# veru

2018 ANNUAL REPORT

We had a successful year and are well on our way to transforming our company into a biopharmaceutical company. We have advanced several near-term and mid-term urology products at the same time to have “multiple shots on goal” to file drug approval applications, and to commercialize several drugs in oncology and urology. We have implemented an effective plan that is growing sales for our existing commercial products. We anticipate solid revenue growth from these commercial products.

**DEAR SHAREHOLDERS,** We had a successful year and are well on our way to transforming our company into a biopharmaceutical company. We have advanced several near-term and mid-term urology products at the same time to have “multiple shots on goal” to file drug approval applications, and to commercialize several drugs in oncology and urology. We have implemented an effective plan that is growing sales for our existing commercial products. We anticipate solid revenue growth from these commercial products.

With this strong foundation in place, it is time for our company to further articulate to our shareholders what our business plans and priorities, as this will inform our objectives and our goals for the next year and beyond.

Our strategy is to become known as “the prostate cancer company.” Rather than focusing on one drug class or on one research platform, we aspire to provide a “continuum of care” for prostate cancer patients. This means we expect our drug development and commercial activities to align with the clinical management of prostate cancer patients. Although prostate cancer remains the second most frequent cause of cancer deaths in men, advances in the diagnosis and effective treatments of prostate cancer have resulted in many men living longer, even decades, with the disease. Thus, prostate cancer is becoming a chronic disease with new challenges as the prostate cancer develops resistance to these current drugs and progresses and as the patient suffers from the long-term side effects of these treatments.

Accordingly, advanced prostate cancer care centers are being established across the country and the world, and urologists and medical oncologists are now actively managing all aspects of prostate cancer from monitoring for disease progression and modifying treatments, to promoting prostate cancer supportive care. Prostate cancer supportive care addresses the management of the various acute and chronic side effects of prostate cancer drugs, like bone loss and fractures, hot flashes, loss of libido, erectile dysfunction, loss of muscle strength and frailty.

The markets for prostate cancer treatment and prostate cancer supportive care are well-established as multi-billion-dollar

markets and given our core expertise and the number and type of drugs in our pipeline, we believe we are uniquely positioned to understand, develop, and commercialize medicines for these unmet medical needs of prostate cancer patients.

Veru is developing and commercializing drug products for multiple unmet needs in advanced prostate cancer treatment with VERU-111 and in prostate cancer supportive care with zuclomiphene citrate (VERU-944) for hot flashes caused by androgen deprivation therapy.

With respect to these drug products, VERU-111, a novel, first-in-class, proprietary, next generation oral tubulin inhibitor, has advanced into an open label Phase 1b/2 clinical trial in men whose prostate cancer cannot be effectively treated with androgen blocking agents like abiraterone or enzalutamide. Zuclomiphene citrate is being evaluated in a Phase 2 clinical trial for the treatment of hot flashes caused by androgen deprivation therapy in men with advanced prostate cancer. These novel, proprietary, prostate cancer drug products are now in human clinical trials with clinical data results on efficacy and safety anticipated in the first half of 2019.

Our strategy is to become known as "the prostate cancer company" and to be supported in part by two sources of revenues:

First, we are establishing a specialty pharmaceutical business in urology by developing low cost, near-term pharmaceuticals using an expedited regulatory pathway known as 505(b)(2). The three drug products currently in clinical development that are utilizing this regulatory pathway are tadalafil/finasteride fixed combination tablets and tamsulosin XR capsules and sprinkles. Tamsulosin treats immediate symptoms of benign prostatic hyperplasia, or BPH in men with smaller prostates; whereas Tadalafil/Finasteride combination tablets treat symptoms of BPH and shrink the size of the prostate in men who have enlarged prostates, as well as treating erectile dysfunction.

Second, we anticipate growing revenue from our commercial products: the FC2 Female Condom/FC2 Internal Condom®, and PREBOOST® (4% benzocaine wipes for premature ejaculation). For FC2, The Female Health Company Division has been able to grow public sector sales by winning 75% of the South African tender of approximately 30 million units per year over three years and also has significantly expanded its US business by a strategy that utilizes a contracted independent sales force and by partnering with a leading telemedicine marketing and sales channel. For PREBOOST®, we have a co-promotion and distribution agreement with Timm Medical Technologies, Inc., a specialty urology sales organization, as well as a partnership with a leading men's health telemedicine company that discreetly sells men's health products via the internet and social media.

We have accomplished quite a lot this past year to advance our business strategy. We paid for these activities this past year in part by the revenue produced from our FC2 Female Condom/FC2 Internal Condom® business. We also successfully closed on an equity financing that allowed key pharma and biotech investment institutions to become shareholders in Veru including Perceptive Advisors, LLC, AWM Investment Company, Inc., Aspire Capital, and UBS O'Connor LLC to name a few.

In summary, we are poised to see open label clinical data for VERU-111, the novel, proprietary, first-in-class, oral tubulin inhibitor for refractory metastatic castration resistant prostate cancer, as well as top line clinical results for the Phase 2 clinical trial evaluating zuclomiphene citrate for the treatment of hot flashes caused by androgen deprivation, during the first half of 2019. We are committed to driving shareholder value by becoming "the prostate cancer company" by providing a "continuum of care" for prostate cancer patients.

Sincerely,

Mitchell S. Steiner, MD FACS
Chairman, 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, 2018**

☐ **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 every Interactive Data File required to be submitted 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 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 | ☑ | 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, 2018, was approximately $64.8 million based on the per share closing price as of March 29, 2018 quoted on the NASDAQ Capital Market for the registrant's common stock, which was $1.81.

There were 62,617,813 shares of the registrant's common stock, $0.01 par value per share outstanding at December 10, 2018.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Proxy Statement for the 2019 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.
INDEX

## 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. Forward-looking statements can be identified by the use of forward-looking words or phrases such as "anticipate," "believe," "could," "expect, " "intend," "may," "opportunity," "plan," "predict," "potential," "estimate," "should, " "will," "would" or the negative of these terms or other words of similar meaning. These statements are based upon the Company's current plans and strategies and reflect the Company's current assessment of the risks and uncertainties related to its business, and are made as of the date of this report. These statements are inherently subject to known and unknown risks and uncertainties. You should read these statements carefully because they discuss our future expectations or state other “forward-looking” information. There may be events in the future that we are not able to accurately predict or control and our actual results may differ materially from the expectations we describe in our forward-looking statements. Factors that could cause actual results to differ materially from those currently anticipated include the following:

- potential delays in the timing of and results from clinical trials and studies and the risk that such results will not support marketing approval and commercialization;
- potential delays in the timing of any submission to the U.S. Food and Drug Administration (the “FDA”) and in regulatory approval of products under development;
- risks related to our ability to secure adequate capital on acceptable terms when needed to fund product development and our operations;
- risks related to the development of our product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market;
- product demand and market acceptance;
- some of our products are in early stages of development and we may fail to successfully commercialize such products;
- risks related to intellectual property, including the uncertainty of obtaining intellectual property protections and in enforcing them, the possibility of infringing a third party’s intellectual property, and licensing risks;
- competition from existing and new competitors including the potential for reduced sales, pressure on pricing and increased spending on marketing;
- risks relating to compliance and regulatory matters, including costs and delays resulting from extensive government regulation and reimbursement and coverage under healthcare insurance and regulation;
- risks inherent in doing business on an international level;
- the disruption of production at our manufacturing facilities due to raw material shortages, labor shortages and/or physical damage to our facilities;
- our reliance on major customers and risks related 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;

- a governmental tender award, including our recent South Africa tender award, indicates acceptance of the bidder's price rather than an order or guarantee of the purchase of any minimum number of units, and as a result government ministries or other public sector customers may order and purchase fewer units than the full maximum tender amount;

- our recent South Africa tender award could be subject in the future to reallocation for potential local manufacturing initiatives, which could reduce the size of the award to us;

- our ability to identify, successfully negotiate and complete suitable acquisitions or other strategic initiatives; and

- our ability to successfully integrate acquired businesses, technologies or products.

All forward-looking statements in this report should be considered in the context of the risks and other factors described above and in "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 except as required by applicable law.

PART I

Item 1. Business

**General**

We are an oncology and urology biopharmaceutical company developing novel medicines for prostate cancer and prostate cancer supportive care as well as near term specialty pharmaceuticals to address significant unmet needs in urology.

Our prostate cancer pipeline consists of VERU-944 (zuclomiphene citrate, which is also known as cis-clomiphene) and VERU-111 (bisindole).

We are evaluating zuclomiphene citrate, an estrogen receptor agonist, in a Phase 2 trial to treat hot flashes, a common side effect caused by hormone treatment for men with advanced prostate cancer.

VERU-111 is an oral, next-generation, first-in-class small molecule that targets and binds to the alpha and beta subunits of microtubules in cells. Microtubules are essential for cell division and for shuttling critical growth receptors into the nucleus where they stimulate cell proliferation. We are developing VERU-111 as a treatment for metastatic prostate cancer patients whose disease is resistant to both castration and androgen-blocking agent (abiraterone or enzalutamide) therapies. We expect to enter a Phase 1b/2 clinical trial of VERU-111 for this indication by no later than early January 2019. We will also evaluate VERU-111 for a variety of other malignancies. In June 2018, as part of the American Society of Clinical Oncology (ASCO) Annual Meeting, we reported preclinical results showing the activity of VERU-111 against novel androgen blocking agent-resistant human prostate cancer, and we also reported preclinical data showing VERU-111's anti-tumor activity against paclitaxel sensitive and resistant triple negative breast, ovarian and pancreatic cancers.

In addition to our oncology drug programs, we are advancing four new drug formulations in our specialty pharmaceutical pipeline addressing unmet medical needs in urology. We are evaluating two different formulations of tamsulosin, the active ingredient in FLOMAX®, which we have developed to avoid the "food effect" inherent in currently marketed formulations of this drug. Tamsulosin taken after a meal has different bioavailability and peak concentration characteristics as compared to when it is taken under fasting conditions, and as a result, patients are directed to take the drug 30 to 60 minutes after a meal to avoid declines in blood pressure that could result in dizziness or fainting. We are developing our Tamulosin DRS (Delayed Release Sachet) granules and Tamsulosin XR (Extended Release) capsules to avoid this food effect, allowing for potentially safer administration and improved patient compliance. In addition, Tamsulosin DRS granules may make it easier for the population of men who have difficulty swallowing pills and tablets (dysphagia) to be able to take this medicine instead of wearing diapers, having a urinary catheter, or having to undergo prostate surgery. We expect to submit a new drug application ("NDA") to the FDA for both Tamsulosin DRS and Tamsulosin XR in 2019. Separately, we are developing Tadalafil (CIALIS®) / Finasteride (PROSCAR®) combination tablets for inhibition of both phosphodiesterase type 5 (PDE5) and 5-alpha-reductase to shrink an enlarged prostate and to treat the symptoms of benign prostatic hyperplasia (BPH or enlarged prostate), with the added benefit of medicine to treat erectile dysfunction, with an NDA submission expected in 2019. We believe Tadalafil and Finasteride combination tablets may increase both patient compliance and patient convenience. We are also developing a delayed-release granule (DRG) formulation of Solifenacin, a selective M3 muscarinic receptor antagonist and the active ingredient in the leading drug for overactive bladder, VESIcare®, for patients who have difficulty with swallowing tablets. We expect to submit an NDA to the FDA for Solifenacin DRG in 2019.

In addition to these products under development, we market and sell the PREBOOST® wipe in the men's health market and the FC2 Female Condom® ("FC2") for women. PREBOOST is a medicated individual wipe used for desensitizing male genitalia for the prevention of premature ejaculation. We co-promote the PREBOOST wipe with Timm Medical Technologies, Inc. We market and sell FC2 in the U.S. market by prescription and other sales channels and through our Female Health Company Division in the global public health sector. Our Female Health Company Division markets to entities, including ministries of health, government health agencies, U.N. agencies, nonprofit organizations and commercial partners, that work to support and improve the lives, health and well-being of women around the world. FC2 is the only currently available female-controlled product approved for marketing by the FDA and cleared by the World Health Organization (the "WHO") for purchase by U.N. agencies that provides dual protection against unintended pregnancy and sexually transmitted infections ("STIs").

In October 2016, we completed our acquisition (the "APP Acquisition") of Aspen Park Pharmaceuticals, Inc. ("APP"). The completion of the APP Acquisition transitioned us from a single product company selling only FC2 to a biopharmaceutical company focused on oncology and urology with multiple drug products under clinical development.

**Company History**

Veru is a Wisconsin corporation that 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. In 1996, we completed a series of actions which resulted in our acquisition of worldwide rights to our first-generation female condom, the divestiture of Wisconsin Pharmacal's other businesses and the change of our name to "The Female Health Company." On October 31, 2016, we completed the APP Acquisition, which transitioned us from a single product company selling FC2 to a biopharmaceutical company with multiple drug products under development for urology and oncology. On July 31, 2017, we changed our corporate name from "The Female Health Company" to "Veru Inc." reflecting our focus on biopharmaceutical products for oncology and urology.

**Strategy**

Our strategy is to develop a pipeline of novel prostate cancer and prostate cancer supportive care medicines as well as urology focused specialty pharmaceuticals while continuing to sell our commercial products to help fund part of this development. We intend to execute this strategy by leveraging the 505(b)(2) FDA regulatory pathway for our urology products in order to create nearer-term revenue to support the development of longer-term novel prostate cancer and prostate cancer supportive care medicines. The key elements of our strategy are as follows:

- **Develop and launch high value novel products for prostate cancer and prostate cancer supportive care.** We are developing two drugs, zuclomiphene citrate and VERU-111, each of which addresses large potential markets relating to prostate cancer and prostate cancer supportive care. We began a Phase 2 trial in the third quarter of 2018 using zuclomiphene citrate for the treatment of hot flashes caused by hormone cancer therapy for men with advanced prostate cancer, with results expected in mid-2019. Androgen deprivation therapy-induced hot flashes affect approximately 600,000 men in the U.S., representing an estimated market of $600 million annually. We also expect to start a Phase 1b/2 open label clinical trial of VERU-111 in treatment-resistant metastatic prostate cancer patients by no later than early January 2019, with clinical data results expected in the first half of 2019. The potential U.S. market for therapies in advanced prostate cancer is over $5 billion.

- **Advance near-term specialty pharmaceutical urology drugs that require only bioequivalence studies by taking advantage of information obtained in previous safety and efficacy studies conducted by other parties.** We are advancing four new urology drug formulations in our specialty pharmaceutical pipeline, consisting of Tamsulosin DRS granules, Tamsulosin XR capsules, Tadalafil/Finasteride combination tablets and Solifenacin DRG granules. Each of these drugs leverage the 505(b)(2) FDA regulatory pathway to provide the potential for nearer-term revenue as compared to our oncology product candidates.

- **Grow our commercial products business.** For FC2, we are focused on growing revenues in the U.S. market through prescription sales and by leveraging our relationships with external sales force groups, distributors and telemedicine providers, while continuing to pursue revenues in the public sector principally outside of the U.S. through tenders in key markets, including our recent tender award in South Africa. We are also focused on growing sales of PREBOOST® in the U.S. through our partner Timm Medical Technologies, Inc.

- **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 facilitate effective management of our 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 our 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 |
|---|---|---|---|
| **Oncology Drug Candidates** | | | |
| VERU-944 (zuclomiphene citrate) | Hot flashes in men on prostate cancer hormonal therapies | 505(b)(2) | Phase 2 |
| VERU-111 (bisindole) – oral, next generation, first-in-class alpha and beta tubulin inhibitor | Metastatic prostate, breast, ovarian and pancreatic cancers | 505(b)(1) | Phase 1b/2 |
| **Urology Specialty Drug Candidates** | | | |
| Tamsulosin Delayed Release Sachet (DRS) (tamsulosin HCl 0.4mg for extended-release oral suspension) | Benign prostatic hyperplasia | 505(b)(2) | Bioequivalence study |
| Tamsulosin XR capsules (tamsulosin HCL 0.4mg extended release capsules) | Benign prostatic hyperplasia | 505(b)(2) | Bioequivalence study |
| Tadalafil/Finasteride combination tablets (tadalafil 5mg/ finasteride 5mg) | Initial treatment of men with lower urinary tract symptoms from an enlarged prostate | 505(b)(2) | Bioequivalence study |
| Solifenacin Delayed Release Granules (DRG) | Overactive bladder | 505(b)(2) | Bioequivalence study |
| **Commercial Products** | | | |
| FC2 Female Condom® | Unintended pregnancy and STIs | FDA approved | Marketed |
| PREBOOST® (4% benzocaine wipes) | Premature ejaculation | FDA monograph compliant | Marketed |

***VERU 944 (zuclomiphene 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 one of the most common and debilitating side effects of prostate cancer hormonal therapies. Hormone therapies include androgen deprivation therapy, 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 with 30-40% having 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 often occur repeatedly and generally 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, off label estrogen treatment is complicated by lack of consistent dosing, 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, consequently, CLOMID® (clomiphene citrate) and generics cannot substitute for zuclomiphene citrate as they will actually exacerbate hot flashes. VERU-944 contains only zuclomiphene as the active ingredient. Zuclomiphene is a nonsteroidal estrogen receptor agonist. We believe that a nonsteroidal hormone therapy like zuclomiphene citrate has the potential to be an efficacious and well tolerated treatment for hot flashes caused by prostate cancer hormonal therapies in men with advanced prostate cancer.

***Development Plan.*** In June 2018, the Company submitted an Investigational New Drug application ("IND") with the FDA for zuclomiphene citrate. In September 2018, the Company advanced zuclomiphene citrate directly to a Phase 2 clinical study and enrolled its first patient. The double-blind, placebo-controlled, dose-finding study is designed to evaluate the safety and efficacy of daily oral zuclomiphene citrate in patients with moderate to severe hot flashes caused by androgen deprivation therapy for advanced prostate cancer. The study, conducted at multiple U.S. sites, is designed to enroll approximately 120 patients randomized to one of four treatment arms (zuclomiphene 10 mg, 50 mg, 100 mg, or placebo). The primary endpoint of the study is the mean change in frequency of hot flashes relative to baseline at week 4 and maintained to week 12. The Company expects to report top-line results from this Phase 2 study in the first half of 2019.

***Market.*** Hot flashes are the most common side effect of prostate cancer hormone therapy, with hot flashes occurring in approximately 80% of men receiving one of the common forms of androgen deprivation therapy, including LUPRON® (Leuprolide), ELIGARD® (Leuprolide), and FIRMAGON® (degarelix) and about up to 40% having moderate to severe hot flashes. Approximately 600,000 men annually in the United States are on androgen deprivation therapy 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-111, an oral, next generation, first-in-class small molecule for the treatment of metastatic prostate 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 cancer 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 chemotherapies 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 (neutropenia) and neurotoxicity such as peripheral neuropathy and muscle weakness.

VERU-111 is an oral, next generation, first-in-class small molecule that targets and binds to the alpha and beta subunits of microtubules in cells. Microtubules are essential for cell division and for shuttling critical growth receptors into the nucleus where they stimulate cell proliferation. 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 high activity against many tumor types including prostate cancer resistant to drugs like novel androgen blocking agents (abiraterone and enzalutamide) and taxanes as well as triple negative breast cancer, ovarian cancer and pancreatic cancer. In preclinical studies, VERU-111 appears to have less neurotoxicity and neutropenia 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 is castration resistant and who have also failed to respond to ZYTIGA® (abiraterone) or XTANDI® (enzalutamide). In September 2018, the Company completed a pre-IND meeting with the FDA for VERU-111 in which the FDA agreed with the Company's plans for a Phase 1b/2 clinical trial and that an IND may be submitted for the indication of men who have metastatic castration resistant prostate cancer and who have become resistant to become resistant to, or who have failed to respond to, ZYTIGA® (abiraterone) or XTANDI® (enzalutamide). The Company anticipates submitting an IND and initiating an open label Phase 1b/2 clinical trial in early January 2019. An open label study means that every patient will receive VERU-111 and so the Company expects to have an early assessment of safety and efficacy of VERU-111 by the early part of 2019. The Company plans to work closely with Johns Hopkins University and other highly regarded clinical sites to conduct this study.

***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 cross-resistance and do not appear to provide additional benefit when given in sequence for the treatment of metastatic prostate cancer. VERU-111, as an oral therapy targeting alpha and beta tubulin, could be used prior to IV given docetaxel and cabazitaxel antitubulin chemotherapies. VERU-111 could also be developed as 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 1st line metastatic indication in men who initially were treated with androgen deprivation therapy and a novel androgen blocking agent (enzalutamide or apalutamide) for nonmetatstatic castration prostate cancer that has now progressed to metastatic prostate cancer. Finally, VERU-111 could also be developed as an oral dosing alternative to chemotherapies for the treatment of metastatic breast, ovarian and pancreatic cancers as these tumors also respond to IV taxane chemotherapies.

***Tamsulosin DRS granules (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 (Delayed Release Sachet) granules and Tamsulosin XR (Extended Release) capsules are new slow release formulations 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 alpha1 adrenergic receptor blocking drug that is specific for the alpha1 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 alpha1 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. 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). The Company is developing its Tamulosin DRS granules and Tamsulosin XR capsules to avoid this food effect, allowing for potentially safer administration and improved patient compliance. In addition, both Tamsulosin DRS and Tamsulosin XR have granule formulations, as opposed to being a pill or a tablet, which may make it easier for the population of men who have difficulty swallowing pills and tablets (dysphagia) to take their medicine, increasing patient compliance. 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, urinary catheters, or prostate surgery.

***Development Plan***. Tamsulosin DRS granules and Tamsulosin XR capsules contain 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®. On August 12, 2016, the FDA agreed that the Company's Tamsulosin DRS medication qualifies for the expedited 505(b)(2) regulatory approval pathway. In March 2017, the Company initiated a 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 patients with Tamsulosin DRS while fasted and Tamsulosin DRS while fed successfully showed bioequivalence with FLOMAX® fed patients 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 during the first quarter of calendar 2019. 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 plans to submit an NDA for Tamsulosin DRS in 2019.

Market. The initial commercialization plan for Tamsulosin DRS granules and Tamsulosin XR capsules is to target urology and primary care physicians with an oral branded product with no food effect for men. The Company may also 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, Tamsulosin DRS and Tamsulosin XR would be the only oral suspension formulation that would be available on formularies in long term care pharmacies. The U.S. market for all alpha blockers for BPH is now estimated to be $386 million annually per IQVIA. 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 granules and Tamsulosin XR capsules, if approved, will be new specialty, not generic products.

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

***Scientific Overview.*** Tadalafil/Finasteride combination tablet 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 Pre-IND meeting, the FDA confirmed that Tadalafil/Finasteride combination tablets qualify for a 505(b)(2) regulatory pathway. The 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 tablets for the initial treatment of lower urinary tract symptoms in men with enlarged prostates. The Company plans to complete the Tadalafil/Finasteride combination tablet 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. Co-administration of CIALIS® and PROSCAR® is currently FDA approved for the initial treatment of symptoms of BPH for 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 tablet is not currently available. A combination tablet 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 U.S. The Company would seek pharmaceutical partnerships in territories outside the U.S.

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

***Scientific Overview***. Solifenacin DRG is a new proprietary granule formulation containing the active pharmaceutical ingredient in VESIcare® (Solifenacin 5mg or 10 mg tablets). Solifenacin is a competitive selective M3 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 a November 2017 Pre-IND meeting, the FDA confirmed that Solifenacin DRG qualifies for a 505(b)(2) regulatory pathway. The 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 and file the NDA in 2019.

***Market***. Solifenacin DRG (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, or difficulty swallowing pills or capsules. In the U.S., the prevalence of OAB was similar in women and men, at 16.9% and 16%, respectively. According to the U.S. 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 M3 muscarinic receptor antagonists, including solifenacin, are only available as tablets. According to the FDA label, tablets should be swallowed whole and not chewed, crushed or broken. Currently, Solifenacin DRG granules formulation is not currently available, and if approved, would be the only granules 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.

***FC2 for dual protection against unintended pregnancy and STIs.***

***Product***. FC2 is the only currently available female-controlled product approved for marketing by the FDA and cleared by the WHO for purchase by U.N. agencies that provides dual protection against unintended pregnancy and STIs. The Centers for Disease Control and Prevention has referenced the use of condoms, including the female condom, as a means to reduce the risk of transmitting STIs, including HIV/AIDS, and the transmission of Zika by sex. FC2 was approved for market by the FDA as a Class III medical device in 2009 and is now classified as a Class II medical device, but still requires special testing controls for FDA approval.

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 before sex, 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% to 20% 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 approved for single-use to prevent pregnancy and the transfer of STIs.

***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 global public health sector, various organizations supply critical products such as FC2, at no cost or low cost, to those who need but cannot afford to buy such products for themselves.

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), the Brazil Ministry of Health either through UNFPA or Semina Indústria e Comércio Ltda (Semina), the Company's distributor in Brazil, and the Republic of South Africa health authorities that purchase through the Company's various local distributors. DKT, a new distributor for FC2, is one of the world's largest providers of family planning and HIV/AIDS prevention products and services with offices in 24 countries. DKT has started registration processes to distribute FC2 in several countries this year to expand market access. These DKT countries include Afghanistan, Argentina, Bolivia, Chile, Colombia, Dominican Republic, Ecuador, El Salvador, Ethiopia, Ghana, Guatemala, Mexico, Nicaragua, Pakistan, Panama, Paraguay, Peru, Uruguay and Venezuela. Other customers in the global public health sector 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 the U.S. and 149 other 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% 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.

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

***U.S. Market***. We are pursuing opportunities to grow the market for FC2 in the U.S. as the only FDA approved female use product that protects against the transmission of STIs and unwanted pregnancies. FC2 is currently reimbursable by prescription under the Patient Protection and Affordable Care Act (the "ACA") and growth of prescription sales in the U.S. is a key part of our strategy for FC2. 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. We have built the necessary infrastructure to allow for broad access across the U.S. 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. We have also contracted with an external sales organization to promote FC2 in the U.S.

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

***Product***. Premature ejaculation (PE) 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.

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.

***Market.*** PREBOOST® is approved in the United States. 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***. FC2 was approved for market by the FDA, via a Premarket Approval Application (PMA), as a Class III medical device in 2009. On September 21, 2018, the FDA issued a final order reclassifying female condoms from Class III to Class II medical devices, renaming them "single-use internal condoms" and requiring new devices in this category to submit a 510(k) premarket notification and comply with various "special controls." Special controls are a battery of product clinical testing which includes, but is not limited to, determining product effectiveness against pregnancy and against infection transmission, and product tolerability. Companies seeking clearance of new single-use internal condoms may now do so by demonstrating to the FDA in a 510(k) submission that a proposed condom is substantially equivalent to FC2 with respect to intended use and technology.

All marketed devices cleared or approved by the FDA are subject to continuing regulation by the FDA. As a result, we are required to register our manufacturing establishments with the FDA and list FC2 with the FDA as a commercially distributed device. We must comply with the FDA's Quality System Regulation (QSR), which requires that devices be manufactured and records be maintained in a prescribed manner with respect to manufacturing, testing, and control activities. We must comply with the Medical Device Reporting (MDR) regulation requires that we provide information to the FDA whenever evidence reasonably suggests that one of our FC2 devices may have caused or contributed to a death or serious injury, or where a malfunction has occurred that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Further, we are required to comply with FDA requirements for labeling, promotion and advertising. Any future modifications to the design, technology or labeling of FC2 that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, require a new 510(k) clearance. Non-compliance with any of these requirements can result in, among other things, fines, injunctions, civil penalties, recalls, total or partial suspension of production, and criminal prosecution.

Because FC2 is a commercially distributed medical device, the facilities in which FC2 is manufactured and tested are subject to periodic FDA inspection to ensure compliance with regulatory requirements, including the QSR and MDR regulations. The Company's most recent FDA inspection of its U.K. and Malaysian facilities was completed in September 2010. The Company's previous office in Chicago was inspected by the FDA in October 2016 for activities related to being a registered agent and the FDA made observations at this inspection that the FDA expects us to have addressed by the next regularly scheduled inspection.

***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 current Good Manufacturing Practices (cGMP) and current 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, Solifenacin DRG, Tadalafil/Finasteride and zuclomiphene citrate 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 have been through Phase 1 studies. On August 12, 2016, the 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 Bone, Reproductive and Urologic Drugs (BRUD) FDA Advisory Committee, we considered plans to file an IND and possibly initiate a Phase 2 clinical study for zuclomiphene citrate. On May 24, 2017, the FDA agreed with plans to enter the Phase 2 dose finding clinical trial to evaluate zuclomiphene citrate for the treatment of hot flashes in men on androgen deprivation therapy. In November 2017, the FDA agreed in Pre-IND meetings that Solifenacin DRG and Tadalafil/Finasteride combination tablets qualify for the 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 the 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 for Pharmaceutical Products.*** Any pharmaceutical 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 ACA 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. Outside the U.S., we are impacted by the privacy and data security requirements at the international, national and regional level, and on an industry specific basis. Legal requirements in the countries in which we do business relating to the collection, storage, handling and transfer of personal data and potentially intellectual property continue to evolve with increasingly strict enforcement regimes. More privacy and security laws and regulations are being adopted, and more are being enforced, with potential for significant financial penalties. In the E.U., the General Data Protection Regulation (GDPR) took effect in May 2018 and imposes increasingly stringent data protection and privacy rules.

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.

***Anti-Corruption Laws.*** 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. Other countries where the Company conducts business have similar anti-corruption laws, including the United Kingdom's Bribery Act.

***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 10, 2018, we owned or held exclusive rights to twelve issued U.S. patents, nine 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 granules that is subject to deferred payment obligations and patents and patent applications relating to our VERU-111 drug candidate that we license from a third party. The foreign issued patent and patent applications are in a number of jurisdictions, including Australia, Canada, China, Europe, Hong Kong, India, Israel, Japan, Korea, Mexico, Russia, and Ukraine. 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.

***Tamsulosin DRS granules, Tamsulosin XR capsules, and Solifenacin DRG granules Patent Applications***. We own two patent applications with respect to Tamsulosin DRS granules, Tamsulosin XR capsules, and Solifenacin DRG granules: (1) an international patent application (would expire on May 2037) and (2) a 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 granules, Tamsulosin XR capsule and Solifenacin DRG granules 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 granules, Tamsulosin XR capsules and Solifenacin DRG granules.

***Zuclomiphene Citrate Patent and Patent Applications.*** We have one issued U.S. patent and ten patent applications in countries outside the United States related to substantially pure zuclomiphene for the treatment of osteoporosis, bone fractures, loss of bone mineral density and hot flashes, especially in men on prostate cancer hormone therapies. The U.S. patent and any patents issuing from the foreign patent applications would expire in July 2035.

***VERU-111 License.*** We hold an exclusive license to seven issued U.S. patents, five pending U.S. patent applications and 50 patents and patent applications in countries outside the United States, including issued patents in the EU and Japan, relating to our VERU-111 drug candidate. 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. The patents relating to VERU-111 have statutory expiration dates from 2029 to 2030. Patent term adjustments or patent term extensions could result in later expiration dates with a maximum five-year patent term extension expected because of clinical development and FDA review time.

***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.

The term of an individual patent depends upon the legal term for patents in the country in which such patent is obtained. In most countries, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office (the "USPTO") in examining and granting a patent or may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a patent that covers a drug or biological product may also be eligible for patent term extension when FDA approval is granted, provided statutory and regulatory requirements are met. In the future, if and when our product candidates receive approval by the FDA or foreign regulatory authorities, we expect to apply for patent term extensions on issued patents covering those products, depending upon the length of the clinical trials for each medicine and other factors. There can be no assurance that any of our pending patent applications will issue or that we will benefit from any patent term extension or favorable adjustment to the term of any of our patents.

As with other biopharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property positions for our product candidates will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, certain patent applications that we have filed or may file, or that we have licensed or may license from third parties, may not result in the issuance of corresponding patents. We also cannot predict the breadth of claims that may be allowed or enforced in our patents. Any issued patents that we may receive in the future may be challenged, invalidated or circumvented. For example, we cannot be certain of the priority of inventions covered by pending third-party patent applications. If third parties prepare and file patent

applications in the United States that also claim intellectual property to which we have rights, we may have to participate in proceedings in the USPTO to determine invention rights, which could result in substantial costs to us, even if the eventual outcome is favorable to us. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate we may develop, it is possible that any related patent may remain in force for a short period following commercialization, thereby reducing any advantage of any such patent.

In addition to patents, we rely upon unpatented trade secrets and know-how and continuing innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, by using confidentiality agreements with any future collaborators, scientific advisors, employees and consultants and by using invention assignment agreements with our employees. We also have agreements requiring assignment of inventions with selected consultants, scientific advisors and collaborators. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements or clauses requiring invention assignment, to grant us ownership of intellectual property that is developed through a relationship with a third party.

**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 2018 were UNFPA, Barrs Medical (PTY) Ltd and USAID. UNFPA accounted for 32% of unit sales in fiscal 2018 and 25% of unit sales in fiscal 2017. Barrs Medical (PTY) Ltd accounted for 24% of unit sales in fiscal 2018. USAID accounted for 23% of unit sales in fiscal 2018 and 44% of unit sales in fiscal 2017. No other single customer accounted for more than 10% of unit sales in fiscal 2018 or 2017. The Company considers its most significant customers to be UNFPA, Barrs Medical (PTY) Ltd and USAID.

**Employees**

As of November 30, 2018, the Company had 171 full-time employees, including 19 located in the U.S., 11 in the U.K., 138 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 2018 or 2017, 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 manufactures and warehouses FC2 within a leased facility with approximately 45,800 square feet of space in Selangor D.E., Malaysia. Production capacity at this facility is approximately 100 million units of FC2 annually. This facility is subject to periodic inspection by the FDA to ensure compliance with current Good

Manufacturing Processes, as well as the U.K.-based notified body, which is responsible for CE and ISO accreditation.

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). It is possible that other female condoms may complete the WHO prequalification process. 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. The FDA's recent reclassification of female condoms from Class III medical devices to Class II medical devices may reduce the barriers for other types of female condoms to enter the U.S. market. If other female condoms enter the U.S. market, we may face increased competition in the U.S., which may put downward pressure on pricing for FC2 and adversely affect sales of FC2 in the U.S.

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. Boehringer Ingelheim has a tablet (non-powder) version of FLOMAX® called FLOMAX® CR now available in Canada that can be taken with or without food. Similarly there is a tablet Tamsulosin product available in the UK called Cositam XL 400 microgram that can be taken independently of food.

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

steroidal estrogens and selective serotonin reuptake inhibitor antidepressants including EFFEXOR® (venlafaxine) and anticonvulsants like NEURONTIN® (gabapentin) which could be competitive with our zuclomiphene citrate 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 expected to be 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.

**Backlog**

Unfilled product orders for FC2 at November 30, 2018 and 2017 totaled $2.9 million and $1.4 million, respectively. Unfilled orders materially fluctuate from quarter-to-quarter, and the amount at November 30, 2018 includes orders with requested delivery dates later in fiscal 2019. The Company expects current unfilled orders for FC2 to be filled during fiscal 2019.

**Available Information**

The Company maintains a corporate website for investors at https://verupharma.com/investors/ 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. 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 zuclomiphene citrate and VERU-111 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 zuclomiphene citrate or VERU-111 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 our zuclomiphene citrate or VERU-111 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 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 political environment 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 that have been discussed or implemented which could have a material impact on us include, but are not limited to, potential changes to the ACA, recently issued regulations offering employers religious and moral exemptions from the ACA’s requirement to provide insurance covering birth control, and the 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 zuclomiphene citrate or VERU-111 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 bioequivalence studies for Tamsulosin DRS granules, Tamsulosin XR capsules, Tadalafil/Finasteride combination tablets or Solifenacin DRG granules are 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 our current drug candidates, 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 these drug candidates, 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 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, may have a material 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 our drug candidates, 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 likelihood of launching a product and on the profitability of any marketed product.

***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 our last two fiscal years and expect to continue to incur losses for the foreseeable future.***

We incurred a net loss of $23.9 million during the year ended September 30, 2018 and a net loss attributable to common stockholders 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 certain of our drug candidates and to commence the commercialization of our drug candidates. This will require us to obtain additional financing for our business as revenues from our current commercial operations will not independently fund our drug development programs. 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. In addition, our ability to raise capital through equity financing may be limited by the number of authorized shares of our common stock, which is currently 77 million shares. In order to raise significant additional amounts from equity financing, we will need to seek stockholder approval to amend our Amended and Restated Articles of Incorporation to increase the number of authorized shares of our common stock, and any such amendment would require the approval of the holders of at least two-thirds of the outstanding shares of our common stock. 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;
- our ability 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 licenses and sales, 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;
- the 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;
- regulatory changes;
- changes to federal, state or local health care or prescription drug programs;
- market and economic conditions; 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 2019. 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.

***The FDA recently issued a final order reclassifying female condoms as Class II medical devices, which may result in increased competition for FC2 in the U.S. market.***

On September 21, 2018, the FDA issued a final order reclassifying female condoms from Class III to Class II medical devices, renaming them "single-use internal condoms" and requiring new devices in this category to submit a 510(k) premarket notification and comply with various "special controls." Special controls are a battery of product clinical testing which includes, but is not limited to, determining product effectiveness against pregnancy and against infection transmission, and product tolerability. While FC2 is the only currently available female condom approved for marketing by the FDA in the U.S., this reclassification by the FDA may reduce the barriers for other types of female condoms to enter the U.S. market. If other female condoms enter the U.S. market, we may face increased competition in the U.S., which may put downward pressure on pricing for FC2 and adversely affect sales of FC2 in the U.S.

***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. The FDA's recent reclassification of female condoms from Class III to Class II medical devices may reduce the barriers for other types of female condoms to enter the U.S. market. 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 three South African tenders. Increasing competition in FC2's markets has 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.

***We may not be able to successfully implement our strategy to grow sales of FC2 in the U.S. market.***

While the global public health sector has been the main market for FC2, we have recently implemented a strategy to grow sales for FC2 in the U.S. market, focusing on prescription sales because FC2 is currently reimbursable by prescription under the ACA. As part of this growth strategy, we have developed relationships with external sales groups, distributors and telemedicine providers in the U.S. It is difficult to predict the degree of market acceptance

and consumer demand we may achieve for FC2 in the U.S., and we may ultimately not be able to achieve or sustain significant sales growth in the U.S. market. Furthermore, because distributors may use promotional offers to drive initial sales of FC2, initial sales growth may not be sustainable when those distributors determine the volume of the product to reorder. Our prescription sales in the U.S. may also be adversely affected by recently issued regulations offering employers religious and moral exemptions from the ACA's requirement to provide insurance covering birth control. Any failure to achieve and sustain sales growth for FC2 in the U.S. market may have a material adverse effect on our results of operations.

***We may not be able to sustain price levels for sales of FC2 in the U.S. market.***

Price levels for sales of FC2 in a developed country such as the U.S. are typically higher than for sales to less developed countries in the global public health sector. Over time, due to increased competition or other factors, we may experience price erosion in the U.S. market. Negative pressure on our price levels for U.S. sales may have a material adverse effect on our net revenues and gross margin in the U.S. market.

***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 three major customers for a significant portion of our net revenues.***

The Company's three largest customers currently are UNFPA, USAID and Barrs Medical (PTY) Ltd. UNFPA accounted for 32% of unit sales in fiscal 2018 and 25% of unit sales in fiscal 2017. USAID accounted for 23% of unit sales in fiscal 2018 and 44% of unit sales in fiscal 2017. Barrs Medical (PTY) Ltd accounted 24% of unit sales in fiscal 2018 and less than 10% of unit sales in fiscal 2017. 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 quantities or prices for 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 response to the APP Acquisition, two purported class action and derivative lawsuits were filed against us and certain of our officers and directors alleging breach of fiduciary duty and violations of the Wisconsin Business Corporation Law. 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 if we sustain cyber-attacks or other privacy or data security incidents that result in security breaches.***

Our information technology may be subject to cyber-attacks, security breaches or computer hacking. Experienced computer programmers and hackers may be able to penetrate our security controls and misappropriate or

compromise sensitive personal, proprietary or confidential information, create system disruptions or cause shutdowns. They also may be able to develop and deploy malicious software programs that attack our systems or otherwise exploit any security vulnerabilities. Our systems and the data stored on those systems may also be vulnerable to security incidents or security attacks, acts of vandalism or theft, misplaced or lost data, human errors, or other similar events that could negatively affect our systems and our data, as well as the data of our business partners. Further, third parties, such as hosted solution providers, that provide services to us, could also be a source of security risk in the event of a failure of their own security systems and infrastructure.

The costs to eliminate or address the foregoing security threats and vulnerabilities before or after a cyber-incident could be significant. Our remediation efforts may not be successful and could result in interruptions, delays or cessation of service, and loss of existing or potential suppliers or customers. In addition, breaches of our security measures and the unauthorized dissemination of sensitive personal, proprietary or confidential information about us, our business partners, participants in our clinical trials or other third parties could expose us to significant potential liability and reputational harm. In addition, the loss of clinical trial data from completed or ongoing or planned clinical trials as a result of a data security incident or other systems failure could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. As threats related to cyber-attacks develop and grow, we may also find it necessary to make additional investments to protect our data and infrastructure, which may impact our profitability. As a global enterprise, we could also be negatively impacted by existing and proposed laws and regulations, as well as government policies and practices related to cybersecurity, data privacy, data localization and data protection such as GDPR.

***Any failure to comply with the FCPA and similar anti-bribery laws in non-U.S. jurisdiction could materially adversely affect our business and result in civil and/or criminal sanctions.***

The FCPA and similar anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to non-U.S. government officials for the purpose of obtaining or retaining business. Because of the importance of the global public health sector for sales of FC2, many of our customer relationships outside of the U.S. are with governmental entities and are therefore potentially subject to such laws. Global enforcement of anti-corruption laws has increased substantially in recent years, with more frequent voluntary self-disclosures by companies, aggressive investigations and enforcement proceedings by U.S. and non-U.S. governmental agencies, and assessment of significant fines and penalties against companies and individuals. Our international operations create the risk of unauthorized payments or offers of payments by one of our employees, consultants, sales agents, or distributors, because these parties are not always subject to our control. Any alleged or actual violations of these regulations may subject us to government scrutiny, severe criminal or civil sanctions and other liabilities, including exclusion from government contracting, and could disrupt our business, and result in a material adverse effect on our reputation, results of operations and financial condition.

***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.

***Our credit agreement contains debt covenants which restrict our current and future operations, including our ability to take certain actions.***

In March 2018, we entered into a credit agreement with SWK Funding, LLC for a synthetic royalty financing transaction. This credit agreement contains provisions that place limitations on a number of our activities, including our ability to:

- incur additional debt;
- create liens on our assets or make guarantees;
- make certain acquisitions;
- pay dividends;
- buy back shares of our common stock; or
- dispose of our assets outside the ordinary course of business or enter into a merger or similar transaction.

Our credit agreement also contains a number of financial covenants. The restrictive covenants in our credit agreement may limit our ability to engage in acts that may be in our best long-term interests. A breach of any of the restrictive covenants in our credit agreement could result in a default under our credit agreement. If a default occurs, the lenders under our credit agreement may elect to declare all outstanding obligations (including a return premium) to be immediately due and payable and to exercise any other rights they have under the credit agreement or applicable law.

Until its maturity on March 5, 2025, we are required to make quarterly payments under our credit agreement based on our product revenue from net sales of FC2. Because such product revenue is based on when product revenue is recognized rather than when we collect on the related receivables, we may owe significant payments to the lenders before receipt of the cash for the sales. Upon maturity under our credit agreement, or an earlier change of control of Veru or sale of the FC2 business, we are required to make a payment to the lenders of all outstanding obligations (including a return premium) under the credit agreement.

***Uncertainties in the interpretation and application of the Tax Cuts and Jobs Act of 2017 could materially affect our deferred tax assets, tax obligations and effective tax rate.***

On December 22, 2017, significant changes were enacted to the U.S. tax law pursuant to the federal tax legislation commonly referred to as the Tax Cuts and Jobs Act of 2017 (the "Tax Act"). The Tax Act makes broad and complex changes to the U.S. tax code. The Tax Act includes a permanent reduction in the U.S. federal corporate income tax rate from 35% to 21%, requires companies to pay a one-time repatriation tax on the previously untaxed earnings of certain foreign subsidiaries, generally eliminates the corporate alternative minimum tax, adds an anti-base erosion tax and makes other changes to deductions, credits and business-related exclusions.

We have reflected the expected impact of the Tax Act in our consolidated financial statements using certain assumptions and estimates. However, the Tax Act is complex and additional interpretative guidance may be issued that could affect the assumptions and estimates we made. In addition, at this stage, it is unclear how a number of U.S. states will incorporate the changes made by the Tax Act into their tax codes. Changes in the assumptions and estimates we have made relating to the Tax Act, as well as actions we may take, could result in a write down of deferred tax assets or otherwise materially affect our tax obligations or effective tax rate, which could negatively affect our financial condition and results of operations.

**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:

- the patent applications that we have filed may fail to result in issued patents in the United States or in foreign countries;
- patents issued or licensed to us or our partners may be challenged or discovered to have been issued on the basis of insufficient, incomplete or incorrect information, and thus held to be invalid or unenforceable;
- the scope of any patent protection may be too narrow to exclude competitors from developing or designing around these patents;
- the scope of any patent protection may be too narrow to exclude competitors from developing or designing around these patents;
- we or our licensor was not the first to make the invention covered by an issued patent or pending patent application;
- we or our licensor was not the first inventor to file a patent application for the technology in the United States or was not the first to file a patent application directed to the technology abroad;
- we may fail to comply with procedural, documentary, fee payment and other similar provisions during the patent application process, which can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights;
- future drug candidates may not be patentable;
- others will claim rights or ownership with regard to patents and other proprietary rights that we hold or license;
- delays in development, testing, clinical trials and regulatory review may reduce the period of time during which we could market our drug candidates under patent protection; and
- we may fail to timely apply for patents on our technologies or products.

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.

***If some or 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 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 drug candidate, 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, Tamsulosin XR, Solifenacin DRG and Tadalafil/Finasteride, there are significant installment payments and milestone payments that are required to be made pursuant to the terms of the applicable purchase agreements. In addition, we granted a security interest in the purchased assets to the sellers to secure our present and future payment and performance obligations under the purchase agreements. 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 certain of our drug candidates 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**

***Ownership in our common stock is highly concentrated and your ability to influence corporate matters may be limited as a result.***

As of December 10, 2018, our executive officers and directors collectively beneficially owned approximately 29.2% of the outstanding shares of our common stock, including approximately 13.2% beneficially owned by Mitchell S. Steiner, M.D., our Chairman, President and Chief Executive Officer, and approximately 12.8% beneficially owned by Harry Fisch, M.D., our Vice Chairman and Chief Corporate Officer. These shareholders may have the ability to exert significant influence over the outcome of shareholder votes, including votes concerning director elections, amendments to our Amended and Restated Articles of Incorporation and other significant corporate transactions. In addition, this concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders. The interests of such stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders.

***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 allocated 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 recorded the excess of the purchase price over those fair values as goodwill. Management's estimates of the fair value of such assets was based upon assumptions that they believed 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 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.

Considering the high-risk nature of research and development and the industry’s success rate of bringing developmental compounds to market, charges relating to impairment of acquired IPR&D are likely to occur in future periods. 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 $250 million or more and annual revenue as of our most recently completed fiscal year is $100 million or more, or 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 $700 million or more, regardless of annual revenue.

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

We are subject to a number of provisions in our charter documents, Wisconsin law and our credit agreement with SWK Funding LLC 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;
- 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; and
- our credit agreement with SWK Funding LLC requires a mandatory prepayment upon a change of control of Veru or a sale of our FC2 business.

***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.

***A substantial number of shares may be sold in the market, which may depress the market price for our common stock.***

Sales of a significant number of shares of our common stock, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. We have also registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans, including upon the exercise of stock options, and shares of common stock we may issue under a common stock purchase agreement with Aspire Capital Fund, LLC, including 2,021,467 shares of common stock that we have issued thereunder through the date of this report. These shares can be freely sold in the public market upon issuance.

Additionally, sales of our common stock by our executive officers or directors, even when done during an open trading window under our policies with respect to insider sales may adversely impact the trading price of our common stock. Although we do not expect that the relatively small volume of such sales will itself significantly impact the trading price of our common stock, the market could react negatively to the announcement of such sales, which could in turn affect the trading 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, our credit agreement with SWK Funding LLC restricts the payment of 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, Florida in approximately 3,900 square feet of office space. 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 was amended in June 2017 to add additional space. The Company has two renewal options to extend the term of the lease for a period of three years each.

The Company leases approximately 6,600 square feet of office space located in Chicago, Illinois. The Company executed the lease for this office space in May 2016, for a seven-year term commencing on November 1, 2016 and ending on October 31, 2023. In June 2017, the Company entered into a sublease for this office space commencing on September 1, 2017 and ending on October 31, 2023. The Company continues to be responsible for performance under this lease until it expires on October 31, 2023.

The Company leases approximately 6,400 square feet of office space located in London, England. The Company executed the lease for this office space in June 2010, for a ten-year term ending in June 2020.

The Company manufactures and warehouses FC2 within a leased facility with approximately 45,800 square feet of space in Selangor D.E., Malaysia. Production capacity at this facility is approximately 100 million units of FC2 annually. The Company executed the lease for this space in September 2016, for a three-year term commencing on September 1, 2016 and ending on August 31, 2019. The Company has an option to extend the term of the lease for a period of three-years. This facility is subject to periodic inspection by the FDA to ensure compliance with current Good Manufacturing Processes, as well as the U.K.-based notified body, which is responsible for CE and ISO accreditation.

We believe that the facilities noted above are suitable and adequate for our current needs.

Item 3. Legal Proceedings.

In response to the APP Acquisition, two purported derivative and class action lawsuits were filed against the Company and certain of its officers and directors in the Circuit Court of Cook County, Illinois, captioned Glotzer v. The Female Health Company, et al., Case No. 2016-CH-13815, and Schartz v. Parrish, et al., Case No. 2016-CH-14488. These lawsuits were originally filed on or about October 21, 2016 and November 7, 2016, respectively. On January 9, 2017, these two lawsuits were consolidated. On March 31, 2017, the plaintiffs filed a consolidated complaint. The consolidated complaint named as defendants Veru, the members of our board of directors prior to the closing of the APP Acquisition and the members of our board of directors after the closing of the APP Acquisition. The consolidated complaint alleged, among other things, that the directors breached their fiduciary duties, or aided and abetted such breaches, by consummating the APP Acquisition in violation of the Wisconsin Business Corporation Law and NASDAQ voting requirements and by causing us to issue the shares of our common stock and Series 4 Preferred Stock to the former stockholders of APP pursuant to the APP Acquisition in order to evade the voting requirements of the Wisconsin Business Corporation Law. The consolidated complaint also alleged that Dr. Steiner, a director and the Chairman, President and Chief Executive Officer of Veru and a co-founder of APP, and Dr. Fisch, a director and Vice Chairman of Veru and a co-founder of APP, were unjustly enriched in receiving shares of our common stock and Series 4 Preferred Stock in the APP Acquisition.

On May 5, 2017, the defendants filed a motion to dismiss the consolidated complaint. On August 15, 2017, the court entered an order dismissing without prejudice the claims that the post-acquisition directors aided and abetted the alleged breaches of fiduciary duties by the pre-acquisition directors and that Dr. Steiner and Dr. Fisch were unjustly enriched. The court did not dismiss the claims that our directors prior to the closing of the APP Acquisition breached their fiduciary duties and the claims that Veru consummated the APP Acquisition in violation of the Wisconsin Business Corporation Law and NASDAQ voting requirements. On November 30, 2018, plaintiffs filed an Amended Consolidated Complaint. The Amended Consolidated Complaint makes allegations similar to those in the original consolidated complaint as to the claims that were not dismissed and names as defendants Veru and the members of our board of directors prior to the closing of the APP Acquisition. The Amended Consolidated Complaint also makes claims against Dr. Steiner for allegedly aiding and abetting the pre-acquisition directors' breach of fiduciary duty and for unjust enrichment. Like the original consolidated complaint, the Amended

Consolidated Complaint seeks equitable relief, including rescission of the APP Acquisition, money damages, disgorgement of the shares of our common stock and Series 4 Preferred Stock issued to Dr. Steiner, and costs and expenses of the litigation, including attorneys' fees. The parties are currently completing discovery. 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 number of record holders of our common stock at December 10, 2018 was approximately 240.

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 Operations Data for the years ended September 30, 2018 and 2017, and the Consolidated Balance Sheet Data as of September 30, 2018 and 2017, are derived from the Consolidated Financial Statements included elsewhere in this report. The Consolidated Statement of Operations Data for the years ended September 30, 2016, 2015 and 2014, and the Consolidated Balance Sheet Data as of September 30, 2016, 2015, and 2014, 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, | | | | |
|---|---|---|---|---|---|
| **Consolidated Statement of Operations Data:** | **2018** | **2017** | **2016** | **2015** | **2014** |
| | *(In thousands, except per share data)* | | | | |
| Net revenues | $ 15,865 | $ 13,656 | $ 22,127 | $ 32,605 | $ 24,491 |
| Cost of sales | 7,082 | 6,636 | 8,778 | 13,635 | 11,370 |
| Gross profit | 8,783 | 7,020 | 13,349 | 18,970 | 13,121 |
| Operating expenses | 29,655 | 15,514 | 10,330 | 12,352 | 9,197 |
| Operating (loss) income | (20,872) | (8,494) | 3,019 | 6,618 | 3,924 |
| Non-operating (expense) income | (2,200) | (108) | (205) | 69 | 33 |
| (Loss) income before income taxes | (23,072) | (8,602) | 2,814 | 6,687 | 3,957 |
| Income tax expense (benefit) | 866 | (1,990) | 2,469 | 2,341 | 1,524 |
| Net (loss) income attributable to common stockholders before preferred stock dividend | $ (23,938) | $ (6,612) | $ 345 | $ 4,346 | $ 2,433 |
| Preferred stock dividend | — | 1,991 | — | — | — |
| Net (loss) income attributable to common stockholders | $ (23,938) | $ (8,603) | $ 345 | $ 4,346 | $ 2,433 |
| | | | | | |
| Net (loss) income per basic common share outstanding | $ (0.44) | $ (0.25) | $ 0.01 | $ 0.15 | $ 0.09 |
| Basic weighted average common shares outstanding | 53,862 | 34,640 | 28,666 | 28,532 | 28,523 |
| Net (loss) income per diluted common share outstanding | $ (0.44) | $ (0.25) | $ 0.01 | $ 0.15 | $ 0.08 |
| Diluted weighted average common shares outstanding | 53,862 | 34,640 | 28,927 | 28,834 | 28,865 |
| Cash dividends declared per share | $ — | $ — | $ — | $ — | $ 0.21 |

| | As of September 30, | | | | |
|---|---|---|---|---|---|
| **Consolidated Balance Sheet Data:** | **2018** | **2017** | **2016** | **2015** | **2014** |
| | *(In thousands)* | | | | |
| Cash and cash equivalents | $ 3,760 | $ 3,278 | $ 2,385 | $ 4,106 | $ 5,796 |
| Working capital | (2,370) | 4,810 | 14,968 | 17,361 | 9,695 |
| Total assets | 48,453 | 55,336 | 38,624 | 37,472 | 31,673 |
| Accumulated deficit | (58,202) | (34,263) | (27,651) | (27,996) | (32,342) |
| Long-term obligations | 4,455 | 1,234 | 1,234 | — | — |

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

Veru Inc. is an oncology and urology biopharmaceutical company developing novel medicines for prostate cancer and prostate cancer supportive care as well as near term specialty pharmaceuticals to address significant unmet needs in urology.

The Company's prostate cancer pipeline consists of VERU-944 (zuclomiphene citrate, which is also known as cis-clomiphene) and VERU-111 (bisindole). The Company is evaluating zuclomiphene citrate, an estrogen receptor agonist, in a Phase 2 trial to treat hot flashes, a common side effect caused by hormone treatment for men with advanced prostate cancer.

VERU-111 is an oral, next-generation, first-in-class small molecule that targets and binds to the alpha and beta subunits of microtubules in cells. Microtubules are essential for cell division and for shuttling critical growth receptors into the nucleus where they stimulate cell proliferation. The Company is developing VERU-111 as a treatment for metastatic prostate cancer patients whose disease is resistant to both castration and androgen-blocking agent (abiraterone or enzalutamide) therapies. The Company expects to enter a Phase 1b/2 clinical trial of VERU-111 for this indication by no later than early January 2019. The Company will also evaluate VERU-111 for a variety of other malignancies. In June 2018, as part of the American Society of Clinical Oncology (ASCO) Annual Meeting, the Company reported preclinical results showing the activity of VERU-111 against novel androgen blocking agent-resistant human prostate cancer, and it also reported preclinical data showing VERU-111's anti-tumor activity against paclitaxel sensitive and resistant triple negative breast, ovarian and pancreatic cancers.

In addition to its oncology drug programs, the Company is advancing four new drug formulations in its specialty pharmaceutical pipeline addressing unmet medical needs in urology. The Company is evaluating two different formulations of tamsulosin, the active ingredient in FLOMAX®, which it has developed to avoid the "food effect" inherent in currently marketed formulations of this drug. Tamsulosin taken after a meal has different bioavailability and peak concentration characteristics as compared to when it is taken under fasting conditions, and as a result, patients are directed to take the drug 30 to 60 minutes after a meal to avoid declines in blood pressure that could result in dizziness or fainting. The Company is developing its Tamulosin DRS (Delayed Release Sachet) granules and XR (Extended Release) capsules to avoid this food effect, allowing for potentially safer administration and improved patient compliance. In addition, Tamsulosin DRS granules may make it easier for the population of men who have difficulty swallowing pills and tablets (dysphagia) to be able to take this medicine instead of wearing diapers, having a urinary catheter, or having to undergo prostate surgery. The Company expects to submit a new drug application (NDA) to the FDA for both Tamsulosin DRS and Tamsulosin XR in 2019. Separately, we are developing Tadalafil (CIALIS®) / Finasteride (PROSCAR®) combination tablets for inhibition of both phosphodiesterase type 5 (PDE5) and 5-alpha-reductase to shrink an enlarged prostate and to treat the symptoms of benign prostatic hyperplasia (BPH or enlarged prostate), with the added benefit of medicine to treat erectile dysfunction, with an NDA submission expected in 2019. The Company believes Tadalafil and Finasteride combination tablets may increase both patient compliance and patient convenience. The Company is also developing a delayed-release granule (DRG) formulation of Solifenacin, a selective M3 muscarinic receptor antagonist and the active ingredient in the leading drug for overactive bladder, VESIcare®, for patients who have difficulty with swallowing tablets. The Company expects to submit an NDA to the FDA for Solifenacin DRG in 2019.

In addition to these products under development, the Company markets and sells the PREBOOST® wipe in the men's health market and the FC2 Female Condom® ("FC2") for women. PREBOOST is a medicated individual wipe used for desensitizing male genitalia for the prevention of premature ejaculation. The Company co-promotes the PREBOOST wipe with Timm Medical Technologies, Inc. The Company markets and sells FC2 in the U.S. market by prescription and other sales channels and through its Female Health Company Division in the global public health sector. The Company's Female Health Company Division markets to entities, including ministries of health, government health agencies, U.N. agencies, nonprofit organizations and commercial partners, that work to support and improve the lives, health and well-being of women around the world. FC2 is the only currently available female-controlled product approved for marketing 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 STIs.

Prior to the completion of the APP Acquisition, the Company had been a single product company, focused on manufacturing, marketing and selling FC2 in the public sector. The Centers for Disease Control and Prevention has referenced the use of condoms, including the female condom, as a means to reduce the risk of transmitting STIs, including HIV/AIDS, and the transmission of Zika by sex. Nearly all of the Company's net revenues for the years ended September 30, 2018 and 2017 were derived from sales of FC2.

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

FC2 has been distributed in the U.S. and 149 other 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, significant customers have included large global agencies, such as the United Nations Population Fund (UNFPA) and the United States Agency for International Development (USAID). Other customers include ministries of health or other governmental agencies, which either purchase directly or via in-country distributors, and non-governmental organizations ("NGOs").

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

In April 2017, the Company launched a small-scale marketing and sales program to support the promotion of FC2 in the U.S. market. The commercial team developed a plan to confirm the "proof of concept" that FC2 represented a significant business opportunity. This required changes in the distribution process for FC2 in the U.S. As part of this reorganization the Company announced new distribution agreements with three of the country's largest distributors that support the pharmaceutical industry. This newly developed network now allows up to 98% of major retail pharmacies the ability to make FC2 available to their customers. In addition to the distribution system, the Company expanded sales and market access efforts that resulted in FC2 now being available through the following access points: community-based organizations, by prescription, utilizing the telemedicine "HeyDoctor" App, through 340B covered entities, college and universities and our patient assistance program. We continue to increase healthcare provider awareness, education and acceptance which has resulted in more women utilizing FC2 in the U.S. We believe that the initial results from these efforts support the U.S. market opportunity and that we will continue to see increased utilization of FC2.

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

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

| Period | 2018 | 2017 | 2016 | 2015 | 2014 |
|---|---|---|---|---|---|
| October 1 — December 31 | 4,399,932 | 6,389,320 | 15,380,240 | 12,154,570 | 11,832,666 |
| January 1 — March 31 | 4,125,032 | 4,549,020 | 9,163,855 | 20,760,519 | 7,298,968 |
| April 1 — June 30 | 10,021,188 | 8,466,004 | 10,749,860 | 14,413,032 | 13,693,652 |
| July 1 — September 30 | 6,755,124 | 6,854,868 | 6,690,080 | 13,687,462 | 9,697,341 |
| Total | 25,301,276 | 26,259,212 | 41,984,035 | 61,015,583 | 42,522,627 |

*Revenues.* The Company's revenues are primarily derived from sales of FC2 in the public sector and are recognized upon shipment of the product to its customers. Other sales are from FC2 into the prescription channel in the U.S. and sales of PREBOOST; however, these sales were not material to our results for fiscal 2018 or fiscal 2017.

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

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

In 2017, the Company began expanding access to FC2 in the U.S. by making it available by prescription. With a prescription, FC2 is covered by most insurance companies with no copay. The Company retained an independent sales organization to help educate doctors, pharmacists, clinics and student health centers on the benefits of FC2 and how to prescribe it. In the U.S., FC2 is sold to major distributors and sold direct to city and state public health departments and non-profit organizations.

Because the Company manufactures FC2 in a leased facility located in Malaysia, a portion of the Company's operating costs are denominated in foreign currencies. While a material portion of the Company's future sales are likely to be in foreign markets, all sales are denominated in the U.S. dollar. Effective October 1, 2009, the Company’s U.K. and Malaysia subsidiaries adopted the U.S. dollar as their functional currency, further reducing the Company’s foreign currency risk.

*Operating Expenses.* The Company manufactures FC2 at its facility located in Selangor D.E., Malaysia. The Company's cost of sales consists primarily of direct material costs, direct labor costs and indirect production and distribution costs. Direct material costs include raw materials used to make FC2, principally a nitrile polymer. Indirect production costs include logistics, quality control and maintenance expenses, as well as costs for electricity and other utilities. All of the key components for the manufacture of FC2 are essentially available from either multiple sources or multiple locations within a source.

Conducting research and development is central to our business model. Since the completion of the APP Acquisition we have invested and expect to continue to invest significant time and capital in our research and development operations. Our research and development expenses were $10.9 million for fiscal 2018 and $3.1 million for fiscal 2017. In fiscal 2019, we expect to increase our expenses relating to research and development due to advancement of multiple drug candidates.

Results of Operations

FISCAL YEAR ENDED SEPTEMBER 30, 2018 COMPARED TO FISCAL YEAR ENDED SEPTEMBER 30, 2017

The Company had net revenues of $15.9 million and net loss of $23.9 million, or $(0.44) per basic and diluted common share, for fiscal 2018, compared to net revenues of $13.7 million and net loss attributable to common stockholders of $8.6 million, or $(0.25) per basic and diluted common share, for fiscal 2017.

Net revenues increased 16% on an increase in average sales price per unit of 21%, partially offset by a 4% decrease in unit sales. The principal factors for the increase in the FC2 average sales price per unit compared to prior year were changes in sales mix and unit price increases for customers in the U.S.

Cost of sales increased to $7.1 million in fiscal 2018 from $6.6 million in fiscal 2017. The increase is primarily due to the mix of units sold with higher costs per unit. Cost of sales was also partially impacted by unfavorable currency exchange rates.

Gross profit increased to $8.8 million in fiscal 2018 from $7.0 million in fiscal 2017. Gross profit margin for fiscal 2018 was 55% of net revenues, compared to 51% of net revenues for fiscal 2017.

Significant quarter-to-quarter variations in the Company's results have historically resulted from the timing and shipment of large orders rather than from any fundamental changes in the business or the underlying demand for female condoms. The Company is also currently seeing pressure on spending for FC2 by large global agencies and donor governments in the developed world. As a result, the Company may continue to experience challenges for unit sales of FC2 in the global public health sector.

Research and development expenses increased to $10.9 million in fiscal 2018 from $3.1 million in fiscal 2017. The increase is primarily due to increased research and development costs associated with the in-process research and development projects acquired pursuant to the APP Acquisition and increased personnel costs associated with the research and development.

Selling, general and administrative expenses increased to $14.8 million in fiscal 2018 from $11.5 million in fiscal 2017. The increase primarily relates to salaries for our U.S. Commercial team, part of our Commercial reporting segment, and additional corporate personnel, severance, investor relations and shared-based compensation expenses. In fiscal 2018, the Company changed its U.S. sales strategy for FC2 by principally relying on an independent sales organization, which resulted in severance payments of $0.5 million.

The Company incurred a loss on net accounts receivable of $4.0 million in connection with a settlement agreement we entered with Semina, our distributor in Brazil, in December 2017. This amount is presented as a separate line item in the accompanying consolidated statement of operations for fiscal 2018.

Business acquisition expenses for fiscal 2018 decreased to zero from $0.9 million in fiscal 2017 for expenses representing costs related to the APP Acquisition.

Interest expense was $3.0 million in fiscal 2018, which consisted of $2.7 million of accretion of the discounts on the SWK Credit Agreement, $0.2 million of accretion of the liability for the SWK Residual Royalty Agreement and $63,000 of amortization of the deferred issuance costs related to the SWK Credit Agreement.

Income associated with the change in fair value of the embedded derivatives was $0.9 million in fiscal 2018. The liabilities associated with embedded derivatives represent the fair value of the change of control provisions in the SWK Credit Agreement and Residual Royalty Agreement. See Note 3 and Note 7 to the financial statements included in this report for additional information.

The Company realized a foreign currency transaction loss of $127,000 in fiscal 2018, compared to $62,000 in fiscal 2017. This foreign currency transaction loss was primarily due to the adverse movement of the U.S. dollar against the Malaysian Ringgit during the period.

The income tax expense for fiscal year 2018 was $0.9 million, compared to an income tax benefit of $2.0 million in fiscal 2017. The increase in income tax expense of $2.9 million is primarily due to the increase in the valuation

allowance of $5.6 million recorded primarily against the U.S. federal and state net operating loss carryforwards, the write-off of $1.3 million of deferred tax assets related to the recharacterization of foreign tax credits that were treated as a tax deduction, net of an increase in the income tax benefit of $3.5 million due to the change in the U.S. federal corporate income tax rate from 35% to 21% under the Tax Act and the increase in the loss before income taxes, $0.3 million for the effect of change in the UK, foreign and state tax rates, and $0.2 million in non-deductible expenses.

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 in fiscal 2017.

Liquidity and Sources of Capital

***Liquidity***

Our cash on hand (including restricted cash) at September 30, 2018 was $3.8 million, compared to $3.3 million at September 30, 2017. At September 30, 2018, the Company had negative working capital of $2.4 million and stockholders' equity of $29.5 million compared to working capital of $4.8 million and stockholders' equity of $48.5 million as of September 30, 2017. The reduction in working capital is primarily due to estimated amounts payable under the SWK Credit Agreement over the next twelve months.

We have incurred quarterly operating losses since the fourth quarter of fiscal 2016 and anticipate that we will continue to consume cash and incur substantial net losses as we develop our drug candidates. Because of the numerous risks and uncertainties associated with the development of pharmaceutical products, we are unable to estimate the exact amounts of capital outlays and operating expenditures necessary to fund development of our product candidates and obtain regulatory approvals. Our future capital requirements will depend on many factors. See Part I, Item 1A, "Risk Factors - Risks Related to Our Financial Position and Need for Capital" for a description of certain risks that will affect our future capital requirements.

The Company believes its current cash position and its ability to secure equity financing or other financing alternatives are adequate to fund planned operations of the Company for the next 12 months. Such financing alternatives may include debt financing, common stock offerings or financing involving convertible debt or other equity-linked securities and may include financings under the Company's effective shelf registration statement on Form S-3 (File No. 333-221120) (the "Shelf Registration Statement"). The Company intends to be opportunistic when pursuing equity financing which could include selling common stock under the Purchase Agreement with Aspire Capital and/or a marketed deal with an investment bank. The Company's ability to raise capital through equity financing may be limited by the number of authorized shares of the Company's common stock, which is currently 77 million shares. In order to raise significant additional amounts from equity financing, the Company will need to seek stockholder approval to amend our Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock, and any such amendment would require the approval of the holders of at least two-thirds of the outstanding shares of the Company's common stock. See Part I, Item 1A, "Risk Factors - Risks Related to Our Financial Position and Need for Capital" for a description of certain risks related to our ability to raise capital on acceptable terms.

As of November 30, 2018, the Company had approximately $10.7 million in cash, net trade accounts receivable of $3.9 million and current trade accounts payable of $4.7 million.

*Operating activities*

Our operating activities used cash of $11.5 million in fiscal 2018. Cash used in operating activities included a net loss of $23.9 million, adjustments for non-cash items totaling $8.9 million and cash from changes in operating assets and liabilities of $3.5 million. Adjustments for non-cash items primarily consisted of $4.0 million for the loss on settlement of accounts receivable, $3.0 million of non-cash interest expense related to the SWK Credit Agreement and $1.6 million of share-based compensation. The increase in cash from changes in operating assets and liabilities included a decrease in net accounts receivable and long-term other receivables of $1.9 million and increases in accounts payable and accrued expenses of $1.8 million.

Our operating activities provided cash of $1.0 million in fiscal 2017. Cash provided by operating activities included a net loss attributable to common stockholders before preferred stock dividend of $6.6 million, adjustments for non-cash items totaling $0.1 million and cash from changes in operating assets and liabilities of $7.7 million. The largest contributor to the increase in cash from changes in operating assets and liabilities was a decrease in accounts receivable of $7.3 million.

On December 27, 2017, we entered into a settlement agreement with Semina pursuant to which Semina made a payment of $2.2 million and was obligated to make a second payment of $1.5 million by February 28, 2018, to settle net amounts due to us totaling $7.5 million relating to the 2014 Brazil tender. Semina did not make its second payment of $1.5 million by February 28, 2018. In July 2018, the Company agreed to accept $1.3 million as settlement of the second payment of $1.5 million that was owed. The $1.3 million was received by us on July 26, 2018. The settlement was not related to our belief in the ultimate collectability of the receivables or in the creditworthiness of Semina. We elected to settle these amounts due to the uncertainty regarding the timing of payment by the Brazilian Government and, ultimately to us, on the remaining amounts due. The result of the settlement was a net loss of $4.0 million, which is presented as a separate line item in the accompanying consolidated statement of operations for fiscal 2018.

In connection with the Company's acquisition of intellectual property rights associated with Solifenacin DRG granules and Tadalafil/Finasteride combination tablets, the Company was obligated to make upfront payments totaling $500,000 by March 2018, as well as future installment payments and milestone payments. Of the $500,000, $250,000 was paid in May 2018 and the Company expects to pay the remaining $250,000 in the first quarter of fiscal 2019. The Company has met the initial milestones for these two product candidates, which will result in additional payments totaling $700,000. These amounts owed, which total $950,000, are included in accounts payable on the accompanying consolidated balance sheet at September 30, 2018.

*Investing activities*

Net cash used in investing activities in fiscal 2018 was $51,000 and was primarily associated with capital expenditures at our UK location. Net cash used in investing activities in fiscal 2017 was $90,000 and was primarily related to office furniture and equipment purchases at our Chicago and Miami locations, net of cash acquired in the APP Acquisition.

*Financing activities*

Net cash provided by financing activities in fiscal 2018 was $12.1 million and primarily consists of the net proceeds from the SWK Credit Agreement (see discussion below) and the net proceeds from the sale of shares under the Purchase Agreement with Aspire Capital (see discussion below).

***Sources of Capital***

*Common Stock Offering*

On October 1, 2018, we completed an underwritten public offering of 7,142,857 shares of our common stock, at a public offering price of $1.40 per share, resulting in gross proceeds of $10.0 million. We also granted the underwriters a 30-day option to purchase additional shares of common stock in an amount not to exceed 1,071,428 shares. The underwriters did not exercise this option. Net proceeds to the Company from this offering were $9.2 million after deducting underwriting discounts and commissions and expenses payable by the Company. All of the shares sold in the offering were sold by the Company. The offering was made pursuant to the Shelf Registration Statement.

*SWK Credit Agreement*

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

After payment by the Company of certain fees and expenses of the Agent and the Lenders as required in the Credit Agreement, the Company received net proceeds of approximately $9.9 million from the initial $10.0 million advance under the Credit Agreement. The first quarterly revenue-based payment due May 15, 2018 was approximately $642,000 and was paid on that date. On August 10, 2018, the Company entered into an amendment (the "Credit Agreement Amendment") to the Credit Agreement. The Credit Agreement Amendment deferred until November 15, 2018 the due date for the quarterly revenue-based payment that would have otherwise been due on August 15, 2018. The Company made a payment of approximately $2.6 million on November 15, 2018, consisting of approximately $1.4 million for the quarterly revenue-based payment originally due on August 15, 2018 and approximately $1.2 million for the quarterly revenue-based payment due on November 15, 2018.

*Aspire Capital Purchase Agreement*

On December 29, 2017, the Company entered into the Purchase Agreement with Aspire Capital which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right, from time to time and in its sole discretion during the 36-month term of the Purchase Agreement, to direct Aspire Capital purchase up to $15.0 million of the Company's common stock in the aggregate. Other than the 304,457 shares of common stock issued to Aspire Capital in consideration for entering into the Purchase Agreement, the Company has no obligation to sell any shares of common stock pursuant to the Purchase Agreement and the timing and amount of any such sales are in the Company's sole discretion subject to the conditions and terms set forth in the Purchase Agreement. During fiscal 2018, we sold an aggregate of 1,717,010 shares of common stock to Aspire Capital under the Purchase Agreement resulting in proceeds to the Company of $3.0 million. As of September 30, 2018, the amount remaining under the Purchase Agreement was $12 million. However, based on the current market price of the Company's common stock and the number of shares of the Company's common stock that are unreserved and available for issuance, the Company will need to seek stockholder approval to amend its Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock to use the full remaining availability under the Purchase Agreement.

*BMO Line of Credit*

The Company's Credit Agreement with BMO Harris Bank N.A. expired on December 29, 2017. No amounts were outstanding under the Credit Agreement during the fiscal years ended September 30, 2018 or 2017.

Critical Accounting Estimates

The Company prepares its financial statements in accordance with accounting principles generally accepted in the United States. The Company is required to adopt various accounting policies and to make estimates and assumptions in preparing its financial statements that affect the reported amounts of assets, liabilities, net revenues and expenses. On an ongoing basis, the Company evaluates its estimates and assumptions. The Company bases its estimates on historical experience to the extent practicable and on various other assumptions that it believes are reasonable under the circumstances and at the time they are made. If the Company's assumptions prove inaccurate or if future results are not consistent with historical experience, the Company may be required to make adjustments in its policies that affect reported results. The Company's significant accounting policies are disclosed in Note 1 to the financial statements included in this report.

The Company's most critical accounting estimates include: valuation of tax assets and liabilities, measurement of fair value and valuation of intangible assets and goodwill. The Company has other key accounting policies that are less subjective and, therefore, their application is less subject to variations that would have a material impact on the Company's reported results of operations. The following is a discussion of the Company's most critical policies, as well as the estimates and judgments involved.

***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.

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 allowances on an annual basis or more frequently if information comes to its attention that would indicate that a revision to its estimates is necessary. In evaluating the Company's ability to realize its deferred tax assets, management considers all available positive and negative evidence on a country by country basis, including past operating results and forecasts of future taxable income, and the potential Section 382 limitation on the net operating loss carryforwards due to a change in control. In determining future taxable income, management makes assumptions to forecast U.S. federal and state, U.K. and Malaysia operating income, the reversal of temporary differences, and the implementation of any feasible and prudent tax planning strategies. These assumptions require significant judgment regarding the forecasts of the future taxable income in each tax jurisdiction, and are consistent with the forecasts used to manage the Company's business. It should be noted that the Company realized significant losses through 2005 on a consolidated basis. From fiscal year 2006 through fiscal year 2015, the Company generated taxable income on a consolidated basis. However, the Company had a cumulative pretax loss in the U.S. for fiscal 2018 and two preceding fiscal years. Forming a conclusion that a valuation allowance is not needed is difficult when there is significant negative evidence such as cumulative losses in recent years. Management has projected future taxable losses in the U.S. driven by the investment in research and development, and based on their analysis concluded that a valuation allowance of $5.5 million should be recorded against the U.S. deferred tax assets related to federal and state net operating loss carryforwards as of September 30, 2018. Management has also concluded that a valuation allowance should be recorded against the deferred tax assets of the Company's holding company for the non-U.S. operating companies, The Female Health Company Limited.

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.

On December 22, 2017, significant changes were enacted to the U.S. tax law pursuant to the federal tax legislation commonly referred to as the Tax Cuts and Jobs Act of 2017 (the "Tax Act"). The Tax Act includes a permanent reduction to the U.S. federal corporate income tax rate from 35% to 21% effective January 1, 2018. Because the

Company is in a net loss carryforward position, it applied the U.S. federal statutory tax rate of 21% that will be in effect when the loss is utilized. The Tax Act made significant changes to the utilization of foreign tax credits and as a result the Company recharacterized the foreign tax credits as a deductible tax expense resulting in an increase to the net operating loss carryforwards. The impact of the U.S. federal statutory rate was also applied to the opening deferred tax balances resulting in a net income tax benefit.

Our effective tax rates have differed from the statutory rate primarily due to the tax impact of foreign operations, state taxes and addition 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.

***Fair Value Measurements***

As of September 30, 2018, the Company's financial liabilities measured at fair value on a recurring basis, which consisted of embedded derivatives, represent the fair value of the change of control provisions in the SWK Credit Agreement and Residual Royalty Agreement. See Note 7 to the financial statements included in this report.

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

***Purchased Intangible Assets and Goodwill***

The Company evaluates the carrying value of its purchased intangible assets whenever events, changes in business circumstances or planned use of the assets indicate that their carrying amounts may not be fully recoverable or that their useful lives are no longer appropriate. If these facts and circumstances exist, the Company assesses for recovery by comparing the carrying values of the assets with their future undiscounted net cash flows. Significant management judgment is required in the forecast of future operating results that are used in the preparation of expected undiscounted cash flows.

The Company also evaluates the carrying value of in-process research and development ("IPR&D") assets which are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. During the period the assets are considered indefinite-lived, they are tested for impairment on an annual basis, as well as between annual tests if the Company becomes aware of any events occurring or changes in circumstances that indicate that the fair values of the IPR&D assets are less than their carrying amounts. If the related project is terminated or abandoned, the Company may have a full or partial impairment related to the IPR&D assets, calculated as the excess of their carrying value over fair value. The valuation process is very complex and requires significant input and judgment using internal and external sources. See further discussion in Note 1 to the financial statements included in this report.

The Company tests goodwill for impairment on an annual basis in the fourth quarter of each fiscal year or more frequently if it believes indicators of impairment exist. Goodwill is considered impaired, and an impairment charge would be recorded, if the excess of the fair value of the reporting unit over the fair value of the net assets is less than the carrying value of goodwill. 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. See further discussion in Note 1 to the financial statements included in this report.

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.

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

Evaluation of 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.

Changes in Internal Control over Financial Reporting

There were no changes in Veru's internal control over financial reporting during the fiscal quarter ended September 30, 2018 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, 2018, based on criteria in “Internal Control - Integrated Framework” issued by the COSO in 2013.

Report of Independent Registered Public Accounting Firm

Because we are a non-accelerated filer, our independent registered public accounting firm is not required to express an opinion on the effectiveness of our internal control over financial reporting.

Item 9B. Other Information

None.

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 2019 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 28, 2019. 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 2019 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 28, 2019.

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), Michael L. Rankowitz and Mario Eisenberger.

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 2019 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 28, 2019.

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 2019 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 28, 2019.

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 2019 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 28, 2019. 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 2019 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 28, 2019.

Item 14. Principal Accounting 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 2019 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 28, 2019.

PART IV

Item 15. Exhibits, 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, 2018 and 2017

Consolidated Statements of Operations for the Years Ended September 30, 2018 and 2017

Consolidated Statements of Stockholders' Equity for the Years Ended September 30, 2018 and 2017

Consolidated Statements of Cash Flows for the Years Ended September 30, 2018 and 2017

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**

| Exhibit Number | Description |
|---|---|
| 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 Exhibit 3.2 to the Company's Form SB-2 Registration Statement (File No. 333-46314) filed with the SEC on September 21, 2000). |
| 3.3 | Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 35,500,000 shares (incorporated by reference to Exhibit 3.3 to the Company's Form SB-2 Registration Statement (File No. 333-99285) filed with the SEC on September 6, 2002). |
| 3.4 | Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 38,500,000 shares (incorporated by reference to Exhibit 3.4 to the Company's Form 10-QSB (File No. 1-13602) filed with the SEC on May 15, 2003). |
| 3.5 | Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company designating the terms and preferences for the Class A Preferred Stock – Series 3 (incorporated by reference to Exhibit 3.5 to the Company's Form 10-QSB (File No. 1-13602) filed with the SEC on May 17, 2004). |
| 3.6 | Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company designating the terms and preferences for the Class A Preferred Stock – Series 4 (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on November 2, 2016). |
| 3.7 | Articles of Amendment to 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 4, 2018). |
| 4.1 | Amended and Restated Articles of Incorporation, as amended (same as Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6 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). |
| 10.1 | 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). |

| | |
|---|---|
| 10.2 | 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). |
| 10.3 | 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). * |
| 10.4 | 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).* |
| 10.5 | 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).* |
| 10.6 | 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). * |
| 10.7 | Separation Agreement and General Release, effective as of April 16, 2018, between the Company and Brian Groch (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on April 20, 2018). * |
| 10.8 | Executive Employment Agreement, dated as of December 31, 2017, between the Company and Harry Fisch, 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 September 27, 2018). * |
| 10.9 | Executive Employment Agreement, dated as of March 21, 2018, between the Company and Michele Greco (incorporated by reference to Exhibit 10.3 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on March 26, 2018). * |
| 10.10 | 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).* |
| 10.11 | 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).* |
| 10.12 | Executive Employment Agreement, dated as of March 21, 2018, between the Company and Dr. Robert H. Getzenberg (incorporated by reference to Exhibit 10.9 to the Company's Form 10-Q (File No. 1-13602) filed with the SEC on May 11, 2018).* |
| 10.13 | Executive Employment Agreement, dated as of September 4, 2018, between the Company and Dr. K. Gary Barnette. *, ** |
| 10.14 | Separation Agreement and General Release, effective as of January 4, 2018, between the Company and Daniel Haines (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on January 10, 2018). * |
| 10.15 | 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). * |

10.16 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). *

10.17 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). *

10.18 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). *

10.19 Form of Nonstatutory Stock Option Grant Agreement for Veru Inc. 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.18 to the Company's Form 10-K (File No. 1-13602) filed with the SEC on January 2, 2018). *

10.20 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). *

10.21 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). *

10.22 Veru Inc. 2018 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 March 26, 2018). *

10.23 Form of Non-Qualified Stock Option Grant Agreement for the Veru Inc. 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on March 26, 2018). *

10.24 Common Stock Purchase Agreement, dated as of December 29, 2017, between the Company and Aspire Capital Fund, LLC (incorporated by reference to Exhibit 10.33 to the Company's Form 10-K (File No. 1-13602) filed with the SEC on January 2, 2018).

10.25 Registration Rights Agreement, dated as of December 29, 2017, between the Company and Aspire Capital Fund, LLC (incorporated by reference to Exhibit 10.34 to the Company's Form 10-K (File No. 1-13602) filed with the SEC on January 2, 2018).

10.26 Credit Agreement, dated as of March 5, 2018, among the Company, SWK Funding LLC and the financial institutions party thereto from time to time (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on March 6, 2018).

10.27 Residual Royalty Agreement, dated as of March 5, 2018, between the Company and SWK Funding LLC (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on March 6, 2018).

10.28 Guarantee and Collateral Agreement, dated as of March 5, 2018, between the Company and SWK Funding LLC (incorporated by reference to Exhibit 10.3 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on March 6, 2018).

10.29 Intellectual Property Security Agreement, dated as of March 5, 2018, between the Company and SWK Funding LLC (incorporated by reference to Exhibit 10.4 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on March 6, 2018).

| | |
|---|---|
| 10.30 | Pledge Agreement, dated as of March 5, 2018, between the Company and SWK Funding LLC (incorporated by reference to Exhibit 10.5 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on March 6, 2018). |
| 10.31 | First Amendment to Credit Agreement, dated as of August 10, 2018, among the Company, SWK Funding LLC and the financial institutions party to the Credit Agreement from time to time (incorporated by reference to Exhibit 10.2 to the Company's Form 10-Q (File No. 1-13602) filed with the SEC on August 14, 2018). |
| 10.32 | Consulting Agreement, dated as of September 13, 2018, between the Company and Dr. Robert Getzenberg, Ph.D. *, ** |
| 21 | Subsidiaries of Registrant. ** |
| 23.1 | Consent of RSM US LLP. ** |
| 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). **, *** |
| 101 | The following materials from the Company's Annual Report on Form 10-K for the year ended September 30, 2018, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Stockholders' Equity, (iv) Consolidated Statements of Cash Flows, and (v) the Notes to Consolidated Financial Statements. |

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

Item 16. Form 10-K Summary

Not Applicable.

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 13, 2018

VERU INC.

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

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

POWER OF ATTORNEY

Each person whose signature appears below hereby appoints Mitchell S. Steiner and Michele Greco, and each of them individually, as his or her true and lawful attorney-in-fact and agent, 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 or she 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 S. Steiner<br>Mitchell S. Steiner | Chairman of the Board, Chief Executive Officer, President and Director<br>(Principal Executive Officer) | December 13, 2018 |
| /s/ Michele Greco<br>Michele Greco | Chief Financial Officer and Chief Administrative Officer<br>(Principal Accounting and Financial Officer) | December 13, 2018 |
| /s/ O.B. Parrish<br>O.B. Parrish | Director | December 13, 2018 |
| /s/ David R. Bethune<br>David R. Bethune | Director | December 13, 2018 |
| /s/ Mario Eisenberger<br>Mario Eisenberger | Director | December 13, 2018 |
| /s/ Harry Fisch<br>Harry Fisch | Vice Chairman of the Board and Director | December 13, 2018 |
| /s/ Lucy Lu<br>Lucy Lu | Director | December 13, 2018 |
| /s/ Michael L. Rankowitz<br>Michael L. Rankowitz | Director | December 13, 2018 |
| /s/ Jesus Socorro<br>Jesus Socorro | Director | December 13, 2018 |

Veru Inc.

**Index to Consolidated Financial Statements**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders
Veru Inc.

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Veru Inc. (the Company) as of September 30, 2018 and 2017, the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended September 30, 2018, and the related notes to the consolidated financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended September 30, 2018, in conformity with accounting principles generally accepted in the United States of America.

**Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ RSM US LLP

We have served as the Company's auditor since 1996.

Chicago, Illinois
December 13, 2018

VERU INC.
CONSOLIDATED BALANCE SHEETS
SEPTEMBER 30, 2018 AND 2017

| | 2018 | 2017 |
|---|---|---|
| ASSETS | | |
| Current Assets: | | |
| Cash | $ 3,759,509 | $ 3,277,602 |
| Accounts receivable, net | 3,972,632 | 3,418,738 |
| Inventory, net | 2,302,030 | 2,767,924 |
| Prepaid expenses and other current assets | 1,148,345 | 833,709 |
| TOTAL CURRENT ASSETS | 11,182,516 | 10,297,973 |
| LONG-TERM ASSETS | | |
| PLANT AND EQUIPMENT | | |
| Equipment, furniture and fixtures | 4,018,284 | 4,067,896 |
| Leasehold improvements | 287,686 | 287,686 |
| Less: accumulated depreciation and amortization | (3,901,418) | (3,800,043) |
| Plant and equipment, net | 404,552 | 555,539 |
| Other trade receivables (Note 4) | — | 7,837,500 |
| Other assets | 965,152 | 186,431 |
| Deferred income taxes | 8,543,758 | 8,827,000 |
| Intangible assets, net | 20,477,729 | 20,752,991 |
| Goodwill | 6,878,932 | 6,878,932 |
| TOTAL ASSETS | $ 48,452,639 | $ 55,336,366 |
| | | |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current Liabilities: | | |
| Accounts payable | $ 3,226,036 | $ 2,685,718 |
| Accrued research and development costs | 981,357 | 200,710 |
| Accrued compensation | 584,047 | 406,110 |
| Accrued expenses and other current liabilities | 1,866,317 | 1,180,526 |
| Credit agreement, short-term portion (Note 7) | 6,692,718 | — |
| Unearned revenue | 202,452 | 1,014,517 |
| TOTAL CURRENT LIABILITIES | 13,552,927 | 5,487,581 |
| LONG-TERM LIABILITIES | | |
| | | |
| Credit agreement, long-term portion (Note 7) | 2,701,570 | — |
| Residual royalty agreement (Note 7) | 1,753,805 | — |
| Other liabilities | 30,000 | 1,263,750 |
| Deferred rent | 88,161 | 131,830 |
| Deferred income taxes | 844,758 | — |
| TOTAL LIABILITIES | 18,971,221 | 6,883,161 |
| | | |
| Commitments and contingencies (Note 11) | | |
| STOCKHOLDERS' EQUITY | | |
| Preferred stock; no shares issued and outstanding at September 30, 2018 and September 30, 2017 | — | — |
| Common stock, par value $0.01 per share; 77,000,000 shares authorized, 57,468,660 and 55,392,193 shares issued and 55,284,956 and 53,208,489 shares outstanding at September 30, 2018 and September 30, 2017, respectively | 574,687 | 553,922 |
| Additional paid-in-capital | 95,496,506 | 90,550,669 |
| Accumulated other comprehensive loss | (581,519) | (581,519) |
| Accumulated deficit | (58,201,651) | (34,263,262) |
| Treasury stock, 2,183,704 shares, at cost | (7,806,605) | (7,806,605) |
| TOTAL STOCKHOLDERS' EQUITY | 29,481,418 | 48,453,205 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | $ 48,452,639 | $ 55,336,366 |

See notes to consolidated financial statements.

VERU INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED SEPTEMBER 30, 2018 AND 2017

| | 2018 | 2017 |
|---|---|---|
| Net revenues | $ 15,864,483 | $ 13,655,592 |
| Cost of sales | 7,081,981 | 6,636,080 |
| Gross profit | 8,782,502 | 7,019,512 |
| Operating expenses: | | |
| Research and development | 10,850,958 | 3,076,390 |
| Selling, general and administrative | 14,817,433 | 11,501,453 |
| Loss on settlement of accounts receivable | 3,986,518 | — |
| Business acquisition | — | 935,781 |
| Total operating expenses | 29,654,909 | 15,513,624 |
| Operating loss | (20,872,407) | (8,494,112) |
| Non-operating (expense) income: | | |
| Interest expense | (2,950,501) | — |
| Change in fair value of derivative liabilities | 893,000 | — |
| Foreign currency transaction loss | (126,928) | (61,835) |
| Other expense, net | (15,451) | (46,543) |
| Total non-operating expenses | (2,199,880) | (108,378) |
| Loss before income taxes | (23,072,287) | (8,602,490) |
| Income tax expense (benefit) | 866,102 | (1,990,443) |
| Net loss attributable to common stockholders before preferred stock dividend | (23,938,389) | (6,612,047) |
| Preferred stock dividend | — | 1,990,771 |
| Net loss attributable to common stockholders | $ (23,938,389) | $ (8,602,818) |
| Net loss per basic and diluted common share outstanding | $ (0.44) | $ (0.25) |
| Basic and diluted weighted average common shares outstanding | 53,861,981 | 34,640,308 |

See notes to consolidated financial statements.

VERU INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

| | Preferred Stock | Common Stock Shares | Common Stock Amount | Additional Paid-in Capital | Accumulated Other Comprehensive Loss | Accumulated Deficit | Treasury Stock, at Cost | Total |
|---|---|---|---|---|---|---|---|---|
| Balance at September 30, 2016 | $ — | 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 546,756 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 stockholders 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 |
| Share-based compensation | — | — | — | 1,638,505 | — | — | — | 1,638,505 |
| Shares issued in connection with common stock purchase agreement | — | 304,457 | 3,045 | 344,036 | — | — | — | 347,081 |
| Sale of shares under common stock purchase agreement | — | 1,717,010 | 17,170 | 2,982,830 | — | — | — | 3,000,000 |
| Amortization of deferred costs | — | — | — | (84,984) | — | — | — | (84,984) |
| Shares issued upon exercise of stock options | — | 55,000 | 550 | 65,450 | — | — | — | 66,000 |
| Net loss | — | — | — | — | — | (23,938,389) | — | (23,938,389) |
| Balance at September 30, 2018 | $ — | 57,468,660 | $ 574,687 | $ 95,496,506 | $ (581,519) | $ (58,201,651) | $ (7,806,605) | $ 29,481,418 |

See notes to consolidated financial statements.

VERU INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED SEPTEMBER 30, 2018 AND 2017

| | 2018 | 2017 |
|---|---|---|
| OPERATING ACTIVITIES | | |
| Net loss attributable to common stockholders before preferred stock dividend | $ (23,938,389) | $ (6,612,047) |
| Adjustments to reconcile net loss attributable to common stockholders before preferred stock dividend to net cash (used in) provided by operating activities: | | |
| Depreciation and amortization | 176,786 | 333,999 |
| Amortization of intangible assets | 275,262 | 147,009 |
| Noncash interest expense | 2,950,501 | — |
| Share-based compensation | 1,638,505 | 756,275 |
| Warrants issued | — | 542,930 |
| Deferred income taxes | 630,150 | (2,255,069) |
| Loss on settlement of accounts receivable | 3,986,518 | — |
| Provision for obsolete inventory | 90,856 | 345,179 |
| Change in fair value of derivative liabilities | (893,000) | — |
| Other | (2,756) | 73,992 |
| Changes in operating assets and liabilities, net of effects of acquisition of a business: | | |
| Decrease in accounts receivable | 1,874,555 | 7,277,349 |
| Decrease (increase) in inventory | 375,038 | (479,418) |
| Increase in prepaid expenses and other assets | (65,570) | (77,520) |
| Increase in accounts payable | 495,971 | 897,471 |
| (Decrease) increase in unearned revenue | (471,775) | 1,014,517 |
| Increase (decrease) in accrued expenses and other current liabilities | 1,331,157 | (981,779) |
| Net cash (used in) provided by operating activities | (11,546,191) | 982,888 |
| INVESTING ACTIVITIES | | |
| Acquisition of Aspen Park Pharmaceuticals | — | 43,118 |
| Capital expenditures | (50,654) | (133,486) |
| Net cash used in investing activities | (50,654) | (90,368) |
| FINANCING ACTIVITIES | | |
| Proceeds from SWK credit agreement | 10,000,000 | — |
| Payment of debt issuance costs | (266,923) | — |
| Installment payment on SWK credit agreement | (642,485) | — |
| Proceeds from sale of shares under common stock purchase agreement | 3,000,000 | — |
| Payment of costs related to common stock purchase agreement | (77,840) | — |
| Proceeds from stock option exercises | 66,000 | — |
| Net cash provided by financing activities | 12,078,752 | — |
| Net increase in cash | 481,907 | 892,520 |
| CASH AT BEGINNING OF YEAR | 3,277,602 | 2,385,082 |
| CASH AT END OF YEAR | $ 3,759,509 | $ 3,277,602 |
| Supplemental disclosure of cash flow information: | | |
| Cash paid for income taxes | $ 222,223 | $ 230,705 |
| Schedule of noncash investing and financing activities: | | |
| Issuance of common stock in connection with the APP Acquisition | $ — | $ 1,826,097 |
| Issuance of Series 4 Preferred Stock in connection with the APP Acquisition | $ — | $ 17,981,883 |
| Reduction of accrued expense upon issuance of shares | $ — | $ 22,176 |
| Shares issued in connection with common stock purchase agreement | $ 347,081 | $ — |
| Amortization of deferred costs related to common stock purchase agreement | $ 84,984 | $ — |
| Increase in other assets from accounts payable and accrued expenses | $ 190,000 | $ — |

See notes to consolidated financial statements.

**Note 1 – Nature of Business and Significant Accounting Policies**

Principles of consolidation and nature of operations: Veru Inc. is referred to in these notes collectively with its subsidiaries as "we," "our," "us," "Veru" or the "Company." The consolidated financial statements include the accounts of Veru and its wholly owned subsidiaries, Aspen Park Pharmaceuticals, Inc. ("APP") and The Female Health Company Limited, and The Female Health Company Limited's wholly owned subsidiary, The Female Health Company (UK) plc, and The Female Health Company (UK) plc's wholly owned subsidiary, The Female Health Company (M) SDN.BHD. All significant intercompany transactions and accounts have been eliminated in consolidation. Prior to the completion of the October 31, 2016 acquisition (the "APP Acquisition") of APP through the merger of a wholly owned subsidiary of the Company into APP, the Company had been a single product company engaged in marketing, manufacturing and distributing a consumer health care product, the FC2 Female Condom® ("FC2"). The completion of the APP Acquisition transitioned the Company into a biopharmaceutical company focused on oncology and urology with multiple drug products under clinical development. Nearly all of the Company's net revenues during fiscal 2018 and 2017 were derived from sales of FC2.

FC2 has been distributed in either or both commercial (private sector) and public health sector markets in 149 countries. It is marketed to consumers in 25 countries through distributors, public health programs, and/or retailers and in the U.S. by prescription.

Reclassifications: Certain prior period amounts in the accompanying consolidated financial statements have been reclassified to conform with the current period presentation. These reclassifications had no effect on the results of operations or financial position for any period presented.

Use of estimates: The preparation of financial statements in conformity with accounting principles generally accepted in the United States ("U.S. GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates.

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

Restricted cash: Restricted cash relates to security provided to one of the Company's U.K. banks for performance bonds issued in favor of customers. The Company has a facility of $250,000 for such performance bonds. Such security has been extended infrequently and only on occasions where it has been a contract term expressly stipulated as an absolute requirement by the customer or its provider of funds. The expiration of the bond is defined by the completion of the event such as, but not limited to, a period of time after the product has been distributed or expiration of the product shelf life. Restricted cash was approximately $135,000 and $139,000 at September 30, 2018 and 2017, respectively, and is included in cash on the accompanying consolidated balance sheets.

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

The Company's standard credit terms vary from 30 to 120 days, depending on the class of trade and customary terms within a territory, so accounts receivable is affected by the mix of purchasers within the period. As is typical in the Company's business, extended credit terms may occasionally be offered as a sales promotion or for certain sales. The Company has agreed to credit terms of up to 150 days with our distributor in the Republic of South Africa. For the order of 15 million units under the Brazil tender in 2014, the Company agreed to up to 360 days credit terms with our distributor in Brazil subject to earlier payment upon receipt of payment by the distributor from the Brazilian Government. See discussion of receivables in Note 4. For the year ended September 30, 2018, the Company's average days' sales outstanding was approximately 78 days.

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

Fixed assets: We record equipment, furniture and fixtures, and leasehold improvements at historical cost. Expenditures for maintenance and repairs are recorded to expense. Depreciation and amortization are primarily computed using the straight-line method. Depreciation and amortization are computed over the estimated useful lives of the respective assets which range as follows:

| | |
|---|---|
| Manufacturing equipment | 5 – 10 years |
| Office equipment | 3 – 5 years |
| Furniture and fixtures | 7 – 10 years |

Leasehold improvements are depreciated on a straight-line basis over the lesser of the remaining lease term or the estimated useful lives of the improvements.

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

Intangible assets: Our intangible assets arose from the APP Acquisition on October 31, 2016. These intangible assets are carried at cost less accumulated amortization. Intangible assets with finite lives are tested for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. In-process research and development ("IPR&D") is tested for impairment at least annually in the fourth quarter of each fiscal year until the underlying projects are completed or abandoned.

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. The most complex and judgmental matters applicable to the valuation process are summarized below:

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

and manufacturing infrastructure. We also consider that any repatriation of earnings would likely have U.S. tax consequences.

- Discount rate – Discount rates are selected after considering the risks inherent in the future cash flows; the assessment of the asset's life cycle and the competitive trends impacting the asset, including consideration of any technical, legal, regulatory, or economic barriers to entry, as well as expected changes in standards of practice for indications addressed by the asset.

Intangible assets are highly vulnerable to impairment charges, particularly newly acquired assets for recently launched products. These assets are initially measured at fair value and therefore any reduction in expectations used in the valuations could potentially lead to impairment. Some of the more common potential risks leading to impairment include competition, earlier than expected loss of exclusivity, pricing pressures, adverse regulatory changes or clinical trial results, delay or failure to obtain regulatory approval and additional development costs, inability to achieve expected synergies, higher operating costs, changes in tax laws and other macro-economic changes. The complexity in estimating the fair value of intangible assets in connection with an impairment test is similar to the initial valuation. Considering the high-risk nature of research and development and the industry's success rate of bringing developmental compounds to market, IPR&D impairment charges are likely to occur in future periods.

Goodwill: Goodwill represents the difference between the purchase price and the estimated fair value of the net assets acquired in the APP Acquisition. All goodwill resides in the Company's Research and Development reporting unit, which consists of multiple drug products under clinical development for oncology and urology.

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

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

Deferred financing costs: Costs incurred in connection with the common stock purchase agreement discussed in Note 8 have been included in other assets on the accompanying consolidated balance sheet at September 30, 2018. When shares of the Company's common stock are sold under the common stock purchase agreement, a pro-rata portion of the deferred costs is recorded to additional paid-in-capital.

As discussed in Note 8, in connection with the common stock offering that closed on October 1, 2018, we incurred costs of approximately $190,000 through September 30, 2018. This amount is included in other assets as well as accounts payable and accrued expenses and other current liabilities on the accompanying consolidated balance sheet at September 30, 2018. These costs will be charged to additional paid-in capital in the first quarter of fiscal 2019 when the common stock offering closed.

Costs incurred in connection with the issuance of debt discussed in Note 7 are presented as a reduction of the debt on the accompanying consolidated balance sheet at September 30, 2018. These issuance costs are being amortized using the effective interest method over the expected repayment period of the debt, which is currently estimated to occur in the fourth quarter of fiscal 2021. The amount of amortization was approximately $63,000 for fiscal 2018 and it is included in interest expense on the accompanying consolidated statements of operations.

Fair value measurements: Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 820 – Fair Value Measurements and Disclosures, defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the

measurement date. FASB ASC Topic 820 requires disclosures about the fair value of all financial instruments, whether or not recognized, for financial statement purposes. Disclosures about the fair value of financial instruments are based on pertinent information available to us as of the reporting dates. Accordingly, the estimates presented in the accompanying consolidated financial statements are not necessarily indicative of the amounts that could be realized on disposition of the financial instruments. See Note 3 for a discussion of fair value measurements.

The carrying amounts reported in the accompanying consolidated balance sheets for cash, accounts receivable, accounts payable and other accrued liabilities approximate their fair value based on the short-term nature of these instruments. The carrying value of long-term debt, taking into consideration debt discounts and related derivative instruments, is estimated to approximate fair value.

Unearned revenue: FC2 is distributed in the U.S. prescription channel principally through large pharmaceutical distributors. These distributors then sell principally to retail pharmacies. Unearned revenue as of September 30, 2018 and September 30, 2017 was approximately $202,000 and $1.0 million, respectively, and was comprised mainly of sales made to a large distributor who has the right to return product sold under certain conditions. We lack the experiential data which would allow us to estimate returns for product sold to this distributor. Therefore, as of September 30, 2018 and September 30, 2017, we determined that we do not yet meet the criteria for the recognition of revenue at the time of shipment to this distributor as returns cannot be reasonably estimated. Accordingly, the Company deferred recognition of revenue on prescription product sold to this particular distributor until the right of return no longer exists, which occurs at the earlier of the time the prescription products were dispensed through patient prescriptions or expiration of the right of return. Subsequent to September 30, 2018, the distributor returned approximately $340,000 of product. The amount of unearned revenue at September 30, 2018 has been reduced to reflect this return, with a corresponding increase in accrued expenses and other current liabilities.

Derivative instruments: The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. The Company reviews the terms of debt instruments it enters into to determine whether there are embedded derivative instruments, which are required to be bifurcated and accounted for separately as derivative financial instruments. Embedded derivatives that are not clearly and closely related to the host contract are bifurcated and are recognized at fair value with changes in fair value recognized as either a gain or loss in earnings. Liabilities incurred in connection with an embedded derivative are discussed in Note 7.

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

Research and development costs: Research and development costs are expensed as they are incurred and include salaries and benefits, clinical trials costs and contract services. Nonrefundable advance payments made for goods or services to be used in research and development activities are deferred and capitalized until the goods have been delivered or the related services have been performed. If the goods are no longer expected to be delivered or the services are no longer expected to be performed, the Company would be required to expense the related capitalized advance payments. The Company did not have any capitalized nonrefundable advance payments as of September 30, 2018 or September 30, 2017.

The Company records estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies and clinical trials and contract manufacturing activities. These costs are a significant component of the Company's research and development expenses. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers under the service agreements. The Company makes significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. The Company has not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed, number of patients enrolled and the rate of patient enrollments may vary from the Company's estimates, resulting in adjustments to expense in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations.

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

Advertising: The Company's policy is to expense advertising costs as incurred. Advertising costs were immaterial to the Company's results of operations for the fiscal years ended September 30, 2018 and 2017.

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

Foreign currency translation and operations: Effective October 1, 2009, the Company determined that there were significant changes in facts and circumstances, triggering an evaluation of its subsidiaries' functional currency. The evaluation indicated that the U.S. dollar is the currency with the most significant influence upon the subsidiaries. Because all of the U.K. subsidiary's future sales and cash flows would be denominated in U.S. dollars following the October 2009 cessation of production of the Company's first-generation product, FC1, the U.K. subsidiary adopted the U.S. dollar as its functional currency effective October 1, 2009. As the Malaysia subsidiary is a direct and integral component of the U.K. parent's operations, it, too, adopted the U.S. dollar as its functional currency as of October 1, 2009. The consistent use of the U.S. dollar as the functional currency across the Company reduces its foreign currency risk and stabilizes its operating results. The cumulative foreign currency translation loss included in accumulated other comprehensive loss was $0.6 million as of September 30, 2018 and September 30, 2017. Assets located outside of the U.S. totaled approximately $5.2 million and $5.6 million at September 30, 2018 and September 30, 2017, respectively.

Other comprehensive loss: Accounting principles generally require that recognized revenue, expenses, gains and losses be included in net loss. Although certain changes in assets and liabilities, such as foreign currency translation adjustments, are reported as a separate component of the equity section of the accompanying consolidated balance sheets, these items, along with net loss, are components of other comprehensive loss.

The U.S. parent company and its U.K. subsidiary routinely purchase inventory produced by its Malaysia subsidiary for sale to their respective customers. These intercompany trade accounts are eliminated in consolidation. The Company's policy and intent is to settle the intercompany trade account on a current basis. Since the U.K. and Malaysia subsidiaries adopted the U.S. dollar as their functional currencies effective October 1, 2009, no foreign currency gains or losses from intercompany trade are recognized. In fiscal 2018 and 2017, comprehensive loss is equivalent to the reported net loss.

Liquidity

The Company has incurred quarterly operating losses since the fourth quarter of fiscal 2016 and anticipates that it will continue to consume cash and incur substantial net losses as it develops its drug candidates. Because of the numerous risks and uncertainties associated with the development of pharmaceutical products, the Company is unable to estimate the exact amounts of capital outlays and operating expenditures necessary to fund development of its product candidates and obtain regulatory approvals. The Company's future capital requirements will depend on many factors.

The Company believes its current cash position and its ability to secure equity financing or other financing alternatives are adequate to fund planned operations of the Company for the next 12 months. Such financing alternatives may include debt financing, common stock offerings or financing involving convertible debt or other equity-linked securities and may include financings under the Company's effective shelf registration statement on Form S-3 (File No. 333-221120) (the "Shelf Registration Statement"). The Company intends to be opportunistic when pursuing equity financing which could include selling common stock under its common stock purchase agreement with Aspire Capital Fund, LLC (see Note 7) and/or a marketed deal with an investment bank. The Company's ability to raise capital through equity financing may be limited by the number of authorized shares of the Company's common stock, which is currently 77 million shares. In order to raise significant additional amounts from equity financing, the Company will need to seek stockholder approval to amend our Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock, and any such amendment would require the approval of the holders of at least two-thirds of the outstanding shares of the Company's common stock.

Recently Issued Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09 *Revenue from Contracts with Customers (Topic 606)*. This new accounting guidance on revenue recognition provides for a single five-step model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations, and recognizing revenue when, or as, an entity satisfies a performance obligation. The new guidance also requires additional financial statement disclosures that will enable users to understand the nature, amount, timing and uncertainty of revenue and cash flows relating to customer contracts. The Company will apply the new guidance effective October 1, 2018 using the modified retrospective method to contracts that are not completed as of October 1, 2018. The Company has completed its assessment of the new guidance and adoption of this guidance is not expected to have a material effect on our financial position or results of operations.

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

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842).* The amendments in this Update increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. ASU 2016-02 will be effective for the Company beginning on October 1, 2019. Early adoption is permitted. In July 2018, the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases to clarify the implementation guidance and ASU No. 2018-11, Leases (Topic 842) Targeted Improvements. This updated guidance provides an optional transition method, which allows for the initial application of the new accounting standard at the adoption date and the recognition of a cumulative-effect adjustment to the opening balance of retained earnings as of the beginning of the period of adoption. We have begun to identify our significant lease contracts and are in the process of evaluating the effect of the new guidance on our consolidated financial statements and related disclosures.

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

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash.* The purpose of ASU 2016-18 is to clarify guidance and presentation related to restricted cash in the statements of cash flows as well as increased disclosure requirements. It requires beginning-of-period and end-of-period total amounts shown on the statements of cash flows to include cash and cash equivalents as well as restricted cash and restricted cash equivalents. ASU 2016-18 will be effective for annual periods beginning after December 15, 2017, including interim reporting periods within those annual periods. Early adoption is permitted. The adoption of ASU 2016-18 is not expected to have a material effect on the presentation of our consolidated statements of cash flows.

In January 2017, the FASB issued ASU 2017-04, *Intangibles - Goodwill and Other Topics (Topic 350):* Simplifying the Test for Goodwill Impairment. The purpose of ASU 2017-04 is to reduce the cost and complexity of evaluating goodwill for impairment. It eliminates the need for entities to calculate the impaired fair value of goodwill by assigning the fair value of a reporting unit to all of its assets and liabilities as if that reporting unit had been acquired in a business combination. Under this amendment, an entity will perform its goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An impairment charge is recognized for the amount by which the carrying value exceeds the reporting unit's fair value. ASU 2017-04 is effective for annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. We do not expect Update No. 2017-04 to have a material effect on our financial position or results of operations.

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

In May 2017, the FASB issued ASU 2017-09, *Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting.* The purpose of ASU 2017-09 is to provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. ASU 2017-09 will be effective for annual periods beginning after December 15, 2017, including interim periods within those annual periods. Early adoption is permitted as of the beginning of an annual or interim period for which financial statements have not been issued or made available for issuance. The amendments in this Update should be applied prospectively to an award modified on or after the adoption date. The adoption of ASU 2017-09 is not expected to have a material effect on our financial position or results of operations.

In June 2018, the FASB issued ASU 2018-07, *Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting.* The purpose of ASU 2018-07 is to expand the scope of Topic 718, Compensation—Stock Compensation (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. ASU 2018-07 will be effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than the Company's adoption date of Topic 606, Revenue from Contracts with Customers. The Company has issued share-based payments to nonemployees in the past but is not able to predict the amount of future share-based payments to nonemployees, if any. The adoption of ASU 2018-07 is not expected to have a material effect on our financial position or results of operations but should simplify the process by which the Company measures compensation expense for share-based payments to nonemployees.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework – Change to the Disclosure Requirements for Fair Value Measurement.* ASU 2018-13 modifies the disclosure requirements by adding, removing, and modifying certain required disclosures for fair value measurements for assets and liabilities disclosed within the fair value hierarchy. ASU 2018-13 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019 and early adoption is permitted. The adoption of ASU 2018-13 is not expected to have a material effect on our financial position or results of operations as it modifies disclosure requirements only.

**Note 2 – APP Acquisition**

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

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 included the following:

- Each share of Series 4 Preferred Stock would 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 would 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" included 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 was 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 was 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 could 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 was eligible to participate in dividends paid to holders of the Company's common stock on an as converted basis.
- The Series 4 Preferred Stock had one vote per share and could 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 21,870,240 shares of the Company’s common stock effective July 31, 2017.

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 five 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 evaluated the RRA under the guidance in ASC 825-20 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 consideration was 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% discount on the shares subject to lock-up agreements, due to the lack of liquidity since the shares are not freely tradeable for a set time period. The shares of Series 4 Preferred Stock were valued on an as-converted basis based on the share price of the Company’s common stock on October 31, 2016 less a 12% discount on approximately 49% of the shares Series 4 Preferred Stock that are subject to an 18-month lockup agreement and a 6% discount on the remaining shares of Series 4 Preferred Stock. The discount was applied since the shares of Series 4 Preferred Stock 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% probability that the shares of Series 4 Preferred Stock would convert to common stock rather than be redeemed, which was assigned a 5% probability.

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 Preferred Stock automatically converted to common stock. As such, approximately $2.0 million was recognized as a dividend to the holders of the Series 4 Preferred Stock.

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 |

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

Purchase price in excess of assets acquired and liabilities assumed was recorded as goodwill. Goodwill from the APP Acquisition principally relates to intangible assets that do not qualify for separate recognition, our expectation to develop and market new products, and the deferred tax liability generated as a result of the transaction. Goodwill is not tax deductible for income tax purposes and was assigned to the Company's Research and Development reporting unit.

The results of operations of APP have been included in the accompanying consolidated financial statements since the date of acquisition. The consolidated statement of operations for fiscal 2017 includes expenses from APP from the October 31, 2016 acquisition date to September 30, 2017 of $3.2 million. Revenues from APP were not material to our consolidated financial results.

The Company incurred acquisition-related costs of approximately $936,000 in fiscal 2017, which are presented on a separate line item in the accompanying consolidated statements of operations. The Company did not incur acquisition-related costs in fiscal 2018.

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 – Fair Value Measurements**

FASB ASC Topic 820 specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

The three levels of the fair value hierarchy are as follows:

Level 1 – Quoted prices for identical instruments in active markets.

Level 2 – Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3 – Instruments with primarily unobservable value drivers.

We review the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels of certain securities within the fair value hierarchy. There were no transfers between Level 1, Level 2 and Level 3 during fiscal 2018 and 2017.

As of September 30, 2018, the Company's financial liabilities measured at fair value on a recurring basis, which consisted of embedded derivatives, were classified within Level 3 of the fair value hierarchy. The Company did not have any financial assets or liabilities measured at fair value on a recurring basis as of September 30, 2017.

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

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

| | | |
|---|---|---|
| Beginning balance at October 1, 2017 | $ | — |
| Additions | | 3,319,000 |
| Change in fair value of derivative liabilities | | (893,000) |
| Ending balance at September 30, 2018 | $ | 2,426,000 |

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

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

The following table presents quantitative information about the inputs and valuation methodologies used to determine the fair value of the embedded derivatives classified in Level 3 of the fair value hierarchy as of September 30, 2018:

| Valuation Methodology | Significant Unobservable Input | Weighted Average (range, if applicable) |
|---|---|---|
| Monte Carlo Simulation | Estimated change of control dates | September 2019 to December 2021 |
| | Discount rate | 11.1% to 12.0% |
| | Probability of change of control | 10% to 90% |

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

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

| | 2018 | 2017 |
|---|---|---|
| Trade receivables | $ 4,008,833 | $ 11,294,341 |
| Less: allowance for doubtful accounts | (36,201) | (38,103) |
| Trade receivables, net | 3,972,632 | 11,256,238 |
| Less: long-term trade receivables | — | (7,837,500) |
| Current trade receivables, net | $ 3,972,632 | $ 3,418,738 |

On December 27, 2017, we entered into a settlement agreement with Semina, our distributor in Brazil, pursuant to which Semina made a payment of $2.2 million and was obligated to make a second payment of $1.5 million by February 28, 2018, to settle net amounts due to us totaling $7.5 million. Semina did not make its second payment of $1.5 million by February 28, 2018. In July 2018, the Company agreed to accept $1.3 million as settlement of the second payment of $1.5 million that was owed. The amounts owed to us related to outstanding accounts receivable for sales to Semina for the 2014 Brazil tender totaling $8.9 million, $7.8 million of which was classified as a long-term trade receivable and $1.1 million as a current account receivable on the accompanying consolidated balance sheet as of September 30, 2017. These receivables were net of payables owed to Semina by us totaling $1.4 million, $1.2 million of which was classified as a long-term liability and $0.2 million was classified as a current liability on the accompanying consolidated balance sheet as of September 30, 2017. The settlement was not related to our belief in the ultimate collectability of the receivables or in the creditworthiness of Semina. We elected to settle these amounts due to the uncertainty regarding the timing of payment by the Brazilian Government and, ultimately to us, on the remaining amounts due. The result of the settlement was a net loss of approximately $4.0 million for the year ended September 30, 2018, which is presented as a separate line item in the accompanying consolidated statements of operations.

At September 30, 2018, USAID's accounts receivable balance represented 15% of current assets. At September 30, 2017, Semina's current accounts receivable balance represented 11% of current assets. No other single customer's accounts receivable balance accounted for more than 10% of current assets at those dates.

At September 30, 2018, three customers had an accounts receivable balance greater than 10% of accounts receivable, representing 74% of accounts receivable in the aggregate. At September 30, 2017, Semina's accounts receivable and long-term other trade receivables balance represented 79% of the Company's total accounts receivable and long-term other trade receivables.

For the year ended September 30, 2018, there were three customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues; the net revenues for UNFPA, USAID and Barrs Medical (PTY) Ltd were $4.1 million, $3.0 million and $2.9 million, respectively. For the year ended September 30, 2017, there were two customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues; the net revenues for UNFPA and USAID were $3.3 million and $5.8 million, respectively.

The Company maintains an allowance for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments on accounts receivable. Management determines the allowance for doubtful accounts by identifying troubled accounts and by using historical experience applied to an aging of accounts. Management also periodically evaluates individual customer receivables and considers a customer's financial condition, credit history, and the current economic conditions. Accounts receivable are charged-off when deemed

uncollectible. The table below summarizes the change in the allowance for doubtful accounts for the years ended September 30, 2018 and 2017, excluding the effects of the amounts that were due from Semina discussed above.

| | 2018 | 2017 |
|---|---|---|
| Beginning balance | $ 38,103 | $ 38,103 |
| Charges to expense | 16,058 | — |
| Charge-offs | (17,960) | — |
| Ending balance | $ 36,201 | $ 38,103 |

Recoveries of accounts receivable previously charged-off are recorded when received. The Company's customers are primarily health care distributors, large global agencies, non-government organizations, ministries of health and other governmental agencies which purchase and distribute FC2 for use in HIV/AIDS prevention and family planning programs.

**Note 5 – Inventory**

Inventory at September 30, 2018 and 2017:

| | 2018 | 2017 |
|---|---|---|
| FC2 | | |
| Raw material | $ 366,220 | $ 530,384 |
| Work in process | 77,669 | 90,164 |
| Finished goods | 2,232,864 | 2,427,386 |
| Inventory, gross | 2,676,753 | 3,047,934 |
| Less: inventory reserves | (391,861) | (312,997) |
| FC2, net | 2,284,892 | 2,734,937 |
| PREBOOST® | | |
| Finished goods | 17,138 | 32,987 |
| Inventory, net | $ 2,302,030 | $ 2,767,924 |

**Note 6 – Goodwill and Intangible Assets**

Goodwill

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

| | 2018 | 2017 |
|---|---|---|
| Beginning balance | $ 6,878,932 | $ — |
| Goodwill arising from APP Acquisition | — | 6,878,932 |
| Ending balance | $ 6,878,932 | $ 6,878,932 |

Intangible Assets

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

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

| | Gross Carrying Amount | Accumulated Amortization | Net Book Value |
|---|---|---|---|
| Intangible assets with finite lives: | | | |
| Developed technology - PREBOOST® | $ 2,400,000 | $ 285,366 | $ 2,114,634 |
| Covenants not-to-compete | 500,000 | 136,905 | 363,095 |
| Total intangible assets with finite lives | 2,900,000 | 422,271 | 2,477,729 |
| Acquired in-process research and development assets | 18,000,000 | — | 18,000,000 |
| Total intangible assets | $ 20,900,000 | $ 422,271 | $ 20,477,729 |

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 |

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

Amortization expense was approximately $275,000 and $147,000, for the years ended September 30, 2018 and 2017, respectively. Based on finite-lived intangible assets recorded as of September 30, 2018, the estimated future amortization expense is as follows:

| Year Ending September 30, | Estimated Amortization Expense |
|---|---|
| 2019 | $ 309,234 |
| 2020 | 316,368 |
| 2021 | 323,706 |
| 2022 | 331,316 |
| 2023 | 339,062 |
| Thereafter | 858,043 |
| Total | $ 2,477,729 |

**Note 7 – Debt**

SWK Credit Agreement

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

The Lenders will be entitled to receive quarterly payments on the term loan based on the Company's product revenue from net sales of FC2 as provided in the Credit Agreement until the Company has paid 175% of the aggregate amount advanced to the Company under the Credit Agreement. If product revenue from net sales of FC2 for the twelve-month period ended as of the last day of the respective quarterly payment period is less than $10.0 million, the quarterly payments will be 32.5% of product revenue from net sales of FC2 during the quarterly period. If product revenue from net sales of FC2 for the twelve month period ended as of the last day of the respective quarterly payment period is equal to or greater than $10.0 million, the quarterly payments are calculated as the sum of 25% of product revenue from net sales of FC2 up to and including $12.5 million in the Elapsed Period (as defined in the Credit Agreement), plus 10% of product revenue from net sales of FC2 greater than $12.5 million in the Elapsed Period. Upon the Credit Agreement's termination date of March 5, 2025, the Company must pay 175% of

the aggregate amount advanced to the Company under the Credit Agreement less the amounts previously paid by the Company from product revenue.

The first quarterly revenue-based payment due May 15, 2018 was approximately $642,000 and was paid on that date. On August 10, 2018, the Company entered into an amendment (the "Credit Agreement Amendment") to the Credit Agreement. The Credit Agreement Amendment deferred until November 15, 2018 the due date for the quarterly revenue-based payment that would have otherwise been due on August 15, 2018. The Company made a payment of approximately $2.6 million on November 15, 2018, consisting of approximately $1.4 million for the quarterly revenue-based payment originally due on August 15, 2018 and approximately $1.2 million for the quarterly revenue-based payment due on November 15, 2018.

Upon a change of control of the Company or sale of the FC2 business, the Company must pay off the loan by making a payment to the Lenders equal to (i) 175% of the aggregate amount advanced to the Company under the Credit Agreement less the amounts previously paid by the Company from product revenue, plus (ii) the greater of (A) $2.0 million or (B) the product of (x) 5% of the product revenue from net sales of FC2 for the most recently completed 12-month period multiplied by (y) five. A "change of control" under the Credit Agreement includes (i) an acquisition by any person of direct or indirect ownership of more than 50% of the Company's issued and outstanding voting equity, (ii) a change of control or similar event in the Company's articles of incorporation or bylaws, (iii) certain Key Persons as defined in the Credit Agreement cease to serve in their current executive capacities unless replaced within 90 days by a person reasonably acceptable to the Agent, which acceptance not to be unreasonably withheld, or (iv) the sale of all or substantially all of the Company's assets.

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

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

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

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

For accounting purposes, the initial $10.0 million advance under the Credit Agreement was allocated between the Credit Agreement and the Residual Royalty Agreement on a relative fair value basis. A portion of the amount allocated to the Credit Agreement and a portion of the amount allocated to the Residual Royalty Agreement, in both cases equal to the fair value of the respective change of control provisions, was allocated to the embedded derivative liabilities. The derivative liabilities will be adjusted to fair market value at each subsequent reporting period. For financial statement presentation, the embedded derivative liabilities have been included with their respective host instruments as noted in the following tables. The debt discounts, which totaled $11.2 million at inception, are being amortized to interest expense over the expected term of the loan using the effective interest method. Additionally, the Company recorded deferred loan issuance costs of approximately $267,000 for legal fees incurred in connection

with the Credit Agreement. The deferred loan issuance costs are presented as a reduction in the Credit Agreement obligation and are being amortized to interest expense over the expected term of the loan using the effective interest method.

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

| | September 30, 2018 |
|---|---|
| Aggregate repayment obligation | $ 17,500,000 |
| Less: Payments | (642,485) |
| Less: Unamortized discounts | (8,475,874) |
| Less: Unamortized deferred issuance costs | (204,353) |
| Credit agreement, net | 8,177,288 |
| Add: Embedded derivative liability at fair value (see Note 3) | 1,217,000 |
| | 9,394,288 |
| Credit agreement, short-term portion | (6,692,718) |
| Credit agreement, long-term portion | $ 2,701,570 |

The short-term portion of the Credit Agreement represents the aggregate of the estimated quarterly revenue-based payments payable during the year ending September 30, 2019.

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

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

| | September 30, 2018 |
|---|---|
| Residual Royalty Agreement liability, fair value at inception | $ 346,000 |
| Less: Unamortized discounts | (2,420) |
| Add: Accretion of liability using effective interest rate | 201,225 |
| Residual Royalty Agreement liability, net | 544,805 |
| Add: Embedded derivative liability at fair value (see Note 3) | 1,209,000 |
| Residual Royalty Agreement liability | $ 1,753,805 |

Interest expense related to the Credit Agreement and the Residual Royalty Agreement consisted of amortization of the discounts, accretion of the liability for the Residual Royalty Agreement and amortization of the deferred issuance costs. For the year ended September 30, 2018, interest expense related to the Credit Agreement was as follows:

| | Year Ended September 30, 2018 |
|---|---|
| Amortization of Credit Agreement and Residual Royalty Agreement discounts | $ 2,686,706 |
| Accretion of Residual Royalty Agreement liability | 201,225 |
| Amortization of deferred issuance costs | 62,570 |
| | $ 2,950,501 |

Revolving Line of Credit

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

**Note 8 – Stockholders' Equity**

Preferred Stock

The Company has 5,000,000 shares designated as Class A Preferred Stock with a par value of $.01 per share. There are 1,040,000 shares of Class A Preferred Stock - Series 1 authorized; 1,500,000 shares of Class A Preferred Stock- Series 2 authorized; 700,000 shares of Class A Preferred Stock - Series 3 authorized; and 548,000 shares of Class A Preferred Stock- Series 4 (the "Series 4 Preferred Stock") authorized. In connection with the completion of the APP Acquisition (see Note 2), a total of 546,756 shares of Series 4 Preferred Stock were issued to the former APP stockholders as of October 31, 2016, and all of the outstanding shares of Series 4 Preferred automatically converted into shares of the Company's common stock effective July 31, 2017. There were no shares of Class A Preferred Stock of any series issued and outstanding at September 30, 2018 or September 30, 2017. The Company has 15,000 shares designated as Class B Preferred Stock with a par value of $0.50 per share. There were no shares of Class B Preferred Stock issued and outstanding at September 30, 2018 or September 30, 2017.

Common Stock

We are authorized to issue up to 77,000,000 shares of common stock, $0.01 par value per share. 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 shares. Holders are entitled to one vote for each share of common stock.

Common Stock Purchase Warrants

In connection with the closing of the APP Acquisition, the Company issued a warrant to purchase up to 2,585,379 shares of the Company's common stock to Torreya Capital, the Company's financial advisor (the "Financial Advisor Warrant"). The Financial Advisor Warrant has a five-year term, a cashless exercise feature and a strike price equal to $1.93 per share, the average price of the Company's common stock for the ten-day period preceding the original announcement of the APP Acquisition on April 6, 2016. The fair value of the Financial Advisor Warrant of $542,930 was estimated at the October 31, 2016 date of grant using the Black-Scholes option pricing model assuming expected volatility of 47.2%, a risk-free interest rate of 1.31%, an expected life of five years, no dividend yield, and the closing price of the Company's common stock on October 31, 2016 of $0.95. The Financial Advisor Warrant vested upon issuance. Half of the shares subject to the Financial Advisor Warrant, or 1,292,690 shares, were locked-up for a period of 18 months from the issuance date. The Financial Advisor Warrant was recorded as a component of additional paid-in-capital and the related expense is included in business acquisition expenses in the accompanying consolidated statement of operations for the year ended September 30, 2017.

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

Aspire Capital Purchase Agreement

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

Under the Purchase Agreement, on any trading day selected by the Company, the Company has the right, in its sole discretion, to present Aspire Capital with a purchase notice (each, a "Purchase Notice"), directing Aspire Capital (as principal) to purchase up to 200,000 shares of the Company's common stock per business day, 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 up to 30% of the aggregate shares of the common stock traded on its principal market on the next trading day (the VWAP Purchase Date), subject to a maximum number of shares the Company may determine. The purchase price per share pursuant to such VWAP Purchase Notice is generally 97% of the volume-weighted average price for the Company's common stock traded on its principal market on the VWAP Purchase Date.

In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, the Company issued to Aspire Capital 304,457 shares of the Company's common stock. The shares of common stock issued as consideration were valued at approximately $347,000. This amount and related expenses of approximately $78,000, which total approximately $425,000, were recorded as deferred costs.

During fiscal 2018, we sold an aggregate of 1,717,010 shares of common stock to Aspire Capital under the Purchase Agreement resulting in proceeds to the Company of $3.0 million. As a result of these sales, we recorded approximately $85,000 of the deferred costs noted above to additional paid-in capital. The unamortized amount of deferred costs of approximately $340,000 is included in other assets on the accompanying consolidated balance sheet at September 30, 2018. As of September 30, 2018, the amount remaining under the Purchase Agreement was $12 million. However, based on the current market price of the Company's common stock and the number of shares of the Company's common stock that are unreserved and available for issuance, the Company will need to seek stockholder approval to amend its Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock to use the full remaining availability under the Purchase Agreement.

Common Stock Offering

On October 1, 2018, we completed an underwritten public offering of 7,142,857 shares of the common stock, at a public offering price of $1.40 per share, resulting in gross proceeds of $10.0 million. We also granted the underwriters a 30-day option to purchase additional shares of common stock in an amount not to exceed 1,071,428 shares. The underwriters did not exercise this option. Net proceeds to the Company from this offering were $9.2 million after deducting underwriting discounts and commissions and expenses payable by the Company. All of the shares sold in the offering were sold by the Company. The offering was made pursuant to the Shelf Registration Statement.

**Note 9 – Share-based Compensation**

We allocate share-based compensation expense to cost of sales, selling, general and administrative expense or research and development expense based on the award holder's employment function. We recorded income tax benefits for share-based compensation expense of approximately $426,000 and $304,000 in fiscal 2018 and 2017, respectively. For fiscal 2018 and 2017, we recorded share-based compensation expenses as follows:

| | 2018 | 2017 |
|---|---|---|
| Cost of sales | $ 9,225 | $ 1,074 |
| Selling, general and administrative | 1,294,249 | 737,258 |
| Research and development | 335,031 | 17,943 |
| | $ 1,638,505 | $ 756,275 |

Equity Plans

In March 2018, the Company's stockholders approved the Company's 2018 Equity Incentive Plan (the "2018 Plan"). A total of 2.0 million shares are authorized for issuance under the 2018 Plan. As of September 30, 2018, 696,900 shares remain available for issuance under the 2018 Plan.

In July 2017, the Company's stockholders approved the Company's 2017 Equity Incentive Plan (the "2017 Plan"). A total of 4.7 million shares are authorized for issuance under the 2017 Plan. As of September 30, 2018, 190,288 shares remain available for issuance under the 2017 Plan. The 2017 Plan replaced the Company's 2008 Stock Incentive Plan (the "2008 Plan"), and no further awards will be made under the 2008 Plan.

Stock Options

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

The following table outlines the weighted average assumptions for options granted during the years ended September 30, 2018 and 2017:

| | Year Ended September 30, | |
|---|---|---|
| Weighted Average Assumptions: | 2018 | 2017 |
| Expected Volatility | 60.95% | 43.19% |
| Expected Dividend Yield | 0.00% | 0.00% |
| Risk-free Interest Rate | 2.65% | 1.53% |
| Expected Term (in years) | 5.9 | 7.0 |
| Fair Value of Options Granted | $ 1.00 | $ 0.64 |

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

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

| | Number of Shares | Weighted Average Exercise Price Per Share | Weighted Average Remaining Contractual Term (years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding at September 30, 2017 | 2,830,805 | $ 1.27 | | |
| Granted | 3,960,151 | 1.73 | | |
| Exercised | (55,000) | 1.20 | | |
| Forfeited | (1,090,644) | 1.33 | | |
| Outstanding at September 30, 2018 | 5,645,312 | $ 1.59 | 8.62 | $ 724,254 |
| Exercisable at September 30, 2018 | 1,133,886 | $ 1.34 | 5.91 | $ 268,905 |

The aggregate intrinsic values in the table above are before income taxes and represent the number of in-the-money options outstanding or exercisable multiplied by the closing price per share of the Company's common stock on the last trading day of the year ended September 30, 2018 of $1.42, less the respective weighted average exercise price per share at period end.

As of September 30, 2018, the Company had unrecognized compensation expense of approximately $3.3 million related to unvested stock options. This expense is expected to be recognized over approximately 3 years.

The total intrinsic value of options exercised during the year ended September 30, 2018 was approximately $44,000. Cash received from options exercised in the year ended September 30, 2018 was $66,000. No stock options were exercised during the year ended September 30, 2017.

During fiscal 2018, the Company modified stock options held by certain optionees upon termination of their employment by the Company, retirement from the board of directors or resignation from the board of directors. The aggregate amount of expense recognized in connection with these modifications for the year ended September 30, 2018 was approximately $362,000.

Restricted Stock

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

A summary of restricted stock activity for the year ended September 30, 2018 is presented in the table below:

| | Shares | Weighted Average Grant Date Fair Value | Vesting Period |
|---|---|---|---|
| Outstanding at September 30, 2017 | 198,750 | $ 0.99 | October 2017 – April 2018 |
| Granted | — | — | |
| Vested | (198,750) | 0.99 | |
| Forfeited | — | — | |
| Outstanding at September 30, 2018 | — | $ — | |

The Company granted a total of 190,000 shares of restricted stock during the year ended September 30, 2017. The fair value of the shares granted was approximately $181,000.

Restricted Stock Units

In connection with the closing of the APP Acquisition, the Company issued 50,000 and 140,000 restricted stock units to an employee and an outside director, respectively, that vest on October 31, 2018. The restricted stock units will be settled in common stock issued under the 2017 Plan. As of September 30, 2018, there was approximately $10,000 of unrecognized compensation cost related to non-vested restricted stock units, which is expected to be recognized by October 31, 2018.

Stock Appreciation Rights

In connection with the closing of the APP Acquisition, the Company issued stock appreciation rights based on 50,000 and 140,000 shares of the Company's common stock to an employee and an outside director, respectively, that vest on October 31, 2018. The stock appreciation rights have a ten-year term and an exercise price per share of $0.95, which was the closing price of a share of the Company's common stock as quoted on NASDAQ on the date of grant. The stock appreciation rights will be settled in common stock issued under the 2017 Plan. As of September 30, 2018, there was approximately $5,000 of unrecognized compensation cost related to non-vested stock appreciation rights, which is expected to be recognized by October 31, 2018.

**Note 10 – Operating Leases and Rental Expense**

The Company leases approximately 3,900 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 was amended in June 2017 to provide for additional space. Effective with the June 2017 amendment, base rent payments are $36.00 per square foot and are subject to a 4% annual escalation on November 1 of each subsequent year. The lease also requires payment of related expenses, including real estate taxes, common area maintenance and insurance. 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. The Company executed the lease for this office in May 2016, for a seven-year period commencing on November 1, 2016 and ending on October 31, 2023. The lease granted the Company a seven-month lease holiday beginning November 1, 2016, a five-month lease abatement beginning June 1, 2017, and provided a tenant improvement allowance. Base rent payments were $14.00 per square foot in year one and increase on an annual basis to $17 per square foot in the final year of the lease. The lease also requires payment of related expenses, including real estate taxes, common area maintenance, utilities and insurance expenses from June 1, 2017 to October 31, 2023. Based on the terms of the lease agreement, the Company made a security deposit of $55,000. Effective September 1, 2017, the Company entered into a sublease for this office space through October 31, 2023. Monthly sublease payments of approximately $15,200 commenced in January 2018 and will end in August 2023. The monthly sublease payment is subject to annual increase in September of each year and will increase to approximately $17,300 per month in the final year of the sublease. The tenant under the sublease provided a security deposit of $30,000 to the Company. The Company continues to be responsible for performance under the lease until it expires on October 31, 2023.

The Company leases approximately 6,400 square feet of office space located in London, England under a lease that requires quarterly payments of approximately $24,000 through June 2020. Based on the terms of the lease agreement, the Company made a security deposit of approximately $57,000.

The Company leases 45,800 square feet of manufacturing and warehouse space in Selangor D.E., Malaysia under a lease that requires monthly payments of approximately $15,500 through August 2019. The Company has an option to extend the term of the lease for a period of three-years. Based on the terms of the lease agreement, the Company made a security deposit of approximately $46,000.

The Company also leases equipment under a number of lease agreements which expire at various dates through May 2023. The aggregate amount of expense associated with these equipment leases is approximately $2,000 per month.

Details of operating lease expense, including real estate taxes, common area maintenance charges and insurance charges, net of sublease income, for the years ended September 30, 2018 and 2017 are as follows:

| | 2018 | 2017 |
|---|---|---|
| Factory and office leases | $ 693,372 | $ 583,778 |
| Other | 23,406 | 23,116 |
| Total | $ 716,778 | $ 606,894 |

Future minimum payments under leases consist of the following as of September 30, 2018:

| | Operating Leases | Sublease Income | Net Total |
|---|---|---|---|
| 2019 | $ 547,911 | $ 188,837 | $ 359,074 |
| 2020 | 203,631 | 193,753 | 9,878 |
| 2021 | 115,096 | 198,668 | (83,572) |
| 2022 | 109,006 | 203,584 | (94,578) |
| 2023 | 111,706 | 190,749 | (79,043) |
| Thereafter | 9,285 | — | 9,285 |
| Total minimum lease payments | $ 1,096,635 | $ 975,591 | $ 121,044 |

The minimum lease payments presented above do not include real estate taxes, common area maintenance charges or insurance charges payable under the Company's operating leases for office and manufacturing facility space. These amounts 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 $10.0 million.

Litigation

In response to the APP Acquisition, two purported derivative and class action lawsuits were filed against the Company and certain of its officers and directors in the Circuit Court of Cook County, Illinois, captioned Glotzer v. The Female Health Company, et al., Case No. 2016-CH-13815, and Schartz v. Parrish, et al., Case No. 2016-CH-14488. These lawsuits were originally filed on or about October 21, 2016 and November 7, 2016, respectively. On January 9, 2017, these two lawsuits were consolidated. On March 31, 2017, the plaintiffs filed a consolidated complaint. The consolidated complaint named as defendants Veru, the members of our board of directors prior to the closing of the APP Acquisition and the members of our board of directors after the closing of the APP Acquisition. The consolidated complaint alleged, among other things, that the directors breached their fiduciary duties, or aided and abetted such breaches, by consummating the APP Acquisition in violation of the Wisconsin Business Corporation Law and NASDAQ voting requirements and by causing us to issue the shares of our common stock and Series 4 Preferred Stock to the former stockholders of APP pursuant to the APP Acquisition in order to evade the voting requirements of the Wisconsin Business Corporation Law. The consolidated complaint also alleged that Dr. Steiner, a director and the Chairman, President and Chief Executive Officer of Veru and a co-founder of APP, and Dr. Fisch, a director and Vice Chairman of Veru and a co-founder of APP, were unjustly enriched in receiving shares of our common stock and Series 4 Preferred Stock in the APP Acquisition.

On May 5, 2017, the defendants filed a motion to dismiss the consolidated complaint. On August 15, 2017, the court entered an order dismissing without prejudice the claims that the post-acquisition directors aided and abetted the alleged breaches of fiduciary duties by the pre-acquisition directors and that Dr. Steiner and Dr. Fisch were unjustly enriched. The court did not dismiss the claims that our directors prior to the closing of the APP Acquisition breached their fiduciary duties and the claims that Veru consummated the APP Acquisition in violation of the Wisconsin Business Corporation Law and NASDAQ voting requirements. On November 30, 2018, plaintiffs filed an Amended Consolidated Complaint. The Amended Consolidated Complaint makes allegations similar to those in the original consolidated complaint as to the claims that were not dismissed and names as defendants Veru and the members of our board of directors prior to the closing of the APP Acquisition. The Amended Consolidated Complaint also makes claims against Dr. Steiner for allegedly aiding and abetting the pre-acquisition directors' breach of fiduciary duty and for unjust enrichment. Like the original consolidated complaint, the Amended Consolidated Complaint seeks equitable relief, including rescission of the APP Acquisition, money damages, disgorgement of the shares of our common stock and Series 4 Preferred Stock issued to Dr. Steiner, and costs and expenses of the litigation, including attorneys' fees. The parties are currently completing discovery. Veru believes that this action is without merit and is vigorously defending itself. No amount has been accrued for possible losses relating to this litigation as any such losses are not both probable and reasonably estimable.

License and Purchase Agreements

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

In connection with the Company's acquisition of intellectual property rights associated with Solifenacin DRG and Tadalafil/Finasteride combination tablets, the Company was obligated to make upfront payments totaling $500,000 by March 2018, as well as future installment payments and milestone payments. Of the $500,000, $250,000 was paid in May 2018 and the Company expects to pay the remaining $250,000 in the first quarter of fiscal 2019. The Company has met the initial milestones for these two product candidates, which will result in additional payments totaling $700,000. These amounts owed, which total $950,000, are included in accounts payable on the accompanying consolidated balance sheet at September 30, 2018.

**Note 12 – Income Taxes**

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

On December 22, 2017, significant changes were enacted to the U.S. tax law pursuant to the federal tax legislation commonly referred to as the Tax Cuts and Jobs Act of 2017 (the "Tax Act"). The Tax Act includes a permanent reduction in the U.S. federal corporate income tax rate from 35% to 21%, a one-time repatriation tax on deferred foreign income, and changes to deductions, credits and business-related exclusions.

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

In accordance with SAB 118, the Company's income tax provision as of September 30, 2018 reflects (i) the current year impacts of the Tax Act on the estimated annual effective tax rate and (ii) the impact from the permanent reduction to the U.S. federal corporate income tax rate from 35% to 21%, which was effective January 1, 2018. When a U.S. federal tax rate change occurs during a fiscal year, tax payers are required to compute a weighted daily average rate for the fiscal year of enactment. However, as the Company is in a net loss carryforward position, it is using the U.S. federal statutory income tax rate of 21% that will be in effect when the net loss is utilized.
The Tax Act also repealed the alternative minimum tax ("AMT") for corporations. The new law provides that AMT carryovers can be utilized to reduce or eliminate the tax liability in subsequent years or to obtain a tax refund. For tax years beginning in 2018, 2019 and 2020, to the extent the AMT credit carryovers exceed regular tax liability, 50 percent of the excess AMT credit carryovers will be refundable. Any remaining credits will be fully refundable in 2021. The Company reclassified $0.5 million of its AMT credit carryovers from its deferred tax assets to prepaid and other assets due to the expectation that the AMT credits will be refundable over the next several years.

Within the calculation of the Company's annual effective tax rate the Company has used assumptions and estimates that may change as a result of future guidance, interpretations, and rule-making from the Internal Revenue Service, the SEC, the FASB and/or various other taxing jurisdictions. For example, the Company anticipates that state jurisdictions will continue to determine and announce their conformity to the Tax Act which would have an impact on the annual effective tax rate. The Company's calculations are based on the information available, prepared or analyzed (including computations) in reasonable detail.

The Company completes a detailed analysis of its deferred income tax valuation allowances on an annual basis or more frequently if information comes to its attention that would indicate that a revision to its estimates is necessary. In evaluating the Company's ability to realize its deferred tax assets, management considers all available positive and negative evidence on a country-by-country basis, including past operating results, forecasts of future taxable income, and the potential Section 382 limitation on the net operating loss carryforwards due to a change in control. In determining future taxable income, management makes assumptions to forecast U.S. federal and state, U.K. and

Malaysia operating income, the reversal of temporary differences, and the implementation of any feasible and prudent tax planning strategies. These assumptions require significant judgment regarding the forecasts of the future taxable income in each tax jurisdiction and are consistent with the forecasts used to manage the Company's business. It should be noted that the Company realized significant losses through 2005 on a consolidated basis. From fiscal year 2006 through fiscal year 2015, the Company generated taxable income on a consolidated basis. However, the Company had a cumulative pretax loss in the U.S. for fiscal 2018 and the two preceding fiscal years. Forming a conclusion that a valuation allowance is not needed is difficult when there is significant negative evidence such as cumulative losses in recent years. Management has projected future taxable losses in the U.S. driven by the investment in research and development, and based on their analysis concluded that a valuation allowance of $5.5 million should be recorded against the U.S. deferred tax assets related to federal and state net operating loss carryforwards as of September 30, 2018. In addition, the Company's holding company for the non-U.S. operating companies, The Female Health Company Limited, continues to have a full valuation allowance of $2.2 million that includes the current year's valuation allowance of $63,000. The operating U.K. subsidiary, The Female Health Company (UK) plc does not have a valuation allowance due to projections of future taxable income for the next 10 years.

As of September 30, 2018, the Company had U.S. federal and state net operating loss carryforwards of approximately $33.2 million and $36.2 million, respectively, for income tax purposes with $14.4 million and $19.6 million, respectively, expiring in years 2022 to 2037 and $18.8 million and $16.6 million, respectively, which can be carried forward indefinitely. The Company's U.K. subsidiary has U.K. net operating loss carryforwards of approximately $62.3 million as of September 30, 2018, which can be carried forward indefinitely to be used to offset future U.K. taxable income.

A reconciliation of income tax expense (benefit) and the amount computed by applying the statutory federal income tax rate to income before income taxes is as follows:

| | 2018 | 2017 |
|---|---|---|
| Income tax benefit at statutory rates | $ (5,820,180) | $ (2,925,000) |
| State income tax benefit, net of federal benefits | (1,148,308) | (538,000) |
| Effect of change in U.S. tax rate | 3,319 | — |
| Non-deductible expenses – other | 14,856 | 215,000 |
| Effect of lower foreign income tax rates | 349,818 | 216,651 |
| Effect of change in U.K. tax rate | — | 615,000 |
| Effect of deemed dividend and repatriation tax | 402,760 | 405,646 |
| Correction of prior year dividend tax rate | — | 440,100 |
| Effect of change in state tax rate | — | (215,000) |
| Other | 265,330 | (49,555) |
| Recharacterization of foreign tax credits to net operating loss | 1,311,429 | — |
| Change in valuation allowance | 5,487,078 | (155,285) |
| Income tax expense (benefit) | $ 866,102 | $ (1,990,443) |

The federal and state income tax expense (benefit) for the years ended September 30, 2018 and 2017 is summarized below:

| | 2018 | 2017 |
|---|---|---|
| Deferred – U.S. | $ 629,381 | $ (2,369,000) |
| Deferred – U.K. | 34,612 | 224,000 |
| Deferred – Malaysia | (33,843) | (110,069) |
| Subtotal | 630,150 | (2,255,069) |
| | | |
| Current – U.S. | — | 1,000 |
| Current – U.K. | 24,662 | — |
| Current – Malaysia | 211,290 | 263,626 |
| Subtotal | 235,952 | 264,626 |
| | | |
| Income tax expense (benefit) | $ 866,102 | $ (1,990,443) |

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

| **Deferred tax assets:** | **2018** | **2017** |
|---|---|---|
| Federal net operating loss carryforwards | $ 6,973,047 | $ 4,075,000 |
| State net operating loss carryforwards | 2,195,865 | 963,000 |
| AMT credit carryforward | — | 533,000 |
| Foreign net operating loss carryforwards – U.K. | 10,595,518 | 10,578,000 |
| Foreign capital allowance – U.K. | 102,098 | 108,000 |
| U.K. bad debts | 1,700 | 2,000 |
| Restricted stock – U.K. | 17,586 | 1,000 |
| U.S. unearned revenue | — | 409,000 |
| U.S. deferred rent | 22,902 | 76,000 |
| Share-based compensation | 622,442 | 447,000 |
| Foreign tax credits | — | 1,797,000 |
| Other, net – U.S. | 91,419 | 82,000 |
| Other, net – Malaysia | 33,843 | — |
| Gross deferred tax assets | 20,656,420 | 19,071,000 |
| Valuation allowance for deferred tax assets | (7,631,078) | (2,144,000) |
| Net deferred tax assets | 13,025,342 | 16,927,000 |
| **Deferred tax liabilities:** | | |
| In process research and development | (4,675,860) | (7,000,000) |
| Developed technology | (549,318) | (900,000) |
| Covenant not-to-compete | (94,321) | (200,000) |
| Other | (6,843) | — |
| Net deferred tax liabilities | (5,326,342) | (8,100,000) |
| **Net deferred tax asset** | $ 7,699,000 | $ 8,827,000 |

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

| | **2018** | **2017** |
|---|---|---|
| Long-term deferred tax asset – U.S. | $ — | $ 282,473 |
| Long-term deferred tax asset – U.K. | 8,509,915 | 8,544,527 |
| Long-term deferred tax asset – Malaysia | 33,843 | — |
| Total long-term deferred tax asset | $ 8,543,758 | $ 8,827,000 |
| | | |
| Long-term deferred tax liability – U.S. | (844,758) | — |
| Total long-term deferred tax liability | $ (844,758) | $ — |

The valuation allowance for our deferred tax assets increased by $5.5 million for the year ended September 30, 2018 and decreased by $155,000 for the year ended September 30, 2017.

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 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 2015 through 2017, which expire in years 2019 through 2021, 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 2013 through 2017, which expire on December 31, 2018 through 2022, respectively.
- 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 2017, which expires in 2019.
- The fiscal year 2018 tax returns for each jurisdiction have not been filed as of the date of this filing. As of September 30, 2018 and 2017, 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, 2018 and 2017.

**Note 13 – Net Loss Per Share**

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

**Note 14 – Industry Segments and Financial Information about Foreign and Domestic Operations**

The Company currently operates in two reporting segments: Commercial and Research and Development. The Commercial segment consists of FC2 and PREBOOST. The Research and Development segment consists of multiple drug products under clinical development for oncology and urology. There are no significant inter-segment sales. We evaluate the performance of each segment based on operating profit or loss. There is no inter-segment allocation of non-operating expenses and income taxes. Our chief operating decision-maker ("CODM") is Mitchell S. Steiner, M.D., our Chairman, President and Chief Executive Officer.

| | Years Ended September 30, | |
|---|---|---|
| | 2018 | 2017 |
| **Operating (loss) income:** | (In thousands) | |
| Commercial | $ 3,189 | $ 3,144 |
| Research and Development | (10,808) | (3,244) |
| Corporate | (13,253) | (8,394) |
| | $ (20,872) | $ (8,494) |
| | | |
| **Net revenues:** | | |
| United States | $ 5,220 | $ 1,288 |
| South Africa | 2,961 | 951 |
| Zimbabwe | 2,159 | 2,227 |
| Mozambique | * | 1,430 |
| Kenya | 1,006 | * |
| Other | 4,518 | 7,759 |
| | $ 15,864 | $ 13,655 |

* Less than 5% of total revenues.

All of our net revenues, which are primarily derived from the sale of FC2, are attributed to our Commercial reporting segment. Depreciation and amortization related to long-lived assets that are not utilized in the production of FC2 are not reported as part of the reporting segments or reviewed by the CODM. These amounts are included in Corporate in the reconciliations above. Total assets are not presented by reporting segment as they are not reviewed by the CODM when evaluating the reporting segments' performance.

**Note 15 – Employee Benefit Plans**

Effective January 1, 2018, the Company established a 401(k) plan in which substantially all U.S. employees are eligible to participate. Contributions made by employees are limited to the maximum allowable for U.S. federal income tax purposes. The Company matches employee contributions at a rate of 100% of applicable contributions up to 4% of included compensation. Company contributions to the 401(k) plan were approximately $83,000 for the year ended September 30, 2018.

Prior to the 401(k) plan, the Company had a Simple Individual Retirement Account plan for its U.S. employees. Employees were eligible to participate in the plan if their compensation reached certain minimum levels and they were allowed to contribute up to a maximum of $15,500 of their annual compensation to the plan. The plan was terminated effective December 31, 2017. The Company had elected to match 100% of employee contributions to the plan up to a maximum of 3% of employee compensation. Company contributions to the plan were approximately $22,000 and $73,000 for the years ended September 30, 2018 and 2017, respectively.

In March 2014, the Company elected to contribute 3% into the personal pension schemes of certain senior U.K. employees. Company contributions were approximately $23,000 and $22,000 for the years ended September 30, 2018 and 2017, respectively.

**Note 16 – Related Party Transactions**

K. Gary Barnette, the Company's Chief Scientific Officer, holds a 25% equity interest in a company from which Aspen Park purchased intellectual property assets relating to our Tamsulosin DRS drug candidate in 2016. We have continuing installment and milestone payment obligations to this company under the purchase agreement. We did not make any payments to this company during the fiscal year ended September 30, 2018. During the fiscal year ended September 30, 2017, we paid a total of $375,000 to this company.

This page intentionally left blank.

# Corporate Information

## OFFICERS

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

Michele Greco
*Chief Financial Officer and*
*Chief Administrative Officer*

K. Gary Barnette, Ph.D.
*Chief Scientific Officer*

Harry Fisch, M.D., F.A.C.S.
*Chief Corporate Officer*

Kevin Gilbert
*Executive Vice President–*
*Corporate Development*

Philip Greenberg
*Executive Vice President–*
*Legal and Secretary*

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

Phillip Kuhn
*Executive Vice President–Strategy, 505 (b) 2, Sales and Marketing*

Domingo Rodriguez, M.D.
*Executive Vice President–*
*Clinical Operations*

Charles T. Todd, Jr.
*Chief Executive Officer of*
*The Female Health Company Division*

Martin Tayler
*Executive Vice President of*
*Global Operations*

Denise van Dijk
*President Global Public Sector of*
*The Female Health Company Division*

## BOARD OF DIRECTORS

Mitchell S. Steiner, M.D., F.A.C.S.
*Chairman of the Board*
*President and Chief Executive Officer*
*Veru Inc.*
*Miami, Florida*

O.B. Parrish
*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.
*Vice Chairman of the Board*
*Chief Corporate Officer*
*Veru Inc.*
*New York, New York*

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

Michael L. Rankowitz
*Senior Advisor*
*Morgan Stanley*
*New York, New York*

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

## 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*

Annual Report Design by Curran & Connors, Inc. / www.curran-connors.com

VERU INC.

www.verupharma.com www.fc2.us.com www.fc2femalecondom.com