men. VERU-722 is a patented, proprietary daily oral tablet that has a specific fixed ratio of the combination of trans- and cis-clomiphene isomers.

Development Plan. VERU-722 is being developed as the first FDA-approved oral agent for the treatment of male infertility. VERU-722 has fixed ratio of the combination of trans- and cis- clomiphene isomers. We believe that using a fixed ratio approach will allow the determination of the correct dose and schedule for efficacy and safety for the treatment of male infertility. The patient population will be men who have hypogonadotropic hypogonadism and oligozoospermia (low sperm count). We met with the FDA for a pre-IND meeting on May 28, 2015 where the FDA confirmed that VERU-722 qualifies for the 505(b)(2) regulatory pathway. The formulation, doses and dosing regimen for VERU-722 will differ from those of CLOMID®. Despite the differences, the approval of VERU-722 will rely on nonclinical and clinical efficacy and safety information from the listed drug labeling and in the published literature. On December 6, 2016, the Company was invited to discuss our clinical trial design and plans with the FDA as part of The Bone, Reproductive, and Urologic Drugs FDA Advisory Committee Meeting. Based on positive regulatory recommendations by the BRUD FDA Advisory Committee, we are reviewing our plans to file an IND and possibly initiate a Phase 2 clinical study.

Market. If approved, VERU-722 will be indicated as the first oral treatment for male infertility. Infertility affects 6.1 million couples in the United States representing 15% of all couples trying to conceive. Up to 50% of infertility is attributed to males who are subsequently found to have abnormal semen analysis, of which 50% of these men are diagnosed with idiopathic, or unexplained, infertility. Ninety percent of men with idiopathic male infertility are empirically treated with off-label use of CLOMID®. VERU-722 may be effective in treating male factor infertility caused by testicular dysfunction [low sperm concentration (oligozoospermia) and low testosterone blood levels (hypogonadotropic hypogonadism)]. The current U.S. market size for male infertility is estimated to be $700 million annually based on current off-label use of CLOMID® and clomiphene generics prescription data (IMS).

VERU-111, a novel oral therapy targeting alpha and beta tubulin for the treatment of metastatic prostate, breast, endometrial ovarian, and other cancers.

Scientific Overview. In 2017, there were approximately 161,000 new cases of prostate cancer in the U.S. and about 25% will die from the disease. In the U.S., 5% of men with prostate cancer will have metastatic cancer and up to 30% of men with high-risk, localized prostate cancer will develop metastatic cancer following initial therapy. The median survival of patients with metastatic prostate cancer ranges from 3.2-4.5 years. For these men, the 1st line therapy is androgen deprivation therapy, or medical castration. Although most will initially respond, nearly all these patients will progress to metastatic castration resistant prostate and have a poor prognosis with an average survival of 1.5 years. New 2nd line hormonal agents, like XTANDI® (enzalutamide) and ZYTIGA® (abiraterone/prednisone) have resulted in an additional four to five months of average survival, but again, nearly all men on these agents will develop progressive metastatic prostate cancer.

Agents that target tubulin, the subunits of microtubules, have been shown to be the most effective targeted cytotoxic chemotherapy for the treatment of metastatic prostate cancer. Microtubules are critical for cancer cell replication and to shuttle the androgen receptor into the nucleus where the receptor stimulates genes for cancer cell proliferation. Docetaxel and cabazitaxel are examples of FDA-approved chemotherapy drugs that are given intravenously (IV) that target tubulin to treat metastatic prostate cancer. Although effective, the challenges for this class of chemotherapy agents, also known as taxanes, include that they must be given intravenously (IV) and that the cancer cells develop resistance to taxanes. There are also serious safety concerns with IV taxanes which include serious hypersensitivity reactions, myelosuppression and neurotoxicity such as peripheral neuropathy and muscle weakness.

VERU-111 is a novel small molecule that is a new chemical entity (NCE) that has been optimized to be a novel oral therapy targeting alpha and beta tubulin subunits of microtubules. Unlike taxanes which bind to just the beta subunit of tubulin, VERU-111 binds strongly to both the alpha and beta subunits of tubulin. VERU-111 has high oral bioavailability; less resistance as it does not interact with multiple drug resistance proteins so it cannot be pumped out of the cancer cell; minimal drug to drug interactions especially not metabolized by CYP3A4, and has high activity against many tumor types including prostate cancer resistant to drugs like enzalutamide, AR-V7 positive, and taxanes as well as triple negative breast cancer, ovarian cancer, pancreatic cancer, lung cancer, and melanoma. In preclinical studies, VERU-111 appears to have less neurotoxicity and leukopenia compared to taxanes and vinca alkaloids chemotherapy agents.

Development Plan. The Company plans to develop VERU-111 initially as a treatment for men with metastatic prostate cancer that have failed hormonal therapy and therefore their disease has progressed. The Company is also evaluating the drug in other cancer

types that are historically known to be sensitive to taxane based chemotherapies including metastatic breast, ovarian and endometrial cancers. Production of the active pharmaceutical ingredient and preclinical safety toxicology studies required for an IND are expected to be completed in 2018, anticipate filing IND in early 2018, and Phase 1/2 studies are planned for 2018. The Company is partnering with The Johns Hopkins Hospital Cancer Center and their cancer center network to conduct the Phase 1/2 clinical studies. Phase 1 studies of VERU-111 are planned in men who have metastatic prostate cancer that has progressed while taking androgen deprivation therapy and abiraterone or enzalutamide as well as in patients with metastatic breast, endometrial, and ovarian cancers.

Market. In the U.S., there is a $5 billion annual market for 2nd line hormone therapies for prostate cancer and a $4.8 billion annual market for IV-given taxanes and vinca alkaloids chemotherapies (docetaxel $1 billion and cabazitaxel $500 million in prostate cancer) per Decision Resources Group and Allied Market Research. Second line hormonal therapies like enzalutamide and abiraterone/prednisone have almost complete cross-resistance and should not be used in sequence for the treatment of metastatic prostate cancer. VERU-111, as an oral therapy targeting alpha and beta tubulin, could be substituted for IV given docetaxel and cabazitaxel antitubulin chemotherapies. VERU-111 could also be developed a 1st line therapy given with androgen deprivation in men who have hormone sensitive, high volume prostate cancer where androgen deprivation therapy and docetaxel have been shown in several studies to increase survival in these men by 17-21 months. Another 1st line indication could be developed in men who have metastatic prostate cancer and splice variants of the androgen receptor including a common variant known as AR-V7. Prostate cancer hormone therapies are not effective in men who have AR-V7. However, this type of cancer appears to respond to docetaxel and may be potentially treated by a novel oral therapy targeting alpha and beta tubulin like VERU-111. VERU-111 could also be developed as an oral dosing alternative to chemotherapies for the treatment of metastatic breast, endometrial, and ovarian cancers as these tumors that responded to IV taxane chemotherapies.

VERU-111/VERU-112 for the treatment of gout and Familial Mediterranean Fever.

Scientific Overview. Colchicine is FDA-approved for prophylaxis and treatment of gout flares in adults (0.6-1.2mg/day) and for FMF in adult and children four years and older (0.3-2.4mg/ day depending on age). Gout is a type of arthritis characterized by sudden, severe attacks of burning joint pain, usually the big toe, because of the deposition of uric acid crystals in the joint. The attacks can be recurrent and last a few days to many weeks until there is pain relief. Gout is a disease of high levels of uric acid in the blood and is ten times more common in men than women. Colchicine is effective to prevent and to treat acute attacks.

FMF is a hereditary inflammatory disorder caused by mutations in the MEFV gene that causes episodes of fever, pain and swelling in the abdomen (peritonitis), lungs (pleuritis), heart (pericarditis) and joints (arthritis) in adults and children. Signs and symptoms of FMF usually begin in childhood with attacks that last for weeks or months. Colchicine is considered the gold standard and the only drug recommended for treating FMF. Colchicine is used at low doses to prevent and treat these FMF patients chronically.

Colchicine has a narrow therapeutic index which means that the doses required to treat the disease and the occurrences of serious safety issues are close. Colchicine has common side effects such as abdominal cramping, nausea and diarrhea that have limited its use. More concerning, however, colchicine has "warning and precautions" in the label for drug-drug interactions and should not be taken in conjunction with other drugs that are P-gycoprotein (P-gp) or strong CYP3A4 inhibitors as this could lead to serious side effects and death. Examples of drugs and other items that could increase the concentration of colchicine in the blood into toxic ranges include certain antibiotics, antidepressants, lipid lowering drugs, tranquilizers, grapefruit juice and antihistamines.

VERU-111, and its back up VERU-112, are NCEs, small molecules that have high oral bioavailability, and like colchicine, bind to the "colchicine binding site" of tubulin. Unlike colchicine, there should not be drug-drug interactions, as VERU-111 does not interact with P-gp or CYP3A4. This may potentially eliminate the possibility of serious and life-threatening side effects when given with other drugs that are P-gp or CYP3A4 inhibitors. VERU-111/112 could be used as a potentially safer alternative to colchicine, which remains the mainstay of therapy for both prevention and treatment of gout and FMF.

Development Plan. The Phase 1 VERU-111 studies that are planned in 2018 in cancer patients will provide the initial pharmacokinetics and safety information that can be used for dosing and safety considerations for filing the IND and conducting the Phase 2 studies for gout expected in 2019.

Market. According to nationally representative data (NHANES), gout is the most common form of inflammatory arthritis in men, with a prevalence of 5.9% in men (6.1 million) and in women the prevalence is 2% (2.2 million). The estimated U.S. annual market for gout therapies is $725 million per IMS. FMF affects primarily people of Mediterranean extraction, mostly Sephardic Jews, Armenians, Arabs and Turks. It is very common in the populations at risk with estimated carrier rates of 1/6 in Armenians, 1/7 in North African Jews and 1/13 in Iraqi Jews. FMF affects less than 200,000 patients in the U.S. population and could be eligible for orphan drug status.

FC2 for dual protection against unintended pregnancy and STIs.

Product. FC2 is the only currently available female-controlled product approved for market by FDA and cleared by the 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. FC2 was approved for market by FDA as a Class III medical device in 2009.

FC2 has basically the same physical design, specifications, safety, and efficacy profile as FC1, the Company's first generation Female Condom. Manufactured from a nitrile polymer formulation that is exclusive to the Company, FC2 is produced more economically than FC1, which was made from a more costly raw material, polyurethane. FC2 consists of a soft, loose fitting sheath and two rings: an external ring of rolled nitrile and a loose internal ring made of flexible polyurethane. FC2's soft sheath lines the vagina, preventing skin-to-skin contact during intercourse. Its external ring remains outside the vagina, partially covering the external genitalia. The internal ring is used for insertion and helps keep the device in place during use.

FC2's primary raw material, a nitrile polymer, offers a number of benefits over natural rubber latex, the raw material most commonly used in male condoms. FC2's nitrile polymer is stronger than latex, reducing the probability that the female condom sheath will tear during use. Unlike latex, FC2's nitrile polymer quickly transfers heat. FC2 can warm to body temperature immediately upon insertion, which may enhance the user's sensation and pleasure. Unlike the male condom, FC2 may be inserted in advance of arousal, eliminating disruption during sexual intimacy. FC2 is also an alternative to latex sensitive users who are unable to use male condoms without irritation. For example, 7 percent to 20 percent of the individuals with significant exposure to latex rubber (i.e., health care workers) experience such irritation. To the Company's knowledge, there is no reported allergy to the nitrile polymer. FC2 is pre-lubricated, disposable, and recommended for use during a single sex act. FC2 is not reusable.

Global Public Health Sector Market. FC2's primary use is for disease prevention and family planning, and the global public health sector has been the main market for FC2. 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.

The Company has a relatively small customer base for FC2, with a limited number of customers who generally purchase in large quantities. Over the past few years, significant customers have included large global agencies, such as the United Nations Population Fund (UNFPA) and the United States Agency for International Development (USAID), Sekunjalo Investments Corporation (PTY) Ltd (Sekunjalo), the Company's distributor in the Republic of South Africa (RSA), and the Brazil Ministry of Health either through UNFPA or Semina Indústria e Comércio Ltda (Semina), the Company's distributor in Brazil. Other customers include ministries of health or other governmental agencies, which either purchase directly or via in-country distributors, and non-governmental organizations (NGOs).

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.

The global public health sector market for male condoms is estimated to be greater than 8-10 billion units annually. The private sector market for male condoms is estimated at 10-15 billion units annually. The combined global male condom market (public and private sector) is estimated at a value of $4.5 billion annually. The female condom market represents a very small portion of the total global condom market, yet 50 percent of individuals living with HIV/AIDS are women. As a result a number of independent women's groups are advocating for increased investment in and distribution of female condoms on a gender equality basis.

The Company has distribution agreements and other arrangements with commercial partners which market as a consumer health product through distributors and retailers in 16 countries, including Brazil, Spain, France, and the United Kingdom. These agreements are generally exclusive for a single country. Under these agreements, the Company sells FC2 to the distributor partners, who market and distribute the product to consumers in the established territory.

U.S. Market.

Recent changes in the U.S. market provided an opportunity for the promotion and expansion of FC2 to protect against STIs and unwanted pregnancies. FC2 is the only device approved by the FDA (Class III medical device) for this use. As FC2 is nonhormonal, it is a viable alternative for many U.S. women who have reported dissatisfaction with the side effects of hormonal birth control. Moreover, there are unique groups of women such as breast cancer survivors who desire contraception and cannot take hormonal birth control because of this underlying condition. FC2 is currently reimbursable by prescription under the Affordable Care Act.. In January 2017 we have built the necessary infrastructure to allow for broad access across the US. As a result, FC2 is now available through multiple access channels including: 98% of retail pharmacies, community based organizations, by prescription, telemedicine, universities, direct purchase and 340B qualified health care clinics, and directly to the public sector without distributors. Marketing and educational programs, both traditional and by digital and social media, are being developed and implemented to target health care

providers (physicians, nurse practitioners, and physician assistants), pharmacies, and women to coordinate awareness and access to FC2 that is fully reimbursable.

PREBOOST® (4% benzocaine medicated individual wipes) for the prevention of premature ejaculation.

Scientific Overview. Premature ejaculation is the most common sexual dysfunction and even more frequent than erectile dysfunction based on epidemiological studies. Premature ejaculation is a self-reported diagnosis. Men with premature ejaculation desire treatment; however, most are reluctant and unlikely to request treatment out of embarrassment. Discrepancies also exist between the man and his partner's reports of the man's ejaculatory behavior as women have been found to report premature ejaculation affecting their relationship more often than their male partner.

There are no FDA-approved prescription products for premature ejaculation (PE). PREBOOST® is a proprietary OTC male genital desensitizer used for the treatment of PE. There are no prescription products for PE approved by the FDA. Off-label use of antidepressants and PDE-5 inhibitors has had limited success because of inconsistent efficacy and unacceptable side effects. Psychological counseling and behavioral therapy are also used with mixed results. Of the consumer health products, the topical anesthetics are administered as sprays and gels. The drawbacks of these approaches include inconsistent dosing leading to too much anesthetic and transference of the anesthetics to the partner. PREBOOST® is compliant with the FDA monograph and is approved in the United States. PREBOOST® is the only individually packaged medicated wipe that contains a desensitizing agent (benzocaine 4.0%). The advantages are: 1) Convenient individually wrapped wipes so it is easier to carry and to be discreet, 2) The correct dose is delivered each time, 3) The medicine is applied topically and dries quickly which prevents the potential for transference to partner, and 4) Benzocaine at 4.0% temporarily desensitizes, but does not completely numb the penis.

Development Plan. PREBOOST® is approved in the United States. The Company has completed a Phase 4 clinical study of PREBOOST®. The PREBOOST® Clinical Study enrolled 26 men aged 18 years or order in a heterosexual, monogamous relationship, with PE, defined as reported poor control over ejaculation, personal distress related to ejaculation and average intravaginal ejaculatory latency time (IELT) of two minutes or less on stopwatch measurement. Subjects were randomized 2-to-1 to treatment with benzocaine wipes or placebo wipes, with men in the placebo group crossed over to the treatment group one month after randomization. The primary outcome measure for the study was change in IELT at two months, with secondary outcomes including change in questionnaire assessments of global rating of distress, medication assessment and IPE. Data showed that patients treated with benzocaine 4% wipes demonstrated a statistically significant improvement in IELT after the first month of treatment (2.75 minutes), with greater improvement after the second month (5.5 minutes), compared to placebo (1.8 minutes). Men in the treatment group also reported greater improvement in distress relating to intercourse, control of ejaculation and satisfaction with sexual intercourse over the study period. After treatment with PREBOOST®, 82 percent of men were no longer considered to have premature ejaculation. 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 on January 6, 2017.

Market. Premature ejaculation is the most prevalent sexual disorder affecting one in four men and is more common than erectile dysfunction. The estimated prevalence is 50 million men in United States and 60 million men in Europe. There are no approved drugs for premature ejaculation and the OTC agents currently available are not optimal or effective. Total worldwide market for premature ejaculation drugs and consumer health care products is estimated to be greater than $500 million. The Company has entered into a co-promotion and distribution agreement for PREBOOST® with Timm Medical Technologies Inc. The Company also plans to increase sales by having a sampling program targeting urologists, introducing the product through additional internet outlets including Walmart, CVS, Walgreens and other OTC distribution outlets, optimizing its internet ecommerce capabilities and digital marketing via www.preboost.com as well as through out-licensing opportunities for markets outside the United States.

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products and medical devices. These agencies and other federal, state, and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, recordkeeping, tracking, approval, import, export, advertising, and promotion of our products.

FDA Regulation of Female Condoms. Female condoms as a group were classified by the FDA as a Class III medical device in 1989. Class III medical devices are deemed by the FDA to carry potential risks with use which must be tested prior to FDA market approval, referred to as Premarket Approval (PMA), for sale in the U.S. As FC2 is a Class III medical device, prior to selling FC2 in the U.S., the Company was required to submit a PMA application containing technical information on the use of FC2, such as pre-clinical and clinical safety and efficacy studies, which was gathered together in a required format and content. The FC2 PMA was approved for market by the FDA as a Class III medical device in March 2009. It is possible that the FDA may consider reclassifying female

condoms as Class II medical devices, which are not subject to PMA. If the FDA were to reclassify female condoms as Class II medical devices, it may significantly reduce the barriers for other types of female condoms to enter the U.S. market.

Pursuant to section 515(a)(3) of the Safe Medical Amendments Act of 1990 (the SMA Act), the FDA may temporarily suspend approval and initiate withdrawal of the PMA if the FDA finds that FC2 is unsafe or ineffective, or on the basis of new information with respect to the device, which, when evaluated together with information available at the time of approval, indicates a lack of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended, or suggested in the labeling. Failure to comply with the conditions of FDA market approval invalidates the approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the SMA Act. As an FDA market approved medical device, the facilities in which FC2 is produced and tested are subject to periodic FDA inspection to ensure compliance with current Good Manufacturing Processes. The Company's most recent FDA inspection of its U.K. and Malaysian facilities was completed in September 2010. The Chicago office was inspected by the FDA in October 2016 for activities related to being a registered agent.

The FDA's market approval order for FC2 includes conditions that relate to product labeling, including information on the package itself and instructions for use called a "package insert" which accompanies each product. The Company believes it is in compliance with the FDA market approval order.

FDA Regulation of Pharmaceutical Products. The process required by the FDA before pharmaceutical product candidates may be marketed in the United States generally involves the following:

- nonclinical laboratory and animal tests, including some that must be conducted in accordance with Good Laboratory Practices;
- submission of an IND, which must become effective before clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug candidate for its intended use;
- pre-approval inspection of manufacturing facilities and selected clinical investigators for their compliance with Good Manufacturing Practices (cGMP) and Good Clinical Practices (cGCP); and
- FDA approval of an NDA to permit commercial marketing for particular indications for use.

The testing and approval process requires substantial time, effort, and financial resources. Prior to commencing the first clinical trial with a drug candidate, we must submit an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the conduct of the clinical trial by imposing a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development. Further, an independent institutional review board (IRB) for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial commences at that center. Regulatory authorities or an IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Some studies also include a data safety monitoring board (DSMB), which receives special access to unblinded data during the clinical trial and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

In general, for purposes of NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1—Studies are initially conducted to test the drug candidate for safety, dosage tolerance, absorption, metabolism, distribution, and excretion in healthy volunteers or patients.
- Phase 2—Studies are conducted with groups of patients with a specified disease or condition to provide enough data to evaluate the preliminary efficacy, optimal dosages and dosing schedule, and expanded evidence of safety. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3—These clinical trials are undertaken in larger patient populations to further evaluate dosage, to provide statistically significant evidence of clinical efficacy, and to further test for safety in an expanded patient population at multiple clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. These trials may be done globally to support global registrations.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 studies may be made a condition to be satisfied after approval. The results of Phase 4 studies can confirm the effectiveness of a drug candidate and can provide important safety information.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug candidate, as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

505(b)(2) Approval Process. Section 505(b)(2) of the Food, Drug and Cosmetic Act (FDCA), which was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act, provides an expedited regulatory pathway to FDA approval for new or improved formulations or new uses of previously approved drug products. Specifically, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon the FDA's findings of safety and effectiveness for an approved product that acts as the Reference Listed Drug (RLD). The FDA may also require 505(b)(2) applicants to perform additional studies or measurements to support the change from the RLD. The FDA may then approve the new drug candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

We expect our Tamsulosin DRS, Tamsulosin XR capsules, Solifenacin DRG, Tadalafil/Finasteride combination capsules, VERU-722 and VERU-944 drug candidates to qualify for the 505(b)(2) regulatory pathway because they are or will be based on already approved active pharmaceutical ingredients rather than new chemical entities, and formulations that has been through Phase 1 studies. On August 12, 2016, FDA cleared Tamsulosin DRS for the expedited 505(b)(2) regulatory approval pathway and agreed with our plans to conduct a single bioequivalence study to support the filing of an NDA. On December 6, 2016, based on positive regulatory recommendations by the BRUD FDA Advisory Committee, we are considering plans to file an investigational new drug application (IND) and possibly initiate a Phase 2 clinical study. On May 24,2017, the FDA agreed with plans to enter the Phase 2 dose finding clinical trial to evaluate VERU-944 for the treatment of hot flashes in men on androgen deprivation therapy. In November 2017, FDA agreed in PreIND meetings that Solifenacin DRG and Tadalafil/Finasteride combination capsules qualify for 505(b)(2) regulatory pathway.

Orange Book Listing. In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the Orange Book. Any applicant who files a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is not sought until after patent expiration; or (iv) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. This last certification is known as a Paragraph IV certification. If the competitor has provided a Paragraph IV certification to the FDA, the competitor must also send notice of the Paragraph IV certification to the holder of the NDA for the RLD and the patent owner once the application has been accepted for filing by the FDA. The NDA holder or patent owner may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification prevents the FDA from approving the application until the earlier of 30 months from the date of the lawsuit, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the applicant. The applicant may also elect to submit a "Section VIII" statement certifying that its proposed label does not contain, or carves out, any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

NDA Submission and Review by the FDA. The results of product development, nonclinical studies, and clinical trials are submitted to the FDA as part of an NDA. The submission of an NDA requires payment of a substantial user fee to the FDA. The FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality, and purity. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Once the NDA submission has been accepted for filing, which occurs, if at all, within 60 days after submission of the NDA, the FDA's goal for a non-priority review of a 505(b)(2) NDA is ten months to complete the review process for the application and respond to the applicant, which can take the form of either a Complete Response Letter or Approval. The review process is often significantly extended by FDA requests for additional information, studies, or clarification. The FDA may delay or refuse approval of an NDA if applicable regulatory criteria are not satisfied, require additional testing or information, and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product. FDA approval of any NDA submitted by us

will be at a time the FDA chooses. Also, if regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require Phase 4 post-marketing studies to monitor the effect of approved products, and may limit further marketing of the product based on the results of these post-marketing studies.

Post-Approval Requirements. Any products manufactured or distributed by us pursuant to FDA approvals will be subject to continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences. Drug and biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP regulations and other FDA regulatory requirements. If our present or future suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall a product from distribution, or withdraw approval of the NDA.

The FDA closely regulates the marketing and promotion of drugs. A company can make only those claims relating to safety and efficacy, purity, and potency that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use.

The recently enacted Drug Supply Chain Security Act imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Among the requirements of this new legislation, manufacturers will be required to provide certain information regarding the drug products to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Other Healthcare Regulations. Our business activities, including but not limited to, research, sales, promotion, distribution, medical education, and other activities will be subject to regulation by numerous regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Department of Justice, the Department of Health and Human Services and its various divisions, including the Centers for Medicare and Medicaid Services, and state and local governments. Our business activities must comply with numerous healthcare laws, including but not limited to, the federal Anti-Kickback Statute, the False Claims Act, the Veterans Health Care Act, and similar state laws.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any item or service reimbursable under Medicare, Medicaid, or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing, or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances.

The federal False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government.

We and our business activities are subject to the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Additionally, the federal Physician Payments Sunshine Act within the Patient Protection and Affordable Care Act (PPACA), and its implementing regulations, require certain manufacturers of drugs and medical devices for which payment is available under Medicare,

Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates—independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The Veterans Health Care Act of 1992 requires manufacturers of "covered drugs" to offer those drugs for sale to certain federal agencies, including but not limited to, the Department of Veterans Affairs, on the Federal Supply Schedule, which requires compliance with applicable federal procurement laws.

Depending on the circumstances, failure to comply with these laws can result in penalties, including criminal, civil, and/or administrative criminal penalties, damages, fines, disgorgement, exclusion of products from reimbursement under government programs, "qui tam" actions brought by individual whistleblowers in the name of the government, refusal to allow us to enter into supply contracts, including government contracts, reputational harm, diminished profits, and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our business.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals designed to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The Foreign Corrupt Practices Act. The Foreign Corrupt Practices Act (FCPA) prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Foreign and Other Regulation. In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products to the extent we choose to develop or sell any products outside of the United States. The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary greatly from country to country.

FC2 received the CE Mark which allows it to be marketed throughout the European Union. FC2 has also been approved by regulatory authorities in Brazil, India, Canada, and other jurisdictions.

The Company's facility may also be subject to inspection by UNFPA, USAID, International Organization for Standardization (ISO), and country specific ministries of health.

Intellectual Property

We will be able to protect our technology from unauthorized use by third parties only to the extent it is covered by valid and enforceable patents or is effectively maintained as trade secrets. Patents and other proprietary rights are an essential element of our business.

As of December 1, 2017, we owned or held exclusive rights to 9 issued U.S. patents, 6 pending U.S. patent applications and additional patents and patent applications in other jurisdictions outside the United States. These include an international patent application

relating to our Tamsulosin DRS product that is subject to deferred payment obligations and patents and patent applications relating to our VERU-111 and VERU-112 drug candidates that we license from a third party. Additional information regarding our patent portfolio is provided below.

PREBOOST® ***Patent Application*****.** PREBOOST®, medicated individual wipes which is a male genital desensitizing drug product that helps in the prevention of premature ejaculation, is covered by a pending U.S. patent application.

VERU-722 Patent. VERU-722, an oral agent we are developing for the treatment of male infertility, is covered by an issued U.S. patent that expires in May 2021. We also own additional patents outside of the United States and patent applications covering VERU-722 some of which, if granted, could provide meaningful protection until February 2037.

Tamsulosin DRS, Tamsulosin XR capsules, and Solifenacin DRG Patent Application. We own two patent applications with respect to Tamsulosin DRS, Tamsulosin XR capsules, and Solifenacin DRG: (1) an international patent application (would expire on May 2037) and (2) an European original application (would expire on October 2037). Veru acquired those patent rights pursuant to a purchase agreement that provides for significant continuing installment and milestone payment obligations. In addition, Veru granted a security interest in the purchased assets to the seller to secure Veru's present and future payment and performance obligations under the purchase agreement. Accordingly, there will be significant payments that Veru will be required to make in the future to the seller of the Tamsulosin DRS, Tamsulosin XR capsulse, and Solifenacin DRG assets and the failure to make such payments may result in Veru losing its rights to such intellectual property. If Veru fails to retain such rights, we would not be able to commercialize any products relating to Tamsulosin DRS, Tamsulosin XR capsules, and Solifenacin DRG

VERU-944 Patent Application. We have one issued U.S. patent application related to substantially pure cis-clomiphene for the treatment of osteoporosis, bone fractures, loss of bone mineral density and hot flashes, especially in men on prostate cancer hormone therapies. Patent expires in July 2035.

VERU-111/VERU-112 License. We hold an exclusive license to 3 issued U.S. patents, 2 pending U.S. patent applications and 50 patents and patent applications in countries outside the United States relating to our VERU-111 and VERU-112 drug candidates. This license contains provisions requiring upfront, milestone and royalty payments to the licensor (Ohio State University). If we fail to comply with these obligations or other obligations to the licensor, the licensor might have the right to terminate the license, in which event we would not be able to commercialize these drug candidates. Patent expires for VERU-111 in July 2029 and with a maximum 5-year patent extention is expected because of clinical development and FDA review time, in which case the patent could expire June 2034.

FC2 Patents. FC2 patents have been issued by the United States, Europe, Canada, Australia, South Africa, the People's Republic of China, Japan, Mexico, Brazil, India and the African Regional Intellectual Property Organization (ARIPO), which includes Botswana, Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Sudan, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe. Further, the European patent for FC2 has been validated in the following countries: Austria, Belgium, Bulgaria, Switzerland, Republic of Cyprus, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Hungary, Ireland, Italy, Luxembourg, Monaco, Netherlands, Portugal, Romania, Sweden, Slovenia, Slovakia, and Turkey. The patents cover the key aspects of FC2, including its overall design and manufacturing process. The patents have expiration dates in 2023 and 2024.

Trademarks. The Company has a registration for the trademarks "FC2 Female Condom" and "PREBOOST" in the United States and has filed applications in the U.S. for the trademarks "Veru Inc.," "Veru Healthcare," "Veru Biopharma," "Veru Pharmaceuticals" and "Veru Pharma." The Company has filed applications or secured registrations in 40 countries or jurisdictions around the world to protect the various names and symbols used in marketing its Female Condoms.

We cannot be certain that any of our pending patent applications, or those of our licensors, will result in issued patents. In addition, because the patent positions of biopharmaceutical companies are highly uncertain and involve complex legal and factual questions, the patents we own and license, or any further patents we may own or license, may not prevent other companies from developing similar or therapeutically equivalent products. Patents also will not protect our product candidates if competitors devise ways of making or using these product candidates without legally infringing our patents. In recent years, several companies have been extremely aggressive in challenging patents covering pharmaceutical products, and the challenges have often been successful. We cannot be assured that our patents will not be challenged by third parties or that we will be successful in any defense we undertake. Failure to successfully defend a patent challenge could materially and adversely affect our business.

In addition, changes in patent laws, rules or regulations or in their interpretations in the United States and other countries by the courts may materially diminish the value of our intellectual property or narrow the scope of our patent protection, which could have a material adverse effect on our business and financial condition.

We also rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive position. We seek to protect our proprietary information by requiring our employees, consultants, contractors, outside scientific collaborators and other advisors to execute non-disclosure and confidentiality agreements and our employees to execute assignment of invention agreements to us on commencement of their employment. Agreements with our employees also prevent them from bringing any proprietary rights of third parties to us. We also require confidentiality or material transfer agreements from third parties that receive our confidential data or materials.

Significant Customers

Because FC2 provides dual protection against both STIs, including HIV/AIDS, and unintended pregnancy, it is an integral part of both HIV/AIDS prevention and family planning programs throughout the world. These programs are typically supplied by global public health sector buyers who purchase products for distribution, at low cost or no cost, to those who need but cannot afford to buy such products themselves. Within the global public health sector are large global agencies, such as UNFPA, USAID, DFID (the U.K.'s Department for International Development), and PSI (Population Services International), other social marketing groups, various government health agencies, and NGOs. The Company's most significant customers are either global public health sector agencies, country specific ministries of health, or those who facilitate their purchases and/or distribution.

The Company's largest customers in fiscal 2017 were USAID and UNFPA. 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. The Brazil Ministry of Health (through 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. The Company considers its most significant customers to be UNFPA, USAID, Sekunjalo, and the Brazil Ministry of Health (either through UNFPA or Semina).

Employees

As of December 23, 2017, the Company had 175 full-time employees, including 27 located in the U.S., 11 in the U.K., 134 in Malaysia, and 3 in other countries to implement training and programs. None of the Company's employees are represented by a labor union. The Company believes that its employee relations are good. In Malaysia, a significant proportion of direct labor is supplied by a contracted work force.

Environmental Regulation

The Company believes there are no material issues or material costs associated with the Company's compliance with environmental laws related to the manufacture and distribution of FC2. The Company has not incurred environmental expenses in fiscal 2017, 2016, or 2015, nor does it anticipate environmental expenses in the foreseeable future.

Raw Materials

The principal raw material used to produce FC2 is a nitrile polymer. While general nitrile formulations are available from a number of suppliers, the Company has chosen to work closely with the technical market leader in synthetic polymers to develop a grade ideally suited to the bio-compatibility and functional needs of a female condom. As a result, the Company relies on supply for its principal raw material for FC2 from one supplier that could produce the raw material from multiple supply points within its organization.

Manufacturing

The Company leases production space in Selangor D.E., Malaysia for the production of FC2, which currently has manufacturing capacity of approximately 100 million units annually. In fiscal 2014 the Company added additional space, resulting in a total of 45,800 sq. ft. in the Company's Malaysia facility, comprised of production and warehouse space and which provides sufficient space to add manufacturing capacity of up to an additional 100 million units annually. The Company will consider manufacturing in other locations as the demand for FC2 develops.

The Company expects to rely on third-party contract manufacturers and other third parties to produce, package and store sufficient quantities of any future drug candidates. The Company has entered into an agreement with a third-party contract manufacturer to produce its PREBOOST® medicated individual wipes for managing premature ejaculation.

Competition

FC2 participates in the same market as male condoms; however, it is not seen as directly competing with male condoms. Rather, studies show that providing FC2 is additive in terms of prevention and choice. Male condoms cost less and have brand names that are more widely recognized than FC2. In addition, male condoms are generally manufactured and marketed by companies with significantly greater financial resources than the Company.

Other parties have developed and marketed female condoms. None of these female condoms marketed or under development by other parties have secured FDA market approval. FDA market approval is required to sell female condoms in the U.S. USAID, a U.S. government funded agency, is required to procure from the FDA product approval for market; however there can be exceptions. Outside of the U.S., the Company has experienced increasing competition and pricing pressures for FC2. In addition to FC2, three female condoms have successfully completed the WHO prequalification process and been cleared by UNFPA for purchase by U.N. agencies: the Cupid female condom (which was prequalified by WHO in July 2012 and cleared by UNFPA thereafter), the Velvet female condom marketed by Hindustan Latex Limited (which was prequalified by WHO and cleared by UNFPA in March 2016) and the female condom marketed by PATH (which was prequalified by WHO and cleared by UNFPA in March 2016). The female condom marketed by Hindustan Latex Limited, which is the Company's former exclusive distributor in India, is substantially similar in design to FC2, except it is made of latex. FC2 has also been competing with other female condoms in markets that do not require either FDA market approval or WHO prequalification. Reflecting increased competition, Cupid received part of the last two South African tenders. Increasing competition in FC2's markets has, and will likely continue to, put pressure on pricing for FC2 and may also adversely affect sales of FC2. Some customers, particularly in the global public health sector, prioritize price over other features where FC2 may have an advantage. It is also possible that other female condoms may receive FDA market approval or complete the WHO prequalification process, which would increase competition from other female condoms in FC2's markets.

The pharmaceutical industry is highly competitive, and is characterized by extensive research efforts and rapid technological progress. The success of our pharmaceutical products will depend on our ability to acquire, develop and commercialize products and our ability to establish and maintain markets for any products for which we receive marketing approval. Potential competitors in North America, Europe and elsewhere include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology firms, universities and other research institutions and government agencies. Many of the competitors with respect to our pharmaceutical products under development have substantially greater research and development and regulatory capabilities and experience, and substantially greater management, manufacturing, distribution, marketing and financial resources, than we will.

All drugs currently used to treat BPH symptoms are tablets or capsules. These drugs include those that decrease size of the prostate, like 5 alpha reductase inhibitors which include PROSCAR® (finasteride) from Merck & Co., Inc. and AVODART® (dutasteride) from GlaxoSmithKline. The other major class of drugs treat BPH by relaxing the smooth muscles of the prostate and bladder neck and include alpha blockers like FLOMAX® (tamsulosin HCI) from Boehringer Ingelheim Pharmaceuticals, HYTRIN® (terazocin), UROXATRAL® (alfuzosin), CARDURA® (doxazosin), and RAPAFLO® (silodosin) from Allergan as well as Phosphodiesterase 5 (PDE5) inhibitors like CIALIS ® (tadalafil) from Eli Lilly. One class of drugs combines a drug that shrinks and another that relaxes the prostate called JALYN® (dutasteride/tamsulosin combination) from GlaxoSmithKline.

There are drugs that have been approved for the treatment of male infertility for the indication of hypogonadotropic hypogonadism. These drugs are only available by injection which include: GONAL-F® (Follitropin Alfa) which is recombinant DNA human follicle stimulating hormone by EMD Serono, Inc., NOVAREL® (chorionic gonadotropin for injection USP) which is human chorionic gonadotropin by Ferring, Inc. and PREGNYL® (chorionic gonadotropin for injection USP) which is human chorionic gonadotropin by Merck & Co., Inc. There are no FDA-approved oral therapies for male infertility. CLOMID® (clomiphene citrate) 50mg tablets are being used off-label using various doses and dosing schedules for idiopathic infertile men. CLOMID® and generics are FDA-approved as 50 mg dose for the treatment of ovulatory dysfunction in women desiring pregnancy. CLOMID® and generics of CLOMID® contain a mixture of two geometric isomers cis-clomiphene (zuclomiphene) and trans-clomiphene (enclomiphene), and contain between 30-50% of the cis-clomiphene isomer.

Although there are no FDA-approved drugs for the treatment of hot flashes in men who have advanced prostate cancer as a side effect of prostate cancer hormone therapies, there are several drugs being used off-label including estrogens and selective serotonin reuptake inhibitor antidepressants including EFFEXOR® (venlafaxine) and anticonvulsants like NEURONTIN® (gabapentin) which could be competitive with our VERU-944 drug candidate for the treatment of hot flashes in men who have advanced prostate cancer as a side effect of prostate cancer hormone therapies.

VERU-111 is a first-in-class oral therapy that targets both alpha and beta tubulin and will be initially developed for prostate, breast and ovarian cancers. All currently available tubulin targeting agents are chemotherapies that are given IV include: Vinca Alkaloids such as VELBAN® (vinblastine), ONCOVIN® (vincristine) and NAVELBINE® (vinorelbine). These chemotherapies are primarily used for hematologic malignancies (leukemia, lymphoma, myeloma, sarcoma), and some neuroblastoma, thyroid cancer and nonsmall cell cancer of the lung. Taxanes such as TAXOL® (paclitaxel), TAXOTERE® (docetaxel) and JEVTANA® (cabazitaxel) are primarily used for solid tumors such as breast, ovarian, endometrial, cervical, lung, head and neck, esophageal, bladder, gastric and prostate. TAXOTERE® (docetaxel) and JEVTANA® (cabazitaxel) are indicated for advanced metastatic prostate cancer, are given IV and bind to the taxane site of tubulin.

The main therapeutic products that are competitive with PREBOOST™ include lidocaine and other anesthetic creams, gels and sprays. Off-label use of selective serotonin reuptake inhibitor antidepressants like PAXIL® (paroxetine) have also been used off-label to prevent premature ejaculation.

Research and Development

Conducting research and development is central to our business model. Since the completion of the APP Acquisition we have invested and expect to continue to invest significant time and capital in our research and development operations. Our research and development expenses were $3.5 million for fiscal 2017 and $0.1 million for fiscal 2016. In fiscal 2018, we expect to increase our expenses relating to research and development due to advancement of multiple drug candidates.

Backlog

Unfilled product orders totaled $2,599,059 at December 6, 2017 and $2,829,535 at December 9, 2016. Unfilled orders materially fluctuate from quarter-to-quarter, and the amount at December 6, 2017 includes orders with requested delivery dates later in fiscal 2018. The Company expects current unfilled orders to be filled during fiscal 2018.

Available Information

The Company maintains a corporate website for investors at www.veruhealthcare.com/investor and it makes available, free of charge, through this website its annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports that the Company files with or furnishes to the Securities and Exchange Commission (SEC), as soon as reasonably practicable after it electronically files such material with, or furnishes it to, the SEC. Information on the Company's website is not part of this report.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with all of the other information included in this Annual Report and our other SEC filings, in considering our business and prospects. The risks described below are not the only risks we face. Additional risks that we do not yet know of or that we currently think are immaterial may also impair our business operations. If any of the events or circumstances described in the following risks occurs, our business, financial condition, results of operations or prospects could be materially adversely affected. In such cases, the trading price of our common stock could decline.

Risks Related to the Regulation and Commercialization of Our Products and Drug Candidates

We have no experience in obtaining regulatory approval for a drug.

Although our President and Chief Executive Officer has experience in obtaining regulatory approval for a drug under development, the Company has never obtained regulatory approval for, or commercialized, a drug. It is possible that the FDA may refuse to accept any or all of our planned NDAs for substantive review or may conclude, after review of our data, that our applications are insufficient to obtain regulatory approval of any of our drug candidates. The FDA may also require that we conduct additional clinical or manufacturing validation studies, which may be costly and time-consuming, and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA required studies, approval of any NDA that we submit may be significantly delayed, possibly for years, or may require us to expend more resources than we have available or can secure. Any delay or inability in obtaining regulatory approvals would delay or prevent us from commercializing our drug candidates, generating revenue from these proposed products and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve any NDA we submit. If any of these outcomes occur, we may be forced to abandon our planned NDAs for one or more of our drug candidates, which would materially adversely affect our business.

Clinical trials involve a lengthy and expensive process with an uncertain outcome and results of earlier studies and trials may not be predictive of future trial results. Clinical trials are expensive, can take many years to complete and have highly uncertain outcomes. Failure can occur at any time during the clinical trial process as a result of inadequate performance of a drug, inadequate adherence by patients or investigators to clinical trial protocols or other factors. New drugs in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through earlier clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials as a result of a lack of efficacy or adverse safety profiles, despite promising results in earlier trials. Our future clinical trials may not be successful or may be more expensive or time-consuming than we currently expect. If clinical trials for any of our drug candidates fail to demonstrate safety or efficacy to the satisfaction of the FDA, the FDA will not approve that drug and we would not be able to commercialize it, which will have a material adverse effect on our business, financial condition, results of operations and prospects.

We may experience delays or other issues in the new bioequivalence clinical study for our Tamsulosin DRS drug candidate.

In November 2017, we received the results of Stage 2 of the bioequivalence clinical study for our Tamsulosin DRS drug candidate. 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. Tamsulosin DRS formulation did not meet the remaining bioequivalence criterion for peak value (Cmax). As a result, we intend to initiate a new bioequivalence study after adjusting the formulation to address Cmax and expect this study to be completed in the first quarter of 2018. There is no guarantee that we will be able to successfully adjust the formulation of Tamsulosin DRS to satisfy the bioequivalence criterion for Cmax. If Tamsulosin DRS does not satisfy the bioequivalence criterion for Cmax in this new bioequivalence clinical study, we would need to make further adjustments to the formulation and then conduct an additional bioequivalence clinical study, which would increase our costs and could cause delays in the NDA submission for Tamsulosin DRS or otherwise jeopardize our ability to commercialize Tamsulosin DRS.

We could experience delays in our planned clinical trials.

We may experience delays in clinical trials that will be required to be conducted for our drug candidates. Our planned clinical trials might not begin on time; may be interrupted, delayed, suspended, or terminated once commenced; might need to be redesigned; might not enroll a sufficient number of patients; or might not be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including the following:

- delays in obtaining regulatory approval to commence a trial;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- imposition of a clinical hold because of safety or efficacy concerns by the FDA, a DSMB, a clinical trial site's IRB or us;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites;
- delays in obtaining required IRB approval at each site;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in recruiting suitable patients to participate in a trial;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new sites;
- delays in obtaining sufficient supplies of clinical trial materials, including suitable active pharmaceutical ingredients; or
- delays resulting from negative or equivocal findings of DSMB for a trial.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Any of these delays in completing our clinical trials could increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue as to the affected drug candidate.

Our clinical trials may be suspended or discontinued.

Before we can obtain regulatory approval for the commercial sale of our VERU-722, VERU-944, VERU-111 and VERU-112 drug candidates, we may be required to complete preclinical development with respect to such drug candidates and/or extensive clinical trials in humans to demonstrate the safety and efficacy of the drug candidates. To date, regulatory approval has not been obtained for any of our drug candidates.

Unfavorable results from preclinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated. In addition, we may report top-line data from time to time, which is based on a preliminary analysis of key efficacy and safety data. Such top-line data may be subject to change following a more comprehensive review of the data related to the applicable clinical trial. If we delay or abandon our development efforts related to our VERU-722, VERU-944, VERU-111 or VERU-112 drug candidates, or any other potential future drug candidate fails to demonstrate sufficient safety and efficacy in any clinical trial, we would experience potentially significant delays in, or be required to abandon, development of that drug candidate. If we delay or abandon our development efforts related to any of the VERU-722, VERU-944, VERU-111 or VERU-112 drug candidates, or any other potential future drug candidate, our business, financial condition, results of operations and prospects may be materially adversely affected.

Our clinical trials may be suspended or terminated at any time for a number of reasons. A clinical trial may be suspended or terminated by us, our collaborators, the FDA or other regulatory authorities because of a failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, presentation of unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using the investigational drug, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial or negative or equivocal findings of the DSMB or the IRB for a clinical trial. An IRB may also suspend or terminate our clinical trials for failure to protect patient safety or patient rights. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe the clinical trials are not being conducted in accordance with applicable regulatory requirements or present an unacceptable safety risk to participants. If we elect or are forced to suspend or terminate any clinical trial of any proposed product that we develop, the commercial prospects of such proposed product will be harmed and our ability to generate product revenue from any of these proposed products will be delayed or eliminated. Any of these occurrences may materially harm our business, financial condition, results of operations and prospects.

We may be subject to risks relating to collaboration with third parties.

As part of our business strategy, we may enter into collaboration arrangements with strategic partners to develop and commercialize our drug candidates. For our collaboration efforts to be successful, we must identify partners whose competencies complement our competencies. We may be unsuccessful in entering into collaboration agreements with acceptable partners or negotiating favorable terms in these agreements. Also, we may be unsuccessful in integrating the resources and capabilities of these collaborators with our own. In addition, we may face a disadvantage in seeking to enter into or negotiating collaborations with potential partners because other potential collaborators may have greater management and financial resources than we do. Our collaborators may prove difficult to work with or less skilled than originally expected. If we are unsuccessful in our collaborative efforts, our ability to develop and market drug candidates could be severely limited.

We intend to rely on CROs to conduct our research and development activities.

We will not have the resources to independently conduct research and development activities. Therefore, we intend to rely on CROs to conduct research and development activities for our drug candidates and for the execution of our clinical studies. Although we will control only certain aspects of our CROs' activities, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We cannot be sure that the CROs will conduct the research properly or in a timely manner, or that the results will be reproducible. We and our CROs are required to comply with the FDA's cGCPs, which are regulations and guidelines enforced by the FDA for all of our drug products in clinical development. The FDA enforces these cGCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable or invalid and the FDA may require us to perform additional clinical trials before approving our drug candidates. In addition, to evaluate the safety and effectiveness compared to placebo of our drug candidates to a statistically significant degree, our clinical trials will require an adequately large number of test subjects. Any clinical trial that a CRO conducts abroad on our behalf is subject to similar regulation. Accordingly, if our CROs fail to comply with these regulations or recruit a sufficient number of patients, we may be required to repeat clinical trials, which would delay the regulatory approval process.

In addition, we will not employ the personnel of our CROs, and, except for remedies available to us under our agreements with such organizations, we cannot control whether or not they will devote sufficient time and resources to our research and development and our clinical studies. Our CROs may also have relationships with other commercial entities, including one or more of our competitors, for which they may also be conducting clinical studies or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised because of the failure to adhere to our clinical protocols or regulatory requirements, or for other reasons, our clinical trials may be extended,

delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates that we seeks to develop. As a result, our financial results and the commercial prospects for our drug candidates that we seek to develop would be harmed, our costs could increase and our ability to generate revenue from such drug candidates could be delayed or ended.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or entering into new relationships with CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially affect our ability to meet our desired clinical development timelines and can increase our costs significantly. We may encounter challenges or delays in entering into or maintaining these relationships, and any such delays or challenges may have a material adverse impact on our business, financial condition, results of operations and prospects.

We expect to rely on third party manufacturers for our drug candidates.

For the foreseeable future, we expect to rely on third-party manufacturers and other third parties to produce, package and store sufficient quantities of any future drug candidates for use in our clinical trials. These drug candidates are complicated and expensive to manufacture. If our future third-party manufacturers fail to deliver our drug candidates for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, we may be required to delay or suspend clinical trials or otherwise discontinue development and production of our drug candidates. While we may be able to identify replacement third-party manufacturers or develop our own manufacturing capabilities for these drug candidates, this process would likely cause a delay in the availability of our drug candidates and an increase in costs. In addition, third-party manufacturers may have a limited number of facilities in which our drug candidates can be produced, and any interruption of the operation of those facilities due to events such as equipment malfunction or failure or damage to the facility by natural disasters could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available drug candidates.

In addition, regulatory requirements could pose barriers to the manufacture of our drug candidates. Third-party manufacturers are required to comply with the FDA's cGMPs. As a result, the facilities used by any of future manufacturers of our drug candidates must be approved by the FDA. Holders of NDAs, or other forms of FDA approvals or clearances, or those distributing a regulated product under their own name, are responsible for manufacturing even though that manufacturing is conducted by a third-party contract manufacturing organization (CMO). Our third-party manufacturers will be required to produce our drug candidates under FDA cGMPs in order to meet acceptable standards for our clinical trials. Our third-party manufacturers may not perform their obligations under their agreements with us or may discontinue their business before the time required by us to gain approval for or commercialize our drug candidates. In addition, our manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. Failure by any of our manufacturers to comply with applicable cGMPs could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply, recalls, withdrawals, issuance of safety alerts and criminal prosecutions, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Finally, we also could experience manufacturing delays if our CMOs give greater priority to the supply of other products over our products or otherwise do not satisfactorily perform according to the terms of their agreements with us.

If any supplier for our drug candidates experiences any significant difficulties in its manufacturing processes, does not comply with the terms of the agreement between us or does not devote sufficient time, energy and care to providing our manufacturing needs, we could experience significant interruptions in the supply of our drug candidates, which could impair our ability to supply our drug candidates at the levels required for our clinical trials and commercialization and prevent or delay their successful development and commercialization.

Changes in law, including as a result of the recent presidential and congressional elections, could have a negative impact on the approval of our drug candidates.

The FDA has established regulations, guidelines and policies to govern the drug development and approval process, as have foreign regulatory authorities. Any change in regulatory requirements resulting from the adoption of new legislation, regulations or policies may require us to amend existing clinical trial protocols or add new clinical trials to comply with these changes. Such amendments to existing protocols or clinical trial applications or the need for new ones, may significantly and adversely affect the cost, timing and completion of the clinical trials for our drug candidates. In addition, the FDA's policies may change and additional government regulations may be issued that could prevent, limit or delay regulatory approval of our drug candidates, or impose more stringent product labeling and post-marketing testing and other requirements. The recent presidential and congressional elections in the U.S. could result in significant changes in, and uncertainty with respect to, legislation, regulation and government policy that could significantly impact our business and the health care industry. While it is not possible to predict whether and when any such changes will occur, specific proposals discussed during and after the election that could have a material impact on us include, but are not limited to, the repeal of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation

Act of 2010 and enactment of the 21st Century Cures Act. If we are slow or unable to adapt to any such changes, our business, prospects and ability to achieve or sustain profitability would be adversely affected.

We may fail to commercialize our drug candidates.

We cannot be sure that, if our clinical trials for any of our VERU-722, VERU-944, VERU-111 or VERU-112 drug candidates are successfully completed, we will be able to submit an NDA to the FDA or that any NDA we submit will be approved by the FDA in a timely manner, if at all. We also cannot be sure that, if our bioequivalence study for Tamsulosin DRS is successfully completed, any NDA we submit will be approved by the FDA in a timely manner, if at all. After completing clinical trials for a drug candidate in humans, a drug dossier is prepared and submitted to the FDA as an NDA, and includes all preclinical studies and clinical trial data relevant to the safety and effectiveness of the product at the suggested dose and duration of use for the proposed indication as well as manufacturing information, in order to allow the FDA to review such drug dossier and to consider a drug candidate for approval for commercialization in the United States. If we are unable to submit an NDA with respect to any of the VERU-722, VERU- 944, VERU-111, VERU-112 or Tamsulosin DRS, or if any NDA we submit is not approved by the FDA, we will be unable to commercialize that product. The FDA can and does reject NDAs and require additional clinical trials, even when drug candidates achieve favorable results in Phase 3 clinical trials. If we fail to commercialize any of the VERU-722, VERU-944, VERU-111 or VERU-112 drug candidates, or Tamsulosin DRS, our business, financial condition, results of operations and prospects may be materially adversely affected and our reputation in the industry and in the investment community would likely be damaged.

We are subject to extensive and costly governmental regulation.

Our products, including FC2 and our drug candidates, are subject to extensive and rigorous domestic government regulation, including regulation by the FDA, the Centers for Medicare & Medicaid Services, other divisions of the U.S. Department of Health and Human Services, including its Office of Inspector General, the U.S. Department of Justice, the Departments of Defense and Veterans Affairs, to the extent our products are paid for directly or indirectly by those departments, state and local governments and their respective foreign equivalents. The FDA regulates the research, development, preclinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import and export of pharmaceutical products and medical devices under various regulatory provisions. Any of our products that are tested or marketed abroad are also be subject to extensive regulation by foreign governments, whether or not we have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding U.S. regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing and selling products. Our failure to comply with these regulations could result in, by way of example, significant fines, criminal and civil liability, product seizures, recalls or withdrawals, withdrawals of approvals, and exclusion and debarment from government programs. Any of these actions, including the inability of our products to obtain and maintain regulatory approval, would have a materially adverse effect on our business, financial condition, results of operations and prospects.

We are subject to additional health care regulation and enforcement by the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order, or recommendation of, any good or service for which payment may be made under government health care programs such as the Medicare and Medicaid programs;
- the federal False Claims Act that prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government health care programs that are false or fraudulent;
- federal criminal laws that prohibit executing a scheme to defraud any health care benefit program or making false statements relating to health care matters; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians.

The scope and enforcement of these laws is uncertain and subject to change in the current environment of health care reform, especially in light of the lack of applicable precedent and regulations. We cannot predict the impact on our business of any changes in these laws. Federal or state regulatory authorities may challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming.

We could experience misconduct by our employees.

We will be exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with federal and state health care fraud and abuse laws and regulations, to comply with the FCPA, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and prevent employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Coverage and reimbursement may not be available for our products.

Market acceptance and sales for VERU-722, VERU-944, VERU-111, VERU-112 and Tamsulosin DRS, if approved, will depend on coverage and reimbursement policies and may be affected by health care reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which products they will pay for and establish reimbursement levels. We cannot be sure that coverage and reimbursement will be available for our drug candidates, if approved. We also cannot be sure that the amount of reimbursement available, if any, will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our drug candidates.

We may not be able to gain and retain market acceptance for our drug candidates.

Physicians may not prescribe our drug candidates, if approved by the appropriate regulatory authorities for marketing and sale, which would prevent any such drug candidate from generating revenue. Market acceptance of our drug candidates, by physicians, patients and payors, will depend on a number of factors, many of which are beyond our control, including the following:

- the clinical indications for which our drug candidates are approved, if at all;
- acceptance by physicians and payors of each product as safe and effective treatment;
- the cost of treatment in relation to alternative treatments;
- the relative convenience and ease of administration of our products in the treatment of the symptoms for which they are intended;
- the availability and efficacy of competitive drugs;
- the effectiveness of our sales force and marketing efforts;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;
- the availability of coverage and adequate reimbursement by third parties, such as insurance companies and other health care payors, or by government health care programs, including Medicare and Medicaid;
- limitations or warnings contained in a product's FDA-approved labeling; and
- prevalence and severity of adverse side effects.

Even if the medical community accepts that our drug candidates are safe and efficacious for their approved indications, physicians may not immediately be receptive to the use or may be slow to adopt such products as an accepted treatment for the symptoms for which they are intended. We cannot be sure that any labeling approved by the FDA will permit us to promote our products as being superior to competing products. If our drug candidates, if approved, do not achieve an adequate level of acceptance by physicians and payors, we may not generate sufficient or any revenue from these products. In addition, our efforts to educate the medical community and third-party payors on the benefits of our products may require significant resources and may never be successful.

In addition, even if our drug candidates achieve market acceptance, we may not be able to maintain that market acceptance over time if:

- new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete;
- unforeseen complications arise with respect to use of our products; or
- sufficient third-party insurance coverage or reimbursement does not remain available.

Our drug products may be subject to governmental pricing controls.

In many foreign markets, including the countries in the European Union, pricing of pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing controls. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our profitability.

Third parties may obtain FDA regulatory exclusivity to our detriment.

We plan to seek to obtain market exclusivity for our drug candidates and any other drug candidates we develop in the future. To the extent that patent protection is not available or has expired, FDA marketing exclusivity may be the only available form of exclusivity available for these proposed products. Marketing exclusivity can delay the submission or the approval of certain marketing applications. Potentially competitive products may also seek marketing exclusivity and may be in various stages of development, including some more advanced than our products. We cannot predict with certainty the timing of FDA approval or whether FDA approval will be granted, nor can we predict with certainty the timing of FDA approval for competing products or whether such approval will be granted. It is possible that competing products may obtain FDA approval with marketing exclusivity before we do, which could delay our ability to submit a marketing application or obtain necessary regulatory approvals, result in lost market opportunities with respect to our drug candidates and materially adversely affect our business, financial condition and results of operations.

Risks Related to Our Financial Position and Need for Capital

We incurred a net loss during fiscal 2017 and expect to continue to incur losses for the foreseeable future.

We incurred a net loss attributable to common shareholders of $8.6 million during the year ended September 30, 2017. Pharmaceutical product development is a speculative undertaking, involves a substantial degree of risk and is a capital-intensive business. We expect to incur significant expenses until we are able to obtain regulatory approval and subsequently sell one or more of our drug candidates under development in significant quantities, which may not happen. We expect to devote most of our financial resources to research and development, including our non-clinical development activities and clinical trials. Our drug candidates will require the completion of regulatory review, significant marketing efforts and substantial investment before they can provide us with any revenue. We are uncertain when or if we will be able to achieve or sustain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair our ability to sustain operations and adversely affect the price of our common stock and our ability to raise capital.

Additional financing will be needed to support our development activities.

We expect to incur significant expenditures over the next several years to support our preclinical and clinical development activities, particularly with respect to clinical trials for our VERU-722, VERU-944, VERU-111 and VERU-112 drug candidates and the bioequivalence study for Tamsulosin DRS, Tamsulosin XR capsules, Solifenacin DRG, and Tadalafil/Finasteride combination capsules and to complete the commercialization of our drug candidates. This will require us to obtain additional financing for our business. We may also need to obtain additional financing to complete the development of any additional drug candidates we might acquire or to pay other operating expenses.

Additional financing may not be available on terms acceptable to us. If we are unable to obtain needed financing on acceptable terms, we may not be able to implement our business plan, which could have a material adverse effect on our business, financial condition, results of operations and prospects. If we raise additional funds through the sale of equity, convertible debt or other equity-linked securities, our shareholders' ownership will be diluted. We may issue securities that have rights, preferences and privileges senior to our common stock.

Our future capital requirements will depend upon a number of factors, including:

- the size, complexity, results and timing of our development programs and clinical trials;
- our ability to successfully commercialize our drug candidates, if approved;
- the cost to obtain sufficient supply of the compounds necessary for our drug candidates at a reasonable cost;
- the time and cost involved in obtaining regulatory approvals;
- the terms and timing of any potential future collaborations, licensing or other arrangements we may establish;
- cash requirements of any future acquisitions or the development of other drug candidates;
- our receipt of funds from other potential sources, including cash flow from sales of FC2 and payments on outstanding receivables;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;
- the costs involved in manufacturing and commercializing our drug candidates;

- amount of sales or other revenues from drug candidates that we may commercialize, if any, including the selling prices for such drug candidates and the availability of adequate third-party coverage and reimbursement; and
- competing technological and market developments.

These factors could result in variations from currently projected operating and liquidity requirements.

If we fail to obtain additional capital, we may need to reduce the scope of our development programs or we could be forced to share our rights to technologies with third parties on terms that may not be favorable to us.

We need large amounts of capital to support our development and commercialization efforts for our drug candidates. If we are unable to secure sufficient capital to fund our operations, we will not be able to continue these efforts and we might have to enter into strategic collaborations that could require us to share commercial rights to one or more of our drug candidates with third parties in ways that we currently do not intend or on terms that may not be favorable to us. We anticipate requiring additional capital to fund our development activities under our current business plan in fiscal 2018. We may also need to raise additional funds if we choose to expand more rapidly than we presently anticipate or we encounter any unforeseen events that affect our current business plan. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms and not enter into strategic collaborations, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

Risks Related to Our Business

Our FC2 business may be affected by contracting risks with government and other international health agencies.

Our customers for FC2 have primarily been large international agencies and government health agencies which purchase and distribute FC2 for use in family planning and HIV/AIDS prevention programs. Sales to such agencies may be subject to government contracting risks, including the appropriations process and funding priorities, potential bureaucratic delays in awarding contracts under governmental tenders, process errors, politics or other pressures, and the risk that contracts may be subject to cancellation, delay, or restructuring. A governmental 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. As a result, government agencies may order and purchase fewer units than the full maximum tender amount and there are no guarantees as to the timing or amount of actual orders or shipments under government tenders. 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. These contracting risks may cause significant quarter-to-quarter variations in our operating results and could adversely affect our net revenues and profitability. Budget issues, spending cuts, and global health spending priorities affecting government health agencies may also adversely affect demand for FC2 and our net revenues.

We will experience intense competition.

We are engaged in the marketing and development of products in industries, including the pharmaceutical industry, that are highly competitive. The pharmaceutical industry is also characterized by extensive research and rapid technological progress. Potential competitors with respect to our drug candidates in North America, Europe and elsewhere include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology firms, universities and other research institutions and government agencies. Many of our competitors have substantially greater research and development and regulatory capabilities and experience, and substantially greater management, manufacturing, distribution, marketing and financial resources, than we have. We may be unable to compete successfully against current and future competitors, and competitive pressures could have a negative effect on our net revenues and profit margins.

Other parties have developed and marketed female condoms, although only three such products have WHO pre-clearance and none of these female condoms have been approved for market by the FDA. FDA market approval is required to sell female condoms in the U.S., and WHO pre-clearance is required to sell female condoms to U.N. agencies. FC2 has also been competing with other female condoms in markets that do not require either FDA market approval or WHO prequalification. We have experienced increasing competition in the global public health sector, and competitors received part of the last two South African tenders. Increasing competition in FC2's markets may put pressure on pricing for FC2 or adversely affect sales of FC2, and some customers, particularly in the global public health sector, may prioritize price over other features where FC2 may have an advantage. It is also possible that other companies will develop a female condom, and such companies could have greater financial resources and customer contacts than us. In addition, other contraceptive methods may compete with FC2 for funding and attention in the global public health sector.

An inability to identify or complete future acquisitions could adversely affect our future growth.

We intend to pursue acquisitions of new products, technologies, and/or businesses that enable us to leverage our competitive strengths. While we continue to evaluate potential acquisitions, we may not be able to identify and successfully negotiate suitable acquisitions, obtain financing for future acquisitions on satisfactory terms, obtain regulatory approval for acquisitions where required, or otherwise complete acquisitions in the future. An inability to identify or complete future acquisitions could limit our future growth.

We may experience difficulties in integrating strategic acquisitions.

The integration of acquired companies and their operations into our operations involves a number of risks, including:

- the acquired business may experience losses that could adversely affect our profitability;
- unanticipated costs relating to the integration of acquired businesses may increase our expenses;
- possible failure to accomplish the strategic objectives for an acquisition;
- the loss of key personnel of the acquired business;
- difficulties in achieving planned cost-savings and synergies may increase our expenses or decrease our net revenues;
- diversion of management's attention could impair their ability to effectively manage our business operations;
- the acquired business may require significant expenditures for product development or regulatory approvals;
- the acquired business may lack adequate internal controls or have other issues with its financial systems;
- there may be regulatory compliance or other issues relating to the business practices of an acquired business;
- we may record goodwill and nonamortizable intangible assets that are subject to impairment testing on a regular basis and potential impairment charges and we may also incur amortization expenses related to intangible assets; and
- unanticipated management or operational problems or liabilities may adversely affect our profitability and financial condition.

Additionally, we may borrow funds or issue equity to finance strategic acquisitions. Debt leverage resulting from future acquisitions could adversely affect our operating margins and limit our ability to capitalize on future business opportunities. Such borrowings may also be subject to fluctuations in interest rates. Equity issuances may dilute our existing shareholders and adversely affect the market price of our shares.

We depend on four major customers for a significant portion of our net revenues.

The Company's four largest customers currently are UNFPA, USAID, Sekunjalo and Semina. UNFPA accounted for 27 percent of units sales in fiscal 2017, 25 percent of unit sales in fiscal 2016 and 18 percent of unit sales in fiscal 2015. USAID accounted for 43 percent of unit sales in fiscal 2017, 24 percent of unit sales in fiscal 2016 and 16 percent of unit sales in fiscal 2015. Sekunjalo accounted for less than 10 percent of unit sales in fiscal 2017, 2016 and 2015. Semina accounted for 27 percent of unit sales in fiscal 2016 and 47 percent of unit sales in fiscal 2015. An adverse change in our relationship with our largest customers could have a material adverse effect on our net revenues and profitability. In addition, we may have a concentration of accounts receivable with one or more of our largest customers, and a delay in payment by a large customer could have a material adverse effect on our cash flows and liquidity.

Since we sell FC2 in foreign markets, we are subject to international business risks that could adversely affect our operating results.

Our international operations subject us to risks, including:

- economic and political instability;
- changes in international regulatory requirements, import duties, or export restrictions, including limitations on the repatriation of earnings;
- difficulties in staffing and managing foreign operations;
- complications in complying with trade and foreign tax laws;
- price controls and other restrictions on foreign currency; and
- difficulties in our ability to enforce legal rights and remedies.

Any of these risks might disrupt the supply of our products, increase our expenses or decrease our net revenues. The cost of compliance with trade and foreign tax laws increases our expenses, and actual or alleged violations of such laws could result in enforcement actions or financial penalties that could result in substantial costs.

Increases in the cost of raw materials, labor, and other costs used to manufacture FC2 could increase our cost of sales and reduce our gross margins.

We may experience increased costs of raw materials, including the nitrile polymer used in FC2, and increased labor costs. We may not be able to pass along such cost increases to our customers. As a result, an increase in the cost of raw materials, labor or other costs associated with manufacturing FC2 could increase our cost of sales and reduce our gross margins.

Currency exchange rate fluctuations could increase our expenses.

Because we manufacture FC2 in a leased facility located in Malaysia, a portion of our operating costs are denominated in a foreign currency. While a material portion of our future sales of FC2 are likely to be in foreign markets, all sales of FC2 are denominated in U.S. dollars. Manufacturing costs are subject to normal currency risks associated with fluctuations in the exchange rate of the Malaysian ringgit (MYR) relative to the U.S. dollar. Historically, we have not hedged our foreign currency risk.

We rely on a single facility to manufacture FC2, which subjects us to the risk of supply disruptions.

We manufacture FC2 in a single leased facility located in Malaysia. Difficulties encountered by this facility, such as fire, accident, natural disaster, or an outbreak of a contagious disease could halt or disrupt production at the facility, delay the completion of orders, or cause the cancellation of orders. Any of these risks could increase our expenses or reduce our net revenues.

Uncertainty and adverse changes in the general economic conditions may negatively affect our business.

If general economic conditions in the U.S. and other global markets in which we operate decline, or if consumers fear that economic conditions will decline, consumers may reduce expenditures for products such as our products. Adverse changes may occur as a result of adverse global or regional economic conditions, fluctuating oil prices, declining consumer confidence, unemployment, fluctuations in stock markets, contraction of credit availability, or other factors affecting economic conditions generally. These changes may negatively affect the sales of our products, increase the cost, and decrease the availability of financing, or increase costs associated with producing and distributing our products. In addition, a substantial portion of the sales of FC2 are made in the public market to government agencies, including USAID and other government agencies around the world. Worsening economic conditions as well as budget deficits and austerity measures may cause pressures on government budgets and result in a reduction in purchases of FC2 by governmental agencies. Sales of FC2 fluctuate, which causes our operating results to vary from quarter-to-quarter.

Sales of FC2 fluctuate based upon demand from our commercial partners and the public sector and the nature of government procurement processes. Historically, our net revenues and profitability have varied from quarter–to-quarter due to such buying patterns. Quarterly variations in operating results may cause us to fail to meet market expectations for our operating results and may tend to depress our stock price during such quarters.

Material adverse or unforeseen legal judgments, fines, penalties, or settlements could have an adverse impact on our profits and cash flows.

We may, from time to time, become a party to legal proceedings incidental to our business, including, but not limited to, alleged claims relating to product liability, environmental compliance, patent infringement, commercial disputes, and employment matters. The current and future use of our drug candidates by us and potential collaborators in clinical trials, and the sale of any approved products in the future, may expose us to product liability claims. We will face an inherent risk of product liability claims as a result of the clinical testing of our drug candidates, and will face an even greater risk if we obtain FDA approval and commercialize our drug candidates in the U.S. or other additional jurisdictions or if we engage in the clinical testing of proposed new products or commercialize any additional products. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourself against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our existing products or drug candidates, if approved. Regardless of the merits or eventual outcome, product liability claims may result in any of the following:

- the inability to commercialize our drug candidates;
- difficulty recruiting subjects for clinical trials or withdrawal of these subjects before a trial is completed;
- labeling, marketing, or promotional restrictions;
- product recalls or withdrawals;
- decreased demand for our products or products that we may develop in the future;
- loss of revenue;
- injury to reputation;
- initiation of investigations by regulators;
- costs to defend the related litigation;

- substantial monetary awards to trial participants or patients; and
- a decline in the value of our shares.

Litigation could require us to record reserves or make payments which could adversely affect our profits and cash flows. Even the successful defense of legal proceedings may cause us to incur substantial legal costs, may divert management's attention and resources away from our business, may prevent us or our partners from achieving or maintaining market acceptance of the affected product and may substantially increase the costs of commercializing our future products and impair the ability to generate revenues from the commercialization of these products either by us or by our strategic alliance partners.

We currently maintain limited general commercial liability insurance coverage. However, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or for liabilities in excess of our insurance limits, our assets may not be sufficient to cover such claims and our business operations could be impaired.

In connection with the APP Acquisition, two putative class action and derivative lawsuits were filed against us and our directors alleging breach of fiduciary duty and/or wasting of corporate assets. These lawsuits are currently in an early stage. Any unfavorable outcomes in these lawsuits, resulting in the payment of damages or affecting our transaction with APP, could have a material adverse effect on our business and prospects and could reduce our profitability. In addition, addressing these lawsuits will likely divert management's attention and resources from our business.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our drug candidates could be delayed.

We will need to increase the size and complexity of our organization in the future, and we may experience difficulties in executing our growth strategy and managing any growth.

Our management, personnel, systems and facilities currently in place may not be adequate to support our business plan and future growth. We will need to further expand our scientific, sales and marketing, managerial, operational, financial and other resources to support our planned research, development and commercialization activities.

Our need to manage our operations, growth and various projects effectively requires that we:

- improve our operational, financial, management and regulatory compliance controls and reporting systems and procedures;
- attract and retain sufficient numbers of talented employees;
- manage our commercialization activities for our drug candidates effectively and in a cost-effective manner;
- manage our relationship with our partners related to the commercialization of our drug candidates;
- manage our clinical trials effectively;
- manage our internal manufacturing operations effectively and in a cost-effective manner while increasing production capabilities for our current drug candidates to commercial levels; and
- manage our development efforts effectively while carrying out our contractual obligations to partners and other third parties.

In addition, historically, we have utilized and continue to utilize the services of part-time outside consultants to perform a number of tasks for us, including tasks related to preclinical and clinical testing. Our growth strategy may also entail expanding our use of consultants to implement these and other tasks going forward. Because we rely on consultants for certain functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. There can be no assurance that we will be able to manage our existing consultants or find other competent outside consultants, as needed, on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our use of consultants, we might be unable to implement successfully the tasks necessary to execute effectively on our planned research, development and commercialization activities and, accordingly, might not achieve our research, development and commercialization goals.

Risks Relating to Our Intellectual Property

We may be unable to protect the proprietary nature of the intellectual property covering our products.

Our commercial success will depend in part on our ability to obtain patents, as well as our ability to maintain adequate protection of other intellectual property for our drug candidates and other products. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and profitability. The patent positions of pharmaceutical products are highly uncertain. The legal principles applicable to patents are in transition due to changing court precedent and legislative action and we cannot be certain that the historical legal standards surrounding questions of validity will continue to be applied or that current defenses relating to issued patents in these fields will be sufficient in the future. Changes in patent laws in the United States, such as the America Invents Act of 2011, may affect the scope, strength and enforceability of our patent rights or the nature of proceedings that may be brought by us related to our patent rights. In addition, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States and we may encounter significant problems in protecting our proprietary rights in these countries. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets.

These risks include the possibility of the following:

- ***all of our or our licensor's patents expire or are invalidated or are found to be unenforceable, or if some or all of our patent applications do not result in issued patents or result in patents with narrow, overbroad, or unenforceable claims, or claims that are not supported in regard to written description or enablement by the specification, or if we are prevented from asserting that the claims of an issued patent cover a product of a third party, we may be subject to competition from third parties with products in the same class of products as our product candidates or products with the same active pharmaceutical ingredients as our product candidates, including in those jurisdictions in which we have no patent protection.***

Our commercial success will depend in part on obtaining and maintaining patent and trade secret protection for our product candidates, as well as the methods for treating patients in the product indications using these product candidates. We will be able to protect our product candidates and the methods for treating patients in the product indications using these product candidates from unauthorized use by third parties only to the extent that we or our exclusive licensor owns or controls such valid and enforceable patents or trade secrets.

Even if our product candidates and the methods for treating patients for prescribed indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope, disclosure and support in the specification, the patents will provide protection only for a limited amount of time. Our and our licensor's ability to obtain patents can be highly uncertain and involve complex and in some cases unsettled legal issues and factual questions. Furthermore, different countries have different procedures for obtaining patents, and patents issued in different countries provide different degrees of protection against the use of a patented invention by others. Therefore, if the issuance to us or our licensor, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement in, a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

While we will apply for patents covering our technologies and products, as we deem appropriate, many third parties may already have filed patent applications or have received patents in our areas of product development. These entities' applications, patents and other intellectual property rights may conflict with our patent applications or other intellectual property rights and could prevent us from obtaining patents, could call into question the validity of any of our patents, if issued, or could otherwise adversely affect our ability to develop, manufacture, commercialize or market our products. In addition, if third parties file patent applications which include claims covering any technology to which we have rights, we may have to participate in interference, derivation or other proceedings with the U.S. Patent and Trademark Office (USPTO), or foreign patent regulatory authorities to determine our rights in the technology, which may be time-consuming and expensive. Moreover, issued patents may be challenged in the courts or in post-grant proceedings at the USPTO, or in similar proceedings in foreign countries. These proceedings may result in loss of patent claims or adverse changes to the scope of the claims.

If we or our licensors or strategic partners fail to obtain and maintain patent protection for our products, or our proprietary technologies and their uses, companies may be dissuaded from collaborating with us. In such event, our ability to commercialize our drug candidates or future drug candidates, if approved, may be threatened, we could lose our competitive advantage and the competition we face could increase, all of which could adversely affect our business, financial condition, results of operations and prospects.

In addition, mechanisms exist in much of the world permitting some form of challenge by generic drug marketers to patents prior to, or immediately following, the expiration of any regulatory exclusivity, and generic companies are increasingly employing aggressive strategies, such as "at risk" launches and compulsory licensing to challenge relevant patent rights.

Our business also may rely on unpatented proprietary technology, know-how, and trade secrets. If the confidentiality of this intellectual property is breached, it could adversely impact our business.

We are dependent in part on some license relationships.

We have acquired by license technology relating to our VERU-111 and VERU-112 drug candidates, and might enter into additional licenses in the future. Licenses to which we are a party contain, and we expect that any future licenses will contain, provisions requiring up-front, milestone and royalty payments to licensors. If we fail to comply with these obligations or other obligations to a licensor, that licensor might have the right to terminate the license on relatively short notice, in which event we would not be able to commercialize the drug candidates that were covered by the license. Also, the milestone and other payments associated with these licenses will make it less profitable for us to develop our drug candidates.

We have continuing obligations under our purchase agreements to acquire the intellectual property rights.

In addition to an upfront payment that we made in connection with the acquisition of the intellectual property rights associated with Tamsulosin DRS, there are significant installment payments and milestone payments that are required to be made pursuant to the terms of the purchase agreement. In addition, we granted a security interest in the purchased assets to the seller to secure our present and future payment and performance obligations under the purchase agreement. We also have obligations to make upfront payments and milestone payments in connection with our recent acquisitions of intellectual property rights associated with Solifenacin DRG and Tadalafil / Finasteride combination capsules. Accordingly, there will be significant payments that we will be required to make in the future to the sellers of these assets and the failure to make such payments may result in us losing our rights to the intellectual property we acquired. If we fail to retain such rights, we would not be able to commercialize any products relating to the rights. In such event, our business, results of operations, financial condition and prospects would be materially adversely affected.

We may face claims that our intellectual property infringes on the intellectual property rights of third parties. If we infringe intellectual property rights of third parties, it may increase our costs or prevent us from being able to commercialize our product candidates.

Our success depends, in part, on not infringing the patents and proprietary rights of other parties and not breaching any license, collaboration or other agreements we enter into with regard to our technologies and products. Numerous United States and foreign issued patents and pending patent applications owned by others also exist in the therapeutic areas in, and for the therapeutic targets for, which we intend to develop drugs. Patent applications are confidential when filed and remain confidential until publication, approximately 18 months after initial filing, while some patent applications remain unpublished until issuance. As such, there may be other third-party patents and pending applications of which we will be unaware with claims directed towards composition of matter, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our products or drug candidates. Therefore, we cannot know with certainty the nature or existence of every third-party patent filing. We cannot be sure that us or our partners will be free to manufacture or market our drug candidates as planned or that us or our licensors' and partners' patents will not be opposed or litigated by third parties. If any third-party patent was held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture or methods of treatment related to the use or manufacture of any of our drug candidates, the holders of any such patent may be able to block our ability to develop and commercialize the applicable drug candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. We may not be able to obtain a license to such patent on favorable terms or at all. Failure to obtain such license may have a material adverse effect on our business.

There is a risk that we are infringing the proprietary rights of third parties because numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields that are the focus of our development and manufacturing efforts. Others might have been the first to make the inventions covered by each of our or our licensor’s pending patent applications and issued patents and/or might have been the first to file patent applications for these inventions. In addition, because patent applications take many months to publish and patent applications can take many years to issue, there may be currently pending applications, unknown to us or our licensor, which may later result in issued patents that cover the production, manufacture, synthesis, commercialization, formulation or use of our product candidates. In addition, the production, manufacture, synthesis, commercialization, formulation or use of our product candidates may infringe existing patents of which we are not aware. Defending ourselves against third-party claims, including litigation in particular, would be costly and time consuming and would divert management’s attention from our business, which could lead to delays in our development or commercialization efforts. If third parties are successful in their claims, we might have to pay substantial damages or take other actions that are adverse to our business.

There is a substantial amount of litigation involving intellectual property in the pharmaceutical industry. If a third party asserts that we infringe its patents or other proprietary rights, we could face a number of risks that could adversely affect our business, financial condition, results of operations and prospects, including the following:

- infringement and other intellectual property claims would be costly and time-consuming to defend, whether or not we are ultimately successful, and could delay the regulatory approval process, consume our capital and divert management's attention from our business;
- we may have to pay substantial damages for past infringement if a court determines that our products or technologies infringe a competitor's patent or other proprietary rights;
- a court may prohibit us from selling or licensing our technologies or future products unless a third party licenses its patents or other proprietary rights to us on commercially reasonable terms, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties or lump sum payments or grant cross licenses to our patents or other proprietary rights to obtain that license; or
- we may need to redesign our products so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

We cannot predict whether third parties will assert these claims against us or our strategic partners or against the licensors of technology licensed to us, or whether those claims will harm our business. In addition, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. If we or our partners were to face infringement claims or challenges by third parties relating to our drug candidates, an adverse outcome could subject us to significant liabilities to such third parties, and force us or our partners to curtail or cease the development of some or all of our drug candidates, which could adversely affect our business, financial condition, results of operations and prospects.

We must submit patent certifications in connection with the 505(b)(2) FDA regulatory pathway.

We intend to submit NDAs for our VERU-722 and VERU-944 drug candidates, assuming that the clinical data justify submission, and for our Tamsulosin DRS, Tamsulosin XR capsules, Solifenacin DRG, and Tadalafil/Finasteride combination capsules products under Section 505(b)(2) of the FDCA, which was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the filing of an NDA when at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product, the Section 505(b)(2) applicant must submit patent certifications in its Section 505(b)(2) NDA with respect to any patents for the approved product on which the application relies that are listed in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the Orange Book. Specifically, the applicant must certify for each listed patent that (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is not sought until after patent expiration; or (iv) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. A certification that the new product will not infringe the previously approved product's listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification.

If the Section 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the referenced NDA for the previously approved product and relevant patent holders within 20 days after the Section 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the Section 505(b)(2) applicant. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification prevents the FDA from approving the application until the earlier of 30 months from the date of the lawsuit, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the applicant. The court also has the ability to shorten or lengthen the 30 month period if either party is found not to be reasonably cooperating in expediting the litigation. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its product only to be subject to significant delay and patent litigation before its product may be commercialized. Alternatively, if the NDA or relevant patent holder does not file a patent infringement lawsuit within the specified 45 day period, the FDA may approve the Section 505(b)(2) application at any time.

If we cannot certify that all of the patents listed in the Orange Book for the approved products referenced in the NDAs for each of our drug candidates have expired, we will be compelled to include a Paragraph IV certification in the NDA for such drug candidate. Our inability to certify that all of the patents listed in the FDA's Orange Book for approved products referenced in the NDAs for each of our drug candidates could have a serious and significant adverse effect on the timing for obtaining approval of our drug candidates.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of our competitors.

As is common in the pharmaceutical industry, we will employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or

we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Such claims may lead to material costs for us, or an inability to protect or use valuable intellectual property rights, which could adversely affect our business, financial condition, results of operations and prospects.

We may need to file lawsuits or take other actions to protect or enforce our intellectual property rights.

We may be subject to competition from third parties with products in the same class of products as our product candidates or products with the same active pharmaceutical ingredients as our product candidates in those jurisdictions in which we have no patent protection. Even if patents are issued to us or our licensor regarding our product candidates or methods of using them, those patents can be challenged by our competitors who can argue such patents are invalid or unenforceable, lack of utility, lack sufficient written description or enablement, or that the claims of the issued patents should be limited or narrowly construed. Patents also will not protect our product candidates if competitors devise ways of making or using these product candidates without legally infringing our patents. The Federal Food, Drug, and Cosmetic Act and FDA regulations and policies create a regulatory environment that encourages companies to challenge branded drug patents or to create non-infringing versions of a patented product in order to facilitate the approval of abbreviated new drug applications for generic substitutes. These same types of incentives encourage competitors to submit new drug applications that rely on literature and clinical data not prepared for or by the drug sponsor, providing another less burdensome pathway to approval.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Moreover, we may not have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights, generally.

In addition, in an infringement proceeding, a court may decide that one of our patents or one of our licensor's patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents, or those of ours licensors, do not cover the technology in question or on other grounds. An adverse result in any litigation or defense proceedings could put one or more of our patents, or those of our licensors, at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications, or those of our licensors, at risk of not issuing. Moreover, we may not be able to prevent, alone or with our licensors, misappropriation of our proprietary rights, particularly in countries in which the laws may not protect those rights as fully as in the United States or in those countries in which we do not file national phase patent applications. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. The occurrence of any of the above could adversely affect our business, financial condition, results of operations and prospects.

We may fail to protect the confidentiality of commercially sensitive information.

We also rely on trade secrets to protect our technology, especially where we do not believe that patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time-consuming, and the outcome is unpredictable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Risks Related to Ownership of Our Common Stock

A limited number of shareholders may be able to exercise substantial influence over us.

As of December 21, 2017, each of Mitchell S. Steiner, M.D. and Harry Fisch, M.D. beneficially owns approximately 14.8% of the shares of common stock outstanding. These shareholders may have the ability to exert significant influence over the outcome of shareholder votes, including votes concerning director elections, amendments to our Articles of Incorporation and possible mergers, corporate control contests and other significant corporate transactions.

Charges to earnings resulting from the APP Acquisition may cause our operating results to suffer.

Under the acquisition method of accounting in accordance with ASC 805, *Business Combinations*, we will allocate the total purchase price of the APP Acquisition to APP's net tangible assets and intangible assets based on their respective fair values as of the date of the APP Acquisition, and we will record the excess of the purchase price over those fair values as goodwill. Management's estimates of the fair value of such assets will be based upon assumptions that they believe to be reasonable but that will be inherently uncertain. The following factors, among others, could result in material charges that would cause our financial results to be negatively impacted:

- impairment of goodwill;
- charges for the amortization of identifiable intangible assets and for stock-based compensation;
- accrual of newly identified pre-acquisition contingent liabilities that are identified subsequent to the finalization of the purchase price allocation; and
- charges to income to eliminate certain of our pre-acquisition activities that duplicate those of APP or to reduce the combined company's cost structure.

Additional costs may include costs of employee redeployment, relocation and retention, including salary increases or bonuses, accelerated amortization of deferred equity compensation and severance payments, reorganization or closure of facilities, taxes and termination of contracts that provide redundant or conflicting services. Some of these costs may have to be accounted for as expenses that would decrease net income and earnings per share for the periods in which those adjustments are made.

If we fail to maintain effective internal control over financial reporting, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management is required annually to deliver a report that assesses the effectiveness of our internal control over financial reporting. However, for as long as we remain a "non-accelerated filer" under the rules of the SEC, our independent registered public accounting firm is not required to deliver an annual attestation report on the effectiveness of our internal control over financial reporting. We will cease to be a non-accelerated filer if the aggregate market value of our outstanding common stock held by non-affiliates as of the last business day of our most recently completed second fiscal quarter is $75 million or more, in which case we would again be subject to the requirement for an annual attestation report by our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. If we are unable to maintain effective internal control over financial reporting as required by Section 404 of the Sarbanes-Oxley Act, we may not be able to produce accurate financial statements, and investors may therefore lose confidence in our operating results, our stock price could decline and we may be subject to litigation or regulatory enforcement actions.

We are a "smaller reporting company" and will be able to avail ourselves of reduced disclosure requirements applicable to smaller reporting companies, which could make our common stock less attractive to investors.

We are a "smaller reporting company," as defined in the Securities Exchange Act of 1934, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "smaller reporting companies," including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer a "smaller reporting company." We will remain a "smaller reporting company" until the aggregate market value of our outstanding common stock held by non-affiliates as of the last business day of our most recently completed second fiscal quarter is $75 million or more.

There are provisions in our charter documents and Wisconsin law that might prevent or delay a change in control of our company.

We are subject to a number of provisions in our charter documents and Wisconsin law that may discourage, delay, or prevent a merger or acquisition that a shareholder may consider favorable. These provisions include the following:

- the authority provided to our Board of Directors in our Amended and Restated Articles of Incorporation to issue preferred stock without further action by our shareholders;
- the provision under Wisconsin law that permits shareholders to act by written consent only if such consent is unanimous;
- the provision under Wisconsin law that requires for a corporation such as us, that was formed before January 1, 1973, the affirmative vote of the holders of at least two-thirds of the outstanding shares of our voting stock to approve an amendment to our articles of incorporation, a merger submitted to a vote of our shareholders, or a sale of substantially all of our assets;
- advance notice procedures for nominations of candidates for election as directors and for shareholder proposals to be considered at shareholders' meetings; and

- the Wisconsin control share acquisition statute and Wisconsin's "fair price" and "business combination" provisions which limit the ability of an acquiring person to engage in certain transactions or to exercise the full voting power of acquired shares under certain circumstances.

The trading price of our common stock has been volatile, and investors in our common stock may experience substantial losses.

The trading price of our common stock has been volatile and may continue to be volatile. The trading price of our common stock could decline or fluctuate in response to a variety of factors, including:

- our failure to meet market expectations for our performance;
- the timing of announcements by us or our competitors concerning significant product developments, acquisitions, or financial performance;
- adverse results or delays in our clinical trials for our drug candidates;
- changes in laws or regulations applicable to our business;
- competition from new products that may emerge;
- actual or anticipated fluctuations in our financial condition or operating results;
- substantial sales of our common stock;
- issuance of new or updated research reports from securities analysts;
- announcement or expectation of additional debt or equity financing efforts;
- additions or departures of key personnel;
- general stock market conditions; or
- other economic or external factors.

You may be unable to sell your stock at or above your purchase price.

If our stock price declines, our common stock may be subject to delisting from the NASDAQ Capital Market.

If the closing bid price of our common stock is less than $1.00 per share for 30 consecutive trading days, we may receive a letter from the staff of The NASDAQ Stock Market LLC stating that our common stock will be delisted unless we are able to regain compliance with the Nasdaq Listing Rule requiring that we maintain a closing bid price for our common stock of at least $1.00 per share. We cannot guarantee that our stock price will continue to trade above $1.00 per share or otherwise meet the NASDAQ listing requirements and therefore our common stock may in the future be subject to delisting. If our common stock is delisted, this would, among other things, substantially impair our ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for us.

Future sales of our common stock may depress our stock price.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur may reduce the prevailing market price of our common stock and make it more difficult for you to sell your common stock at a time and price that you deem appropriate. In addition, certain of the former stockholders of APP are entitled to rights with respect to the registration of the shares they received pursuant to the APP Acquisition under the Securities Act of 1933, as amended (the Securities Act). Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act. Any sales of securities by existing shareholders could have a material adverse effect on the market price of our common stock.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be our shareholders' sole source of gain.

We have not declared or paid cash dividends on our common stock since May 2014. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of existing or any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be our shareholders' sole source of gain for the foreseeable future.

Item 1B. Unresolved Staff Comments

Not Applicable

Item 2. Properties

The Company's headquarters are located in Miami, FL in approximately 2,600 sq. ft. of office space that the Company leased in November 2016. The Miami lease expires on November 1, 2019, although the Company has two renewal options to extend the term for a period of three years each. Effective August 2017, the Company entered into a sublease for its prior headquarters in Chicago, IL. The Company continues to be responsible for performance under the Chicago lease until it expires on October 31, 2023. The Company utilizes warehouse space and sales fulfillment services of an independent public warehouse located in Glendale Heights, IL and La Vergne, TN for storage and distribution of FC2 and an independent public warehouse in Lakewood, New Jersey for storage and distribution of PREBOOST®. In June 2010, the Company entered a new lease agreement for 6,400 square feet of office space located in London, England. The lease expires in June 2020. The Company manufactures and warehouses FC2 within a leased facility with 45,800 sq. ft. of production and warehouse space, in Selangor D.E., Malaysia. The FDA-approved manufacturing process is subject to periodic inspections by the FDA as well as the U.K. based "notified body", which is responsible for CE and ISO accreditation. The lease currently has an expiration date of September 1, 2019. The Company's Malaysian production capacity is approximately 100 million units annually.

Item 3. 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 4. Mine Safety Disclosures

Not Applicable

PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Shares of our common stock trade on the NASDAQ Capital Market under the symbol "VERU". The approximate number of record holders of our common stock at December 6, 2017 was 269. The Company has not paid cash dividends on its common stock since May 2014. The Company intends to retain any earnings for use in operations and, therefore, does not anticipate paying cash dividends for the foreseeable future. The Company's credit facility with BMO Harris Bank N.A., restricts dividends and share repurchases. The credit facility with BMO Harris, N.A. will expire on December 29, 2017 and will not be renewed. Information regarding the high and low reported closing prices for our common stock is set forth in the table below.

	QUARTERS			
	FIRST	**SECOND**	**THIRD**	**FOURTH**
2017 Fiscal Year				
Price per common share – High	$ 1.20	$ 1.13	$ 1.27	$ 2.84
Price per common share – Low	$ 0.82	$ 0.92	$ 0.92	$ 1.04
2016 Fiscal Year				
Price per common share – High	$ 2.01	$ 2.65	$ 1.90	$ 1.47
Price per common share – Low	$ 1.38	$ 1.20	$ 1.25	$ 1.17

Item 6. Selected Financial Data

The data set forth below should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Consolidated Financial Statements and Notes thereto appearing in this Annual Report on Form 10-K. The Consolidated Statement of Income Data for the years ended September 30, 2017, 2016, and 2015, and the Consolidated Balance Sheet Data as of September 30, 2017 and 2016, are derived from the Consolidated Financial Statements included elsewhere in this report. The Consolidated Statement of Income Data for the years ended September 30, 2014 and 2013, and the Consolidated Balance Sheet Data as of September 30, 2015, 2014, and 2013, are derived from Consolidated Financial Statements that are not included in this report. The historical results are not necessarily indicative of results to be expected for future periods.

	Year ended September 30,				
Condensed Consolidated Statement of Income Data:	**2017**	**2016**	**2015**	**2014**	**2013**
	(In thousands, except per share data)				
Net revenues	$ 13,656	$ 22,127	$ 32,605	$ 24,491	$ 31,457
Cost of sales	6,636	8,778	13,635	11,370	13,953
Gross profit	7,020	13,349	18,970	13,121	17,504
Operating expenses	15,514	10,330	12,352	9,197	7,714
Operating (loss) income	(8,494)	3,019	6,618	3,924	9,790
Non-operating (expense) income	(108)	(205)	69	33	144
(Loss) income before income taxes	(8,602)	2,814	6,687	3,957	9,934
Income tax (benefit) expense	(1,990)	2,469	2,341	1,524	(4,409)
Net (loss) income attributable to common shareholders before preferred stock dividend	$ (6,612)	$ 345	$ 4,346	$ 2,433	$ 14,343
Preferred dividends	1,991	-	-	-	-
Net (loss) income attributable to common stockholders	$ (8,603)	$ 345	$ 4,346	$ 2,433	$ 14,343
Net (loss) income per basic common share outstanding	$ (0.25)	$ 0.01	$ 0.15	$ 0.09	$ 0.51
Basic weighted average common shares outstanding	34,640	28,666	28,532	28,523	28,377
Net (loss) income per diluted common share outstanding	$ (0.25)	$ 0.01	$ 0.15	$ 0.08	$ 0.50
Diluted weighted average common shares outstanding	34,640	28,927	28,917	28,865	28,726
Cash dividends declared per share	$ —	$ —	$ —	$ 0.21	$ 0.26

	Year ended September 30,				
Condensed Consolidated Balance Sheet Data:	**2017**	**2016**	**2015**	**2014**	**2013**
	(In thousands)				
Cash and cash equivalents	$ 3,278	$ 2,385	$ 4,106	$ 5,796	$ 8,922
Working capital	4,810	14,968	17,361	9,695	13,424
Total assets	55,306	38,624	37,472	31,673	35,170
Accumulated deficit	(34,263)	(27,651)	(27,996)	(32,342)	(28,715)
Long-term obligations	1,234	1,234	15	39	67

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 (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 maunfacturing 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 US 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 (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 (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 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.

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 US 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 (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 $2.4 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 7A. 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 8. Financial Statements and Supplementary Data

The response to this item is submitted in a separate section of this report. See "Index to Consolidated Financial Statements" for a list of the financial statements being filed herein.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, our management evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act), as of the end of the period covered by this Annual Report on Form 10-K (the "Evaluation Date"). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms and (ii) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Change in Internal Controls

There were no changes in Veru's internal control over financial reporting during the year to which this report relates that have materially affected, or are reasonably likely to materially affect Veru's internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. As required by Rule 13a-15(c) under the Exchange Act, our management has carried out an evaluation, with the participation of the Chief Executive Officer and Chief Financial Officer, of the effectiveness of its internal control over financial reporting as of the end of the last fiscal year. The framework on which such evaluation was based is contained in the report entitled "Internal Control-Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO Report") in 2013.

Our system of internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Based on its assessment, management has concluded that we maintained effective internal control over financial reporting as of September 30, 2017, based on criteria in "Internal Control - Integrated Framework" issued by the COSO in 2013.

Report of Independent Registered Public Accounting Firm

Not required as a smaller reporting company.

Item 9B. Other Information

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

On December 29, 2017, the Company entered into the Purchase Agreement with Aspire Capital which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right, from time to time 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), if needed, one or more registration statements, as permissible and necessary, 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.

The Purchase Price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the period(s) used to compute the Purchase Price. The Company may deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the Purchase Agreement, so long as the most recent purchase has been completed.

The Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement on any purchase date where the closing sale price of the Company's common stock is less than $0.25 per share. There are no trading volume requirements or restrictions under the Purchase Agreement, and the Company will control the timing and amount of sales of the Company's common stock to Aspire Capital. Aspire Capital has no right to require any sales by the Company, but is obligated to make purchases from the Company as directed by the Company in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. 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 Purchase Agreement may be terminated by the Company at any time, in its discretion, without any cost to the Company. Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging of the Company's common stock during any time prior to the termination of the Purchase Agreement. Any proceeds that the Company receives under the Purchase Agreement are expected to be used for working capital and general corporate purposes, which may include research and development, clinical trial and marketing expenditures.

The foregoing is a summary description of certain terms of the Purchase Agreement and the Registration Rights Agreement and, by its nature, is incomplete. Copies of the Purchase Agreement and Registration Rights Agreement are filed herewith as Exhibits 10.33 and 10.34, respectively, to this Annual Report on Form 10-K and are incorporated herein by reference. All readers are encouraged to read the entire text of the Purchase Agreement and the Registration Rights Agreement.

The Company is filing the opinion of its counsel, Reinhart Boerner Van Deuren s.c., relating to the legality of the shares of common stock offered and sold pursuant to the Purchase Agreement, as Exhibit 5.1 hereto.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information with respect to this item is incorporated herein by reference to the discussion under the headings "Proposal 1: Election of Directors," "Executive Officers," "Section 16(a) Beneficial Ownership Reporting Compliance," "Corporate Governance Matters-Director Nominations" and "Audit Committee Matters – Audit Committee Financial Expert" in the Company's Proxy Statement for the 2018 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 29, 2018. Information regarding the Company's Code of Business Ethics is incorporated herein by reference to the discussion under "Corporate Governance Matters – Code of Business Ethics" in the Company's Proxy Statement for the 2018 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 29, 2018.

The Audit Committee of the Company's Board of Directors is an "audit committee" for purposes of Section 3(a)(58)(A) of the Securities Exchange Act of 1934. The members of the Audit Committee are Jesus Socorro (Chairperson), Elgar Peerschke and Georges Makhoul.

Item 11. Executive Compensation

Information with respect to this item is incorporated herein by reference to the discussion under the headings "Director Compensation and Benefits," and "Executive Compensation" in the Company's Proxy Statement for the 2018 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 29, 2018.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Information with respect to this item is incorporated herein by reference to the discussion under the headings "Security Ownership" and "Equity Compensation Plan Information" in the Company's Proxy Statement for the 2018 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 29, 2018.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information with respect to this item is incorporated herein by reference to the discussion under the heading "Certain Relationships and Related Transactions" in the Company's Proxy Statement for the 2018 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 29, 2018. Information regarding director independence is incorporated by reference to the discussion under "Corporate Governance Matters – Director Independence" in the Company's Proxy Statement for the 2018 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 29, 2018.

Item 14. Principal Accountant Fees and Services.

Information with respect to this item is incorporated herein by reference to the discussion under the heading "Audit Committee Matters – Fees of Independent Registered Public Accounting Firm" in the Company's Proxy Statement for the 2018 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 29, 2018.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this report:

1. Financial Statements

The following consolidated financial statements of the Company are included in Item 8 of this report:

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of September 30, 2017 and 2016

Consolidated Statements of Income for the Years Ended September 30, 2017, 2016, and 2015

Consolidated Statements of Stockholders' Equity for the Years Ended September 30, 2017, 2016, and 2015

Consolidated Statements of Cash Flows for the Years Ended September 30, 2017, 2016, and 2015

Notes to Consolidated Financial Statements

2. Financial Statement Schedules

All schedules for which provision is made in the applicable accounting regulations of the SEC are not required under the related instructions, are inapplicable or the required information is shown in the financial statements or notes thereto, and therefore, have been omitted.

3. 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 (included as part of the signature page hereof).
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.

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*Indicates management contract or compensatory plan.

The response to this portion of Item 15 is submitted as a separate section of this report.

(c) Financial Statement Schedules

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: December 29, 2017

VERU INC.

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

BY: /s/ Daniel Haines
Daniel Haines, Chief Financial Officer

POWER OF ATTORNEY

Each person whose signature appears below hereby appoints Mitchell Steiner and Daniel Haines, and each of them individually, his true and lawful attorney-in-fact, with power to act with or without the other and with full power of substitution and resubstitution, in any and all capacities, to sign any or all amendments to the Form 10-K and file the same with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitutes, may lawfully cause to be done by virtue hereof.

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)	December 29, 2017
/s/ Daniel Haines Daniel Haines	Chief Financial Officer (Principal Accounting and Financial Officer)	December 29, 2017
/s/ Elgar Peerschke Elgar Peerschke	Chairman of the Board	December 27, 2017
/s/ O.B. Parrish O.B. Parrish	Vice Chairman of the Board	December 29, 2017
/s/ David R. Bethune David R. Bethune	Director	December 29, 2017
/s/ Mario Eisenberger Mario Eisenberger	Director	December 26, 2017
/s/ Harry Fisch Harry Fisch	Director	December 24, 2017
/s/ Mary Margaret Frank Mary Margaret Frank	Director	December 29, 2017
/s/ Lucy Lu Lucy Lu	Director	December 29, 2017
/s/ Georges Makhoul Georges Makhoul	Director	December 29, 2017
/s/ Jesus Socorro Jesus Socorro	Director	December 29, 2017

Veru Inc.

Index to Consolidated Financial Statements

Document	Page No.
Audited Consolidated Financial Statements.	
Report of RSM US LLP, Independent Registered Public Accounting Firm.	F-2
Consolidated Balance Sheets as of September 30, 2017 and 2016.	F-3
Consolidated Statements of Operations for the years ended September 30, 2017, 2016, and 2015.	F-4
Consolidated Statements of Stockholders' Equity for the years ended September 30, 2017, 2016, and 2015.	F-5 through F-7
Consolidated Statements of Cash Flows for the years ended September 30, 2017, 2016 and 2015.	F-8
Notes to Consolidated Financial Statements.	F-9 through F-29

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
Veru Inc.

We have audited the accompanying consolidated balance sheets of Veru Inc. (formerly known as The Female Health Company) as of September 30, 2017 and 2016, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended September 30, 2017. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Veru Inc. (formerly known as The Female Health Company) as of September 30, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended September 30, 2017, in conformity with U.S. generally accepted accounting principles.

/s/ RSM US LLP

Chicago, Illinois
December 29, 2017

VERU INC.
CONSOLIDATED BALANCE SHEETS
SEPTEMBER 30, 2017 AND 2016

	2017	2016
ASSETS		
Current Assets		
Cash	$ 3,277,602	$ 2,385,082
Accounts receivable, net of allowance for doubtful accounts of $38,103 for 2017 and 2016	3,555,350	10,775,200
Income tax receivable	—	2,387
Inventory, net	2,767,924	2,492,644
Prepaid expenses and other current assets	697,097	634,588
TOTAL CURRENT ASSETS	10,297,973	16,289,901
LONG-TERM ASSETS		
PLANT AND EQUIPMENT		
Equipment, furniture and fixtures	4,067,896	4,625,472
Leasehold improvements	287,686	323,147
Less accumulated depreciation and amortization	(3,800,043)	(4,123,532)
Plant and equipment, net	555,539	825,087
Other trade receivables (Notes 1 and 14)	7,837,500	7,837,500
Other assets	156,431	189,219
Deferred income taxes	8,827,000	13,482,000
Intangible assets, net	20,752,991	—
Goodwill	6,878,932	—
TOTAL ASSETS	$ 55,306,366	$ 38,623,707
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 2,685,718	$ 701,035
Unearned revenue	1,014,517	—
Accrued expenses and other current liabilities	1,441,359	2,380,571
Accrued compensation	345,987	264,871
TOTAL CURRENT LIABILITIES	5,487,581	3,346,477
LONG-TERM LIABILITIES		
Other liabilities	1,233,750	1,233,750
Deferred rent	131,830	—
Deferred income taxes	—	110,069
TOTAL LIABILITIES	6,853,161	4,690,296
Commitments and Contingencies	—	—
STOCKHOLDERS' EQUITY:		
Preferred stock; no shares issued and outstanding in 2017 or 2016.	—	—
Common Stock, par value $0.01 per share; 77,000,000 and 38,500,000 shares authorized, 55,392,193 and 31,273,954 shares issued and 53,208,489 and 29,090,250 shares outstanding in 2017 and 2016, respectively	553,922	312,740
Additional paid-in-capital	90,550,669	69,660,010
Accumulated other comprehensive loss	(581,519)	(581,519)
Accumulated deficit	(34,263,262)	(27,651,215)
Treasury stock, at cost	(7,806,605)	(7,806,605)
TOTAL STOCKHOLDERS' EQUITY	48,453,205	33,933,411
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 55,306,366	$ 38,623,707

See notes to consolidated financial statements.

VERU INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED SEPTEMBER 30, 2017, 2016, AND 2015

	2017	2016	2015
Net revenues	$ 13,655,592	$ 22,127,342	$ 32,604,865
Cost of sales	6,636,080	8,777,858	13,634,906
Gross profit	7,019,512	13,349,484	18,969,959
Operating expenses:			
Research and development	3,504,482	99,393	219,815
Advertising	54,270	88,866	—
Selling, general, and administrative	11,019,091	8,660,174	12,131,737
Business acquisition	935,781	1,482,539	—
Total operating expenses	15,513,624	10,330,972	12,351,552
Operating (loss) income	(8,494,112)	3,018,512	6,618,407
Non-operating (expense) income:			
Interest and other (expense) income, net	(46,543)	(57,056)	10,150
Foreign currency transaction (loss) gain	(61,835)	(147,540)	58,483
Total non-operating (expense) income	(108,378)	(204,596)	68,633
(Loss) income before income taxes	(8,602,490)	2,813,916	6,687,040
Income tax (benefit) expense	(1,990,443)	2,469,191	2,341,004
Net (loss) income attributable to common shareholders before preferred stock dividend	(6,612,047)	344,725	4,346,036
Preferred stock dividend	1,990,771	—	—
Net (loss) income attributable to common shareholders	$ (8,602,818)	$ 344,725	$ 4,346,036
Net (loss) income per basic common share outstanding	$ (0.25)	$ 0.01	$ 0.15
Basic weighted average common shares outstanding	34,640,308	28,666,477	28,532,327
Net (loss) income per diluted common share outstanding	$ (0.25)	$ 0.01	$ 0.15
Diluted weighted average common shares outstanding	34,640,308	28,926,557	28,917,048

See notes to consolidated financial statements.

VERU INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED SEPTEMBER 2017, 2016, AND 2015

	Preferred Stock	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Treasury Stock at Cost	Total
		Shares	Amount					
Balance at September 30, 2014 (balance forward)	$ —	30,958,669	$ 309,587	$ 68,484,889	$ (581,519)	$ (32,341,976)	$ (7,805,655)	$ 28,065,326
Share-based compensation	—	233,867	2,338	720,312	—	—	—	722,650
Stock repurchase – total 250 treasury shares	—	—	—	—	—	—	(950)	(950)
Net income and comprehensive income	—	—	—	—	—	4,346,036	—	4,346,036
Balance at September 30, 2015	$ —	31,192,536	$ 311,925	$ 69,205,201	$ (581,519)	$ (27,995,940)	$ (7,806,605)	$ 33,133,062

See notes to consolidated financial statements.

VERU INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED SEPTEMBER 2017, 2016, AND 2015

	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, 2015 (balance forward)	$ —	31,192,536	$ 311,925	$ 69,205,201	$ (581,519)	$ (27,995,940)	$ (7,806,605)	$ 33,133,062
Share-based compensation	—	81,418	815	454,809	—	—	—	455,624
Net income and comprehensive income	—	—	—	—	—	344,725	—	344,725
Balance at September 30, 2016	$ —	31,273,954	$ 312,740	$ 69,660,010	$ (581,519)	$ (27,651,215)	$ (7,806,605)	$ 33,933,411

See notes to consolidated financial statements.

VERU INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED SEPTEMBER 2017, 2016, AND 2015

	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, 2016 (balance forward)	$ —	31,273,954	$ 312,740	$ 69,660,010	$ (581,519)	$ (27,651,215)	$ (7,806,605)	$ 33,933,411
Share-based compensation	—	247,999	2,480	778,451	—	—	—	780,931
Issuance of 2,000,000 shares of common stock in connection with the APP Acquisition	—	2,000,000	20,000	1,806,097	—	—	—	1,826,097
Issuance of 2,585,379 warrants in connection with the APP Acquisition	—	—	—	542,930	—	—	—	542,930
Recognition of beneficial conversion feature on Series 4 Preferred Stock	—	—	—	1,990,771	—	—	—	1,990,771
Preferred Stock dividend	—	—	—	(1,990,771)	—	—	—	(1,990,771)
Conversion of 546,576 shares of Series 4 Preferred Stock to Common Stock	—	21,870,240	218,702	17,763,181	—	—	—	17,981,883
Net loss attributable to common shareholders before Preferred Stock dividend	—	—	—	—	—	(6,612,047)	—	(6,612,047)
Balance at September 30, 2017	$ —	55,392,193	$ 553,922	$ 90,550,669	$ (581,519)	$ (34,263,262)	$ (7,806,605)	$ 48,453,205

See notes to consolidated financial statements.

VERU INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED SEPTEMBER 30, 2017, 2016, AND 2015

	2017	2016	2015
OPERATIONS			
Net (loss) income	$ (6,612,047)	$ 344,725	$ 4,346,036
Adjustments to reconcile net (loss) income to net cash provided by (used in) operating activities:			
Depreciation and amortization	333,999	422,873	494,258
Amortization of intangible assets	147,009	—	—
Share-based compensation	756,275	499,873	489,689
Warrants issued	542,930	—	—
Deferred income taxes	(2,255,069)	2,054,817	1,925,739
Provision for obsolete inventory	345,179	(8,630)	173,634
Loss on disposal of fixed assets	73,992	699	3,483
Changes in operating assets and liabilities, net of effects of acquisition of a business:			
Decrease (increase) in accounts receivable	7,226,825	(4,524,310)	(11,144,540)
Decrease (increase) in income tax receivable	2,387	18,864	(21,251)
Decrease (increase) in inventory	(479,418)	(738,834)	1,064,633
Decrease (increase) in prepaid expenses and other assets	(29,383)	(77,721)	58,241
(Decrease) increase in accounts payable	897,471	(376,314)	(47,510)
Increase in unearned revenue	1,014,517	—	—
(Decrease) increase in accrued expenses and other current liabilities	(981,779)	669,600	1,108,891
Net cash provided by (used in) operating activities	982,888	(1,714,358)	(1,548,697)
INVESTING ACTIVITIES			
Acquisition of Aspen Park Pharmaceuticals	43,118	—	—
Capital expenditures	(133,486)	(6,374)	(135,424)
Net cash used in investing activities	(90,368)	(6,374)	(135,424)
FINANCING ACTIVITIES			
Purchases of common stock for treasury shares	—	—	(950)
Dividends paid on common stock	—	—	(5,338)
Net cash used in financing activities	—	—	(6,288)
Net increase (decrease) in cash	892,520	(1,720,732)	(1,690,409)
Cash at beginning of year	2,385,082	4,105,814	5,796,223
CASH AT END OF YEAR	$ 3,277,602	$ 2,385,082	$ 4,105,814
Supplemental Disclosure of Cash Flow Information:			
Cash payments for income taxes	230,705	352,856	294,441
Acquisiton of Aspen Park Pharmaceuticals			
Identifiable non-cash assets acquired	21,049,645	—	—
Identifiable liabilities assumed	(8,163,715)	—	—
Net identifiable non-cash assets acquired	12,885,930	—	—
Goodwill	6,878,932	—	—
Subtotal	19,764,862	—	—
Less: consideration issued			
Common stock	1,826,097	—	—
Series 4 Preferred Stock	17,981,883	—	—
Net cash acquired	43,118	—	—
Schedule of noncash financing and investing activities:			
Reduction of accrued expense upon issuance of shares	22,176	19,785	255,577

See notes to consolidated financial statements.

Note 1. Nature of Business and Significant Accounting Policies

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 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 through distributors, public health programs and retailers in 16 countries.

The Company's standard credit terms vary from 30 to 120 days, depending on the class of trade and customary terms within a territory, so accounts receivable is affected by the mix of purchasers within the period. As is typical in the Company's business, extended credit terms may occasionally be offered as a sales promotion or for certain sales. The Company has agreed to credit terms of up to 150 days with our distributor in the Republic of South Africa. For the 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. For the past twelve months, the Company's average days' sales outstanding was approximately 377 days. The balance in the allowance for doubtful accounts was $38,000 at both September 30, 2017 and September 30, 2016.

Use of estimates: The preparation of financial statements requires management to make estimates and use assumptions that affect certain reported amounts and disclosures. Significant accounting estimates include the deferred income tax valuation allowance and the value of share-based compensation. Actual results may differ from those estimates.

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 components of accounts receivable consist of the following at September 30, 2017 and 2016:

	2017	2016
Trade receivables	$ 11,330,814	$ 18,616,342
Other receivables	100,139	34,461
Accounts receivable, gross	11,430,953	18,650,803
Less: allowance for doubtful accounts	(38,103)	(38,103)
Accounts receivable, net	11,392,850	18,612,700
Less: long-term trade receivables	(7,837,500)	(7,837,500)
Current accounts receivable, net	$ 3,555,350	$ 10,775,200

The Company has long-term trade receivables that may not be collectable within one year of the balance sheet date based on the credit terms with our Brazil distributor.

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 for the years ended September 30:

Year	Balance at October 1	Provision Charges to Expenses	Write offs/ Recoveries	Balance at September 30
2015	$ 48,068	$ —	$ —	$ 48,068
2016	$ 48,068	$ —	$ (9,965)	$ 38,103
2017	$ 38,103	$ —	$ —	$ 38,103

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. In fiscal year 2017, our significant customers were the United States Agency for International Development (USAID) and the United Nations Population Fund (UNFPA). In fiscal year 2016 and fiscal year 2015, our significant customers were Semina Indústria e Comércio Ltda (Semina), UNFPA, and USAID. No other single customer accounted for more than 10 percent of unit sales during those periods.

	Percentage of Unit Sales		
Significant Customers	**2017**	**2016**	**2015**
USAID	44%	24%	16%
UNFPA	25%	25%	18%
Semina	*	27%	47%
Total Percentage of Unit Sales	69%	76%	81%

* Less than 10 percent of unit sales.

Semina's current accounts receivable balance represented 11 percent and 44 percent of current assets at September 30, 2017 and 2016, respectively. No other single customer's accounts receivable balance accounted for more than 10 percent of current assets at the end of those periods. Semina's total accounts receivable balance represented 78 percent and 85 percent of trade receivables at September 30, 2017 and 2016, respectively.

Inventory: Inventories are valued at the lower of cost or market. 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 market 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 functional currency across the Company reduces its foreign currency risk and stabilizes its operating results. The Company recognized a foreign currency transaction loss of $61,835, a foreign currency transaction loss of $147,540, and a foreign currency transaction gain of $58,483 for the years ended September 30, 2017, 2016, and 2015, respectively. The cumulative foreign currency translation loss included in accumulated other comprehensive loss was $581,519 as of September 30, 2017 and 2016. Assets located outside of the U.S. totaled approximately $5,600,000 and $5,500,000 at September 30, 2017 and 2016, 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. FC2 patents have been issued by the United States, Europe, Canada, Australia, South Africa, the People's Republic of China, Japan, Mexico, Brazil, India and the African Regional Intellectual Property Organization (ARIPO), which includes Botswana, Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Sudan, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe. Further, the European patent for FC2 has been validated in the following countries: Austria, Belgium, Bulgaria, Switzerland, Republic of Cyprus, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Hungary, Ireland, Italy, Luxembourg, Monaco, Netherlands, Portugal, Romania, Sweden, Slovenia, Slovakia, and Turkey. The patents cover the key aspects of FC2, including its overall design and manufacturing process. The patents have expiration dates in 2023 and 2024.

The Company has a registration for the trademark "FC2 Female Condom" in the United States. Furthermore, the Company has filed applications or secured registrations in 40 countries or jurisdictions around the world to protect the various names and symbols used in

marketing its Female Condoms. In addition, the experience that has been gained through years of manufacturing its Female Condoms (FC1 and FC2) has allowed the Company to develop trade secrets and know-how, including certain proprietary production technologies, which further protect its competitive position.

Financial instruments: The Company follows ASC Topic 820, *Fair Value Measurements and Disclosures*, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. The fair value framework requires the categorization of assets and liabilities into three levels based upon the assumptions (inputs) used to price the assets or liabilities. Level 1 provides the most reliable measure of fair value, whereas Level 3 generally requires significant management judgment.

The Company currently does not have any assets or liabilities measured at fair value on a recurring or non-recurring basis as of September 30, 2017. The Company did value the assets and liabilities assumed as part of the APP Acquisition. See Note 2 for additional detail.

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.

Research and development costs: 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 amount of costs expensed for the years ended September 30, 2017, 2016, and 2015 were $3.5 million, $99,393, and $219,815, respectively.

Restricted cash: Restricted cash relates to security provided to one of the Company's U.K. banks for performance bonds issued in favor of customers. The Company has a facility of $250,000 for such performance bonds. Such 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 $138,725 and $134,443 for the years ended September 30, 2017 and 2016, respectively, and is included in cash on the accompanying 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 September 30, 2017 was $1,014,517 and was comprised mainly of sales made to wholesalers. We lack the experiential data which would allow us to estimate returns; therefore, as of September 30, 2017, we have determined that we do not yet meet the criteria for the recognition of revenue at the time of shipment to 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: We acquired our intangible assets, net, in the APP Acquisition on October 31, 2016 which account for $20.8 million at September 30, 2017.

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

- Unit of account – Most intangible assets are valued as single global assets rather than multiple assets for each jurisdiction or indication after considering the development stage, expected levels of incremental costs to obtain additional approvals, risks

associated with further development, amount and timing of benefits expected to be derived in the future, expected patent lives in various jurisdictions and the intention to promote the asset as a global brand.

- Estimated useful life – The asset life expected to contribute meaningful cash flows is determined after considering all pertinent matters associated with the asset, including expected regulatory approval dates (if unapproved), exclusivity periods and other legal, regulatory or contractual provisions as well as the effects of any obsolescence, demand, competition, and other economic factors, including barriers to entry.
- Probability of Technical and Regulatory Success ("PTRS") Rate – PTRS rates are determined based upon industry averages considering the respective 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. Intangible assets are carried at cost less accumulated amortization. Amortization is 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 operating expenses.

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, 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, in-process research and development ("IPR&D") impairment charges are likely to occur in future periods. IPR&D is closely monitored and assessed each period for impairment.

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging from 7 to 10 years. We use the straight-line method of amortization as there is no reliably determinable pattern in which the economic benefits of our intangible assets are consumed or otherwise used up. Since intangible assets were acquired in October 31, 2016 there is no amortization expense for 2016. Amortization expense was $147,009 at September 30, 2017.

Goodwill: Goodwill represents the difference between the purchase price and the estimated fair value of the net assets acquired accounted for by the acquisition method of accounting and arose from the APP Acquisition. The Company has two reporting units which are the Commercial reporting unit and the Research and Development reporting unit. All goodwill resides in the Company's Research and Development reporting unit.

Goodwill was $6.9 million and zero at September 30, 2017 and 2016. 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 stock-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 $54,270, $88,866, and $0 for the years ended September 30, 2017, 2016, and 2015, respectively.

Income taxes: 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.

Earnings per share (EPS): Basic EPS is computed by dividing net income by the weighted average number of common shares outstanding for the period. Diluted EPS 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 and unvested shares granted to employees and directors.

Other comprehensive income: Accounting principles generally require that recognized revenue, expenses, gains and losses be included in net income. 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 consolidated balance sheets, these items, along with net income, are components of comprehensive income.

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 fiscal 2017, 2016, and 2015, comprehensive income is equivalent to the reported net income.

Recently issued accounting pronouncements: In May 2014, the FASB issued 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. We are currently evaluating the impact of the new guidance on our consolidated financial statements and have not yet selected a transition approach to implement the standard.

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 will be effective for the Company beginning on October 1, 2017. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

In November 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes, which requires deferred tax liabilities and assets to be classified as non-current in the consolidated balance sheet. Current accounting principles require an entity to separate deferred income tax liabilities

and assets into current and non-current amounts in a classified statement of financial position. ASU 2015-17 will be effective for the Company beginning on October 1, 2017. Early adoption of the standard is permitted, and the Company adopted this standard during the quarter ended December 31, 2016 and applied it to all periods presented. Adoption of this standard resulted in presenting current and prior period deferred tax assets and liabilities as non-current and net of one another on the balance sheet. These non-current deferred tax assets and liabilities are netted by tax jurisdiction.

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. We are currently evaluating the impact of the new guidance on our consolidated financial statements and have not yet selected a transition approach to implement the standard.

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 will be effective for the Company beginning on October 1, 2017. We are currently evaluating the impact of the new guidance on our consolidated financial statements and have not yet selected a transition approach to implement the standard.

In November 2016, the FASB issued ASC Update No. 2016-18, *Statement of Cash Flows* (Topic 230)*: Restricted Cash.* The purpose of Update No. 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. Update No. 2016-18 is 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 ASC Update No. 2017-04, Intangibles - Goodwill and Other Topics (Topic 350): Simplifying the Test for Goodwill Impairment. The purpose of Update No. 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. We do not expect Update No. 2017-04 to have a material impact on our financial position or results of operations.

In January 2017, the FASB issued ASC Update No. 2017-01, *Business Combinations* (Topic 805)*: Clarifying the Definition of a Business*. The purpose of Update No. 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 is 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 Update No. 2017-01 is not expected to have a material impact on our financial position or results of operations.

In May 2017, the FASB issued ASC Update No. 2017-09, *Compensation - Stock Compensation* (Topic 718)*: Scope of Modification Accounting*. The purpose of Update No. 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. Update No. 2017-09 is 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 Update No. 2017-09 is not expected to have a material impact on our financial position or results of operations.

Out-of-Period Adjustment: Included in the results of operations for the year ended September 30, 2017 are out-of-period adjustments which represent corrections of prior-period errors relating to the accounting for foreign tax credits from our Malaysian subsidiary. During the fourth fiscal quarter of 2017, the Company determined that a deferred tax asset for the foreign tax credit associated with a deemed dividend was appropriately recorded, however the rate used to record the asset was incorrect resulting in an understatement of income tax expense. The out-of-period impact of the error recorded was approximately $440,000 related to the year ended September 30, 2016. The correction of these errors was not material to the year ended September 30, 2017 or any of the prior interim or annual periods.

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 its acquisition of APP through the APP Acquisition. 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 APP Acquisition was pursuant to an Amended and Restated Agreement and Plan of Merger, dated as of October 31, 2016, (the Amended Merger Agreement), among the Company, APP, and the Company's wholly owned subsidiary Blue Hen Acquisition, Inc. (APP Merger Sub). Pursuant to the Amended Merger Agreement, on October 31, 2016, APP became a wholly-owned subsidiary of the Company through the merger of APP Merger Sub with and into APP with APP continuing as the surviving corporation. Consummation of the APP Acquisition did not require the current approval of the Company's shareholders.

Under the terms of the Amended Merger Agreement, pursuant to the APP Acquisition, the outstanding shares of APP common stock and preferred stock were converted into the right to receive in the aggregate 2,000,000 shares of the Company's common stock and 546,756 shares of Series 4 Preferred Stock.

The terms of the Series 4 Preferred Stock include the following:

- Each share of Series 4 Preferred Stock will automatically convert into 40 shares of the Company's common stock upon receipt by the Company of approval by the affirmative vote of the Company's shareholders by the required vote under the Wisconsin Business Corporation Law and the NASDAQ listing rules, as applicable, of (i) an amendment to the Company's Amended and Restated Articles of Incorporation to increase the total number of authorized shares of the Company's common stock by a sufficient amount to permit such conversion and (ii) the conversion of the Series 4 Preferred Stock pursuant to applicable NASDAQ rules.
- Upon a Liquidation Event, the holders of the Series 4 Preferred Stock will be entitled to a liquidation preference equal to the greater of (a) $1.00 per share (or $546,756 in the aggregate for all of the shares of Series 4 Preferred Stock), or (b) the amount holders would have received if the Series 4 Preferred Stock had converted to the Company's common stock. A "Liquidation Event" includes any voluntary or involuntary liquidation, dissolution or winding up of the Company and certain transactions involving an acquisition of the Company (which are referred to as Fundamental Changes).
- The Series 4 Preferred Stock is redeemable on the first to occur of (i) the 20th anniversary of the date of original issuance or (ii) a Fundamental Change, at a price equal to $1.00 per share, unless converted into the Company's common stock prior to such redemption.
- The Series 4 Preferred Stock is senior to all existing and future classes of the Company's capital stock upon a Liquidation Event, and no senior or additional pari passu preferred stock may be issued without the consent of the holders of a majority of the outstanding shares of Series 4 Preferred Stock.
- The Series 4 Preferred Stock participates in dividends paid to holders of the Company's common stock on an as converted basis.
- The Series 4 Preferred Stock has one vote per share and will generally vote with the Company's common stock on a one share to one share basis.

On July 28, 2017, the Company held a Special Meeting at which the Company's stockholders approved, among other proposals, an increase in the number of authorized shares of common stock from 38,500,000 to 77,000,000 and approval of the issuance of common stock upon conversion of the Series 4 Preferred Stock pursuant to the NASDAQ Listing Rules. The outstanding shares of Series 4 Preferred Stock automatically converted into shares of the Company's common stock effective July 31, 2017. In addition, the Stock Appreciation Rights and Restricted Stock Units described in Note 7 have been reclassified to the equity section of the balance sheet, as the Company now has available authorized shares to settle these awards.

Each of Harry Fisch, M.D., Karen Fisch, K&H Fisch Family Partners, LLC and Mitchell Steiner, M.D., has entered into an Amended and Restated Lock-Up Agreement (the Lock-Up Agreements) with the Company which generally prohibits each such holder from transferring 75% of the shares of the Company's common stock and Series 4 Preferred Stock the holder is entitled to receive in the APP Acquisition for a period of 18 months following the closing of the APP Acquisition.

The shares of the Company's common stock and Series 4 Preferred Stock that are subject to the Lock-Up Agreements are being held in escrow for a period of one-year following the closing of the APP Acquisition as the sole remedy for APP's indemnification obligations set forth in the Amended Merger Agreement pursuant to the terms of an Escrow Agreement. Seventy-five percent of the shares held in escrow are eligible for release from escrow six months after the closing of the APP Acquisition, although any shares released from escrow will remain subject to the Lock-Up Agreements until the end of their term.

In connection with the APP Acquisition, the Company entered into a Registration Rights Agreement (the RRA) with the former APP stockholders granting them certain "Demand" and "Piggyback" registration rights for a period of up to 5 years. The Company will pay for the expenses of registration and related costs but not the selling expenses related thereto. The Company is only required to use its best efforts and in the event the registration does not occur, the Company is not required to pay any compensation to the former APP stockholders. The Company has evaluated the RAA under ASC 825-20, Registration Payment Arrangements, and determined accounting recognition is not required.

A summary of the total purchase consideration on October 31, 2016 is as follows:

Common stock	$	1,826,097
Series 4 Preferred Stock		17,981,883
Total purchase consideration	$	19,807,980

The total purchase price of approximately $19,807,980 is based on the issuance to the APP stockholders of a total of 2,000,000 shares of the Company's common stock and 546,756 shares of Series 4 Preferred Stock. The common stock issued was valued based on the share price of the Company's common stock on October 31, 2016 less an 8 percent discount on the shares subject to the Lock-Up Agreements, due to the lack of liquidity since the shares are not freely tradeable for a set time period. The Series 4 Preferred Stock were valued using an as-converted basis based on the share price of the Company's common stock on October 31, 2016 less a 12 percent discount on approximately 49 percent of the preferred shares that are subject to an 18 month lockup agreement and a 6 percent discount on the remaining preferred shares. The discount is applied since the preferred shares are not registered and inherently difficult to sell prior to the conversion to common stock. The valuation of the Series 4 Preferred Stock also applied a 95 percent probability that the preferred stock would convert to common stock rather than be redeemed, which was assigned a 5 percent probability. After giving effect to the conversion of the Series 4 Preferred Stock to common stock, the Company issued a total of 23,870,240 shares of the Company's common stock to the former APP stockholders, constituting approximately 45 percent of the outstanding shares of the Company's common stock as of October 31, 2016.

The value of the Series 4 Preferred Stock was initially classified on the Mezzanine section of the balance sheet because the potential conversion to common stock was considered substantive and, as long as the conversion feature exists, the Series 4 Preferred Stock is not considered mandatorily redeemable. Also, since the increase in authorized shares required to convert the Series 4 Preferred Stock to common stock is outside the control of the Company and, therefore, the settlement for cash is outside the control of the Company, the Series 4 was classified as temporary equity outside of the permanent equity section in the mezzanine section between liabilities and permanent equity until sufficient common stock is authorized or until the expiration of the maturity date.

Upon issuance on October 31, 2016, the value of the Series 4 Preferred Stock, on a per share basis, was less than the fair value of the Company's common stock into which it would be converted, thus creating a beneficial conversion feature.

The contingent beneficial conversion feature was measured upon issuance, but was not recognized until the contingency was resolved. In this case, the conversion of the Series 4 Preferred Stock was based on the Company obtaining shareholder approval for the authorization of the additional shares of common stock. On July 28, 2017, the Company obtained shareholder approval for the increase in authorized common stock and the Series 4 automatically converted to common stock. As such, $2.0 million was recognized as a dividend to the Series 4 Preferred Stock.

The results of operations and the estimated fair values of the acquired assets and liabilities assumed have been included in the accompanying consolidated financial statements since the acquisition date.

The Company incurred $935,781 in acquisition-related costs which were recorded within operating expenses for the fiscal year ended September 30, 2017, compared to $1,482,539 for the fiscal year ended September 30, 2016.

The following table summarizes the fair value of assets acquired and liabilities assumed on October 31, 2016:

Recognized amounts of identifiable assets acquired:		
Cash	$	43,118
Accounts receivable		6,975
Inventory		141,041
Prepaid expenses and other		339
Equipment, furniture, and fixtures		1,290
Intangible assets:		
In-process research and development		18,000,000
Developed technology - PREBOOST®		2,400,000
Covenants not-to-compete		500,000
Total intangible assets		20,900,000
		21,092,763
Recognized amounts of identifiable liabilities assumed:		
Accounts payable		(1,087,212)
Accrued expenses		(276,503)
Deferred tax liabilities		(6,800,000)
		(8,163,715)
Total identifiable net assets acquired		12,929,048
Goodwill		6,878,932
	$	19,807,980

APP has a developed technology in PREBOOST®. In-process research and development represents incomplete research and development projects at APP. The fair value of the developed technology and in-process research and development were determined using the income approach, which was prepared based on forecasts by management.

Purchase price in excess of assets acquired and liabilities assumed is recorded as goodwill. Goodwill from the APP acquisition principally relates to intangible assets that do not qualify for separate recognition (for instance, APP's assembled workforce), 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 & Development reporting segment.

The weighted average amortization periods for intangible assets recognized in the APP acquisition are 10 years for the developed technology, 7 years for covenants not-to-compete. Our IPR&D assets will not be amortized until the underlying development programs are completed. Upon obtaining regulatory approval, the IPR&D assets are then accounted for as finite-lived intangible assets and amortized on a straight-line basis over its estimated useful life.

Net loss in the Consolidated Statement of Operations for the year ended September 30, 2017 includes expense from APP from the date of acquisition to September 30, 2017 of $3.2 million. Revenues from APP were not material to our financial results.

Pro Forma Financial Information

The amounts of pro forma, unaudited net revenues and net (loss) income of the combined entity had the acquisition date been October 1, 2015 are as follows:

	For the years ended September 30,			
		2017		2016
Net revenues	$	13,657,572	$	22,145,875
Net (loss) attributable to common shareholders	$	(8,777,818)	$	(2,363,251)
Net (loss) per basic and diluted common share outstanding	$	(0.25)	$	(0.08)

The unaudited pro forma financial information is presented for information purposes only. The unaudited pro forma financial information may not necessarily reflect our future results of operations or what the results of operations would have been had we owned and operated APP as of the beginning of the period presented.

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 11 for additional detail.

Note 3. Inventory

The components of inventory consist of the following at September 30, 2017 and 2016:

	2017	2016
FC2		
Raw material	$ 530,384	$ 670,802
Work in process	90,164	—
Finished goods	2,427,386	1,834,958
Inventory, gross	3,047,934	2,505,760
Less: inventory reserves	(312,997)	(13,116)
FC2, net	$ 2,734,937	$ 2,492,644
PREBOOST®		
Finished goods	32,987	—
Inventory, net	$ 2,767,924	$ 2,492,644

The change in the inventory reserve for the years ended September 30 is as follows:

Year	Balance at October 1	Charged to Costs and Expenses	Write-offs	Balance at September 30
2015	$ 60,873	$ 173,634	$ (194,755)	$ 39,752
2016	$ 39,752	$ (8,630)	$ (18,006)	$ 13,116
2017	$ 13,116	$ 345,179	$ (45,298)	$ 312,997

Note 4. 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 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 year 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.

Income before income taxes was taxed by the following jurisdictions for the years ended September 30, 2017, 2016, and 2015:

	2017	2016	2015
Domestic	$ (7,833,649)	$ 1,068,580	$ 4,524,499
Foreign	(768,841)	1,745,336	2,162,541
Total	$ (8,602,490)	$ 2,813,916	$ 6,687,040

A reconciliation of income tax expense and the amount computed by applying the statutory Federal income tax rate to income before income taxes for the years ended September 30, 2017, 2016, and 2015 is as follows:

	2017	2016	2015
Income tax (benefit) expense at statutory rates	$ (2,925,000)	$ 957,000	$ 2,274,000
State income tax (benefit) expense, net of federal benefits	(538,000)	149,000	362,000
Non-deductible expenses - other	27,000	50,000	51,000
Non-deductible business acquisition expenses	188,000	556,000	—
Effect of lower foreign income tax rates	216,651	(305,648)	(351,244)
Effect of change in U.K. tax rate	615,000	1,251,000	—
Effect of deemed dividend - Malaysia	405,646	—	—
Correction of prior year dividend tax rate	440,100	—	—
Effect of export allowance - Malaysia	—	—	(85,000)
Effect of change in Illinois tax rate	(215,000)	—	202,000
Effect of conversion of charitable contribution to NOL	—	—	(36,174)
Other	(49,555)	87,839	(59,578)
Change in valuation allowance	(155,285)	(276,000)	(16,000)
Income tax (benefit) expense	$ (1,990,443)	$ 2,469,191	$ 2,341,004

As of September 30, 2017, the Company had 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 September 30, 2017, which can be carried forward indefinitely to be used to offset future U.K. taxable income.

The federal and state income tax (benefit) expense for the years ended September 30, 2017, 2016, and 2015 is summarized below:

	2017	2016	2015
Deferred – U.S.	$ (2,369,000)	$ 881,000	$ 1,856,000
Deferred – U.K.	224,000	1,162,000	162,000
Deferred – Malaysia	(110,069)	11,817	(92,261)
Subtotal	(2,255,069)	2,054,817	1,925,739
Current – U.S.	1,000	104,000	83,606
Current – Malaysia	263,626	310,374	331,659
Current - U.K.	—	—	—
Subtotal	264,626	414,374	415,265
Income tax (benefit) expense	$ (1,990,443)	$ 2,469,191	$ 2,341,004

Significant components of the Company's deferred tax assets and liabilities are as follows at September 30, 2017 and 2016:

Deferred Tax Assets	**2017**	**2016**
Federal net operating loss carryforwards	$ 4,075,000	$ 2,756,000
State net operating loss carryforwards	963,000	400,000
AMT credit carryforward	533,000	489,000
Foreign net operating loss carryforwards - U.K.	10,578,000	10,955,000
Foreign capital allowance - U.K.	108,000	112,000
UK bad debts	2,000	—
Other, net - Malaysia	—	9,850
Restricted stock - U.K.	1,000	1,000
US unearned revenue	409,000	—
US deferred rent	76,000	—
Share-based compensation	447,000	101,000
Foreign tax credits	1,797,000	942,000
Other, net - U.S.	82,000	25,000
Gross deferred tax assets	19,071,000	15,790,850
Valuation allowance for deferred tax assets	(2,144,000)	(2,299,000)
Net deferred tax assets	16,927,000	13,491,850
Deferred Tax Liabilities:		
Foreign capital allowance - Malaysia	—	(119,919)
In process R&D	(7,000,000)	—
Developed technology	(900,000)	—
Covenant not-to-compete	(200,000)	—
Net deferred tax assets	$ 8,827,000	$ 13,371,931

The deferred tax amounts have been classified in the accompanying consolidated balance sheets at September 30 as follows:

	2017	**2016**
Long-term assets – U.S.	282,000	4,713,000
Long-term assets – U.K	8,545,000	8,769,000
Total long-term assets	8,827,000	13,482,000
Long-term liability – Malaysia	—	(110,069)
	$ 8,827,000	$ 13,371,931

The change in the valuation allowance for deferred tax assets for the years ended September 30 is as follows:

Year	**Balance at October 1**	**Charged to Costs and Expenses**	**Deductions/Other**	**Balance at September 30**
2015	$ 2,591,000	$ (16,000)	$ —	$ 2,575,000
2016	$ 2,575,000	$ (276,000)	$ —	$ 2,299,000
2017	$ 2,299,000	$ (155,000)	$ —	$ 2,144,000

The valuation allowance decreased by $155,000, $276,000, and $16,000 for the years ended September 30, 2017, 2016, and 2015, respectively. Under the Internal Revenue Code, certain ownership changes, including the prior issuance of preferred stock, the public offering of common stock and the exercise of common stock warrants and options may subject the Company to annual limitations on the utilization of its net operating loss carryforward. Under the Inland Revenue statutes, certain triggering events may subject the Company to limitations on the utilization of its net operating loss carryforward in the U.K. As of September 30, 2017, management does not believe any limitations have occurred. As of September 30, 2017, the U.K. has a valuation allowance of $2,144,000.

ASC Topic 740 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. ASC Topic 740 developed a two-step process to evaluate a tax position and also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The Company has not recorded a reserve for any tax positions for which the ultimate deductibility is highly certain but for which there is uncertainty about the timing of such deductibility.

The Company files tax returns in all appropriate jurisdictions, including foreign, U.S. Federal and Illinois and Virginia State tax returns. The following summarizes open tax years in the relevant jurisdictions:

- For the U.S., a tax return may be audited any time within 3 years from filing date. The U.S. open tax years are for fiscal years 2014 through 2016, which expire in years 2018 through 2020, respectively.

- For Malaysia, a tax return may be audited any time within 5 years from filing date (7 months after the fiscal year end). The Malaysia open tax years are for 2012 through 2016, which expire on December 31, 2017 through 2021.

- For the U.K., a tax return may be audited within 1 year from the later of: the filing date or the filing deadline (1 year after the end of the accounting period). The U.K. open tax year is for 2016, which expires in 2018.

The fiscal year 2017 tax returns for each jurisdiction have not been filed as of the date of this filing. As of September 30, 2017 and 2016, the Company has no recorded liability for unrecognized tax benefits.

The Company recognizes interest and penalties related to uncertain tax positions as income tax expense as incurred. No expense for interest and penalties was recognized for the years ended September 30, 2017, 2016, and 2015.

Note 5. Goodwill and Intangible Assets

Goodwill

The gross carrying amount of goodwill is as follows:

Balance at September 30, 2016	$ —
Goodwill arising from APP Merger	6,878,932
Balance at September 30, 2017	$ 6,878,932

Intangible assets

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 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 operating expenses.

Amortization expense was $147,009 for the year ended September 30, 2017. Based on finite-lived intangible assets recorded as of September 30, 2017, the estimated future amortization expense is as follows:

Year Ending September 30,	Estimated Amortization Expense
2018	$ 275,262
2019	309,234
2020	316,369
2021	323,707
2022	331,316
Thereafter	1,197,103
Total	$ 2,752,991

Note 6. Revolving Line of Credit

On December 29, 2015, the Company entered into a Credit Agreement (the Credit Agreement) with BMO Harris Bank N.A. (BMO Harris Bank). The Credit Agreement provides the Company with a revolving line of credit of up to $10 million with a term that extends to December 29, 2017. Borrowings under the Credit Agreement bear interest, at the Company's option, at a base rate or at LIBOR plus 2.25%. The Company is also required to pay a commitment fee at the rate of 0.10% per annum on the average daily unused portion of the revolving line of credit. The Company's obligations under the Credit Agreement are secured by a lien against substantially all of the assets of the Company and a pledge of 65% of the outstanding shares of The Female Health Company Limited and all of the outstanding shares of APP. In addition to other customary representations, covenants and default provisions, the Company is required to maintain a minimum tangible net worth and to not exceed a maximum total leverage ratio. Among the non-financial covenants, the Company is restricted in its ability to pay dividends, buy back shares of its common stock, incur additional debt and make acquisitions above certain amounts.

The completion of the APP Acquisition (see Note 2, APP Acquisition) resulted in a default in the Company's compliance with certain covenants in the Credit Agreement and constituted an "event of default" under the Credit Agreement.

On November 28, 2016, the Company, Badger Acquisition Sub, Inc., wholly owned subsidiary of the Company, APP and BMO Harris Bank entered into a Third Amendment to the Credit Agreement (the Amendment). Pursuant to the Amendment, BMO Harris Bank waived the defaults in the Company's compliance with the covenants in the Credit Agreement as a result of the completion of the APP Acquisition and APP became a co-borrower under the Credit Agreement. As a result, the revolving line of credit remains in effect under the terms of the Credit Agreement until the end of its term on December 29, 2017.

No amounts were outstanding under the Credit Agreement at September 30, 2017 and 2016.

Note 7. Equity and Share-based Payments

In July 2017, the Company's shareholders 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 September 30, 2017, a total of 2,913,305 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 2,533,305 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.

Stock Options

The following table outlines the weighted average assumptions for options granted during the year ended September 30, 2017:

Expected Volatility		43.19%
Expected Dividend Yield		0.00%
Risk-free Interest Rate		1.53%
Expected Term (in years)		7
Fair Value of Options Granted	$	0.64

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

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 stock-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.

Stock Options

The following table summarizes the stock options outstanding and exercisable at September 30, 2017:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2014	180,000	$ 2.60		
Granted	—	—		
Exercised	—	—		
Forfeited	—	—		
Outstanding at September 30, 2015	180,000	$ 2.60		
Granted	17,500	1.82		
Exercised	—	—		
Forfeited	—	—		
Outstanding at September 30, 2016	197,500	$ 2.53		
Granted	2,723,305	1.18		
Exercised	—	—		
Forfeited	(90,000)	1.27		
Outstanding at September 30, 2017	2,830,805	$ 1.27	9.63	$ 4,010,817
Exercisable on September 30, 2017	98,750	$ 3.73	2.25	$ 7,263

No stock options were exercised during the years ended September 30, 2017, September 30, 2016, or 2015. During the year ended September 30, 2017, stock option holders forfeited 90,000 stock options.

The aggregate intrinsic value in the table above is before income taxes, based on the Company's closing stock price of $2.65 on the last day of business for the period ended September 30, 2017. As of September 30, 2017, the Company had unrecognized compensation expense of $1.6 million related to unvested stock options. These expenses will be recognized over approximately 3 years.

Restricted Stock

The Company issues restricted stock to employees, directors and consultants. Such issuances may have vesting periods that range from one to three years. In addition, the Company has issued stock awards to certain employees and directors that provide for future issuance contingent on continued employment or performance of services for periods that range from one to three years.

A summary of the non-vested stock activity for fiscal years 2017, 2016, and 2015 is summarized in the table below:

	Shares	Weighted Average Grant -Date Fair Value	Vesting Period
Total Outstanding September 30, 2014	141,435	$ 7.30	
Stock Granted	293,500	1.70	September 2015 - August 2018
Vested	(92,963)	4.70	
Forfeited	(58,250)	7.36	
Total Outstanding September 30, 2015	283,722	$ 2.31	
Stock Granted	101,250	1.52	September 2016 - January 2019
Vested	(195,002)	2.73	
Forfeited	—	—	
Total Outstanding September 30, 2016	189,970	$ 2.31	
Stock Granted	190,000	0.95	October 2017 - April 2018
Vested	(181,220)	2.31	
Forfeited	—	—	
Total Outstanding September 30, 2017	198,750	$ 0.99	

The Company granted a total of 190,000, 101,250 and 293,500 shares of restricted stock or shares issuable pursuant to promises to issue shares of common stock during the years ended September 30, 2017, 2016, and 2015, respectively. The fair value of the awards granted was approximately $181,000, $153,000 and $499,000 for the years ended September 30, 2017, 2016, and 2015, respectively. 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 or issuance date. There were 26,500, 27,666 and 58,250 shares of restricted stock forfeited or elected to be taken in cash during the years ended September 30, 2017, 2016, and 2015, respectively.

The Company recognized the fair value of the restricted stock or promises to issue shares of common stock that vested during the fiscal year as share-based compensation expense of approximately $209,000, $495,000 and $437,000 for the years ended September 30, 2017, 2016, and 2015, respectively, $0, $29,000 and $23,000 of which was included in accrued expenses at year end related to shares that had not yet been issued at September 30, 2017, 2016, and 2015, respectively. The share-based compensation expense was included in selling, general and administrative expenses for the respective periods. The Company recorded a tax benefit for stock-based compensation expenses of approximately $115,000, $114,000, and $204,000 for the years ended September 30, 2017, 2016, and 2015, respectively. The Company realized the tax benefit for stock-based compensation expenses, for the shares which vested, of approximately $141,000, $190,000 and $0 for the years ended September 30, 2017, 2016, and 2015, respectively. As of September 30, 2017, there was approximately $23,000 of total unrecognized compensation cost related to non-vested restricted stock compensation arrangements granted under the incentive plans. This unrecognized cost will be recognized over the weighted average period of the next 0.50 years.

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 is based on the closing price of the Company's common stock on October 31, 2016 of $0.95. The fair value of the Financial Advisor Warrant of $542,930 was estimated at the date of grant using the Black-Scholes option pricing model assuming expected volatility of 47.2 percent, risk-free interest rate of 1.31 percent, expected life of five years, and no dividend yield. 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 operating expenses for the year ended September 30, 2017.

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 the Company’s common stock if, prior to the vesting date, the Company receives shareholder approval under NASDAQ Rule 5635(c) to increase the number of authorized shares under the 2008 Stock Incentive Plan sufficient to issue such shares or adopt a new plan under which such shares would be issued. With the approval of the 2017 Equity Incentive Plan by shareholders on July 28, 2017, such restricted stock units will be settled in common stock issued under the 2017 Equity Incentive Plan. The restricted stock units were revalued using the Company’s current stock price on July 28, 2017 and reclassified to the equity section of the balance sheet.

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 appreciations rights have a ten-year term and an exercise price per share was $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 the Company's common stock if, prior to the exercise date, the Company receives shareholder approval under NASDAQ Rule 5635(c) to increase the number of authorized shares under the 2008 Stock Incentive Plan sufficient to issue such shares or adopt a new plan under which such shares would be issued. With the approval of the 2017 Equity Incentive Plan by shareholders on July 28, 2017, such stock appreciation rights will be settled in common stock issued under the 2017 Equity Incentive Plan. The stock appreciation rights were measured using the option-pricing model (Black-Scholes) to estimate the fair value on July 28, 2017 and reclassified to the equity section of the balance sheet.

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 authorized. In connection with the completion of the APP Acquisition (see Note 2, APP Acquisition), 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 in fiscal 2017 or 2016. 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 in fiscal 2017 or 2016.

Note 8. Industry Segments and Financial Information about Foreign and Domestic Operations

The Company currently operates in two reportable 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 years ended September 30,		
(In thousands)	**2017**	**2016**	**2015**
Operating (loss) income:			
Commercial	$ 3,144	$ 9,932	$ 13,445
R&D	(3,244)	(89)	(220)
Corporate	(8,394)	(6,824)	(6,607)
	$ (8,494)	$ 3,019	$ 6,618
Revenues:			
Zimbabwe	$ 2,227	$ 3,305	$ 2,696
Mozambique	1,430	—	—
United States	1,288	2,464	2,029
South Africa	951	1,117	2,331
Cameroon	891	—	—
Nigeria	846	—	—
Brazil	—	6,008	14,841
Other	6,022	9,233	10,708
	$ 13,655	$ 22,127	$ 32,605

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

Note 9. Employee Benefit Plan

The Company has a Simple Individual Retirement Account (IRA) plan for its employees. Employees are eligible to participate in the plan if their compensation reaches certain minimum levels and are allowed to contribute up to a maximum of $15,500 annual compensation to the plan. The Company has elected to match 100 percent of employee contributions to the plan up to a maximum of 3 percent of employee compensation for the years ended September 30, 2017, 2016, and 2015. Annual Company contributions were approximately $73,000, $33,000, and $37,000 for the years ended September 30, 2017, 2016, and 2015, respectively.

In March 2014, the Company elected to contribute 3 percent into the personal pension schemes of certain senior U.K. employees. Contributions for the years ended September 30, 2017, 2016, and 2015 were approximately $22,000, $23,000, and $26,000, respectively.

Note 10. Operating Leases and Rental Expense

The Company leases approximately 2,600 square feet of office space located in Miami, Florida. The Company executed the lease for this office space effective October 31, 2016, for a three year term commencing on November 1, 2016 and ending on October 31, 2019. The lease requires escalating monthly payments ranging from $9,240 to $9,994. The Company has two renewal options to extend the term for a period of three years each.

The Company leases approximately 6,600 square feet of office space located in Chicago, Illinois. On May 11, 2016, the Company signed a new lease, effective November 1, 2016, for this office space for a seven year period commencing on November 1, 2016 and ending on October 31, 2023. The lease grants the Company a seven month lease holiday beginning November 1, 2016, a five month lease abatement beginning June 1, 2017, and provides a tenant improvement allowance. The lease requires escalating monthly payments ranging from $5,833 to $9,285, plus real estate taxes, utilities and maintenance expenses from June 1, 2017 to October 31, 2023. Based on the terms of the lease agreement, the Company was required to make a security deposit of $55,000. Effective August 2017, the Company entered into a sublease for its office space in Chicago, Illinois. The Company continues to be responsible for performance under the lease until it expires on October 31, 2023.

The Company leases 6,400 square feet of office space located in London, England. The lease expires in June 2020. The lease requires quarterly payments of approximately $13,500 through December 2011, quarterly payments of approximately $27,000 from January 2012 through June 2015 and quarterly payments of approximately $24,000 from June 2016 through June 2020. Based on the terms of the lease agreement, the Company made a security deposit of $59,000.

The Company leases 45,800 square feet of manufacturing space in Selangor D.E., Malaysia under a lease that requires monthly payments of approximately $15,000 through August 2019 and may be renewed at the option of the Company for an additional three year term.

The Company also leases equipment under a number of lease agreements which expire at various dates through September 2021. Details of operating lease expense, including real estate taxes and insurance, for the years ended September 30, 2017, 2016, and 2015 are as follows:

	2017	2016	2015
Factory and office leases	$ 482,182	$ 455,956	$ 470,049
Other	23,116	15,176	7,387
Total	$ 505,298	$ 471,132	$ 477,436

Future minimum payments under leases consist of the following as of September 30, 2017:

	Operating Leases	Sublease Income	Net Total
2018	$ 518,733	$ 138,044	$ 380,689
2019	524,326	188,837	335,489
2020	201,378	193,753	7,625
2021	113,373	198,668	(85,295)
2022	108,015	203,584	(95,569)
Thereafter	120,430	190,749	(70,319)
Total minimum lease payments	$ 1,586,255	$ 1,113,635	$ 472,620

The minimum lease payments presented above do not include CAM charges or real estate taxes due under the Company's office operating leases. These charges are generally not fixed and can fluctuate from year to year.

Note 11. Contingent Liabilities

The testing, manufacturing and marketing of consumer products by the Company entail an inherent risk that product liability claims will be asserted against the Company. The Company maintains product liability insurance coverage for claims arising from the use of its products. The coverage amount is currently $10 million.

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.

Note 12. Earnings per Share

Basic EPS is computed by dividing net income by the weighted average number of common shares outstanding for the period. Diluted EPS 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 and unvested shares granted to employees and directors.

	Year Ended September 30,		
Denominator	**2017**	**2016**	**2015**
Weighted average common shares outstanding - basic	34,640,308	28,666,477	28,532,327
Net effect of dilutive securities:			
Options	—	11,443	50,473
Unvested restricted shares	—	248,637	334,248
Total net effect of dilutive securities	—	260,080	384,721
Weighted average common shares outstanding - diluted	34,640,308	28,926,557	28,917,048
(Loss) income per common share – basic	$ (0.25)	$ 0.01	$ 0.15
(Loss) income per common share – diluted	$ (0.25)	$ 0.01	$ 0.15

Options to purchase approximately 2.7 million shares of common stock at weighted average exercise prices of $1.30 that were both outstanding for the year ended September 30, 2017 were not included in the computation of diluted net income per share because their effect was anti-dilutive. Options to purchase approximately 90,000 shares of common stock at an exercise price of $3.92 per share that were outstanding for the year ended September 30, 2015 were not included in the computation of diluted net income per share because their effect was anti-dilutive. All other outstanding stock options were included in the computation of diluted net income per share for the years ended September 30, 2017, 2016, and 2015.

Note 13. Quarterly Financial Data (Unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Year Ended
2017					
Net revenues	$ 3,243,599	$ 2,405,519	$ 4,314,068	$ 3,692,406	$ 13,655,592
Gross profit	1,652,284	1,277,655	2,294,914	1,794,659	7,019,512
Operating expenses	3,526,974	3,856,888	3,561,050	4,568,712	15,513,624
Income tax expense (benefit)	(530,069)	(824,033)	(509,713)	(126,628)	(1,990,443)
Net loss attributable to common shareholders before preferred stock dividend	(1,366,181)	(1,776,642)	(789,889)	(2,679,335)	(6,612,047)
Preferred stock dividend	—	—	—	1,990,771	1,990,771
Net loss attributable to common shareholders	(1,366,181)	(1,776,642)	(789,889)	(4,670,106)	(8,602,818)
Net income (loss) per common share – basic	(0.04)	(0.06)	(0.03)	(0.12)	(0.25)
Net income (loss) per common share – diluted	(0.04)	(0.06)	(0.03)	(0.12)	(0.25)
2016					
Net revenues	$ 8,230,659	$ 4,772,801	$ 5,560,776	$ 3,563,106	$ 22,127,342
Gross profit	5,402,337	2,845,395	3,233,193	1,868,559	13,349,484
Operating expenses	3,009,782	2,774,970	2,384,674	2,161,546	10,330,972
Income tax expense (benefit)	829,453	(27,824)	231,211	1,436,351	2,469,191
Net income (loss)	1,490,363	35,045	570,258	(1,750,941)	344,725
Net income (loss) per common share – basic	0.05	—	0.02	(0.06)	—
Net income (loss) per common share – diluted	0.05	—	0.02	(0.06)	—

Note 14. Subsequent Events

On December 22, 2017, the Tax Cuts and Jobs Act (the "Act") was signed into United States tax law and included numerous provisions that will affect businesses. The Act, for instance, introduces changes that impact U.S. corporate tax rates, business-related exclusions, and deductions and credits. The Act will also have international tax consequences for many companies that operate internationally. The Act has widespread applicability and it will impact the carrying value of our U.S. deferred tax assets and liabilities. The Company is currently assessing the impact of the Act and will provide an update in subsequent filings.

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 is classified as a long term trade receivable and $1.1 million as a current account receivable on our Consolidated Balance Sheet as of September 30, 2017. These receivables are net of payables owed to Semina by us totaling $1.4 million, $1.2 million of which is classified as long term liability and $0.2 million classified as current liability on our Consolidated Balance Sheet as of September 30, 2017. 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 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 is a net loss of approximately $3.75 million which will be reflected in our results for the fiscal quarter ending December 31, 2017.

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 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), if needed, one or more registration statements, as permissible and necessary, 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.

CORPORATE INFORMATION

OFFICERS

Mitchell Steiner, M.D., F.A.C.S.
President and
Chief Executive Officer

Brian Groch
Chief Commercial Officer

Robert Getzenberg, Ph.D.
Executive Vice President of
Clinical Development

Kevin Gilbert
Senior Vice President of Corporate
Development and Legal

Matthew Gosnell, Ph.D.
Senior Vice President of Pharmaceutical
Manufacturing, Preclinical and Development

Michele Greco
Executive Vice President of Finance and
Chief Administrative Officer

Martin Tayler
Executive Vice President of
Global Operations

BOARD OF DIRECTORS

Elgar Peerschke
Chairman of the Board
Formerly with QuintilesIMS
Durham, North Carolina

Mitchell S. Steiner, M.D., F.A.C.S.
President and
Chief Executive Officer
Veru Inc.
Miami, Florida

O.B. Parrish
Vice Chairman of the Board
Former Chairman and
Chief Executive Officer
The Female Health Company
Chicago, Illinois

David R. Bethune
Former Executive Chairman
Zila, Inc.
Phoenix, Arizona

Mario Eisenberger, M.D.
Dale Hughes Professor of Oncology
The Johns Hopkins University
Baltimore, Maryland

Harry Fisch, M.D., F.A.C.S.
Chief Corporate Officer
Veru Inc.
New York, New York

Mary Margaret Frank, Ph.D.
Associate Professor
University of Virginia
Darden Graduate School of Business
Charlottesville, Virginia

Lucy Lu, M.D., M.B.A.
Chief Executive Officer
Avenue Therapeutics
Executive Vice President and
Chief Financial Officer
Fortress Biotech, Inc.
New York, New York

Georges Makhoul
Chief Executive Officer
Constellation Holdings, LLC
Dubai, United Arab Emirates

Jesus Socorro
Managing Principal, Risk &
Transaction Advisory Practice
Morrison, Brown, Argiz & Farra
Miami, Florida

BOARD OBSERVER

Andrew Love
Chairman
Love Savings Holding Company
St. Louis, Missouri

ADDITIONAL INFORMATION

Corporate Headquarters
4400 Biscayne Boulevard
Suite 888
Miami, Florida 33137
305-509-6897

U.K. Global Operations
3 Mansfield Road
Western Avenue Business Park
London W3 0BZ
England
011-44-208-993-4669

Manufacturing Facilities
Cheras Jaya, Balakong
Selangor D.E., Malaysia

Web Addresses
www.verupharma.com
www.Fc2.us.com
www.Fc2femalecondom.com

E-mail Address
info@verupharma.com

Transfer Agent and Registrar
Computershare Investor Services
Highlands Ranch, Colorado

Independent Auditors
RSM US LLP
Chicago, Illinois

Stock Exchange Listing
NASDAQ Capital Market, under the trading
symbol "VERU"

Inquiries
Shareholders, prospective investors,
stockbrokers, financial analysts and other
parties seeking additional information about
Veru Inc, (including Securities and Exchange
Commission Form 10-K and Form 10-Q Reports)
should contact Investor Relations at
1-800-972-0538.

Send an e-mail request to:
veruinvestor@verupharma.com

Or write to:
Investor Relations
c/o Kevin Gilbert
Veru Inc.
4400 Biscayne Boulevard
Suite 888
Miami, Florida 33137

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