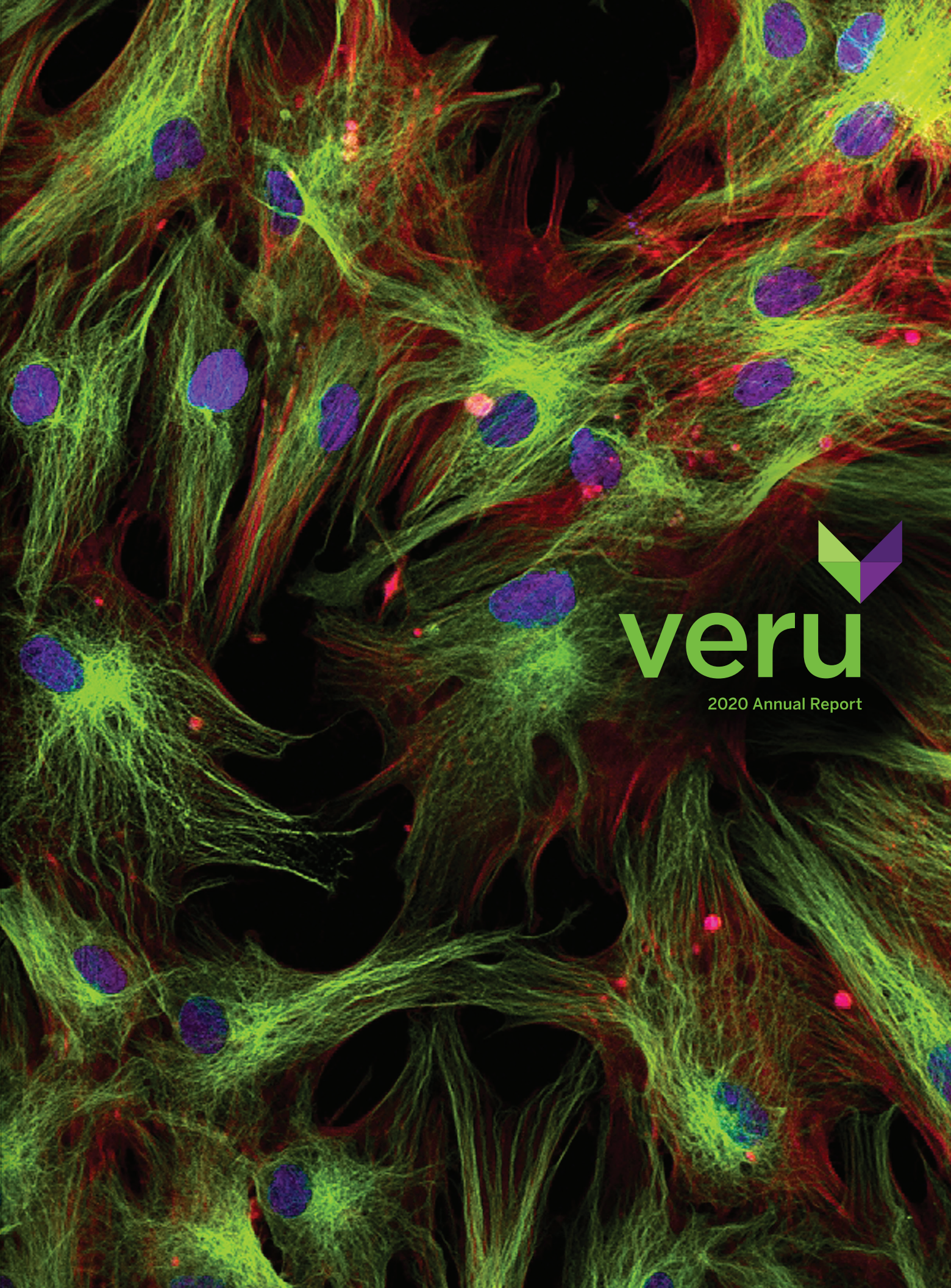

# veru

2020 Annual Report

## DEAR SHAREHOLDERS,

Veru has transformed into a late-stage clinical oncology biopharmaceutical Company focused on the development and the commercialization of novel medicines for the management of two of the most prevalent cancers—prostate cancer and breast cancer. We continue to invest cash generated from our Sexual Health Business into the clinical development of our high-value oncology drug candidates so that our shareholders can realize the growing value of our oncology biopharmaceutical Company.

Our team accomplished this great and significant Company milestone because we set a new commercial strategy for FC2® and launched PREBOOST®. We focused on creating an FC2 commercial sector in the U.S., where we launched FC2 as a prescription product through retail pharmacies and partnered with multiple telemedicine and internet pharmacies. We decreased our reliance on the global public sector, which is volatile and inconsistent. We launched PREBOOST, and after growing revenues, in December 2020 we sold the PREBOOST business to Roman Health Ventures for $20 million, further strengthening our financial balance sheet.

In FY2017, the year that the Female Health Company acquired Aspen Park Pharmaceuticals to create Veru, the annual net revenues were $13.7 million, and this year I am pleased to report that we had a record year of $42.6 million in net revenues. The Sexual Health Business continues to generate record revenues and we expect robust and growing revenues from the Sexual Health Business for another record year in fiscal year 2021.

Given our core expertise and the significant assets in our drug pipeline, we are uniquely positioned to understand, to develop, and to commercialize medicines for these unmet medical needs. We are dedicated to the development and commercialization of drug candidates to address unmet medical needs for prostate and breast cancer management, and for which we have made great progress. We are excited to advance our prostate cancer drug candidates, VERU-111 and VERU-100, as well as our breast cancer drug candidates, the recently acquired Enobosarm and the new additional indication for VERU-111 in triple negative breast cancer, into registration clinical studies.

The current oncology drug candidates in our pipeline: VERU-111 is an oral, first-in-class, new chemical entity that targets, crosslinks, and disrupts alpha and beta tubulin subunits of microtubules to disrupt the cytoskeleton being developed in both metastatic castration resistant prostate cancer and metastatic triple negative breast cancer; VERU-100 is a novel, proprietary long-acting gonadotropin-releasing hormone (GnRH) antagonist peptide, 3-month subcutaneous depot formulation designed to address the current limitations of commercially available androgen deprivation therapies for advanced prostate cancer; and Enobosarm is an oral, first-in-class, new chemical entity, selective androgen receptor (AR) targeted agent. Enobosarm, by targeting the AR, which is present in up to 90% of advanced hormone receptor positive breast cancers, represents the first new class of targeting endocrine therapy in advanced breast cancer in decades. Enobosarm has extensive nonclinical and clinical experience having been evaluated in over 25 separate clinical studies in more than 2,100 subjects, including five prior Phase 2 clinical studies in advanced breast cancer involving more than 250 patients. Enobosarm binds to the AR in breast cancer tissue to inhibit AR+ ER+ breast cancer cell proliferation and tumor growth as demonstrated in Phase 2 human clinical trials as well as in animal models. Enobosarm has additional selective clinical properties that could have potential benefit in women with hormone receptor positive metastatic breast cancer. More specifically, preclinical studies have shown that Enobosarm builds and heals cortical and trabecular bone with the potential to treat osteoporosis and skeletal related cancer events. Enobosarm has also been shown to build muscle and improve physical function in clinical studies involving elderly subjects and patients with cancer cachexia, including breast cancer. Furthermore, the tissue selectivity of Enobosarm also results in a favorable side effect profile with no virilization (facial hair and acne), no increase in hematocrit, and no liver toxicity. Furthermore, Enobosarm is not chemotherapy, so there is no neutropenia, anemia, hair loss, nausea, vomiting, and diarrhea that is typically associated with chemotherapy.

Veru anticipates the potential for 4 registration clinical trials for 4 oncology indications commencing in calendar year 2021. The indications are as follows:

- The Phase 3 registration VERACITY clinical study will evaluate VERU-111 for men with metastatic castration resistant prostate cancer who have also become resistant to one androgen receptor targeting agent. The Company anticipates starting the VERACITY Phase 3 study in the first quarter of calendar year 2021.

- The Phase 2 dose-finding study to evaluate VERU-100 as a new 3-month long-acting GnRH peptide formulation for androgen deprivation therapy in men with advanced prostate cancer is anticipated to begin early in the first quarter of calendar year 2021 and the Phase 3 registration study is anticipated to start in the second half of calendar year 2021.

- The Phase 3 registration ARTEST clinical study to evaluate the efficacy and safety of Enobosarm versus an active control (exemestane or tamoxifen) for the treatment of metastatic ER+/HER2- breast cancer in patients who have failed a nonsteroidal aromatase inhibitor (anastrozole or letrozole), fulvestrant, and a CDK4/6 inhibitor, is anticipated to commence in the first half of calendar year 2021.

- The Phase 2b clinical trial for possible accelerated approval for VERU-111 versus active control Trodelvy in patients with taxane resistant triple negative breast cancer, making the proposed trial a potential registration trial. The Phase 2b clinical study is planned to commence in the second half of calendar year 2021.

In summary, with cash resources in place, we will continue to advance our late-stage clinical programs to and through the highest value point, which is enrolling Phase 3 clinical studies, and we anticipate having Phase 3 positive clinical results. Registration oncology clinical studies are ideal as they are typically single clinical studies for access to premium large global markets after NDA approval.

As you can see, we have evolved into a biopharmaceutical oncology Company dedicated to prostate cancer and breast cancer. Furthermore, we believe our strategy to advance clinical development supported by revenues from our growing Sexual Health Business is working. Our base Sexual Health Business is valuable, profitable, and growing. We are developing multiple new drug candidates in well-established multi-billion-dollar global markets to ensure future growth. We are committed to driving shareholder value by developing and commercializing novel medicines addressing significant unmet medical needs for the management of prostate cancer and breast cancer.

Sincerely,

Mitchell 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, 2020**

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

**For the transition period from _____ to _____**

**Commission file number 1-13602**

# Veru Inc.

(Name of registrant as specified in its charter)

| **Wisconsin** | **39-1144397** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **48 NW 25th Street, Suite 102, Miami, Florida** | **33127** |
| (Address of principal executive offices) | (Zip Code) |

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

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| **Common stock, $0.01 par value** | **VERU** | **NASDAQ Capital Market** |

Securities registered pursuant to Section 12(g) of the Act:
**None**

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 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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 common stock held by non-affiliates of the registrant as of March 31, 2020, was approximately $162.3 million based on the per share closing price as of March 31, 2020 quoted on the NASDAQ Capital Market for the registrant's common stock, which was $3.27.

There were 70,075,460 shares of the registrant's common stock, $0.01 par value per share outstanding on December 7, 2020.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Proxy Statement for the 2021 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.
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## FORWARD LOOKING STATEMENTS

Certain statements included in this Annual Report on Form 10-K which are not statements of historical fact are intended to be, and are hereby identified as, "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about the anticipated or potential impact of COVID-19 and the global response thereto on our financial condition or business, future financial and operating results, plans, objectives, expectations and intentions, costs and expenses, debt repayments, 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, estimated future sales or market sizes, 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, including potential delays in the recruitment of patients and their ability to effectively participate in such trials and studies due to COVID-19, 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, including the risk of a delay or failure in reaching agreement with the FDA on the design of a clinical trial or in obtaining authorization to commence a clinical trial;
- clinical results or early data from clinical trials may not be replicated or continue to occur in additional trials or may not otherwise support further development in the specified product candidate or at all;
- risks related to our ability to obtain sufficient financing on acceptable terms when needed to fund product development and our operations, including our ability to secure timely grant or other funding to develop VERU-111 as a potential COVID-19 treatment;
- risks related to the development of our product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market;
- risks related to the impact of the COVID-19 pandemic on our business, the nature and extent of which is highly uncertain and unpredictable;
- our pursuit of a COVID-19 treatment candidate is at an early stage and we may be unable to develop a drug that successfully treats the virus in a timely manner, if at all;
- risks related to our commitment of financial resources and personnel to the development of a COVID-19 treatment which may cause delays in or otherwise negatively impact our other development programs, despite uncertainties about the longevity and extent of COVID-19 as a global health concern;
- government entities may take actions that directly or indirectly have the effect of limiting opportunities for VERU-111 as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments;
- product demand and market acceptance;
- some of our products are in 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 related to compliance and regulatory matters, including costs and delays resulting from extensive government regulation and reimbursement and coverage under healthcare insurance and regulation;
- the risk that we will be affected by regulatory and legal developments, including a reclassification of products or repeal of the Patient Protection and Affordable Care Act (the "ACA");
- risks inherent in doing business on an international level, including currency risks, regulatory requirements, political risks, export restrictions and other trade barriers;

- the disruption of production at our manufacturing facilities or facilities of third parties on which we rely and/or of our ability to supply product due to raw material shortages, labor shortages, physical damage to our or third parties' facilities, COVID-19 (including the impact of COVID-19 on suppliers of key raw materials), product testing, transportation delays or regulatory actions;
- our reliance on major customers and risks related to delays in payment of accounts receivable by major customers;
- risks related to 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, including the appropriations process and funding priorities, potential bureaucratic delays in awarding contracts, process errors, politics or other pressures, and the risk that government tenders and contracts may be subject to cancellation, delay, restructuring or substantial delayed payments;
- 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, and as a result government ministries or other public health sector customers may order and purchase fewer units than the full maximum tender amount;
- 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**

Veru is an oncology biopharmaceutical company with a focus on developing novel medicines for the management of prostate and breast cancers.

**The Company's prostate cancer drug pipeline includes VERU-111, VERU-100 and Zuclomiphene citrate.**

*VERU-111 for the treatment of men with metastatic castration resistant prostate cancer who have also become resistant to one androgen receptor targeting agent*

VERU-111 is an oral, first-in-class, new chemical entity that targets, crosslinks, and disrupts alpha and beta tubulin subunits of microtubules to disrupt the cytoskeleton. VERU-111 is being evaluated in open label Phase 1b and Phase 2 clinical studies in men with metastatic castration and androgen receptor targeting agent resistant prostate cancer. The Phase 1b clinical study completed enrollment of 39 men and is ongoing. The Phase 1b study has yielded promising efficacy and safety clinical data. Based on the Phase 1b study results, the recommended Phase 2 dose is 63mg oral daily continuous dosing for 21-day cycles. Daily chronic drug administration appears feasible and safe. At the recommended Phase 2 dose, there were no reports of neutropenia, neurotoxicity, or Grade 3 diarrhea. The Phase 2 clinical study has completed enrollment of approximately 40 men with metastatic castration resistant prostate cancer who have also become resistant to androgen receptor targeting agents, such as abiraterone, enzalutamide, or apalutamide, but prior to proceeding to IV chemotherapy. In July 2020, the Company had an FDA meeting and received positive input from the FDA on the pivotal Phase 3 trial design for VERU-111. The Company received regulatory clarity that the indication of treatment in men with metastatic castration resistant prostate cancer who have failed one androgen receptor targeting agent, but prior the IV chemotherapy was acceptable, that an open label, randomized study using an alternative androgen receptor targeting agent as the active control is reasonable, and that the primary endpoint may be radiographic progression-free survival. By allowing radiographic progression-free survival as the primary endpoint, the sample size of the Phase 3 study could be potentially between 200 and 300 men. The Company anticipates starting the Phase 3 pivotal study evaluating VERU-111 for men with metastatic castration resistant prostate cancer who have also become resistant to one androgen receptor targeting agent in the first quarter of calendar year 2021.

*VERU-100 for the palliative treatment of advanced prostate cancer*

VERU-100 is a novel, proprietary long-acting gonadotropin-releasing hormone (GnRH) antagonist peptide three-month subcutaneous depot formulation designed to address the current limitations of commercially available androgen deprivation therapies (ADT). Androgen deprivation therapy is currently the mainstay of advanced prostate cancer treatment and is used as a foundation of treatment throughout the course of the disease. Furthermore, ADT is continued even as other endocrine, chemotherapy, or radiation treatments are added or stopped. Specifically, VERU-100 is a chronic, long-acting GnRH antagonist peptide administered as a small volume, three-month depot subcutaneous injection without a loading dose. VERU-100 immediately suppresses testosterone with no testosterone surge upon initial or repeated administration, a concern that occurs with currently approved luteinizing hormone-releasing hormone (LHRH) agonists used for ADT. There are no GnRH antagonist depot injectable formulations commercially approved beyond a one-month duration. A Phase 2 study to evaluate VERU-100 dosing is anticipated to begin early in the first quarter of calendar year 2021.

*Zuclomiphene citrate for the treatment of men who have hot flashes caused by androgen deprivation therapy for advanced prostate cancer*

Zuclomiphene citrate is an oral nonsteroidal estrogen receptor agonist being developed to treat hot flashes, a common side effect caused by ADT in men with advanced prostate cancer. The Company is planning an End of Phase 2 meeting with the FDA.

**The Company's new breast cancer drug pipeline includes Enobosarm and VERU-111.**

*Enobosarm, selective androgen receptor targeting agonist, for the treatment of androgen receptor positive (AR+), estrogen receptor positive (ER+) and human epidermal growth factor receptor 2 (HER2-) metastatic breast cancer*

Enobosarm is an oral, first-in-class, new chemical entity, selective androgen receptor agonist that targets the androgen receptor (AR) in AR+/ER+/HER2- metastatic breast cancer without the unwanted virilizing side effects. Enobosarm is the first new class of targeting endocrine therapy in advanced breast cancer in decades. Enobosarm has extensive nonclinical and clinical experience having been evaluated in 25 separate clinical studies in over 2,100 subjects, including five prior Phase 2 clinical studies in advanced breast cancer involving more than 250 patients. In the two Phase 2 clinical studies conducted in women with AR+/ER+/HER2- metastatic breast cancer, enobosarm demonstrated significant antitumor efficacy in heavily pretreated cohorts and was well tolerated with a favorable safety profile. In October 2020, the FDA agreed to the Phase 3 registration clinical trial design to evaluate the efficacy and safety of enobosarm, selective androgen receptor targeting agonist, versus active control, either exemestane or tamoxifen (physician's choice) for the treatment of ER+/HER2- metastatic breast cancer in approximately 240 patients who have failed a nonsteroidal aromatase inhibitor (anastrozole or letrozole), fulvestrant and a CDK4/6 inhibitor and prior to IV chemotherapy. The primary endpoint is radiographic progression-free survival. The pivotal Phase 3, open label, randomized, active control study is anticipated to commence in the first half of calendar year 2021.

*VERU-111 for treatment of taxane resistant metastatic triple negative breast cancer*

Metastatic triple negative breast cancer (TNBC) is an aggressive form of breast cancer that occurs in 15% of all breast cancers. This form of breast cancer does not express ER, progesterone receptor (PR), or HER2 and is resistant to endocrine therapies. The first line of treatment usually includes IV taxane chemotherapy. Almost all women will eventually develop taxane resistance. VERU-111 is an oral, first-in-class, new chemical entity that targets, crosslinks, and binds to alpha and beta tubulin subunits of microtubules to disrupt the cytoskeleton and is not a substrate for P-glycoprotein drug resistance protein. Over expression of P-glycoprotein is a common mechanism that results in taxane resistance in TNBC. Preclinical studies in human triple negative breast cancer grown in animal models demonstrate that VERU-111 significantly inhibits cancer proliferation, migration, metastases, and invasion of triple negative breast cancer cells and tumors that have become resistant to paclitaxel (taxane). Using the safety information from the Phase 1b and Phase 2 VERU-111 prostate cancer clinical studies in a total of approximately 80 men, the Company plans to meet with the FDA in first half of calendar year 2021 and to commence a Phase 2b clinical study in the fourth quarter of calendar year 2021 to evaluate oral daily dosing of VERU-111 in approximately 100 women with metastatic TNBC that has become resistant to taxane IV chemotherapy.

**Anti-Viral and Anti-Inflammatory Drug Candidate – COVID-19**

*VERU-111 for the treatment of SARS-CoV-2 in subjects at high risk for acute respiratory distress syndrome (ARDS)*

VERU-111 is also being evaluated in a Phase 2 clinical trial to assess the efficacy of VERU-111 in combating COVID-19 to prevent ARDS. VERU-111 by targeting microtubules may have broad antiviral and strong anti-inflammatory effects including the potential to treat the cytokine release syndrome that is associated with the high COVID-19 mortality rates. If the clinical results of the Phase 2 clinical trial are positive, the Company intends to apply for grant funding through third party agencies.

**Sexual Health Division**

The Company's Sexual Health Division includes a drug candidate, TADFYN®, for the treatment of BPH and a commercial product, the FC2 Female Condom/Internal Condom® (FC2), an FDA-approved product for the dual protection against unintended pregnancy and sexually transmitted infections.

TADFYN® (tadalafil 5mg and finasteride 5mg combination capsule) is being developed to treat urinary tract symptoms caused by benign prostatic hyperplasia (BPH). Tadalafil (CIALIS®) is currently approved for treatment of BPH and erectile dysfunction and finasteride is currently approved for treatment of BPH (finasteride 5mg PROSCAR®) and male pattern hair loss (finasteride 1mg PROPECIA®). The co-administration of tadalafil and finasteride has been shown to be more effective for the treatment of BPH than by finasteride alone. The Company had a successful pre-New Drug Application (NDA) meeting with the FDA and expects to submit the NDA for TADFYN® in early calendar year 2021. The Company's Sexual Health Business segment will include future revenues for TADFYN®. Costs associated with the development of TADFYN® are currently included in our Research and Development segment.

The Company sells FC2 in both the commercial sector in the U.S. and in the public health sector in the U.S. and globally. In the U.S., FC2 is available by prescription through the Company's multiple telemedicine (telemedicine being the remote diagnosis and treatment of patients by means of telecommunications technology) and internet pharmacy partners and retail pharmacies. It is also available to public health sector entities such as state departments of health and 501(c)(3) organizations. In the global public health sector, the Company markets FC2 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.

Most of the Company's net revenues are currently derived from sales of FC2 in the commercial and public health sectors.

**PREBOOST® Sale**

On December 8, 2020, the Company entered into an Asset Purchase Agreement (the "Purchase Agreement") with Roman Health Ventures Inc. (the "Purchaser"). Pursuant to, and subject to the terms and conditions of, the Purchase Agreement, the Purchaser purchased substantially all of the assets related to the Company's PREBOOST® business. PREBOOST® is a 4% benzocaine medicated individual wipes for the treatment of premature ejaculation and was a commercial product in the Company's Sexual Health Division during fiscal 2020. The transaction closed on December 8, 2020. The purchase price for the transaction was $20.0 million, consisting of $15.0 million paid at closing, $2.5 million payable 12 months after closing and $2.5 million payable 18 months after closing.

**Risk Factors Summary**

Our business is subject to a number of risks of which you should be aware before making an investment decision. The following summary highlights some of the risks you should consider with respect to our business and prospects. This summary is not complete and the risks summarized below are not the only risks we face. For a more complete understanding of the risks related to our business and an investment in our common stock, we encourage you to read and consider the discussion in "Risk Factors" in Item 1A. of this report. These risks include, but are not limited to, the following:

- We have incurred significant net losses in recent fiscal years and expect to continue to incur losses for the foreseeable future;
- We will need substantial additional financing to support our development activities;
- Our drug development efforts are at an early stage, and we may fail or elect not to commercialize any of our drug candidates;
- We may encounter substantial delays in the commencement, enrollment or completion of our clinical trials or in submissions to applicable regulatory authorities or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities, which could prevent us from commercializing our drug candidates on the timetable expected or at all;
- We rely, and expect to continue to rely, on third parties in connection with our drug development efforts, including contract research organizations, third party manufacturers and other third party collaborators;
- Clinical results or early data from clinical trials may not be replicated or continue to occur in additional trials or may not otherwise support further development in the specified product candidate or at all;
- We may not be able to gain and retain market acceptance for our drug candidates;
- We may not be able to produce a COVID-19 treatment candidate that successfully treats the virus in a timely manner, if at all;
- Our success will depend on our ability to protect our intellectual property and proprietary technologies;
- We are subject to extensive and costly governmental regulation;

- The COVID-19 pandemic may disrupt our operations and the operations of our suppliers and customers, including affecting our ability to initiate or complete clinical trials and disrupting regulatory activities;
- We may experience intense competition, which may result in others discovering, developing or commercializing products before us or more successfully than us and which may adversely affect sales of our commercial products;
- We may not be able to successfully implement our strategy to grow sales or sustain price levels of FC2 in the U.S. market;
- Our FC2 business may be affected by contracting risks with government and other international health agencies;
- Our reliance on major customers and risks related to delays in payment of accounts receivable by major customers;
- Our reliance on a single facility to manufacture FC2 subjects us to the risk of supply disruptions;
- 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; and
- Ownership in our common stock is highly concentrated and your ability to influence corporate matters may be limited as a result.

**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 our acquisition of Aspen Park Pharmaceuticals, Inc. (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 developing and commercializing biopharmaceutical products for oncology.

**Strategy**

Veru is an oncology biopharmaceutical company with a focus on developing novel medicines for the management of advanced prostate and breast cancers. Our strategy is primarily to focus on the clinical development and commercialization of oncology drugs for the management of two of the most prevalent cancers globally – prostate cancer and breast cancer.

Prostate cancer is the most commonly diagnosed cancer in men with estimated 191,930 new cases and 33,330 deaths expected for 2020 in the U.S. One in nine men will develop prostate cancer in their lifetime. Prostate cancer has become a chronic disease with new challenges as prostate cancer develops resistance to current drugs and spreads throughout the body and as the patient suffers from the long-term side effects of these cancer treatments like hot flashes, bone loss and fractures, loss of libido, erectile dysfunction, and loss of muscle strength and frailty.

Breast cancer is the most commonly diagnosed cancer in women with estimated 276,480 new cases and 42,170 deaths expected for 2020 in the U.S. One in eight women will develop invasive breast cancer in their lifetime. Breast cancer is a heterogenous disease with diverse clinical and molecular characteristics. Estrogen is one of the main drivers of breast cancer proliferation, tumor progression, and metastasis. Consequently, treatments that target the ER are the mainstay of breast cancer therapy, but unfortunately almost all women will eventually develop resistance to endocrine therapies and alternative treatment approaches will be required including IV chemotherapy. Another form of breast cancer that occurs in 15% of all breast cancers is called triple negative breast cancer (TNBC). Triple negative breast cancer does not have ER or PR and does not make HER2. As a consequence, TNBC is an endocrine resistant, aggressive cancer that grows and spreads faster than ER+ and/or HER2+ breast cancers. Triple negative breast cancer also develops resistance to currently used chemotherapy drugs like taxanes and anthracyclines, and as such, treatment options for TNBC are limited.

Accordingly, we are dedicated to the development and commercialization of drug candidates to address unmet medical needs for prostate and breast cancer management while continuing to sell the commercial product in our sexual health business to help fund part of this development. The key elements of our strategy are as follows:

- **Develop and launch high value, novel biopharmaceutical products for prostate cancer management.** We are developing three drugs, VERU-111, VERU-100, and Zuclomiphene citrate, each of which addresses large potential markets relating to prostate cancer and prostate cancer supportive care.

    - We initiated a Phase 1b open label clinical trial of VERU-111 in metastatic castration resistant and androgen receptor targeting agent resistant prostate cancer patients in January 2019. The Phase 1b study has yielded promising efficacy and safety clinical data. In September 2020, the Phase 2 clinical study completed enrollment of approximately 40 men with metastatic castration resistant prostate cancer who have also become resistant to at least one androgen receptor targeting agent, such as abiraterone, enzalutamide, or apalutamide, but prior to proceeding to IV chemotherapy. The Company anticipates starting the Phase 3 pivotal VERU-111 prostate cancer study in the first quarter of calendar year 2021. The potential U.S. market for oral cancer therapies in advanced prostate cancer is over $5 billion.

    - VERU-100 is a long-acting GnRH antagonist formulation administered as a small volume, subcutaneous three-month depot injection without a loading dose with multiple beneficial clinical attributes addressing the shortfalls of current FDA-approved ADT formulations for advanced prostate cancer. VERU-100 immediately suppresses testosterone with no testosterone surge upon initial or repeated administration, a problem which occurs with currently approved LHRH agonists used for ADT. There are no GnRH antagonist depot formulations commercially approved beyond a one-month duration injection. A Phase 2 study to evaluate VERU-100 dosing is anticipated to begin in the first quarter of calendar year 2021. The global market for ADT was $2.6 billion in 2018.

    - Zuclomiphene citrate, an oral nonsteroidal estrogen receptor agonist, is being developed to treat hot flashes, a common side effect caused by ADT in men with advanced prostate cancer. The Company plans to have an End of Phase 2 meeting with the FDA. ADT-induced hot flashes affect approximately 600,000 men in the U.S., representing estimated annual sales of $600 million for Zuclomiphene citrate in the U.S. alone.

- **Develop and launch high value, novel biopharmaceutical products for breast cancer.** The Company's breast cancer pipeline includes enobosarm and VERU-111.

    - Enobosarm is an oral, first-in-class, new chemical entity, selective androgen receptor agonist that targets the androgen receptor (AR) in AR+/ER+/HER2- metastatic breast cancer without unwanted virilizing side effects. Enobosarm is the first new class of targeted endocrine therapy in advanced breast cancer in decades. Enobosarm has extensive nonclinical and clinical experience having been evaluated in 25 separate clinical studies in over 2,100 subjects, including five prior Phase 2 clinical studies in advanced breast cancer involving more than 250 patients. In the two Phase 2 clinical studies conducted in women with AR+/ER+/HER2- breast cancer, enobosarm demonstrated significant antitumor efficacy in heavily pretreated cohorts and was well tolerated with a favorable safety profile. In October 2020, the FDA agreed to a Phase 3 registration clinical trial study to evaluate the efficacy and safety of enobosarm, selective androgen receptor targeting agonist, versus active control of either exemestane or tamoxifen (physician's choice) for the treatment of ER+/HER2- metastatic breast cancer in approximately 240 patients who have failed a nonsteroidal aromatase inhibitor (anastrozole or letrozole), fulvestrant, and a CDK4/6 inhibitor, but prior to IV chemotherapy. The primary endpoint is radiographic progression-free survival. The pivotal Phase 3, open label, randomized, active control study is anticipated to commence in the first half of calendar year 2021. Global revenues for endocrine therapies for advanced breast cancer are over $6 billion.

    - VERU-111 is an oral, first-in-class, new chemical entity that targets, crosslinks, and disrupts alpha and beta tubulin subunits of microtubules to disrupt the cytoskeleton for treatment of taxane resistant metastatic triple negative breast cancer. The first line of treatment usually includes IV taxane chemotherapy. Almost all women will eventually develop taxane resistance. Using the safety information from the Phase 1b and Phase 2 VERU-111 prostate cancer clinical studies, the Company plans to meet with the FDA in first half of calendar year 2021 and to commence a Phase 2b clinical study in the fourth quarter of calendar year 2021 to evaluate VERU-111 in women with metastatic triple negative breast cancer that has become resistant to taxane IV chemotherapy. Global revenues for oral therapies for advanced breast cancer are over $6 billion.

- **Continue to grow our sexual health business to invest proceeds in the clinical development of our drug pipeline to access large premium oncology markets in prostate and breast cancer.**

    - TADFYN® for the administration of tadalafil 5mg and finasteride 5mg combination capsule to treat lower urinary tract symptoms caused from BPH- We plan to advance TADFYN® toward commercialization in the U.S., Europe, and South America. The Company had a successful pre-NDA meeting with the FDA and the expected submission of the NDA for TADFYN® in early calendar year 2021. We plan to initially launch TADFYN® by telemedicine channels, if approved by the FDA, in late 2021 in the U.S. We also plan to secure partnership opportunities to commercialize TADFYN® outside the U.S.

    - FC2- We expect to continue the rapid growth of revenues in the U.S. market through prescription sales by leveraging our relationships with telemedicine and pharmacy internet providers and distributors, while continuing to pursue revenues in the public health sector in key markets both in the U.S. and globally.

- **Capitalize on expertise and reputation of our management team and board members.** Our management team has significant expertise and experience in urology and oncology as well as drug development, regulatory, 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.

- **Be opportunistic.** VERU-111 is also being evaluated in a Phase 2 clinical trial to assess the efficacy of VERU-111 in combating COVID-19 to prevent ARDS. VERU-111, by targeting microtubules, may have broad antiviral and strong anti-inflammatory effects, including the potential to treat the cytokine release syndrome that is associated with the high COVID-19 mortality rates. If the clinical results of the Phase 2 clinical trial are positive, the Company intends to apply for grant funding through third party agencies.

**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 – Prostate** | | | |
| VERU-111 – oral, first-in-class, cytoskeleton disruptor small molecule | Metastatic castration and androgen receptor targeting agent resistant prostate cancer | 505(b)(1) | Phase 2 ongoing, Planned Phase 3 registration study |
| VERU-100 –GnRH antagonist peptide subcutaneous three-month depot injection formulation | Palliative treatment of advanced prostate cancer | 505(b)(2) | Planned Phase 2 |
| Zuclomiphene citrate – oral, non-steroidal, estrogen receptor agonist | Hot flashes in men with advanced prostate cancer | 505(b)(2) | Phase 2 completed |

| PRODUCT | INDICATION | U.S. REGULATORY PATHWAY | DEVELOPMENT PHASE |
|---|---|---|---|
| **Oncology Drug Candidates – Breast** | | | |
| Enobosarm – selective androgen receptor agonist that targets the androgen receptor (AR) without adverse virilizing side effects | ER+/HER2- metastatic breast cancer | 505(b)(1) | Planned Phase 3 registration study |
| VERU-111 – oral, first-in-class, cytoskeleton disruptor small molecule | Taxane resistant metastatic triple negative breast cancer | 505(b)(1) | Planned Phase 2b |
| **Anti-Viral and Anti-Inflammatory Drug Candidate** | | | |
| VERU-111 – oral, first-in-class, cytoskeleton disruptor small molecule | COVID-19 | 505(b)(1) | Phase 2 ongoing |
| **Sexual Health Division** | | | |
| **Drug Candidate** | | | |
| TADFYN® – Tadalafil 5mg and Finasteride 5mg combination capsule | Initial treatment of men with lower urinary tract symptoms from an enlarged prostate | 505(b)(2) | Bioequivalence study |
| **Commercial Product** | | | |
| FC2 Female Condom/FC2 Internal Condom® | Unintended pregnancy and STIs | FDA approved | Marketed |

**Oncology Drug Candidates – Prostate Cancer**

***VERU-111, an oral, first-in-class alpha and beta tubulin inhibitor/cytoskeleton disruptor small molecule for the treatment of metastatic castration resistant and androgen receptor targeting agent resistant prostate cancer.***

***Scientific Overview.*** In 2020, there were an estimated 191,930 new cases and 33,330 deaths of prostate cancer in the U.S. 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 first line therapy is ADT, 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 second line androgen receptor targeting 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 eventually develop progressive metastatic castration resistant and androgen receptor targeting agent prostate cancer within 12-15 months.

VERU-111 is an oral, first-in-class small molecule that targets, binds to, and crosslinks the alpha and beta tubulin subunits of microtubules and intermediate filaments of cells resulting in disruption of the cytoskeleton. Furthermore, VERU-111 causes apoptosis, or cell death by cleaving poly ADP ribose polymerase (PARP) which is important for DNA repair in cancer cells. VERU-111 has high oral bioavailability; less possibility for drug resistance as it does not interact with multiple drug resistance proteins (P-glycoprotein); and minimal potential for drug to drug interactions. VERU-111 has shown in preclinical studies to have efficacy against many tumor types including castration resistant prostate cancer, triple negative breast cancer resistant to anthracyclines and taxanes as well as ovarian cancer, cervical cancer, lung cancer, melanoma, leukemia, glioma, and pancreatic cancer. In current clinical prostate cancer studies, VERU-111 appears to be well tolerated with minimal neurotoxicity and no neutropenia, which are common side effects of taxanes and vinca alkaloids anti-microtubule chemotherapy agents.

***Development Plan.*** The Company plans to develop VERU-111 as a treatment for men with metastatic castration resistant prostate cancer who have also become resistant to androgen receptor targeting agents like ZYTIGA® (abiraterone) or XTANDI® (enzalutamide) and prior to proceeding to IV chemotherapy. In September 2018, the Company completed a pre-Investigational New Drug Application (IND) meeting with the FDA for VERU-111 in which the FDA agreed with the Company's plans for a Phase 1b and Phase 2 clinical trials. The Company submitted an IND and initiated an open label Phase 1b clinical trial in January 2019 at Johns Hopkins Cancer Center and four other clinical centers. The Phase 1b clinical study has completed enrollment of 39 men with castration resistant prostate cancer who have become resistant to androgen receptor targeting agent and may have had taxane IV chemotherapy. Although the Phase 1b clinical study is ongoing, it has yielded interim promising clinical efficacy and safety data. Evidence of antitumor activity was based on PSA declines and responses as well as objective and durable antitumor responses. Based on the Phase 1b clinical study, the recommended Phase 2 dose is 63mg oral daily continuous dosing for 21-day cycles as daily chronic drug administration appears to be feasible and safe. The recommended Phase 2 dose is well tolerated as there have been no reports of neutropenia, neurotoxicity, or Grade 3 diarrhea. The Phase 2 clinical study has completed enrollment of approximately 40 men with metastatic castration resistant prostate cancer who have also become resistant to androgen receptor targeting agents, such as abiraterone, enzalutamide, or apalutamide, but prior to proceeding to IV chemotherapy. In addition, in July 2020, the Company received input from the FDA in the design the Phase 3 VERU-111 clinical registration study. The Company received regulatory clarity that the indication, men with metastatic castration resistant prostate cancer who have failed one androgen receptor targeting agent, but prior to proceeding to IV chemotherapy was acceptable, and that an open label, randomized study using an alternative androgen receptor targeting agent as the active control is reasonable. Furthermore, the primary endpoint for the Phase 3 study may be radiographic progression-free survival. By allowing radiographic progression-free survival as the primary endpoint, the sample size of the Phase 3 study could be potentially between 200 and 300 men. The Company anticipates starting the Phase 3 clinical registration study called the VERACITY study evaluating VERU-111 for men with metastatic castration resistant prostate cancer who have also become resistant to one androgen receptor targeting agent in the first quarter of calendar year 2021.

***Market.*** In the U.S., the annual market for oral hormone therapies for prostate cancer is $6.5 billion per Decision Resources Group and Allied Market Research. The first indication for which VERU-111 is being developed is metastatic castration resistant and androgen receptor targeting agent resistant prostate cancer. Furthermore, VERU-111 can be expanded to a broader oncology market as it has shown in preclinical studies to have efficacy against many other tumor types including triple negative breast cancer resistant to anthracyclines and taxanes as well as ovarian cancer, cervical cancer, lung cancer, melanoma, leukemia, glioma, and pancreatic cancer.

***VERU-100, a novel, proprietary, long-acting, GnRH antagonist peptide three-month depot small volume, subcutaneous injection formulation for androgen deprivation therapy for advanced prostate cancer.***

***Scientific Overview.*** Androgen deprivation therapy remains the mainstay primary first line therapy for advanced prostate cancer, but current ADT products, such as LUPRON® and ELIGARD® (leuprolide), FIRMAGON® (degarelix), and ZOLADEX® (goserelin) have several important shortfalls. LUPRON, ELIGARD, and ZOLADEX are LHRH agonists whose initial administration leads to an initial 14 to 21-day testosterone surge (flare) and interval micro elevations (spikes or escapes) in testosterone blood concentrations. FIRMAGON, a GnRH antagonist, is a large-volume subcutaneous injection formulation designed for only a single month release. FIRMAGON requires a loading dose of two 3 mL subcutaneous injections followed by a monthly maintenance dose of 4 mL subcutaneous injection repeated. In contrast, VERU-100 is designed to address a number of these important shortfalls of currently marketed ADT products: VERU-100 is a long-acting GnRH antagonist designed to be administered as a small volume (<2 mL) subcutaneous three-month depot injection without a loading dose. VERU-100, as a GnRH antagonist, immediately suppresses testosterone with no testosterone surge upon initial or repeated administration unlike what occurs with the currently approved LHRH agonists. Furthermore, as a class, GnRH antagonists have been shown to have fewer cardiovascular adverse events than LHRH agonists in men on ADT.

***Development Plan.*** The Company had a Pre-IND meeting with the FDA in May 2019 clarifying the requirements for regulatory development pathway. The FDA agreed to an expedited regulatory development pathway for VERU-100. The Company plans to conduct a single Phase 2 open label, multicenter clinical study of up to three doses of VERU-100 in men with advanced prostate cancer (n=35-60) for a single three-month injection, and a single Phase 3-open label single arm study in men with advanced prostate cancer (n=100) as the pivotal, registration study for NDA submission. The Company plans to initiate the Phase 2 dose finding study in the first quarter of calendar year 2021 and Phase 3 registration study in 100 men in the second half of calendar year 2021.

***Market.*** VERU-100 is a long-acting GnRH antagonist for ADT designed to be administered as a small volume subcutaneous three-month depot injection without a loading dose. Currently, there are no GnRH antagonists commercially approved beyond a one-month depot injection, making VERU-100, if approved, the only commercially available GnRH antagonist three-month depot. Global sales of ADT drugs in 2018 were $2.6 billion.

***Zuclomiphene citrate for the treatment of hot flashes caused by prostate cancer hormonal therapies in men with advanced prostate cancer.***

***Scientific Overview.*** In 2020, there were an estimated 191,930 new cases and 33,330 deaths of prostate cancer in the U.S. The estimated prevalence of prostate cancer in the U.S. is 3 million cases for which over one-third will have received ADT. ADT results in very low, castrate levels of testosterone. Eliminating testosterone is an effective therapy as testosterone is a powerful growth factor for prostate cancer. As estrogen is derived from testosterone in men, low levels in testosterone also results in very low levels of estrogen. Low estrogen side effects include hot flashes, bone loss and fractures, loss of libido, memory disturbances, and adverse blood lipid changes.

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 ADT, like LUPRON® and ELIGARD® (leuprolide), FIRMAGON® (degarelix), 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 ADT complain of hot flashes with 30-40% having moderate to severe hot flashes. Patients on ADT report significant effects on daily functioning and quality of life. Hot flashes are one of the main reasons that prostate cancer patients want to delay or stop being treated by ADT.

Hormonal and nonhormonal therapies have been used off-label to treat hot flashes in men on prostate cancer hormonal therapies. In general, use of off-label hormonal agents, especially estrogens, have been shown to be helpful for treating hot flashes. However, off-label estrogen treatment is complicated by lack of consistent dosing, and known side effects such as gynecomastia (breast enlargement), gynecodynia (painful breasts), and increase in thromboembolic events like deep venous thrombosis, pulmonary embolus, and stroke. Progesterone hormone agents, like MEGACE® (megestrol), have also been used off-label but the side effects include weight gain, increase in thromboembolic events like deep venous thrombosis, pulmonary embolus, and stroke, and the potential to stimulate the growth of prostate cancer. Nonhormonal agents that also have been used off-label include antiseizure agents and antidepressants that have serious and unwanted side effects. Moreover, nonhormonal agents have demonstrated less effectiveness 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. As estrogen deficiency is the reason for the hot flashes, we believe that Zuclomiphene citrate, a nonsteroidal estrogen receptor agonist, has the potential to replace estrogen and be an efficacious and well tolerated treatment for hot flashes caused by ADT in men with advanced prostate cancer.

***Development Plan.*** In June 2018, the Company submitted an IND with the FDA for Zuclomiphene citrate. In September 2018, the Company enrolled its first subject in the Phase 2 double-blind randomized placebo-controlled dose finding study evaluating two doses of oral daily Zuclomiphene citrate (10mg or 50mg) treatment versus placebo in approximately 95 men with advanced prostate cancer who have ADT induced moderate to severe hot flashes. The clinical study had a treatment duration of 12 weeks and was being conducted in 24 clinical centers in the U.S. The primary endpoint was the frequency of moderate to severe hot flashes. Secondary endpoints included severity of hot flashes and improvement in bone marker. In October 2019, the Company announced that it had achieved full enrollment for its Phase 2 clinical study.

A topline interim analysis of the Zuclomiphene citrate Phase 2 study was performed in which 93 men with ADT-induced hot flashes were enrolled. The objectives of the study were to evaluate the estrogenic activity of Zuclomiphene citrate on hot flashes, to confirm a no-effect dose (the 10mg dose), and to evaluate the effect of a higher dose (the 50mg dose) of Zuclomiphene citrate on the frequency of moderate to severe hot flashes at Day 42. The topline interim clinical results demonstrated that a statistically significant decrease in moderate to severe hot flashes from baseline was observed in the 50mg treatment group ($p<0.001$). The 10mg treatment group, as expected, did not show a statistically significant reduction in hot flashes from baseline ($p=0.15$). Based on this result, the 10mg dose group was established as a no-effect dose as was planned for in the study. Furthermore, when comparing the 50mg treatment group (-41% reduction in hot flashes from baseline) versus the 10mg treatment group (-21% reduction in hot flashes from baseline), a statistically significant reduction ($p=0.03$) in the frequency of moderate to severe hot flashes at Day 42 is observed. Moreover, the observed estrogenic activity of the 50mg group was statistically different from 10mg and placebo groups ($p<0.0001$). Zuclomiphene citrate appears to be well tolerated as there have been no reports of drug related serious adverse events nor drug related severe adverse events and no observations of adverse events of special interest, such as breast enlargement or pain, or venothromboembolic events (blood clots in legs or lungs, or stroke) in the safety database for the Phase 2 clinical study. Adverse events of special interest are side effects commonly seen with off-label use of steroidal estrogens and progestins for hot flashes. The 50mg treatment group shows statistical and clinically meaningful reductions in moderate to severe hot flashes from baseline without any clinically relevant safety findings. The Company plans to meet with the FDA for an End of Phase 2 meeting in the last quarter of calendar year 2021.

***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 ADT, including LUPRON® (Leuprolide), ELIGARD® (Leuprolide), and FIRMAGON® (degarelix) and about up to 40% of such men experience moderate to severe hot flashes. Approximately 600,000 men annually in the U.S. are on ADT for advanced prostate cancer. There are currently no FDA-approved therapies for hot flashes associated with prostate cancer hormonal therapies. Based on independent market research sponsored by the Company, U.S. peak sales for Zuclomiphene citrate to treat hot flashes in men with prostate cancer in ADT are estimated to be approximately $600-800 million.

**Oncology Drug Candidates- Breast Cancer**

***Enobosarm, selective androgen receptor targeting agonist, for the treatment of androgen receptor positive (AR+), estrogen receptor positive (ER+), and human epidermal growth factor receptor 2 (HER2-) metastatic breast cancer.***

***Scientific Overview.*** In the U.S., breast cancer is the most commonly diagnosed cancer in women with an estimated 276,480 new cases and 42,170 deaths expected for 2020 with one in eight women developing invasive breast cancer in their lifetime. Breast cancer is heterogenous disease with diverse clinical and molecular characteristics. The initial molecular assessment is to determine hormone receptor status, ER and PR, as well as HER2 status. Estrogen is one of the main drivers of breast cancer proliferation, tumor progression, and metastasis. Consequently, treatments that target the ER are the mainstay of breast cancer therapy, but unfortunately almost all women will eventually develop resistance to endocrine therapies and alternative treatment approaches will be required including IV chemotherapy.

Targeting the AR has the potential to be the next important endocrine therapy for women with breast cancer. 1) AR is the most abundantly expressed steroid receptor in breast cancer being detected between 70 to 95% of breast cancer specimens; 2) Androgen receptor agonists inhibit cellular proliferation and have anti-tumor efficacy in ER+ human breast cancer models; and, 3) the presence of AR in breast cancer specimens predicts favorable disease-free survival and overall survival.

Targeting AR using both steroidal androgens and synthetic androgens (e.g. fluoxymesterone and medroxyprogesterone acetate) have been shown to have efficacy in the treatment of breast cancer similar to first line tamoxifen. Most recently, a contemporary retrospective study in 103 women with AR+ ER+ breast cancer who have failed a median of 3 endocrine therapies (range 1-10) were treated with fluoxymesterone with a clinical benefit rate at 6 months of 43% and evidence of objective tumor responses (2 complete responses and 7 partial responses). Unfortunately, the use of synthetic androgens has been limited by their unacceptable side effects including virilization, increase in hematocrit, liver toxicity, and inability to source the drugs.

Enobosarm is an oral, first-in-class, new chemical entity, selective androgen receptor targeting agent, for the treatment of AR+/ER+, HER2- metastatic breast cancer, but prior to IV chemotherapy. Enobosarm is a member of a new class of endocrine therapy called selective androgen receptor agent which means it is both an agonist and an

antagonist depending on the tissue type. Enobosarm binds to the AR in breast tissue and inhibits AR+ ER+ breast cancer cell proliferation and tumor growth in animal models. Unlike testosterone, enobosarm cannot be aromatized to estrogen. Enobosarm has selective clinical properties that could have potential benefit in women with AR+ ER+ breast cancer. Preclinical studies have shown that enobosarm builds and heals cortical and trabecular bone with the potential to treat osteoporosis and skeletal related cancer events. Enobosarm has been shown to build muscle and reduce fat and improve physical function in clinical studies involving elderly subjects and patients with cancer cachexia including breast cancer. Furthermore, the tissue selectivity of enobosarm also results in a favorable side effect profile with no virilization (facial hair and acne), no polycythemia, and no liver toxicity.

***Development Plan.*** Enobosarm has extensive nonclinical and clinical experience having been evaluated in 25 separate clinical studies in over 2,100 subjects, including five prior Phase 2 clinical studies in advanced breast cancer involving more than 250 patients. In the two Phase 2 clinical studies conducted in women with AR+/ER+/HER2- metastatic breast cancer, enobosarm demonstrated significant antitumor efficacy in heavily pretreated cohorts and was well tolerated with a favorable safety profile.

The first Phase 2 clinical trial (G200801) was a single arm study evaluating 9mg oral daily dose of enobosarm in a heavily pretreated endocrine resistant cohort of 22 subjects with AR+/ER+/HER2- metastatic breast cancer. The patients participating in the study on average had 3 (range 1-5) previous lines of endocrine therapy and 68% had previous chemotherapy. The clinical benefit rate at 6 months was 35.3% (90% CI:16.6%, 58%). Progression free probability was 57.5% at Day 84 and 50.5% at Day 168. The 6-month Kaplan-Meier estimate for radiographic progression free survival was 43.8%. Enobosarm was well tolerated without evidence of virilization, no polycythemia, and no liver toxicity.

The second Phase 2 clinical trial (G200802) was a 2-arm study evaluating 9mg and 18mg enobosarm daily oral dosing in 136 women with ER+ HER2- advanced breast cancer who previously responded to endocrine treatment. The patients in this study were also heavily pretreated having failed an average of 4 endocrine treatments and 88% had received prior chemotherapy. Enobosarm showed efficacy with a clinical benefit rate at 6 months which for 9mg was 32% (95% CI 19.5%,46.7%) and for the 18mg cohort was 29% (95% CI 17.1%,43.1%). The median duration of clinical benefit was not reached for the 9mg group (8.2 month - Not reached) and for the 18mg group was 14.1 months (11 months - 16.5 months). The best overall objective tumor response rate based on RECIST 1.1 which was determined through a central read was: 2 complete responses and 10 partial responses for the 9 mg cohort and 5 complete responses and 5 partial responses for the 18 mg cohort. The median progression free survival in the evaluable subjects was 5.6 months (2.9, 27.5) in the 9 mg group and 4.2 months (2.8, 11.0) for the 18 mg group. Quality of life assessments showed significant improvement from baseline for both the 9mg and 18mg enobosarm cohorts. Enobosarm was well tolerated without unwanted virilizing effects at both the 9mg and 18mg doses.

Overall, these studies of enobosarm clearly establish the clinical relevance of targeting the AR with a selective AR agonist, both from an efficacy perspective and with additional other clinical benefits. Owing to its high tissue selectivity, enobosarm increases in lean body mass (muscle) and physical function, decreases in fat mass, improves bone strength, and lacks androgenic adverse side effects including virilization, liver toxicity, and polycythemia. By targeting the AR in ER+ HER2- metastatic breast cancer, enobosarm introduces a novel endocrine therapy to patients with breast cancer that have exhausted endocrine therapies targeting ER, but prior to IV chemotherapy.

In October 2020, the FDA agreed to the Phase 3 registration clinical trial study to evaluate the efficacy and safety of enobosarm, selective androgen receptor targeting agonist, versus active control, either exemestane or tamoxifen (physician's choice), for the treatment of metastatic ER+/HER2- breast cancer in approximately 240 patients who have failed a nonsteroidal aromatase inhibitor (anastrozole or letrozole), fulvestrant, and a CDK4/6 inhibitor, but prior to IV chemotherapy. The primary endpoint is radiographic progression-free survival. The Phase 3, open label, randomized, active control registration ARTEST Phase 3 study is anticipated to commence in the first half of calendar year 2021.

***Market.*** Enobosarm represents the first new class of targeted endocrine therapy in advanced breast cancer in decades. Enobosarm targets AR in ER+ HER2- metastatic breast cancer as a potential second line and/or third line oral daily dosing endocrine therapy option in breast cancer patients that have exhausted endocrine therapies targeting ER, but prior to IV chemotherapy. The global annual market for an oral agent in an ER endocrine resistant setting would be similar to CDK 4/6 inhibitor drugs which is a $6 billion dollar market.

***VERU-111, an oral, first-in-class alpha and beta tubulin inhibitor/cytoskeleton disruptor small molecule, for the treatment of taxane resistant metastatic triple negative breast cancer***

***Scientific Overview.*** Breast cancer is the most commonly diagnosed cancer in women with estimated 276,480 new cases and 42,170 deaths expected for 2020 and one in eight women will develop invasive breast cancer in their lifetime. Breast cancer is a heterogenous disease with diverse clinical and molecular characteristics. Metastatic triple negative breast cancer is an aggressive form of breast cancer that occurs in 15% of all breast cancers. This form of breast cancer does not express ER, PR, or HER2 and is resistant to endocrine therapies. The first line of treatment usually includes IV taxane chemotherapy. Almost all women will eventually develop taxane resistance. VERU-111 is an oral, first-in-class, new chemical entity that targets, crosslinks, and disrupts alpha and beta tubulin subunits of microtubules and is not a substrate for P-glycoprotein drug resistance protein. Over expression of P-glycoprotein is a common mechanism that causes taxane resistance in breast cancer. Preclinical studies in human triple negative breast cancer grown in animal models demonstrate that VERU-111 significantly inhibited cancer proliferation, migration, metastases, and invasion of triple negative breast cancer cells and tumors that have become resistant to paclitaxel (taxane).

***Development Plan.*** Based upon the strong *in vitro* and *in vivo* animal preclinical data of VERU-111 in triple negative breast cancer models and using the safety information from the Phase 1b and Phase 2 VERU-111 prostate cancer clinical studies in over 80 men, the Company plans to meet with the FDA in first half of calendar year 2021 and to commence a single arm, open label, Phase 2b clinical study in Q4 2021 to evaluate VERU-111 in women with metastatic triple negative breast cancer that has become resistant to IV taxane chemotherapy.

***Market.*** The number of new U.S. breast cancer cases in 2020 totaled 276,480 with triple negative breast cancer accounting for 10-15% or approximately 41,472 patients. The majority of women will receive IV chemotherapy including taxanes. Almost all these women will develop taxane resistance and will be a candidate for VERU-111. The annual U.S. market for taxane resistant metastatic triple negative breast cancer is over $1 billion annually.

**Anti-Viral and Anti-Inflammatory Drug Candidate – COVID-19**

***VERU-111, an oral, first-in-class alpha and beta tubulin inhibitor/cytoskeleton disruptor small molecule, for the treatment of COVID-19 patients at high risk for acute respiratory distress syndrome***

***Scientific Overview.*** Drugs like VERU-111 that target microtubules have broad antiviral activity by disrupting the intracellular transport of viruses such as SARS CoV-2, along microtubules. Microtubule trafficking is critical for viruses to cause infection. Furthermore, microtubule depolymerization agents that target alpha and beta tubulin subunits of microtubules also have strong anti-inflammatory effects including the potential to treat the cytokine release syndrome (cytokine storm) induced by the SARS-CoV-2 viral infection that seems to be associated with high COVID-19 mortality rates. VERU-111 could therefore have a two-pronged approach to the treatment of SARS-CoV-2 (COVID-19) virus infection and the debilitating and sometimes lethal respiratory effects of the virus. First, as an antiviral, it would have direct effects on S protein-microtubule trafficking with the potential to reduce the production of infectious virions particularly affecting viral replication and assembly and virion egress. Secondly, as an anti-inflammatory agent, it may reduce virally induced severe inflammation in the respiratory system and reduce the incidence of cytokine storm and septic shock that can occur in patients that progress.

***Development Plan.*** Veru is currently enrolling a double-blind randomized (1:1) placebo-controlled Phase 2 clinical trial evaluating daily oral doses of VERU-111 versus placebo for 21 days in 40 hospitalized patients who tested positive for the SARS-CoV-2 virus and are at high risk for ARDS. The primary efficacy endpoint is the proportion of patients that are alive and without respiratory failure at Day 22. Secondary endpoints include the measured improvements on the WHO Disease Severity Scale (8-point ordinal scale) which captures COVID-19 disease symptoms and signs including hospitalization to progression of pulmonary symptoms to mechanical ventilation as well as death. If the clinical results of the Phase 2 clinical trial are positive, the Company intends to apply for grant funding through third party agencies including the Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services (BARDA) and the Defense Advanced Research Projects Agency of the U.S. Department of Defense (DARPA). There can be no assurances that any such grant funding will be provided.

***Market.*** Approximately 20% of symptomatic cases require hospitalization with 5% ending up in the ICU. In the U.S. there are an estimated 250,000 new COVID cases per week resulting in 2,500 patients per week being eligible for VERU-111 treatment or 130,000 patients per year with a market value of greater than $600 million.

**Sexual Health Division**

***Drug candidate***

***TADFYN® (tadalafil 5mg and finasteride 5mg combination capsule) for the initial treatment of men with lower urinary tract symptoms and enlarged prostate***

***Scientific Overview.*** Tadalafil and finasteride combination product in capsules 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 for 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 the tadalafil and finasteride combination qualifies 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 the tadalafil and finasteride combination for the initial treatment of lower urinary tract symptoms in men with enlarged prostates. The purpose of the meeting was to discuss the proposed NDA and to confirm the clinical, non-clinical, and chemistry, manufacturing and controls (CMC) requirements for the Company's NDA submission utilizing the FDA expedited 505(b)(2) regulatory pathway. The Company submitted a pre-NDA briefing document to the FDA that outlined the Company's preliminary data package being prepared for the NDA submission, including bioequivalence and bioavailability clinical study results, CMC and other regulatory elements for a 505(b)(2) submission. In June 2018, the Company announced that it concluded its pre-NDA meeting with the FDA for TADFYN® (tadalafil 5mg and finasteride 5mg combination capsule) for the treatment of BPH. The Company believes it has reached agreement with the FDA on the regulatory data package requirements that will be sufficient for submission. The FDA requested that the Company submit 12-month stability data on manufacturing batches to support the expiry date of TADFYN® at the time of the NDA submission. The Company plans to submit an NDA for TADFYN® in very early calendar year 2021.

***Market.*** The worldwide prevalence of BPH lower urinary symptoms is estimated to be 10-25% of the male population and was estimated to grow to 1.1 billion men by 2018. Other men who may benefit from this combination 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® (terazosin), 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 and finasteride 5mg combination is not currently available. TADFYN®, if approved, would be the first fixed combination of tadalafil and finasteride approved by the FDA. TADFYN® would provide clinical benefit both by increasing dosing convenience and drug compliance as poor compliance with a BPH medicine could lead to an increased chance of acute urinary retention, urosepsis, and death. The Company plans to sell TADFYN® through men's health telemedicine internet channels in the U.S. and to out-license TADFYN® to urology specialty pharmaceutical marketing and sales organizations for upfront payment, milestones, and royalties in the U.S. and in territories outside the U.S.

***Commercial product***

***FC2 for dual protection against unintended pregnancy and transmission of STIs***

***Product.*** 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 the transmission of 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 in 2009.

FC2 is manufactured from a nitrile polymer formulation that is exclusive to the Company and 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 21% 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.

***U.S. Market.*** The market for FC2 in the U.S., as the only FDA approved for market female use product that protects against the transmission of STIs and unintended pregnancies, is rapidly growing. FC2 is currently reimbursable by prescription under the ACA and the laws of 20+ states prior to enactment of the ACA. The ACA was signed into law in March 2010 and was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms. Among these many rules, the ACA requires non-grandfathered health plans and health insurance issuers to provide 100% coverage of preventive care services. ACA guidance defines preventive services to include contraception methods. The ACA guidance further requires health plans to cover at 100% payment of at least one form of contraception within each method identified by the FDA in its current Birth Control Guide. As a result, with FC2 currently reimbursable by prescription under the ACA, as well as the laws of 20+ states prior to enactment of the ACA, prescription sales of FC2 in the U.S. have grown rapidly 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: 95% of major retail pharmacies, community-based organizations, by prescription, telemedicine, universities, direct purchase and 340B qualified health care clinics, and directly to the public health sector without distributors. In particular, we have partnered with fast-growing, highly reputable telemedicine firms (telemedicine being the remote diagnosis and treatment of patients by means of telecommunications technology) to bring our much-needed FC2 product to patients in a cost-effective and highly convenient manner. Marketing and educational programs, both traditional and by digital and social media, are being developed for the U.S. public health sector and implemented to target health care providers, community-based organizations, and women to coordinate awareness and access to FC2 that is fully reimbursable and to educate on the use of FC2.

***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 currently has a limited number of customers in the global public health sector, 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, Ecuador, Ethiopia, Ghana, Nigeria, Pakistan, Paraguay, Peru, and Uruguay. 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 unintended 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 market for condoms is estimated to be $9.4 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 FC2 as a consumer health product through distributors and retailers in 22 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. In October 2020, the Company was awarded 20 million units through its distributor in Brazil under the new Brazil Female Condom tender. The units under the Brazil tender are to be delivered over two years.

**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. For example, 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, among other things, 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. We must also maintain records of any corrections or removal of FC2 and make reports to the FDA of certain corrections or removals. Further, we are required to comply with FDA requirements for labeling, promotion and advertising. Any future modifications to the design, components, methods of manufacturing, 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 and November 2019, respectively.

***FDA Regulation of Prescription 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, 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. At least two adequate and well-controlled Phase 3 trials are generally required for approval of a new drug. A single Phase 3 or Phase 2 trial may be sufficient in rare instances, including (1) where the trial is a large, multicenter trial demonstrating internal consistency and a statistically persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible, or (2) when in conjunction with other confirmatory evidence. Approval on the basis of a single trial may be subject to the requirement of additional post-approval studies.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These 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 Federal 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 require 505(b)(2) applicants to perform additional studies or provide other data to support any 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 Zuclomiphene citrate, TADFYN®, and VERU-100 drug candidates to be submitted under the 505(b)(2) regulatory pathway because they are or will be based, in part on data or information already in the public domain. On May 24, 2017, the FDA agreed with the Company's plans to enter the Phase 2 dose finding clinical trial to evaluate Zuclomiphene citrate for the treatment of hot flashes in men on ADT. In November 2017, the FDA also agreed in Pre-IND meetings that the Tadalafil/Finasteride combination qualifies 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.

***505(b)(1) Approval Process.*** Drug development via Section 505(b)(1) of the FDCA is typically used for novel drugs that have not previously been approved by FDA for commercial sale in the United States. 505(b)(1) drug development stipulates that all of the studies required for approval are conducted by or for the Company. VERU-111 for metastatic castration and androgen receptor targeting agent resistant prostate cancer and VERU-111 for taxane resistant metastatic triple negative breast cancer, as well as enobosarm for ER+/HER2- metastatic breast cancer, is expected to follow this regulatory pathway.

***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 to complete the review process for a non-priority review of an NDA under 505(b)(2) or 505(b)(1) is ten months and for a priority review is six 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. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. 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 supported by appropriate evidence. Generally, these are found in the approved prescribing information. Failure to comply with these requirements can result in adverse publicity, warning or untitled 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 Drug Supply Chain Security Act imposes obligations on manufacturers of finished pharmaceutical human drug products related to product tracking and tracing. Among the requirements of this legislation, manufacturers are required to provide certain information regarding the drug products to individuals and entities to which product ownership is transferred, label drug products with a product identifier, and maintain 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 are also required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this 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.

***Federal Trade Commission (FTC) Regulation of Advertising.*** The FTC regulates OTC drug and non-restricted medical device advertising and promotional materials under the Federal Trade Commission Act (FTC Act), which prohibits unfair or deceptive acts or practices as well as the dissemination of any false advertisement that is likely to induce the purchase of drugs and non-restricted medical devices. The FTC requires that all express and implied claims must be substantiated. The FTC has historically applied a standard of competent and reliable scientific evidence for health-related claims. This standard is defined generally to require tests, analyses, research or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results. In some instances, the FTC has interpreted this standard as requiring randomized, double-blind, placebo-controlled clinical trials. The FTC is authorized to issue cease-and-desist orders enforceable by injunctions, civil penalties, and criminal contempt proceedings for violating the FTC Act, as well as to proceed directly in federal court for injunctive relief and to obtain ancillary consumer redress.

***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 health care program anti-kickback statute (the "AKS") and state equivalents, the Federal False Claims Act and state equivalents, federal and state health care practitioner payment sunshine laws, federal and state health information privacy laws, state price increase transparency laws, and various federal laws requiring price reporting or discounted pricing to the government.

The AKS 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 Medicare/Medicaid 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 practitioner payment sunshine requirements 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, certain other health care practitioners and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, such practitioners or 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 European Union (EU), the General Data Protection Regulation (GDPR) took effect in May 2018 and imposes increasingly stringent data protection and privacy rules.

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 U.S. 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 U.S. 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 U.S., 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 U.S. 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 U.S., 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 U.S. 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 has been approved by regulatory authorities in Brazil, Canada, and other jurisdictions.

FC2 also received the CE Mark which allows it to be marketed throughout the EU. In conjunction with the U.K.'s exit from the EU, we were required to change our Notified Body. As a result, our EU accreditation will cease on December 31, 2020. We are currently seeking new accreditation under the Medical Devices Directive and do not believe that this will have a material impact on our business in fiscal 2021.

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.

***VERU-111 and Related Compounds License.*** We hold an exclusive worldwide license to eleven issued U.S. patents, seven pending U.S. patent applications and 79 patents and patent applications in countries outside the United States, including issued patents in the EU and Japan, relating to our VERU-111 drug candidates and related compounds. This license contains provisions requiring upfront, milestone and royalty payments to the licensor (Ohio State Innovation Fund). 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 and related compounds have statutory expiration dates from 2029 to 2034. 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.

***VERU-100 Patent Applications.*** We have two U.S. patent applications and twelve patent applications in countries outside the United States relating to the long-term release of a GnRH antagonist hormone for ADT for men with advanced prostate cancer. The U.S. patent and any patents issuing from the foreign patent applications would expire in January 2038.

***Enobosarm and Related Compounds License.*** We hold an exclusive worldwide license to thirteen issued U.S. patents, two pending U.S. patent applications and 64 patents and patent applications in countries outside the United States, including issued Composition of Matter and Method of Use patents in the EU and Japan, relating to our enobosarm drug candidate and related compounds. This license contains provisions requiring milestone and royalty payments to the licensor (University of Tennessee Research Foundation). 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 our drug candidate. The patents relating to enobosarm and related compounds have statutory expiration dates from 2024 to 2034. 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.

***Zuclomiphene Citrate Patent and Patent Applications.*** We have three issued U.S. patents and twelve patents and patent applications in countries outside the United States related to substantially pure zuclomiphene for the treatment of hot flashes, osteoporosis, bone fractures, and loss of bone mineral density, 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. 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, South Africa, Mexico, Brazil and India. The patents cover 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 trademark "FC2 Female Condom" in the U.S. and has filed applications in the U.S. for the trademarks "Veru" and "Veru" together with the chevron. 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 or enforcement in the U.S. 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**

The Company's three largest customers in fiscal 2020 accounted for 76% of the Company's net revenues. In the U.S. market, the Company has experienced fast growth in prescription sales of FC2 in fiscal 2020 largely through supply agreements with leading telemedicine providers. One of these telemedicine providers has become one of our largest customers and accounted for 42% of the Company's net revenues in fiscal 2020.

Because FC2 provides dual protection against both the transmission of 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, the U.K.'s Department for International Development (DFID), and Population Services International (PSI), other social marketing groups, various government health agencies, and NGOs. Within the global public health sector, 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.

**Employees**

As of November 30, 2020, the Company had 339 full-time employees, including 28 located in the U.S., 12 in the U.K., 297 in Malaysia, and two in other countries to implement training and programs. The Company does not currently have any collective bargaining agreements with its employees, and the Company believes that its employee relations are good.

**Environmental Regulation**

The Company believes there are no material issues or material costs associated with the Company's compliance with environmental laws. The Company did not incur environmental expenses in fiscal 2020 or 2019, nor does it anticipate environmental expenses in the foreseeable future. The Company's operations in Malaysia are audited and certified against ISO 14001, the environmental management standard that was developed by the International Organization for Standardization (ISO) to help organizations manage the environmental impacts of their processes, products, and services.

**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. The principal partially finished component used to produce FC2 is a dipped nitrile polymer sheath. The Company procures its component sheaths from one of the leading manufacturers of nitrile surgical gloves. These sheaths are sourced from multiple manufacturing sites controlled by this vendor.

**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 cGMP, 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, label and store sufficient quantities of any future drug candidates.

**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, prefers to procure from the FDA product approval for market; however, there can be exceptions. Outside of the U.S., the Company has experienced increasing competition and pricing pressures for FC2. In addition to FC2, three female condoms have successfully completed the WHO prequalification process and been cleared by UNFPA for purchase by U.N. agencies: the Cupid female condom (which was prequalified by WHO in July 2012 and cleared by UNFPA thereafter), the Velvet female condom marketed by Hindustan Latex Limited (which was prequalified by WHO and cleared by UNFPA in March 2016) and the female condom marketed by PATH (which was prequalified by WHO and cleared by UNFPA in March 2016). The PATH female condom lost its prequalification in 2019, which leaves only two other competitive female condoms with WHO prequalification in addition to FC2. 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, competitors received part of the last three South African tenders and the last two Brazilian 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 reclassification of female condoms in 2018 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 have or will have.

VERU-111 is a first-in-class oral therapy that targets both alpha and beta tubulin and will be initially developed for prostate, breast and ovarian cancers. All currently available tubulin targeting agents are chemotherapies that are given IV and 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 non-small 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 Trop-2 directed antibody and topoisomerase inhibitor, TRODELVY ® (sacituzumab govitecan-hzyl), PARP inhibitors, LYNPARZA® (olaparib) and TALZENNA® (talazoparib), capecitabine, TECENTRIQ ® (atezolizumab) and ABRAXANE® (albumin-bound paxlitaxel) and platinum-based chemotherapies including cisplatin and PARAPLATIN ®(carboplatin) are indicated for advanced breast cancers such as triple negative breast cancer.

VERU-100 is a long-acting GnRH antagonist for ADT designed to be administered as a small volume subcutaneous three-month depot injection without a loading dose. As a GnRH antagonist, it should immediately suppress testosterone with no testosterone surge upon initial or repeated administration and no testosterone micro-increases which may adversely affect patient outcomes—a problem which potentially occurs with approved LHRH agonist drugs like LUPRON®, ZOLADEX® and ELIGARD®. Currently, there are no GnRH antagonists commercially approved beyond 1 month, making VERU-100, if approved, the only commercially available GnRH antagonist three-month depot.

Enobosarm is an oral, first-in-class, new chemical entity, selective androgen receptor targeting agonist, for the treatment of AR+/ER+, HER2- metastatic breast cancer, but prior to IV chemotherapy. Other existing drugs currently prescribed for advanced breast cancer are nonsteroidal aromatase inhibitors including, FEMARA® (letrozole) and ARIMIDEX® (anastrozole), irreversible steroidal inhibitors including AROMASIN® (exemestane), selective estrogen receptor degraders including FASLODEX® (fulverstrant), and CDK 4/6 inhibitors including IBRANCE® (palbociclib), KISQUALI ® (ribociclib), and VERZENIO® (abemaciclib). Chemotherapy agents used for the treatment of advanced breast cancer include the taxanes TAXOL® (paclitaxel), TAXOTERE® (docetaxel), ABRAXANE® (albumin-bound paclitaxel), ADRIAMYCIN® (doxorubicin), ELLENCE® (epirubicin), capecitabine, CYTOXAN® (cyclophosphamide) and PARAPLATIN® (carboplatin).

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.

All drugs currently used to treat BPH symptoms are sold in 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® (terazosin), 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 U.K. called Cositam XL 400 microgram that can be taken independently of food.

**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. In addition, there is significant uncertainty regarding the COVID-19 pandemic and its impact on the economic environment and our business which could affect the risk factors set forth below. 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 and our Chief Scientific Officer have 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. In addition, if the requirements for approval of any of our drug candidates under Section 505(b)(2) are not as we expect, it will likely take significantly longer, cost significantly more and be significantly more complicated to gain FDA approval for these drug candidates, and in any case may not be successful. 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. 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 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, the ongoing COVID-19 pandemic, 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 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 any of our drug candidates, 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 drug candidates, 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 drug candidate we are developing, the commercial prospects of such drug candidate will be harmed and our ability to generate revenue from such drug candidate 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 in a timely manner or on a cost-effective basis, 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 drug candidates for use in our clinical trials. These drug candidates are complicated and expensive to manufacture. If our 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 manufacturers of our drug candidates must maintain a compliance status acceptable to 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 or elect not to commercialize our drug candidates.***

We cannot be sure that, if our clinical trials for any of our 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, or that the submission of any NDA is commercially feasible. 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, if any NDA we submit is not approved by the FDA, or we elect not to file an NDA, 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.

***Due to the COVID-19 pandemic, we may find it difficult to effectively recruit new clinical trial patients in a timely manner and to partner with clinical trial investigators and sites, which could delay or prevent us from proceeding with, or otherwise adversely affect, clinical trials of our drug candidates.***

Identifying and qualifying patients to participate in, and partnering with investigators and sites to run, clinical trials of our drug candidates is critical to the timely completion of our clinical trials. Patients may be unwilling to participate in our clinical trials because of the ongoing COVID-19 pandemic. The severe burden on healthcare systems caused by the COVID-19 pandemic has also impaired the ability of many research sites to start new clinical trials or to enroll new patients in clinical trials. The imposed mandatory sheltering in place and social distancing restrictions may delay the recruitment of patients and impede their ability to effectively participate in such trials. Significant fees may also be owed to contract research organizations associated with starting and stopping clinical trials, typically more so than delaying the start of a clinical trial.

There is a risk that changing circumstances relating to the COVID-19 pandemic may not allow our healthcare clinical trial investigators, their healthcare facilities or other necessary parties to continue to participate in our clinical trials through completion or may delay the initiation of planned clinical trials. Any delays related to clinical trials could result in increased costs, delays in advancing our drug candidates, delays in testing the effectiveness of our drug candidates or termination of the clinical trials altogether.

***Disruptions at the FDA caused by the COVID-19 pandemic could delay or prevent new drugs from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent the FDA from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

Disruptions at the FDA caused by the COVID-19 pandemic may slow the time necessary for new drugs to be reviewed and/or approved, which would adversely affect our business. In response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products through April 2020. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. The FDA has also prioritized the review of submissions relating to COVID-19. The FDA may adopt other restrictions or policy measures in response to the COVID-19 pandemic or issue guidance materially affecting the conduct of clinical trials. If global health concerns continue to prevent the FDA from conducting its regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

***Our pursuit of a COVID-19 treatment candidate is at an early stage. We may be unable to produce a drug that successfully treats the virus in a timely manner, if at all.***

In May 2020, we announced that we have received FDA permission to initiate a Phase 2 clinical trial to assess the efficacy of VERU-111, a microtubule depolymerization agent, in combating COVID-19. Our development of a COVID-19 treatment is in its early stages, and we may be unable to produce a drug that successfully treats the virus in a timely manner, if at all. We are also committing financial resources and personnel to the development of a COVID-19 treatment which may cause delays in or otherwise negatively impact our other development programs, despite uncertainties surrounding the longevity and extent of coronavirus as a global health concern. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our treatment, if developed, may not be partially or fully effective. In addition, conducting a clinical trial of a COVID-19 treatment is challenging in the current environment due to a number of factors, including a large number of competitive clinical trials seeking to enroll COVID-19 patients, the high workload of hospital staff, and the difficulty of enrolling patients in intensive care or similar environments. These challenges may delay the clinical trial, increase its costs or otherwise adversely affect the clinical trial.

***Government entities may take actions that directly or indirectly have the effect of limiting opportunities for VERU-111 as a COVID-19 treatment.***

Various government entities, including the U.S. government, are offering incentives, grants and contracts to encourage additional investment by commercial organizations into preventative and therapeutic agents against COVID-19, which may have the effect of increasing the number of competitors and/or providing advantages to competitors. Accordingly, there can be no assurance that we will be able to successfully establish a competitive market share if we develop a COVID-19 treatment. COVID-19 treatments may also be subject to government pricing controls, which could adversely affect the profitability of any COVID-19 treatment we are able to develop and commercialize.

***We are subject to extensive and costly governmental regulation, including healthcare reform measures that may negatively impact sales of FC2.***

Our commercial product, FC2, and our drug candidates are subject to extensive and rigorous domestic government regulation, including regulation by the FDA, the FTC, the Centers for Medicare & Medicaid Services (CMS), 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. The FTC also regulates the advertising, marketing, and promotion of the Company's products. 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.

There have been judicial and Congressional challenges to the entirety and certain aspects of the ACA, as well as recent efforts by the Trump administration to essentially repeal and replace certain aspects of the ACA through regulatory action, and we expect such challenges to continue. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA, while Congress has considered legislation that would repeal and replace all or part of the ACA and bills affecting the implementation of certain taxes under the ACA have been enacted. In addition, the Supreme Court is considering a case challenging the constitutionality of the ACA because the tax associated with the "individual mandate" was eliminated by Congress as part of the Tax Cuts and Jobs Act of 2017. In this case, on December 14, 2018, a federal judge in Texas ruled that the individual mandate is unconstitutional and as a result, the ACA is unconstitutional in its entirety. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case to the District Court to determine whether the individual mandate could be severed from the remaining provisions of the ACA. The Supreme Court held oral arguments in this case on November 10, 2020, and a decision is expected in 2021. While the district court judge, as well as the Trump administration and CMS have stated that the lower court's ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision and any other efforts to repeal and replace the ACA or any of the 20+ states providing reimbursement for FC2 will impact sales.

Specific to the contraception coverage mandate, ACA regulations provide exemptions from this requirement for qualifying religious employers and individuals and non-governmental entities that object to providing the coverage on the basis of sincerely held religious beliefs. The Trump administration issued two interim final regulations in October 2017 expanding the exemptions to those entities objecting to the requirement on the basis of religious and moral convictions, which were finalized in November 2018. Federal court judges in Pennsylvania and California separately blocked enforcements of these exemption regulations, with appellate courts upholding the decisions. On July 8, 2020, the Supreme Court reversed the lower courts' rulings, allowing the rules to go into effect. Challenges or future regulatory efforts to erode the contraception mandate may persist and, if successful, may adversely impact sales of FC2 in states that do not separately provide for reimbursement of FC2.

Medical devices such as FC2 are cleared or approved for one or more specific intended uses and performance claims that must be adequately substantiated. Promoting a device for an off-label use or making misleading or unsubstantiated claims could result in government enforcement action. Any changes to the device, including labeling, post-clearance or approval must be assessed to determine if a new clearance or approval is required. Furthermore, the facility in which we manufacture FC2 is subject to periodic inspection by the FDA and other federal, state and foreign government authorities, which require manufacturers of medical devices to adhere to certain regulations, including the FDA's Quality System Regulation, which requires, among other things, periodic audits, design controls, quality control testing and documentation procedures, as well as complaint evaluations and investigation. The FDA also requires the reporting of certain adverse events and product malfunctions and may require the reporting of recalls or other correction or removals of devices in commercial distribution. Issues identified through such inspections and reports may result in FDA enforcement action. Moreover, issues identified through such inspections and reports may require significant resources to resolve.

The FDA may inspect our facilities periodically to determine compliance with provisions of the FDC Act and FDA regulations. The FDA also requires the reporting of certain adverse events and product malfunctions and may require the reporting of recalls or other field safety corrective actions. Issues identified through such inspections and reports may result in FDA enforcement action. Moreover, issues identified through such inspections and reports may require significant resources to resolve.

Failure to comply with applicable laws and regulations could lead to the following actions:

- partial suspension or total shutdown of manufacturing;
- product shortages;
- delays in product manufacturing;
- FDA warning letters or other notifications of violations of law;
- fines or civil penalties;
- delays in or restrictions on obtaining new regulatory clearances or approvals;
- withdrawal or suspension of required clearances, approvals or licenses;
- product seizures or recalls;
- injunctions;
- criminal prosecution;
- advisories or other field actions;
- operating restrictions; and
- prohibitions against exporting of products to, or importing products from, countries outside the U.S.

Any of these actions could have a material adverse effect on our business.

The FTC regulates the advertising, marketing, and promotion of FC2. The FTC requires substantiation by competent and reliable scientific data or evidence for performance claims. If we do not meet the standard for substantiation or if there is evidence available through us or third parties that our products do not perform as we anticipate, we may need to change the way we market, or cease marketing, our current or future products. FTC enforcement actions may result in consent decrees and monetary payments by the companies involved.

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 burdensome than U.S. regulation.

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 by drug and device manufacturers to health care practitioners. Some states, such as California, Connecticut, Massachusetts and Nevada, mandate implementation of corporate compliance programs, while other state laws prohibit, or require tracking and reporting of, certain gifts, compensation and other remuneration to physicians and other health care practitioners.

In recent years, a number of states, including California, Minnesota, Oregon, Texas and Washington, have enacted laws requiring manufacturers to submit reports on drugs whose list price has increased by more than a certain percentage during a specified period and/or new drugs that are being launched at a price exceeding a specified amount. Among other things, the reports must explain the justifications for the price or price increase.

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 anti-corruption laws, including 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 conditions for which they are intended;
- the availability and efficacy of competitive drugs;
- the effectiveness of our sales 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 or other applicable regulatory agency's 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 conditions for which they are intended. Without head-to-head comparative data, we will also not be able 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 EU, 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 drug candidates. 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 have incurred net losses in recent fiscal years and expect to continue to incur losses for the foreseeable future.***

We incurred net losses of $19.0 million, $12.0 million, and $23.9 million during the years ended September 30, 2020, 2019 and 2018, respectively. 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 may require us to obtain additional financing for our business until revenues from our current commercial operations 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. 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.

***COVID-19 and its impact on the economic environment and capital markets could adversely affect our access to capital when needed.***

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. Market volatility resulting from the COVID-19 pandemic or other factors could adversely affect our ability to access capital as and when needed and could also adversely affect the terms of a financing. If sales of FC2 decline due to the current economic environment, supply constraints or other issues, we may need additional financing to make up for reduced cash flows from our FC2 business. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate some of our research and development activities or we may be unable to take advantage of future business opportunities.

***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 may 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 as needed, 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 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.

***Our application for our PPP Loan could in the future be determined to have been impermissible or could result in damage to our reputation.***

In April 2020, we received proceeds of approximately $540,000 from a forgivable loan (the "PPP Loan") under the U.S. Small Business Administration's (the "SBA") Paycheck Protection Program established by the CARES Act, which we used to retain employees, maintain payroll and make lease and utility payments. In November 2020, the SBA approved the forgiveness of the full amount of the PPP Loan.

In order to apply for the PPP Loan, we were required to certify, among other things, that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. We made this certification in good faith after analyzing, among other things, our financial situation and access to alternative forms of capital, and believe that we satisfied all eligibility criteria for the PPP Loan, and that our receipt of the PPP Loan is consistent with the broad objectives of the Paycheck Protection Program of the CARES Act. The certification described above does not contain any objective criteria and is subject to interpretation. However, on April 23, 2020, the SBA issued guidance stating that it is unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith. The lack of clarity regarding loan eligibility under the Paycheck Protection Program has resulted in significant media coverage and controversy with respect to public companies applying for and receiving loans. If, despite our good-faith belief that we satisfied all eligible requirements for the PPP Loan, we are later determined to have violated any of the laws or governmental regulations that apply to us in connection with the PPP Loan, such as the False Claims Act, or it is otherwise determined that we were ineligible to receive the PPP Loan, we may be subject to penalties, including significant civil, criminal and administrative penalties, or damages or could be required to repay the PPP Loan in its entirety. In addition, our receipt of the PPP Loan may result in adverse publicity and damage to our reputation, and a review or audit by the SBA or other government entity or claims under the False Claims Act could consume significant financial and management resources.

**Risks Related to Our Business**

***The COVID-19 pandemic has disrupted, and may continue to disrupt, our operations and the operations of our suppliers and customers.***

In December 2019, a novel strain of coronavirus was reported to have emerged in Wuhan, China. COVID-19, the disease caused by the coronavirus, has since spread to over 100 countries, including every state in the United States. On March 11, 2020, the World Health Organization declared COVID-19 a pandemic, and on March 13, 2020, the United States declared a national emergency with respect to the COVID-19 outbreak. The outbreak and government measures, which in the U.S. have been largely left to individual states with varying approaches, including orders to close businesses considered non-essential and orders for quarantining, taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. We have also adopted various recommended policies and procedures applicable to office-based employees, including work from home measures, to protect the health and safety of our employees.

If COVID-19 continues to spread and to affect economic activity in the United States and other markets in which we conduct business, we may experience disruptions that could severely impact our business, including:

- if our Malaysian manufacturing facility is closed again our ability to supply product to our customers could be disrupted;
- we may encounter labor or raw material shortages, transportation delays or other issues at our Malaysian manufacturing facility or to our various customers;
- our personnel may not be able to travel between our facilities in the United States, the United Kingdom and Malaysia, which may impact our ability to effectively oversee our international operations;
- customer demand for FC2 may be adversely affected, including with respect to FC2 in the U.S. prescription market if insurance coverage is affected by job losses and in the global public health sector if governments delay future tenders or reduce spending on female condoms due to financial strains or changed spending priorities caused by the COVID-19 pandemic;
- our customers, including in the global public health sector, may reduce or delay orders or delay paying their accounts receivable balances due to liquidity issues, spending priorities or other issues related to the COVID-19 pandemic, including government imposed closures or operating reductions;
- there may be limitations in employee resources, potentially including key executives, because of sickness of employees or their families or the desire of employees to avoid contact;
- we may face delays in receiving approval from the FDA or other applicable regulatory authorities in connection with our clinical trials;
- there may be delays or difficulties in enrolling patients in our clinical trials or in recruiting clinical site investigators and staff;
- there may be delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including delays or interruptions in manufacturing and interruption in shipping;
- there may be changes in local regulations as part of a response to the COVID-19 outbreak which may require us to change the ways in which our clinical trials are conducted, to incur unexpected costs, or to discontinue the clinical trials altogether;
- healthcare resources may be diverted away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- key clinical trial activities may be interrupted, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or the clinical research organizations or clinical trial sites' own risks related to the COVID-19 outbreak, which could affect the integrity of clinical data or the conduct of the trial;
- participants enrolled in our clinical trials could acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- necessary interactions with local regulators, ethics committees and other important agencies and contractors may be delayed due to limitations in employee resources or forced furlough of government employees; and
- the FDA may refuse to accept data from clinical trials in affected geographies.

Significant uncertainty remains as to the potential impact of the COVID-19 pandemic on our operations, and on the global economy. It is currently not possible to predict how long the pandemic will last or the time that it will take for economic activity to return to prior levels. We do not yet know the full extent of any impact on our business or our operations, and it is possible that its effect on our business and operations will significantly worsen in the future.

***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 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 may 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 two such products presently 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 and the latest Brazilian tender. Increasing competition in FC2's markets has put pressure on pricing for FC2 and adversely affected 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.***

In 2017, we 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 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. Our prescription sales in the U.S. may also be adversely affected by regulations offering employers religious and moral exemptions from the ACA's requirement to provide insurance covering birth control. In addition, while we experienced fast growth in prescription sales of FC2 in fiscal 2020 largely through our agreement with two leading telemedicine providers, we may not be able to achieve sales growth with other telemedicine providers, which could cause us to be dependent on these leading telemedicine providers and could limit our growth in this market. In fact, U.S. market Rx sales of FC2 in fiscal 2020 exceeded those of FC2 global public health sector sales. 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, including any changes to and validity of ACA, 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 in fiscal 2020 accounted for 76% of the Company's net revenues, with one customer accounting for 42% of the Company's net revenues. 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;
- disruptions in the global transportation network, such as work stoppages, strikes or shutdowns of ports of entry or such other transportation sources, or delays or difficulties in products clearing customs;
- difficulties in staffing and managing foreign operations;
- greater difficulty in collecting accounts receivable and longer collection periods;
- the uncertainty of protection for intellectual property in some countries;
- multiple, conflicting and changing laws and regulations such as privacy regulations, including GDPR, tax laws, export and import restrictions, employment laws, immigration laws, labor laws, regulatory requirements and other governmental approvals, permits and licenses;
- complications in complying with trade and foreign tax laws and greater risk of a failure of foreign employees, distributors or other agents to comply with both U.S. and foreign laws, including antitrust regulations, the FCPA and other anti-bribery or corruption laws, and trade regulations;
- 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.

***Disruptions from an exit of the United Kingdom from the European Union could adversely affect our business and results of operations.***

On January 31, 2020, the U.K. left the EU with a transition period due to end on December 31, 2020. All the Company's EU shipments are arranged by the customer and shipped directly from Malaysia to the country of destination. All transactions are conducted in U.S. dollars, so the exchange rate risk is assumed by the customer. The current change in Notified Body may have an initial negative impact on both U.K. and EU sales as all sales in the U.K. and into the EU will be suspended from December 31, 2020 until the new accreditations are in place. It is possible that changes made as a result of the U.K.'s exit from the EU could subject us to heightened risks in that region, including disruptions to trade, changes in regulatory oversight, increased foreign exchange volatility with respect to the British pound and additional legal and economic uncertainty. Such changes may adversely affect our business and results of operations.

***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, labor disruptions, or an outbreak of a contagious disease, including COVID-19, 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 existing and potential products. Adverse changes may occur as a result of adverse global or regional economic conditions, fluctuating oil prices, declining consumer confidence, a continuation or worsening of the COVID-19 pandemic or another pandemic, 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 existing or development of future products, increase the cost, and decrease the availability of financing, or increase costs associated with producing and distributing our products and potential drug candidates. 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 health 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, securities laws, antitrust and competition laws, regulatory or administrative actions, corporate matters 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 ourselves 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.

***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 and the California Consumer Privacy Act.

***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 repayment of the credit agreement or 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 tax rules in the various jurisdictions in which we operate could materially affect our deferred tax assets, tax obligations and effective tax rate.***

We are subject to a variety of taxes and tax collection and remittance obligations in the U.S. and foreign jurisdictions. Additionally, at any point in time, we may be under examination for value added, sales-based, payroll, product, import or other non-income taxes. We may recognize additional tax expense, be subject to additional tax liabilities, or incur losses and penalties, due to changes in laws, regulations, administrative practices, principles, assessments by authorities and interpretations related to tax, including tax rules in various jurisdictions. We compute our income tax provision based on enacted tax rates in the countries in which we operate. As tax rates vary among countries, a change in earnings attributable to the various jurisdictions in which we operate could result in an unfavorable change in our overall tax provision. Changes in enacted tax rates and the assumptions and estimates we have made, 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 depends in part on our ability to obtain and maintain intellectual property rights to our products, drug candidates and technology as well as successfully defending these rights against third party challenges. 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 are limited in protecting our proprietary rights from unauthorized use by third parties by 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;
- 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 or our proprietary technologies may not be patentable or legal decisions may limit patent-eligible subject matter;
- others may 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;
- we may fail to timely apply for patents on our technologies or products; and
- inability to control patent prosecution, maintenance, or enforcement of any in-licensed intellectual property.

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.

***Our or our licensors' patents may expire or be invalidated, found to be unenforceable, narrowed or otherwise limited or our or our licensors' patent applications may not result in issued patents or may result in patents with narrow, overbroad, or unenforceable claims.***

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

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

***We 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 we 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 or other intellectual property 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 drug candidates or products with the same active pharmaceutical ingredients as our drug candidates in those jurisdictions in which we have no patent protection. Even if patents are issued to us or our licensor regarding our drug 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 7, 2020, our executive officers and directors collectively beneficially owned approximately 25.7% of the outstanding shares of our common stock, including approximately 12.2% beneficially owned by Mitchell Steiner, M.D., our Chairman, President and Chief Executive Officer, and 12.0% 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.

***We incurred a charge to earnings in fiscal 2020 resulting from the APP Acquisition, and additional charges to earnings resulting from the APP Acquisition in the future 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 intangible assets, including in-process research and development (IPR&D); and
- impairment of goodwill.

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. For example, during the fourth quarter of fiscal 2020, we recognized $14.1 million of impairment charges related to the IPR&D acquired in connection with the APP Acquisition, which increased our net loss and net loss per share for fiscal 2020. If there are additional impairment charges in the future, they would also 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 (a) 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 and we reported annual net revenues of greater than $100 million for our most recently completed fiscal year or (b) 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 net revenues. If we cease to be a non-accelerated filer, 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 (a) 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 we reported annual net revenues as of our most recently completed fiscal year is $100 million or more, or (b) 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 our current common stock purchase agreement with Aspire Capital Fund, LLC (Aspire Capital), including 8,375,667 shares of common stock that we have issued under our current common stock purchase agreement with Aspire Capital and a prior agreement 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 4,640 square feet of office space. The Company executed the lease for this office space in June 2019 and executed an amendment to the lease in August 2019 to modify the commencement date. The lease, as amended, is for a 30-month term commencing on September 1, 2019 and ending on February 27, 2022.

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 lease has a five-year term that expires in August 2025 and a tenant's option to cancel in August 2023. Costs related to this office are fully dedicated to FC2 and, as such, are part of our Sexual Health Business segment.

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 August 2019, for a three-year term commencing on September 1, 2019 and ending on August 31, 2022. 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 cGMP, as well as the U.K.-based notified body, which is responsible for CE and ISO accreditation. Costs related to this manufacturing facility are fully dedicated to FC2 and, as such, are part of our Sexual Health Business segment.

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

Item 3. Legal Proceedings.

Neither the Company nor any of its subsidiaries is a party to any material pending legal proceedings at the date of filing of this Annual Report on Form 10-K.

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 on December 7, 2020 was approximately 203.

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 and the Consolidated Balance Sheet Data as of and for the years ended September 30, 2020 and 2019 are derived from the Consolidated Financial Statements included elsewhere in this report. The Consolidated Statement of Operations Data and the Consolidated Balance Sheet Data as of and for the years ended September 30, 2018, 2017 and 2016 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:** | **2020** | **2019** | **2018** | **2017** | **2016** |
| | *(In thousands, except per share data)* | | | | |
| Net revenues | $ 42,592 | $ 31,803 | $ 15,865 | $ 13,656 | $ 22,127 |
| Cost of sales | 11,805 | 10,146 | 7,092 | 6,636 | 8,778 |
| Gross profit | 30,787 | 21,657 | 8,773 | 7,020 | 13,349 |
| Operating expenses | 45,534 | 28,093 | 29,645 | 15,514 | 10,330 |
| Operating (loss) income | (14,747) | (6,436) | (20,872) | (8,494) | 3,019 |
| Non-operating expense | (5,305) | (5,885) | (2,200) | (108) | (205) |
| (Loss) income before income taxes | (20,052) | (12,321) | (23,072) | (8,602) | 2,814 |
| Income tax (benefit) expense | (1,078) | (304) | 866 | (1,990) | 2,469 |
| Net (loss) income attributable to common stockholders before preferred stock dividend | $ (18,974) | $ (12,017) | $ (23,938) | $ (6,612) | $ 345 |
| Preferred stock dividend | — | — | — | 1,991 | — |
| Net (loss) income attributable to common stockholders | $ (18,974) | $ (12,017) | $ (23,938) | $ (8,603) | $ 345 |
| Net (loss) income per basic common share outstanding | $ (0.28) | $ (0.19) | $ (0.44) | $ (0.25) | $ 0.01 |
| Basic weighted average common shares outstanding | 66,753 | 63,323 | 53,862 | 34,640 | 28,666 |
| Net (loss) income per diluted common share outstanding | $ (0.28) | $ (0.19) | $ (0.44) | $ (0.25) | $ 0.01 |
| Diluted weighted average common shares outstanding | 66,753 | 63,323 | 53,862 | 34,640 | 28,927 |

| | As of September 30, | | | | |
|---|---|---|---|---|---|
| **Consolidated Balance Sheet Data:** | **2020** | **2019** | **2018** | **2017** | **2016** |
| | *(In thousands)* | | | | |
| Cash and cash equivalents | $ 13,589 | $ 6,295 | $ 3,760 | $ 3,278 | $ 2,385 |
| Working capital | 12,288 | 2,787 | (2,370) | 4,810 | 14,968 |
| Total assets | 51,544 | 53,629 | 48,453 | 55,336 | 38,624 |
| Accumulated deficit | (89,193) | (70,219) | (58,202) | (34,263) | (27,651) |
| Long-term obligations | 5,617 | 6,732 | 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 biopharmaceutical company with a focus on developing novel medicines for the management of prostate and breast cancers. Revenues generated by our growing sexual health division are used to invest and partly fund the clinical development of our cancer drug pipeline.

**The Company's prostate cancer drug pipeline includes VERU-111, VERU-100 and Zuclomiphene citrate.**

*VERU-111 for the treatment of men with metastatic castration resistant prostate cancer who have also become resistant to one androgen receptor targeting agent*

VERU-111 is an oral, first-in-class, new chemical entity that targets, crosslinks, and disrupts alpha and beta tubulin subunits of microtubules to disrupt the cytoskeleton. VERU-111 is being evaluated in open label Phase 1b and Phase 2 clinical studies in men with metastatic castration and androgen receptor targeting agent resistant prostate cancer in approximately 80 men. In July 2020, the Company had an FDA meeting and received positive input from FDA on the pivotal Phase 3 trial design for VERU-111. The Company anticipates starting the Phase 3 pivotal study evaluating VERU-111 for men with metastatic castration resistant prostate cancer who have also become resistant to one androgen receptor targeting agent (VERACITY study) in the first quarter of calendar year 2021.

*VERU-100 for the palliative treatment of advanced prostate cancer*

VERU-100 is a novel, proprietary long-acting gonadotropin-releasing hormone (GnRH) antagonist peptide 3 month subcutaneous depot formulation designed to address the current limitations of commercially available androgen deprivation therapies (ADT). There are no GnRH antagonist depot injectable formulations commercially approved beyond a one-month duration. A Phase 2 study to evaluate VERU-100 dosing is anticipated to begin early in the first quarter of calendar year 2021 and Phase 3 registration study in 100 men will commence in the second half of calendar year 2021.

*Zuclomiphene citrate for the treatment of men who have hot flashes caused by androgen deprivation therapy for advanced prostate cancer*

Zuclomiphene citrate is an oral nonsteroidal estrogen receptor agonist being developed to treat hot flashes, a common side effect caused by ADT in men with advanced prostate cancer. The Company is planning an End of Phase 2 meeting with the FDA in the last quarter of calendar year 2021.

**The Company's breast cancer drug pipeline includes Enobosarm and VERU-111.**

*Enobosarm, selective androgen receptor targeting agonist, for the treatment of androgen receptor positive (AR+), estrogen receptor positive (ER+) and human epidermal growth factor receptor 2 (HER2-) metastatic breast cancer*

Enobosarm is an oral, first-in-class, new chemical entity, selective androgen receptor agonist that targets the androgen receptor (AR) in AR+/ER+/HER2- metastatic breast cancer without unwanted virilizing side effects. Enobosarm is the first new class of targeting endocrine therapy in advanced breast cancer in decades. Enobosarm has extensive nonclinical and clinical experience having been evaluated in 25 separate clinical studies in over 2,100 subjects, including five prior Phase 2 clinical studies in advanced breast cancer involving more than 250 patients. In the two Phase 2 clinical studies conducted in women with AR+/ER+/HER2- breast cancer, enobosarm demonstrated significant antitumor efficacy in heavily pretreated cohorts and was well tolerated with a favorable safety profile. In October 2020, the FDA agreed to the Phase 3 registration clinical trial design to evaluate the efficacy and safety of enobosarm, selective androgen receptor targeting agonist, versus active control, either exemestane or tamoxifen (physician's choice), for the treatment of ER+/HER2- metastatic breast cancer in approximately 240 patients who have failed a nonsteroidal aromatase inhibitor (anastrozole or letrozole), fulvestrant, and a CDK 4/6 inhibitor, but prior to IV chemotherapy. The pivotal Phase 3, open label, randomized, active control study (ARTEST study) is anticipated to commence in the first half of calendar year 2021.

*VERU-111 for treatment of taxane resistant metastatic triple negative breast cancer*

Preclinical studies in human triple negative breast cancer grown in animal models demonstrate that VERU-111 significantly inhibits cancer proliferation, migration, metastases, and invasion of triple negative breast cancer cells and tumors that have become resistant to paclitaxel (taxane). Using the safety information from the Phase 1b and Phase 2 VERU-111 prostate cancer clinical studies in a total of approximately 80 men, the Company plans to meet with the FDA in first half of calendar year 2021 and to commence a Phase 2b clinical study in the fourth quarter of calendar year 2021 to evaluate oral daily dosing of VERU-111 in approximately 100 women with metastatic TNBC that has become resistant to taxane IV chemotherapy.

**Anti-Viral and Anti-Inflammatory Drug Candidate – COVID-19**

*VERU-111 for the treatment of SARS-CoV-2 in subjects at high risk for acute respiratory distress syndrome (ARDS)*

VERU-111 is also being evaluated in a Phase 2 clinical trial to assess the efficacy of VERU-111 in combating COVID-19 to prevent ARDS. If the clinical results of the Phase 2 clinical trial are positive, the Company intends to apply for grant funding through third party agencies.

**Sexual Health Division**

The Company's Sexual Health Division includes a drug candidate, TADFYN®, for the treatment of BPH and a commercial product, the FC2 Female Condom/ Internal Condom® (FC2), an FDA-approved product for the dual protection against unintended pregnancy and sexually transmitted infections.

TADFYN® (tadalafil 5mg and finasteride 5mg combination capsule) is being developed to treat urinary tract symptoms caused by benign prostatic hyperplasia (BPH). The co-administration of tadalafil and finasteride has been shown to be more effective for the treatment of BPH than by finasteride alone. The Company had a successful pre-NDA meeting with FDA and expects to submit the NDA for TADFYN® in early calendar year 2021. The Company's Sexual Health Business segment will include future revenues for TADFYN®. Costs associated with the development of TADFYN® are currently included in our Research and Development segment.

The Company sells FC2 in both commercial sector in U.S. and in the public health sector in the U.S. and globally. In the U.S., FC2 is available by prescription through the Company's multiple telemedicine (telemedicine being the remote diagnosis and treatment of patients by means of telecommunications technology) and internet pharmacy partners and retail pharmacies. It is also available to public health sector entities such as state departments of health and 501(c)(3) organizations. In the global public health sector, the Company markets FC2 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.

Most of the Company's net revenues are currently derived from sales of FC2 in the commercial and public health sectors.

**PREBOOST® Sale**

On December 8, 2020, the Company entered into an Asset Purchase Agreement (the "Purchase Agreement") with Roman Health Ventures Inc. (the "Purchaser"). Pursuant to, and subject to the terms and conditions of, the Purchase Agreement, the Purchaser purchased substantially all of the assets related to the Company's PREBOOST® business. PREBOOST® is a 4% benzocaine medicated individual wipes for the treatment of premature ejaculation and was a commercial product in the Company's Sexual Health Division during fiscal 2020. The transaction closed on December 8, 2020. The purchase price for the transaction was $20.0 million, consisting of $15.0 million paid at closing, $2.5 million payable 12 months after closing and $2.5 million payable 18 months after closing.

COVID-19 Environment

In December 2019, a novel strain of coronavirus was reported to have emerged in Wuhan, China. COVID-19, the disease caused by the coronavirus, has since spread to over 100 countries, including every state in the United States. On March 11, 2020, the World Health Organization declared COVID-19 a pandemic, and on March 13, 2020, the United States declared a national emergency with respect to the COVID-19 outbreak.

In an effort to contain and mitigate the spread of COVID-19, many countries, including the United States, the United Kingdom and Malaysia, have imposed unprecedented restrictions on travel, and there have been business closures and a substantial reduction in economic activity in countries that have had significant outbreaks of COVID-19. In addition and in an attempt to slow the rapid growth of the COVID-19 infection rate, many governments around the world, including in the United States at the federal, state and local levels as well as in the United Kingdom and Malaysia, have imposed mandatory sheltering in place and social distancing restrictions that severely limit the ability of its citizens to travel freely and to conduct activities.

The COVID-19 pandemic has substantially impacted the global healthcare system, including the conduct of clinical trials. Many healthcare systems have restructured operations to prioritize caring for those suffering from COVID-19 and to limit or cease other activities. The severe burden on healthcare systems caused by this pandemic has also impaired the ability of many research sites to start new clinical trials or to enroll new patients in clinical trials. The imposed mandatory sheltering in place and social distancing restrictions may delay the recruitment of patients and impede their ability to effectively participate in such trials. Significant fees may also be owed to contract research organizations associated with starting and stopping clinical trials, typically more so than delaying the start of a clinical trial.

The Phase 1b portion of our ongoing VERU-111 clinical trial is fully enrolled. The Phase 2 clinical study has completed enrollment of approximately 40 men with metastatic castration resistant prostate cancer who have also become resistant to androgen receptor targeting agents, such as abiraterone, enzalutamide, or apalutamide, but prior to proceeding to IV chemotherapy. However, there is a risk that changing circumstances relating to the COVID-19 pandemic may not allow our healthcare clinical trial investigators, their healthcare facilities, or other necessary parties to continue to participate in these trials through completion.

COVID-19 has had, and will likely continue to have, an impact on our operations. On March 16, 2020, the Malaysian government issued an order closing non-essential businesses in that country due to the COVID-19 pandemic. As a result, the sole facility where the Company manufactures FC2 was unable to manufacture or ship product starting March 16, 2020. Because FC2 is a health product, the Company received an exemption to reopen the facility with limited staff to ship existing inventory on March 27, 2020, to reopen for manufacturing with 50% of the regular number of workers and social distancing requirements on April 20, 2020 and to return to 100% of the regular number of workers but continued social distancing requirements on May 4, 2020. The Company has had a sufficient quantity of FC2 outside of Malaysia to continue to satisfy customer demand, and with the facility reopening the Company does not expect to have issues with supply of FC2. The Company has adopted measures to protect the employees at its Malaysian facility, to respond in the event an employee at the facility is determined to have tested positive for COVID-19, and to mitigate the impact of COVID-19 on the Company's Malaysian manufacturing operations. However, no such measures can eliminate risks relating to the COVID-19 pandemic, and if the Company's Malaysian manufacturing facility encounters labor or raw material shortages, transportation delays or other issues, our ability to supply product to our customers could be disrupted.

The sole supplier of the nitrile polymer sheath for FC2 has recently been prioritizing production of surgical gloves during the COVID-19 pandemic and may continue to do so, which could disrupt the Company's supply of a critical raw material. Malaysian ports are currently open for shipment but at limited capacity, and the Company may also encounter issues shipping product into key markets or through freight or other carriers. The COVID-19 pandemic and related economic disruption may also adversely affect customer demand for FC2. For example, sales of FC2 could be impacted in the U.S. prescription market if insurance coverage is affected by job losses and in the global public health sector if governments delay future tenders or reduce spending on female condoms due to financial strains or changed spending priorities caused by the COVID-19 pandemic. The COVID-19 pandemic did not have a material net impact on our consolidated operating results during the year ended September 30, 2020.

To protect the health and safety of our workforce, we have closed our offices in the United States and the United Kingdom and our personnel have largely been working remotely. Travel between our facilities in the United States, the United Kingdom and Malaysia has also been restricted. As of the date of this report, our operations have not been significantly impacted by such remote work requirements and travel restrictions.

Significant uncertainty remains as to the potential impact of the COVID-19 pandemic on our operations, and on the global economy. It is currently not possible to predict how long the pandemic will last or the time that it will take for economic activity to return to prior levels. We do not yet know the full extent of any impact on our business or our operations; however, we will continue to monitor the COVID-19 situation and its impact on our business closely and expect to reevaluate the timing of our anticipated clinical trials as the impact of COVID-19 on our industry becomes clearer.

Sales of FC2 in commercial and public health sectors

*FC2 Commercial Sector.* 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 under the ACA and the laws of 20+ states prior to enactment of the ACA. In 2018, we dissolved our small-scale marketing and sales program to focus our efforts in partnering with fast-growing, highly reputable telemedicine firms (telemedicine being the remote diagnosis and treatment of patients by means of telecommunications technology) to bring our much-needed FC2 product to patients with a prescription in a cost-effective and highly convenient manner. As a result of these efforts, the Company now supplies FC2 to telemedicine providers in the U.S. prescription channel. The Company is working to develop supply and distributor relationships with additional telemedicine and other providers.

*FC2 Public Health Sector.* FC2's use is for the prevention of HIV/AIDS and other sexually transmitted diseases 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 sexually transmitted infections and unintended 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 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 strategic arrangements with companies with the necessary marketing and financial resources and local market expertise.

The Company currently has a limited number of customers for FC2 in the global public health sector who generally purchase in large quantities. Over the past few years, significant customers have included large global agencies, such as UNFPA, 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. Other customers include ministries of health or other governmental agencies, which either purchase directly or via in-country distributors, and NGOs.

Purchasing patterns for FC2 in the public health sector 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, exchange rate risk, process errors, changes in leadership, funding priorities and/or other pressures may delay or derail the process and affect the purchasing patterns of public health sector customers. As a result, the Company may experience significant quarter-to-quarter sales variances in the global public health sector due to the timing and shipment of large orders 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. The Company began shipping units under this tender award in the third quarter of fiscal 2019 and we have shipped approximately 10 million units through September 30, 2020. In October 2020, the Company was awarded 20 million units through its distributor in Brazil under the new Brazil Female Condom tender. These units are to be delivered over two years.

The Company classified approximately $0.3 million of trade receivables with its distributor in Brazil as long-term as of September 30, 2019 because payment was expected in greater than one year.

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

| Period | 2020 | 2019 | 2018 | 2017 | 2016 |
|---|---|---|---|---|---|
| October 1 – December 31 | 10,070,700 | 7,382,524 | 4,399,932 | 6,389,320 | 15,380,240 |
| January 1 – March 31 | 6,884,472 | 9,792,584 | 4,125,032 | 4,549,020 | 9,163,855 |
| April 1 – June 30 | 10,532,048 | 10,876,704 | 10,021,188 | 8,466,004 | 10,749,860 |
| July 1 - September 30 | 5,289,908 | 9,842,020 | 6,755,124 | 6,854,868 | 6,690,080 |
| Total | 32,777,128 | 37,893,832 | 25,301,276 | 26,259,212 | 41,984,035 |

*Revenues*. The Company's revenues are primarily derived from sales of FC2 in the U.S. prescription channel and global public health sector. Other revenues were from sales of PREBOOST® (Roman Swipes). These sales are recognized upon shipment or delivery of the product to the customers depending on contract terms.

The Company’s most significant customers have been telemedicine providers in the U.S. who sell into the prescription channel and global public health sector agencies who purchase and/or distribute FC2 for use in preventing the transmission of HIV/AIDS and/or family planning.

The Company manufactures FC2 in a leased facility located in Selangor D.E., Malaysia, resulting in a portion of the Company's operating costs being denominated in foreign currencies. While a significant portion of the Company's future unit 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 Malaysian facility. 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 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. The Company’s Research and Development segment includes multiple products and management routinely evaluates each product in its portfolio of products. Advancement is limited to available working capital and management’s understanding of the prospects for each product. If future prospects do not meet management’s strategic goals, advancement may be discontinued. 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 $16.9 million and $13.7 million for fiscal 2020 and 2019, respectively. In fiscal 2021, we expect to continue this trend of increased expenses relating to research and development due to advancement of multiple drug candidates.

Results of Operations

YEAR ENDED SEPTEMBER 30, 2020 COMPARED TO YEAR ENDED SEPTEMBER 30, 2019

The Company generated net revenues of $42.6 million and net loss of $19.0 million, which includes a $14.1 million non-cash impairment charge, or $(0.28) per basic and diluted common share, in fiscal 2020, compared to net revenues of $31.8 million and net loss of $12.0 million, or $(0.19) per basic and diluted common share, in fiscal 2019. Net revenues increased 34% year over year.

FC2 net revenues represented 95% of total net revenues. FC2 net revenues increased 31% year over year. There was a 14% decrease in total FC2 unit sales, attributable to the global public health sector, and an increase in FC2 average sales price per unit of 52%. The principal factor for the increase in the FC2 average sales price per unit compared to prior year was the change in the sales mix with the U.S. prescription channel representing 64% of total net revenues in fiscal 2020 compared to 44% of total net revenues in fiscal 2019. The Company experienced an increase of 93% in FC2 net revenues in the U.S. prescription channel and a decrease of 20% in FC2 net revenues in the global public health sector due to timing of orders and tenders.

Cost of sales increased to $11.8 million in fiscal 2020 from $10.1 million in fiscal 2019 primarily due to an increase in labor, transportation, and equipment maintenance costs and increased period costs of approximately $0.3 million resulting from decreased production due to the temporary shutdown of the Company's manufacturing facility in Malaysia as a result of the COVID-19 pandemic.

Gross profit increased to $30.8 million in fiscal 2020 from $21.7 million in fiscal 2019. Gross profit margin for fiscal 2020 was 72% of net revenues, compared to 68% of net revenues for fiscal 2019. In fiscal 2020, the Company experienced an increase in FC2 sales in the U.S. prescription channel with higher profit margins, contributing to the increase in overall gross profit margin, which was partially offset by the increase in labor, transportation, and equipment maintenance costs and increased period costs of approximately $0.3 million resulting from decreased production due to the temporary shutdown of the Company's manufacturing facility in Malaysia as a result of the COVID-19 pandemic.

Significant quarter-to-quarter variances 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 FC2. The Company is experiencing a significant increase in revenue from sales in the U.S prescription channel, which is helping grow net revenues quarter to quarter and year to year. The Company is also currently seeing pressure on pricing for FC2 by large global agencies and donor governments in the developed world. As a result, the Company may continue to experience challenges for revenue from sales of FC2 in the global public health sector.

Research and development expenses increased to $16.9 million in fiscal 2020 from $13.7 million in fiscal 2019. The increase is primarily due to increased costs associated with the in-process research and development projects and increased personnel costs.

Selling, general and administrative expenses increased to $14.5 million in fiscal 2020 from $14.3 million in fiscal 2019. The increase is primarily due to increased personnel, personnel costs, and related benefits.

During the fourth quarter of fiscal 2020, we recorded an impairment charge of $14.1 million related to IPR&D associated with the APP Acquisition. The charge was primarily a result of deferred development timelines and the decision to cease development work on Tamsulosin DRS, VERU-722 (male infertility), and VERU-112 (gout), in response to management's strategic decision to prioritize the development of other research projects. The Company has several other highly differentiated, unique, patent-protected drugs under development addressing larger and potentially more profitable markets. The Company met the criteria for abandonment under applicable accounting standards. This resulted in writing off the carrying amounts for these three IPR&D assets during the year ended September 30, 2020. The remaining book value of other IPR&D assets acquired in the APP Acquisition is $3.9 million as of September 30, 2020. There was no impairment charge recorded in fiscal 2019.

Interest expense, which primarily consists of items related to the Credit Agreement and Residual Royalty Agreement, was $4.6 million in fiscal 2020, which is comparable with $4.7 million in fiscal 2019.

Expense associated with the change in fair value of the embedded derivatives related to the Credit Agreement and Residual Royalty Agreement was $0.6 million in fiscal 2020 compared to expense of $1.2 million in fiscal 2019. The liabilities associated with embedded derivatives represent the fair value of the change of control provisions in the Credit Agreement and Residual Royalty Agreement. See Note 3 and Note 9 to the financial statements included in this report for additional information.

The income tax benefit in fiscal 2020 was $1.1 million, compared to the income tax benefit of $0.3 million in fiscal 2019. The increase in income tax benefit of $0.8 million is primarily due to the increase in the federal and state income tax benefit of $1.7 million related to the increase in the loss before income taxes for the year and $1.1 million primarily for the increase of 2% in U.K. tax rates partially offset by an increase in federal tax expense of $2.0 million due to the increase in the valuation allowance.

Liquidity and Sources of Capital

***Liquidity***

Our cash and cash equivalents on hand on September 30, 2020 was $13.6 million, compared to $6.3 million on September 30, 2019. On September 30, 2020, the Company had working capital of $12.3 million and stockholders' equity of $30.1 million compared to working capital of $2.8 million and stockholders' equity of $32.3 million as of September 30, 2019. The increase in working capital is primarily due to the increase in cash on hand partially offset by an increase in the current portion of the Credit Agreement and Residual Royalty Agreement liabilities.

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 drug 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 cash expected to be generated from sales of the Company's commercial product are adequate to fund planned operations of the Company for the next 12 months. To the extent the Company may need additional capital for its operations, it may access financing alternatives that 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 current effective shelf registration statement on Form S-3 (File No. 333-239493). In August 2020, the Company terminated its 2017 shelf registration statement on Form S-3 (File No. 333-221120), and as a result no additional securities will be sold under that registration statement. The Company intends to be opportunistic when pursuing equity or debt financing which could include selling common stock under the 2020 Purchase Agreement with Aspire Capital (see discussion below). 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, 2020, the Company had approximately $15.3 million in cash and cash equivalents, net trade accounts receivable of $6.6 million and current trade accounts payable of $2.8 million.

*Operating activities*

Our operating activities used cash of $1.9 million in fiscal 2020. Cash used in operating activities included a net loss of $19.0 million, adjustments for non-cash items totaling $21.4 million and changes in operating assets and liabilities of $4.3 million. Adjustments for non-cash items primarily consisted of $14.1 million of impairment of intangible assets, $4.3 million of non-cash interest expense, and $2.6 million of share-based compensation, partially offset by deferred income taxes of $1.3 million. The decrease in cash from changes in operating assets and liabilities included an increase in inventory of $3.3 million and a decrease in accrued expenses and other current liabilities of $1.0 million.

Our operating activities used cash of $5.5 million in fiscal 2019. Cash used in operating activities included a net loss of $12.0 million, adjustments for non-cash items totaling $8.1 million and changes in operating assets and liabilities of $1.6 million. Adjustments for non-cash items primarily consisted of $4.7 million of non-cash interest expense and $1.9 million of share-based compensation. The decrease in cash from changes in operating assets and liabilities included an increase in accounts receivable of $1.4 million and an increase in inventories of $1.5 million. These were partially offset by an increase in accrued expenses and other current liabilities of $2.1 million.

*Investing activities*

Net cash used in investing activities in fiscal 2020 and fiscal 2019 was $0.1 million, associated with capital expenditures.

*Financing activities*

Net cash provided by financing activities in fiscal 2020 was $9.3 million and primarily consisted of $13.4 million from the sale of shares under the 2020 Purchase Agreement and 2017 Purchase Agreement with Aspire Capital (see discussion below), less principal payments on the Credit Agreement (see discussion below) totaling $4.4 million.

Net cash provided by financing activities in fiscal 2019 was $8.1 million and primarily consisted of net proceeds from the underwritten public offering of the Company's common stock of $9.1 million (see discussion below) and $3.6 million from the sale of shares under the 2017 Purchase Agreement with Aspire Capital (see discussion below), less payments on the Credit Agreement (see discussion below) totaling $4.9 million.

***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. Net proceeds to the Company from this offering were $9.2 million after deducting underwriting discounts and commissions and costs paid by the Company. All of the shares sold in the offering were by the Company. The offering was made pursuant to the Company's 2017 shelf registration statement on Form S-3 (File No. 333-221120).

*Credit Agreement*

On March 5, 2018, the Company entered into a Credit Agreement (as amended, 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 provided the Company with a term loan of $10.0 million, which was advanced to the Company on the date of 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. On May 13, 2019, the Company entered into an amendment to the Credit Agreement (the "Second Amendment") which included a reduction to the percentages to be used to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar year 2019, a return to the original percentages to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar year 2020 and an increase to the percentages to be used to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar year 2021 and thereafter until the loan has been repaid.

In connection with the Credit Agreement, Veru and the Agent also entered into a Residual Royalty Agreement, dated as of March 5, 2018 (as amended, the "Residual Royalty Agreement"), which provides for an ongoing royalty payment of 5% of product revenue from net sales of FC2 commencing after the Lenders would have received their return premium based on the return premium and calculation of revenue-based payments under the Credit Agreement without taking into account the amendments effected by the Second Amendment. 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.

The Company made total payments under the Credit Agreement of $4.7 million and $4.9 million during fiscal 2020 and 2019, respectively. As a result of the Second Amendment, the Company currently estimates the aggregate amount of quarterly revenue-based payments payable during the 12-month period subsequent to September 30, 2020 will be approximately $7.3 million under the Credit Agreement. The Company also estimates that it will begin making payments under the Residual Royalty Agreement during the 12-month period subsequent to September 30, 2020 and estimates such payments within that period to be approximately $1.1 million.

*Common Stock Purchase Agreements*

On June 26, 2020, the Company entered into a common stock purchase agreement (the "2020 Purchase Agreement") with Aspire Capital which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right, from time to time in its sole discretion during the 36-month term of the 2020 Purchase Agreement, to direct Aspire Capital to purchase up to $23.9 million of the Company's common stock in the aggregate. Upon execution of the 2020 Purchase Agreement, the Company issued and sold to Aspire Capital under the 2020 Purchase Agreement 1,644,737 shares of common stock at a price per share of $3.04, for an aggregate purchase price of $5,000,000. Other than the 212,130 shares of common stock issued to Aspire Capital in consideration for entering into the 2020 Purchase Agreement and the initial sale of 1,644,737 shares of common stock, the Company has no obligation to sell any shares of common stock pursuant to the 2020 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 2020 Purchase Agreement.

Effective June 26, 2020, upon the execution of the 2020 Purchase Agreement, the Company's prior purchase agreement with Aspire Capital dated December 29, 2017 (the "2017 Purchase Agreement") was terminated. Under the 2017 Purchase Agreement, the Company had the right, from time to time and in its sole discretion during the 36-month term of the 2017 Purchase Agreement, to direct Aspire Capital to purchase up to $15.0 million of the Company's common stock in the aggregate. As of the date of termination of the 2017 Purchase Agreement, the Company sold a total of 6,214,343 shares of common stock to Aspire Capital under the 2017 Purchase Agreement for aggregate proceeds of $15.0 million. During fiscal 2020, the Company sold 2,497,333 shares of common stock to Aspire Capital under the 2017 Purchase Agreement resulting in proceeds to the Company of $8.4 million.

*U.S. Small Business Administration's Paycheck Protection Program*

In April 2020, the Company was approved for a loan under the Paycheck Protection Program established by the CARES Act in the amount of $0.5 million. The PPP Loan proceeds were received on April 20, 2020. The PPP Loan had a maturity of two years and bore interest at an annual rate of 1%. Payments on the PPP Loan were deferred for six months. Pursuant to the CARES Act, the PPP Loan would be fully forgiven if the funds were used for payroll costs, rent and utilities, subject to certain conditions, including maintaining employees and maintaining salary levels. As of the date of this report, the Company has not terminated any employees in the U.S. due to the COVID-19 pandemic. The Company expended the funds received under the PPP Loan in full on qualifying expenses, and maintained the conditions set forth by the CARES Act. The Company submitted its application for forgiveness in September 2020. The loan and related interest incurred were forgiven by the SBA on November 10, 2020.

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 goodwill and intangible assets. 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 2006 through fiscal 2015, the Company generated taxable income on a consolidated basis. However, the Company had a cumulative pretax loss in the U.S. for fiscal 2020 and the three 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 pretax losses in the U.S. driven by the investment in research and development, and based on their analysis concluded that an additional valuation allowance of $4.1 million should be recorded against the U.S. deferred tax assets related to federal and state net operating loss carryforwards as of September 30, 2020. In addition, the Company's U.K. holding company for the non-U.S. operating companies, The Female Health Company Limited, continues to have a full valuation allowance of $2.4 million. 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.

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 included a permanent reduction to the U.S. federal corporate income tax rate from 35% to 21% effective January 1, 2018.

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, 2020, 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 Credit Agreement and Residual Royalty Agreement. See Note 9 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.

***Goodwill and Intangible Assets***

The Company evaluates the carrying value of its goodwill and indefinite-lived intangible assets, which consists of in-process research and development (IPR&D), on an annual basis in the fourth quarter of each fiscal year or more frequently when indicators of impairment exist. An impairment of goodwill could occur if the carrying amount of a reporting unit exceeded the fair value of that reporting unit. An impairment of indefinite-lived intangible assets would occur if the fair value of the intangible asset is less than the carrying value. Intangible assets with finite lives are tested for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. 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.

Regarding 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.

IPR&D assets 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. 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 with respect to the Company's future volume, revenue and expense growth rates, changes in working capital use, the selection of an appropriate discount rate, asset groupings, and other assumptions and estimates. The Company recorded an impairment charge of $14.1 million related to the IPR&D assets during the year ended September 30, 2020. See further discussion in Note 1 and Note 8 to the financial statements included in this report.

Recent Accounting Pronouncements

See Note 1 to the financial statements included in this report for additional information on recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted.

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 Securities Exchange Act of 1934), 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 Securities Exchange Act of 1934 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 the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended) during the fiscal quarter ended September 30, 2020 that have materially affected, or are reasonably likely to materially affect, the Company'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 Securities Exchange Act of 1934. As required by Rule 13a-15(c) under the Securities Exchange Act of 1934, 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, 2020, 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

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

On December 8, 2020, the Company entered into an Asset Purchase Agreement (the "Purchase Agreement") with Roman Health Ventures Inc. (the "Purchaser"). Pursuant to, and subject to the terms and conditions of, the Purchase Agreement, the Purchaser purchased substantially all of the assets related to the Company's PREBOOST® business. The transaction closed on December 8, 2020. The purchase price for the transaction was $20.0 million, consisting of $15.0 million paid at closing, $2.5 million payable 12 months after closing and $2.5 million payable 18 months after closing.

The Company and the Purchaser made customary representations and warranties, and agreed to certain customary covenants, in the Purchase Agreement. Subject to certain exceptions and limitations, each party has agreed to indemnify the other for breaches of representations, warranties and covenants and for certain other matters.

The foregoing summary of the Purchase Agreement and the transactions contemplated thereby does not purport to be a complete description and is qualified in its entirety by reference to the terms and conditions of the Purchase Agreement, a copy of which is attached hereto as Exhibit 2.2 and incorporated herein by reference.

Disclosure Pursuant to Item 2.01 of Form 8-K – Completion of Acquisition or Disposition of Assets

The information contained in Item 1.01 above is incorporated herein by reference.

Disclosure Pursuant to Item 9.01 of Form 8-K – Financial Statements and Exhibits

The following unaudited pro forma financial information of the Company is included as Exhibit 99.1 of this report and is incorporated herein by reference:

(i) Unaudited pro forma consolidated balance sheet as of September 30, 2020;

(ii) Unaudited pro forma consolidated statement of operations for the fiscal year ended September 30, 2020; and

(iii) Notes to the unaudited pro forma consolidated financial statements.

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," "Delinquent Section 16(a) Reports," "Corporate Governance Matters-Director Nominations" and "Audit Committee Matters – Audit Committee Financial Expert" in the Company's Proxy Statement for the 2021 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 28, 2021. 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 2021 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 28, 2021.

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 2021 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 28, 2021.

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 heading "Security Ownership" in the Company's Proxy Statement for the 2021 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 28, 2021.

Equity Compensation Plan Information

The following table summarizes share information, as of September 30, 2020, for the Company's equity compensation plans and arrangements. In March 2008, the Company's shareholders approved the 2008 Stock Incentive Plan and authorized 2,000,000 shares (subject to adjustment in the event of stock splits and other similar events) for issuance under the plan; in July 2017, the Company's shareholders approved the 2017 Equity Incentive Plan and authorized 4,700,000 shares (subject to adjustment in the event of stock splits and other similar events) for issuance under the plan; and in March 2018, the Company's shareholders approved the 2018 Equity Incentive Plan and in March 2020 the Company's shareholders approved an increase in the number of shares authorized to be issued under the 2018 Equity Incentive Plan to 11,000,000 shares (subject to adjustment in the event of stock splits and other similar events).

| Equity Plan Category | Number of Shares to be Issued upon Exercise of Outstanding Options, SARs, and Warrants | Weighted-Average Exercise Price of Outstanding Options, SARs, and Warrants | Shares Remaining Available for Issuance Under Compensation Plans |
|---|---|---|---|
| Equity compensation plans approved by shareholders | 8,649,000 | $ 1.67 | 6,004,569 |
| Equity compensation plans not approved by shareholders (1) | 2,326,841 | 1.93 | — |
| Total | 10,975,841 | $ 1.73 | 6,004,569 |

(1) In connection with the closing of the APP Acquisition, the Company issued warrants to purchase up to 2,585,379 shares of the Company's common stock to Torreya Capital, the Company's financial advisor. These warrants vested upon issuance, have a five-year term expiring October 31, 2021, a cashless exercise feature and an exercise price equal to $1.93 per share. The issuance of these warrants was not required to be approved by the Company's shareholders.

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 2021 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 28, 2021. 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 2021 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 28, 2021.

Item 14. Principal Accountant Fees and Services.

Information with respect to this item is incorporated herein by reference to the discussion under the heading “Audit Committee Matters – Fees of Independent Registered Public Accounting Firm” in the Company’s Proxy Statement for the 2021 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 28, 2021.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

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

**1. Financial Statements**

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

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of September 30, 2020 and 2019

Consolidated Statements of Operations for the Years Ended September 30, 2020 and 2019

Consolidated Statements of Stockholders' Equity for the Years Ended September 30, 2020 and 2019

Consolidated Statements of Cash Flows for the Years Ended September 30, 2020 and 2019

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). |
| 2.2 | Asset Purchase Agreement, dated as of December 8, 2020, between the Company and Roman Health Ventures Inc. ** |
| 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 | Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 154,000,000 shares (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on March 29, 2019). |
| 3.9 | 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, 3.7 and 3.8). |

| | |
|---|---|
| 4.2 | Articles II, VII and XI of the Amended and Restated By-Laws of the Company (included in Exhibit 3.8). |
| 4.3 | Description of Capital Stock ** |
| 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 | 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). * |
| 10.7 | 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). * |
| 10.8 | 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).* |
| 10.9 | 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).* |
| 10.10 | Executive Employment Agreement, dated as of September 4, 2018, between the Company and Dr. K. Gary Barnette. (incorporated by reference to Exhibit 10.13 to the Company's Form 10-K (File No. 1-13602) filed with the SEC on December 13, 2018). * |
| 10.11 | 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). * |
| 10.12 | 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). * |
| 10.13 | 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). * |

10.14 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). *

10.15 Form of Non-Qualified Stock Option Grant Agreement under Veru Inc. 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Form 10-Q (File No. 1-13602) filed with the SEC on May 13, 2020). *

10.16 Veru Inc. 2018 Equity Incentive Plan (as amended and restated effective March 24, 2020) (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, 2020. *

10.17 Form of Non-Qualified Stock Option Grant Agreement under Veru Inc. 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Form 10-Q (File No. 1-13602) filed with the SEC on May 13, 2020). *

10.18 Common Stock Purchase Agreement, dated as of June 26, 2020, between the Company and Aspire Capital Fund, LLC (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on June 26, 2020).

10.19 Registration Rights Agreement, dated as of June 26, 2020, between the Company and Aspire Capital Fund, LLC (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on June 26, 2020).

10.20 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).

10.21 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).

10.22 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).

10.23 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).

10.24 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).

10.25 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).

10.26 Second Amendment to Credit Agreement & Amendment to Residual Royalty Agreement, dated as of May 13, 2019, among the Company, SWK Funding LLC and the financial institutions party thereto from time to time (incorporated by reference to Exhibit 10.3 to the Company's Form 10-Q (File No. 1-13602) filed with the SEC on May 15, 2019).

10.27 Third Amendment to Credit Agreement, dated as of October 5, 2020, among the Company, SWK Funding LLC and the financial institutions party thereto from time to time.**

| | |
|---|---|
| 10.28 | Separation Agreement and General Release, dated as of March 27, 2019, between the Company and Charles T. Todd, Jr. (incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q (File No. 1-13602) filed with the SEC on May 15, 2019). * |
| 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). **, *** |
| 99.1 | Pro Forma Financial Information. ** |
| 101 | The following materials from the Company's Annual Report on Form 10-K for the year ended September 30, 2020, 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. |

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| | |
|---|---|
| * | 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 10, 2020

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 10, 2020 |
| /s/ Michele Greco<br>Michele Greco | Chief Financial Officer and Chief Administrative Officer<br>(Principal Accounting and Financial Officer) | December 10, 2020 |
| /s/ Mario Eisenberger<br>Mario Eisenberger | Director | December 10, 2020 |
| /s/ Harry Fisch<br>Harry Fisch | Vice Chairman of the Board and Director | December 10, 2020 |
| /s/ Grace S. Hyun<br>Grace S. Hyun | Director | December 10, 2020 |
| /s/ Michael L. Rankowitz<br>Michael L. Rankowitz | Director | December 10, 2020 |
| /s/ Jesus Socorro<br>Jesus Socorro | Director | December 10, 2020 |

Veru Inc.

**Index to Consolidated Financial Statements**


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**Report of Independent Registered Public Accounting Firm**

To the Stockholders and Board of Directors of Veru Inc.

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Veru Inc. (the Company) as of September 30, 2020 and 2019, the related consolidated statements of operations, stockholders' equity and cash flows for the years then ended, 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, 2020 and 2019, and the results of its operations and its cash flows for the years then ended 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 10, 2020

VERU INC.
CONSOLIDATED BALANCE SHEETS
AS OF SEPTEMBER 30, 2020 AND 2019

| | 2020 | 2019 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 13,588,778 | $ 6,295,152 |
| Accounts receivable, net | 5,227,237 | 5,021,057 |
| Inventory, net | 6,704,134 | 3,647,406 |
| Prepaid expenses and other current assets | 1,494,541 | 1,843,297 |
| Total current assets | 27,014,690 | 16,806,912 |
| Property and equipment, net | 312,691 | 351,895 |
| Operating lease right-of-use asset | 1,352,315 | — |
| Deferred income taxes | 9,466,800 | 8,433,669 |
| Intangible assets, net | 5,752,127 | 20,168,495 |
| Goodwill | 6,878,932 | 6,878,932 |
| Other assets | 766,120 | 988,867 |
| Total assets | $ 51,543,675 | $ 53,628,770 |
| | | |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,812,673 | $ 3,124,751 |
| Accrued research and development costs | 934,110 | 2,475,490 |
| Accrued compensation | 2,274,396 | 1,597,197 |
| Accrued expenses and other current liabilities | 1,177,126 | 1,436,888 |
| Credit agreement, short-term portion (Note 9) | 5,841,874 | 5,385,649 |
| Residual royalty agreement, short-term portion (Note 9) | 1,100,193 | — |
| Operating lease liability, short-term portion | 586,769 | — |
| Total current liabilities | 14,727,141 | 14,019,975 |
| Credit agreement, long-term portion (Note 9) | — | 2,886,382 |
| Residual royalty agreement, long-term portion (Note 9) | 5,617,494 | 3,845,518 |
| Operating lease liability, long-term portion | 990,020 | — |
| Deferred income taxes | 74,724 | 296,605 |
| Other liabilities | 22,980 | 247,154 |
| Total liabilities | 21,432,359 | 21,295,634 |
| | | |
| Commitments and contingencies (Note 13) | | |
| | | |
| Stockholders' equity: | | |
| Preferred stock, no shares issued and outstanding at September 30, 2020 and 2019, respectively | — | — |
| Common stock, par value $0.01 per share; 154,000,000 shares authorized, 72,047,385 and 67,221,951 shares issued and 69,863,681 and 65,038,247 shares outstanding at September 30, 2020 and 2019, respectively | 720,474 | 672,220 |
| Additional paid-in-capital | 126,971,518 | 110,268,057 |
| Accumulated other comprehensive loss | (581,519) | (581,519) |
| Accumulated deficit | (89,192,552) | (70,219,017) |
| Treasury stock, 2,183,704 shares, at cost | (7,806,605) | (7,806,605) |
| Total stockholders' equity | 30,111,316 | 32,333,136 |
| Total liabilities and stockholders' equity | $ 51,543,675 | $ 53,628,770 |

See notes to consolidated financial statements.

VERU INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED SEPTEMBER 30, 2020 AND 2019

| | 2020 | 2019 |
|---|---|---|
| Net revenues | $ 42,592,060 | $ 31,803,387 |
| Cost of sales | 11,805,202 | 10,146,565 |
| Gross profit | 30,786,858 | 21,656,822 |
| Operating expenses: | | |
| Research and development | 16,935,222 | 13,743,826 |
| Selling, general and administrative | 14,498,330 | 14,348,890 |
| Impairment of intangible assets | 14,100,000 | — |
| Total operating expenses | 45,533,552 | 28,092,716 |
| Operating loss | (14,746,694) | (6,435,894) |
| Non-operating (expenses) income: | | |
| Interest expense | (4,621,422) | (4,706,056) |
| Change in fair value of derivative liabilities | (557,000) | (1,199,000) |
| Other (expense) income, net | (126,860) | 19,651 |
| Total non-operating expenses | (5,305,282) | (5,885,405) |
| Loss before income taxes | (20,051,976) | (12,321,299) |
| Income tax benefit | (1,078,441) | (303,933) |
| Net loss | $ (18,973,535) | $ (12,017,366) |
| Net loss per basic and diluted common share outstanding | $ (0.28) | $ (0.19) |
| Basic and diluted weighted average common shares outstanding | 66,753,450 | 63,323,127 |

See notes to consolidated financial statements.

VERU INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED SEPTEMBER 30, 2020 AND 2019

| | Common Stock | | Additional Paid-in | Accumulated Other Comprehensive | Accumulated | Treasury Stock, | |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Capital | Loss | Deficit | at Cost | Total |
| Balance at September 30, 2018 | 57,468,660 | $ 574,687 | $ 95,496,506 | $ (581,519) | $ (58,201,651) | $ (7,806,605) | $ 29,481,418 |
| Share-based compensation | — | — | 1,906,098 | — | — | — | 1,906,098 |
| Shares issued in connection with public offering of common stock, net of fees and costs | 7,142,857 | 71,429 | 9,060,538 | — | — | — | 9,131,967 |
| Sale of shares under common stock purchase agreement | 2,000,000 | 20,000 | 3,580,000 | — | — | — | 3,600,000 |
| Amortization of deferred costs | — | — | (101,981) | — | — | — | (101,981) |
| Issuance of shares pursuant to share-based awards | 610,434 | 6,104 | 326,896 | — | — | — | 333,000 |
| Net loss | — | — | — | — | (12,017,366) | — | (12,017,366) |
| Balance at September 30, 2019 | 67,221,951 | 672,220 | 110,268,057 | (581,519) | (70,219,017) | (7,806,605) | 32,333,136 |
| Share-based compensation | — | — | 2,646,246 | — | — | — | 2,646,246 |
| Shares issued in connection with common stock purchase agreement | 212,130 | 2,121 | 678,816 | — | — | — | 680,937 |
| Sale of shares under common stock purchase agreement | 4,142,070 | 41,421 | 13,358,578 | — | — | — | 13,399,999 |
| Amortization of deferred costs | — | — | (390,931) | — | — | — | (390,931) |
| Issuance of shares pursuant to share-based awards | 362,091 | 3,621 | 411,843 | — | — | — | 415,464 |
| Issuance of shares pursuant to common stock purchase warrants | 109,143 | 1,091 | (1,091) | — | — | — | — |
| Net loss | — | — | — | — | (18,973,535) | — | (18,973,535) |
| Balance at September 30, 2020 | 72,047,385 | $ 720,474 | $ 126,971,518 | $ (581,519) | $ (89,192,552) | $ (7,806,605) | $ 30,111,316 |

See notes to consolidated financial statements.

VERU INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED SEPTEMBER 30, 2020 AND 2019

| | 2020 | 2019 |
|---|---|---|
| OPERATING ACTIVITIES | | |
| Net loss | $ (18,973,535) | $ (12,017,366) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 146,373 | 162,187 |
| Amortization of intangible assets | 316,368 | 309,234 |
| Impairment of intangible assets | 14,100,000 | — |
| Noncash change in right-of-use assets | 320,900 | — |
| Noncash interest expense | 4,306,927 | 4,706,056 |
| Share-based compensation | 2,646,246 | 1,906,098 |
| Deferred income taxes | (1,255,012) | (438,064) |
| Provision for obsolete inventory | 244,823 | 109,107 |
| Change in fair value of derivative liabilities | 557,000 | 1,199,000 |
| Other | 6,091 | 142,590 |
| Changes in operating assets and liabilities: | | |
| Increase in accounts receivable | (87,790) | (1,351,709) |
| Increase in inventory | (3,301,551) | (1,454,483) |
| Decrease (increase) in prepaid expenses and other assets | 621,777 | (704,306) |
| Decrease in accounts payable | (312,078) | (56,938) |
| (Decrease) increase in accrued expenses and other current liabilities | (946,390) | 2,003,387 |
| Decrease in operating lease liabilities | (320,244) | — |
| Net cash used in operating activities | (1,930,095) | (5,485,207) |
| INVESTING ACTIVITIES | | |
| Capital expenditures | (105,760) | (108,517) |
| Net cash used in investing activities | (105,760) | (108,517) |
| FINANCING ACTIVITIES | | |
| Proceeds from sale of shares in public offering | — | 9,400,000 |
| Payment of costs related to public offering | — | (268,033) |
| Installment payments on SWK credit agreement | (4,421,915) | (4,935,600) |
| Proceeds from sale of shares under common stock purchase agreement | 13,399,999 | 3,600,000 |
| Payment of costs related to common stock purchase agreement | (50,284) | — |
| Proceeds from stock option exercises | 415,464 | 333,000 |
| Proceeds from premium finance agreement | 836,780 | — |
| Installment payments on premium finance agreement | (836,780) | — |
| Cash paid for debt portion of finance lease | (13,783) | — |
| Net cash provided by financing activities | 9,329,481 | 8,129,367 |
| Net increase in cash and cash equivalents | 7,293,626 | 2,535,643 |
| CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR | 6,295,152 | 3,759,509 |
| CASH AND CASH EQUIVALENTS AT END OF YEAR | $ 13,588,778 | $ 6,295,152 |
| Supplemental disclosure of cash flow information: | | |
| Cash paid for income taxes | $ 362,060 | $ 303,582 |
| Cash paid for interest | $ 314,495 | $ — |
| Schedule of non-cash investing and financing activities: | | |
| Right-of-use assets recorded in exchange for lease liabilities | $ 1,673,215 | $ — |
| Shares issued in connection with common stock purchase agreement | $ 680,937 | $ — |
| Amortization of deferred costs related to common stock purchase agreement | $ 390,931 | $ 101,981 |
| Acquisition of equipment, furniture, and fixtures through capital lease | $ — | $ 43,567 |

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, The Female Health Company Limited's wholly owned subsidiary, The Female Health Company (UK) plc (The Female Health Company Limited and The Female Health Company (UK) plc, collectively, the "U.K. subsidiary"), and The Female Health Company (UK) plc's wholly owned subsidiary, The Female Health Company (M) SDN.BHD (the "Malaysia subsidiary"). All significant intercompany transactions and accounts have been eliminated in consolidation. The Company is an oncology biopharmaceutical company with a focus on developing novel medicines for the management of prostate and breast cancers. The Company has multiple drug products under clinical development. The Company's Sexual Health Business segment includes its commercial product, FC2, an FDA-approved product for the dual protection against unintended pregnancy and sexually transmitted infections. During fiscal 2020 and 2019, the Sexual Health Business segment also included PREBOOST® 4% benzocaine medicated individual wipe for the treatment of premature ejaculation. The PREBOOST® business was sold on December 8, 2020. See Note 20 for additional information. Most of the Company's net revenues during fiscal 2020 and 2019 were derived from sales of FC2.

FC2 has been distributed in either or both commercial (private sector) and public health sector markets in 150 countries. It is marketed to consumers in 22 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 and cash equivalents and concentration: Cash and cash equivalents, which primarily consist of cash on deposit with financial institutions and highly liquid money market funds, are recorded in the consolidated balance sheets at cost, which approximates fair value. The Company treats short-term, highly liquid funds that are readily convertible to known amounts of cash and have original maturities of three months or less as cash equivalents. The Company's cash is maintained primarily in three financial institutions, located in Chicago, Illinois; London, England; and Kuala Lumpur, Malaysia.

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

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

Leases: Leases are classified as either operating or finance leases at inception. A right-of-use (ROU) asset and corresponding lease liability are established at an amount equal to the present value of fixed lease payments over the lease term at the commencement date. The ROU asset includes any initial direct costs incurred and lease payments made at or before the commencement date and is reduced by lease incentive payments. The Company has elected not to separate the lease and nonlease components for all classes of underlying assets. The Company uses its incremental borrowing rate as the discount rate to determine the present value of the lease payments for leases that do not have a readily determinable implicit discount rate. The incremental borrowing rate is the rate of interest that the Company would be charged to borrow on a collateralized basis over a similar term and amount in a similar economic environment. The Company determines the incremental borrowing rates for its leases by adjusting the risk-free interest rate with a credit risk premium corresponding to the Company's credit rating.

Operating lease costs are recognized for fixed lease payments on a straight-line basis over the term of the lease. Finance lease costs are a combination of the amortization expense for the ROU asset and interest expense for the outstanding lease liability using the applicable discount rate. Variable lease payments are recognized when incurred based on occurrence or usage. Short-term leases with an initial term of 12 months or less are not recorded on the balance sheet; we recognize lease expense for short-term leases on a straight-line basis over the lease term.

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

Goodwill and intangible assets: The Company's goodwill and intangible assets, primarily developed technology and in-process research and development (IPR&D), arose from the acquisition of APP (the "APP Acquisition") on October 31, 2016. Goodwill and indefinite-lived intangible assets are not amortized. IPR&D is accounted for as indefinite-lived intangible assets until the underlying project receives regulatory approval, at which point the intangible asset will be accounted for as a finite-lived intangible asset, or discontinuation, at which point the intangible asset will be written off. Goodwill and indefinite-lived assets are subject to an impairment review annually, in the fourth quarter of each fiscal year, and more frequently when indicators of impairment exist. An impairment of goodwill could occur if the carrying amount of a reporting unit exceeded the fair value of that reporting unit. An impairment of indefinite-lived intangible assets would occur if the fair value of the intangible asset is less than the carrying value. Intangible assets with finite lives are tested for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. These intangible assets are carried at cost less accumulated amortization.

Goodwill consists of the cost of an acquired business in excess of the fair value of the net assets acquired. The Company's goodwill is assigned to the Company's sole reporting unit in the Company's Research and Development reporting segment. The Company tests goodwill and indefinite-lived intangible assets for impairment by first assessing qualitative factors to determine whether it is more likely than not that the fair value is less than its carrying amount. If the Company concludes it is more likely than not that the fair value is less than its carrying amount, a quantitative impairment test is performed. For its quantitative impairment tests, the Company uses an estimated future cash flow approach that requires significant judgment with respect to future volume, revenue and expense growth rates, changes in working capital use, the selection of an appropriate discount rate, asset groupings and other assumptions and estimates. The estimates and assumptions used are consistent with the Company's business plans and a market participant's views. The use of alternative estimates and assumptions could increase or decrease the estimated fair value of the assets and potentially result in different impacts to the Company's results of operations. Actual results may differ from the Company's estimates.

Regarding 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. 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.

Intangible assets are highly vulnerable to impairment charges, particularly IPR&D. 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, 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. During the fourth quarter of fiscal 2020, the Company recorded an impairment charge of $14.1 million related to IPR&D. The charge was primarily a result of deferred development timelines on certain drug candidates due to the prioritization of other drug candidates. See Note 8 for additional information. Considering the high-risk nature of research and development and the industry's success rate of bringing developmental compounds to market, additional IPR&D impairment charges are likely to occur in future periods.

Deferred financing costs: Costs incurred in connection with the common stock purchase agreements discussed in Note 10 have been included in other assets on the accompanying consolidated balance sheets at September 30, 2020 and 2019. When shares of the Company's common stock are sold under the common stock purchase agreement, a pro-rata portion of the deferred costs is recorded to additional paid-in-capital.

Costs incurred in connection with the issuance of debt discussed in Note 9 are presented as a reduction of the debt on the accompanying consolidated balance sheet at September 30, 2020 and 2019. 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 amortization 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.

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 9.

Revenue recognition: Revenue is recognized when control of the promised goods is transferred to the customer in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those products. See Note 4 for further discussion on revenue.

Government grants: U.S. GAAP for profit-oriented entities does not define government grants nor is there specific guidance applicable to government grants. Under the Company's accounting policy for government grants and consistent with non-authoritative guidance, government grants are recognized as a reduction of the related expense. Government grants are recognized when there is reasonable assurance that the Company has met the requirements of the grant and there is reasonable assurance that the grant will be received. Grants that compensate the Company for expenses incurred are recognized as a reduction of the related expenses in the same period in which the expenses are recognized. The Company has elected to treat forgivable loans from a government as a government grant when it is probable that the Company will meet the terms for forgiveness of the loan.

Research and development costs: Research and development costs are expensed as they are incurred and include salaries and benefits, costs to conduct clinical trials, 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, 2020 and 2019.

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 recognizes share-based compensation expense in connection with its share-based awards, based on the estimated fair value of the awards on the date of grant, on a straight-line basis over the vesting period. Calculating share-based compensation expense requires the input of highly subjective judgment and assumptions, including estimates of the expected life of the share-based award, stock price volatility and risk-free interest rate.

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 years ended September 30, 2020 and 2019.

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, resulting in the adoption of the U.S. dollar as the functional currency for all foreign subsidiaries. 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, 2020 and 2019. Assets located outside of the U.S. totaled approximately $9.2 million and $8.2 million at September 30, 2020 and 2019, 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 2020 and 2019, comprehensive loss is equivalent to the reported net loss.

Recently adopted accounting pronouncements: In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-02, Leases (Topic 842), which requires that lessees recognize an ROU asset and a lease liability for all leases with lease terms greater than twelve months in the balance sheet. ASU 2016-02 distinguishes leases as either a finance lease or an operating lease, which affects how the leases are measured and presented in the statement of operations and statement of cash flows, and requires disclosure of key information about leasing arrangements. A modified retrospective transition approach is required upon adoption. 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. In December 2018, the FASB issued ASU 2018-20, Leases (Topic 842): Narrow-Scope Improvements for Lessors to address certain implementation issues facing lessors when adopting ASU 2016-02. In March 2019, the FASB issued ASU 2019-01, Leases (Topic 842): Codification Improvements to address, among other things, certain transition disclosure requirements subsequent to the adoption of ASU 2016-02.

The Company adopted the new lease accounting standard using the modified retrospective approach on October 1, 2019 and elected certain practical expedients, including the optional transition method that allows for the application of the new standard at its adoption date with no restatement of prior period amounts. We elected the package of practical expedients permitted under the transition guidance, which allowed us to not reassess our prior conclusions about lease identification, lease classification, and initial direct costs. Adoption of the new standard resulted in the recording of ROU assets and lease liabilities of approximately $1.2 million and $1.5 million, respectively, and the derecognition of prepaid expenses and operating lease deferred rent liabilities of $23,000 and $247,000, respectively, as of October 1, 2019 with zero cumulative-effect adjustment to retained earnings. The new standard did not materially impact our consolidated statement of operations or cash flows.

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 previously only included 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. 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. We adopted ASU 2018-07 effective October 1, 2019. The adoption of ASU 2018-07 did not have a material impact on our consolidated financial statements and related disclosures.

Recent accounting pronouncements not yet adopted: 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 implied 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 and will be applied on a prospective basis. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. We do not expect the adoption of ASU 2017-04 to have a material effect on our financial position or results of operations.

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 will be applied retrospectively for all periods presented. 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.

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740). Simplifying the Accounting for Income Taxes. The new guidance eliminates certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period, and the recognition of deferred tax liabilities for outside basis differences. It also clarifies and simplifies other aspects of the accounting for income taxes. ASU 2019-12 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020 and the applicable amendments will be applied on a prospective basis. Early adoption is permitted. The adoption of ASU 2019-12 is not expected to have a material effect on our consolidated financial statements and related disclosures.

**Note 2 – 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 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 drug candidates and obtain regulatory approvals. The Company's future capital requirements will depend on many factors.

The Company believes its current cash position and cash expected to be generated from sales of the Company's commercial product are adequate to fund planned operations of the Company for the next 12 months. To the extent the Company may need additional capital for its operations, it may access financing alternatives that 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 current effective shelf registration statement on Form S-3 (File No. 333-239493). The Company intends to be opportunistic when pursuing equity or debt financing which could include selling common stock under its common stock purchase agreement with Aspire Capital Fund, LLC (see Note 10).

**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 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.

There were no transfers between Level 1, Level 2 and Level 3 during fiscal 2020 and 2019.

Amounts capitalized as IPR&D are subject to impairment testing until the completion or abandonment of the associated research and development efforts. During the fourth quarter of fiscal 2020, we recognized an impairment charge of $14.1 million associated with IPR&D intangible assets acquired in connection with the APP Acquisition. For the year ended September 30, 2020 we used probability-adjusted discounted cash flow calculations using Level 3 fair value measurements and inputs including estimated revenues, costs, probability of technical and regulatory success and discount rates to measure the impairment. See Note 8 for additional information.

As of September 30, 2020 and 2019, 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 determines the fair value of hybrid instruments based on available market data using appropriate valuation models, considering 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 years ended September 30, 2020 and 2019:

| | 2020 | 2019 |
|---|---|---|
| Beginning balance | $ 3,625,000 | $ 2,426,000 |
| Change in fair value of derivative liabilities | 557,000 | 1,199,000 |
| Ending balance | $ 4,182,000 | $ 3,625,000 |

The expense or income associated with the change in fair value of the embedded derivatives is presented as a separate line item in the accompanying consolidated statements of operations.

The liabilities associated with embedded derivatives represent the fair value of the change of control provisions in the Credit Agreement and Residual Royalty Agreement. See Note 9 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. 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. The increase in fair value of derivative liabilities in fiscal 2020 was driven by shifts in the estimated change of control dates, which brought the estimated change of control date closer to the balance sheet date, and an increase in the expected cash outflows under the Residual Royalty Agreement. The increase in fiscal 2019 was driven by an increase in the expected cash outflows under the Residual Royalty Agreement.

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, 2020 and 2019:

| | | Weighted Average (range, if applicable) | |
|---|---|---|---|
| Valuation Methodology | Significant Unobservable Input | 2020 | 2019 |
| Monte Carlo Simulation | Estimated change of control dates | December 2021 to June 2022 | September 2020 to December 2021 |
| | Discount rate | 14.1% to 16.0% | 14.4% to 16.8% |
| | Probability of change of control | 20% to 90% | 10% to 90% |

**Note 4 – Revenue from Contracts with Customers**

The Company generates nearly all its revenue from direct product sales. Revenue from direct product sales is generally recognized when the customer obtains control of the product, which occurs at a point in time, and may be upon shipment or upon delivery based on the contractual shipping terms of a contract. Sales taxes and other similar taxes that the Company collects concurrent with revenue-producing activities are excluded from revenue.

The amount of consideration the Company ultimately receives varies depending upon sales discounts, and other incentives that the Company may offer, which are accounted for as variable consideration when estimating the amount of revenue to recognize. The estimate of variable consideration requires significant judgment. The Company includes estimated amounts in the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved. The estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely upon an assessment of current contract sales terms and historical payment experience.

Product returns are typically not significant because returns are generally not allowed unless the product is damaged at time of receipt.

The Company's revenue is from sales of FC2 in the U.S. prescription channel and direct sales of FC2 in the global public health sector, and also included sales of PREBOOST® medicated wipes for the treatment of premature ejaculation. The following table presents net revenues from these three categories for the years ended September 30, 2020 and 2019:

| | 2020 | 2019 |
|---|---|---|
| FC2 | | |
| U.S. prescription channel | $ 27,124,462 | $ 14,083,368 |
| Global public health sector | 13,432,356 | 16,835,998 |
| Total FC2 | 40,556,818 | 30,919,366 |
| PREBOOST® | 2,035,242 | 884,021 |
| Net revenues | $ 42,592,060 | $ 31,803,387 |

The following table presents net revenue by geographic area for the years ended September 30, 2020 and 2019:

| | 2020 | 2019 |
|---|---|---|
| United States | $ 30,338,115 | $ 17,260,174 |
| Other | 12,253,945 | 14,543,213 |
| Net revenues | $ 42,592,060 | $ 31,803,387 |

The Company's performance obligations consist mainly of transferring control of products identified in the contracts which occurs either when: i) the product is made available to the customer for shipment; ii) the product is shipped via common carrier; or iii) the product is delivered to the customer or distributor, in accordance with the terms of the agreement. Some of the Company's contracts require the customer to make advanced payments prior to transferring control of the products. These advanced payments create a contract liability for the Company. The balances of the Company's contract liability, included in accrued expenses and other current liabilities on the accompanying consolidated balances sheets, was approximately $6,000 and $249,000 at September 30, 2020 and 2019, respectively.

The Company records an unearned revenue liability if a customer pays consideration for product that was shipped by the Company but revenue recognition criteria have not been met under the terms of a contract; for example, if a distributor has a right to return product sold under certain conditions. Unearned revenue is recognized as revenue after control of the product is transferred to the customer and all revenue recognition criteria have been met. The Company had no unearned revenue at September 30, 2020 or 2019.

The amount of revenue recognized that was included in the contract liabilities and unearned revenues balance at the beginning of the period was $249,000 and $191,000 during the years ended September 30, 2020 and 2019, respectively, after satisfying its contract obligations and transferring control.

**Note 5 – Accounts Receivable and Concentration of Credit Risk**

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 sales 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. For sales to the Company's distributor in Brazil, the Company has agreed to credit terms of up to 180 days subsequent to clearance of the product by the Ministry of Health in Brazil. The Company classified approximately $300,000 of trade receivables with its distributor in Brazil as long-term as of September 30, 2019, because payment was expected in greater than one year. The long-term portion of trade receivables is included in other assets on the accompanying consolidated balance sheet. No trade receivables are classified as long-term as of September 30, 2020.

The components of accounts receivable consist of the following at September 30, 2020 and 2019:

| | 2020 | 2019 |
|---|---|---|
| Trade receivables, gross | $ 5,332,786 | $ 5,410,165 |
| Less: allowance for doubtful accounts | (25,643) | (33,143) |
| Less: allowance for sales returns and payment term discounts | (79,906) | (49,623) |
| Less: long-term trade receivables* | — | (306,342) |
| Accounts receivable, net | $ 5,227,237 | $ 5,021,057 |

*Included in other assets on the accompanying consolidated balance sheets

No customer had a current accounts receivable balance that represented 10% of current assets at September 30, 2020 and 2019.

At September 30, 2020, three customers had an accounts receivable balance greater than 10% of net accounts receivable, representing 89% of net accounts receivable in the aggregate. At September 30, 2019, two customers had an accounts receivable balance greater than 10% of net accounts receivable and long-term trade receivables, representing 66% of the Company's net accounts receivable and long-term trade receivables in the aggregate.

For the year ended September 30, 2020, there were three customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 76% of the Company's net revenues in the aggregate. For the year ended September 30, 2019, there were three customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 64% of the Company's net revenues in the aggregate.

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, 2020 and 2019:

| | 2020 | 2019 |
|---|---|---|
| Beginning balance | $ 33,143 | $ 36,201 |
| Charges to expense | — | — |
| Charge-offs | (7,500) | (3,058) |
| Ending balance | $ 25,643 | $ 33,143 |

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 and, in the U.S. prescription channel, telemedicine providers.

**Note 6 – Inventory**

Inventory consisted of the following at September 30, 2020 and 2019:

| | 2020 | 2019 |
|---|---|---|
| FC2 | | |
| Raw material | $ 962,860 | $ 426,590 |
| Work in process | 106,272 | 187,970 |
| Finished goods | 5,634,612 | 3,157,952 |
| FC2, gross | 6,703,744 | 3,772,512 |
| Less: inventory reserves | (29,331) | (125,106) |
| FC2, net | 6,674,413 | 3,647,406 |
| PREBOOST® | | |
| Finished goods | 29,721 | — |
| Inventory, net | $ 6,704,134 | $ 3,647,406 |

**Note 7 – Property and Equipment**

Property and equipment consisted of the following at September 30, 2020 and 2019:

| | Estimated Useful Life | 2020 | 2019 |
|---|---|---|---|
| Property and equipment: | | | |
| Manufacturing equipment | 5 - 8 years | $ 2,752,854 | $ 2,716,647 |
| Office equipment, furniture and fixtures | 3 - 10 years | 803,484 | 795,228 |
| Leasehold improvements | 3 - 8 years | 298,886 | 298,886 |
| Total property and equipment | | 3,855,224 | 3,810,761 |
| Less: accumulated depreciation and amortization | | (3,542,533) | (3,458,866) |
| Property and equipment, net | | $ 312,691 | $ 351,895 |

Depreciation and amortization expense for the years ended September 30, 2020 and 2019 was $146,000 and $162,000, respectively.

In September 2019, the Company entered into a lease agreement for office space, which included a finance lease for office equipment, furniture, and fixtures. The value of the assets under finance lease was $44,000 at September 30, 2020 and 2019 and is included in office equipment, furniture and fixtures above.

**Note 8 –Intangible Assets and Goodwill**

Intangible Assets

Intangible assets acquired in the APP Acquisition included IPR&D, developed technology consisting of PREBOOST® medicated wipes for the treatment 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, 2020:

| | Gross Carrying Amount | Accumulated Amortization | Net Book Value |
|---|---|---|---|
| Intangible assets with finite lives: | | | |
| Developed technology - PREBOOST® | $ 2,400,000 | $ 768,111 | $ 1,631,889 |
| Covenants not-to-compete | 500,000 | 279,762 | 220,238 |
| Total intangible assets with finite lives | 2,900,000 | 1,047,873 | 1,852,127 |
| Acquired in-process research and development assets | 3,900,000 | — | 3,900,000 |
| Total intangible assets | $ 6,800,000 | $ 1,047,873 | $ 5,752,127 |

The gross carrying amounts and net book value of intangible assets are as follows at September 30, 2019:

| | Gross Carrying Amount | Accumulated Amortization | Net Book Value |
|---|---|---|---|
| Intangible assets with finite lives: | | | |
| Developed technology - PREBOOST® | $ 2,400,000 | $ 523,172 | $ 1,876,828 |
| Covenants not-to-compete | 500,000 | 208,333 | 291,667 |
| Total intangible assets with finite lives | 2,900,000 | 731,505 | 2,168,495 |
| Acquired in-process research and development assets | 18,000,000 | — | 18,000,000 |
| Total intangible assets | $ 20,900,000 | $ 731,505 | $ 20,168,495 |

During the fourth quarter of fiscal 2020, we performed quantitative impairment testing of our IPR&D intangible assets using a probability-weighted income approach that discounts expected future cash flows to present value. The estimated net cash flows were discounted using a discount rate of 41%, which is based on the estimated weighted-average cost of capital for companies with profiles similar to our profile and represents the rate that market participants would use to value the intangible assets. In response to management's strategic decision during the fourth quarter of fiscal 2020 to prioritize the development of other research projects, we adjusted the development timelines for Tamsulosin DRS, VERU-722 (male infertility), and VERU-112 (gout) IPR&D assets that were recognized as part of the APP Acquisition. The Company has several other highly differentiated, unique, patent-protected drugs under development addressing larger and potentially more profitable markets. The delay in timing of expected future cash flows for Tamsulosin DRS, VERU-722, and VERU-112 reduced the fair value of these IPR&D intangible assets to zero, which is significantly below the carrying value, resulting in an impairment charge of $14.1 million, which is presented as a separate line item in the accompanying consolidated statement of operations. Further, the Company has decided to cease its development work on Tamsulosin DRS, VERU-722, and VERU-112 and met the criteria for abandonment under the accounting standards. This resulted in writing off the carrying amounts for these three IPR&D assets during the year ended September 30, 2020.

Amortization was 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.

Amortization expense was approximately $316,000 and $309,000, for the years ended September 30, 2020 and 2019, respectively. Based on finite-lived intangible assets recorded as of September 30, 2020, the estimated future amortization expense is as follows:

| Year Ending September 30, | Estimated Amortization Expense |
|---|---|
| 2021 | $ 323,706 |
| 2022 | 331,316 |
| 2023 | 339,062 |
| 2024 | 281,603 |
| 2025 | 283,940 |
| Thereafter | 292,500 |
| Total | $ 1,852,127 |

Goodwill

The carrying amount of goodwill at September 30, 2020 and 2019 was $6.9 million. There was no change in the balance during the years ended September 30, 2020 and 2019.

**Note 9 – Debt**

SWK Credit Agreement

On March 5, 2018, the Company entered into a Credit Agreement (as amended, 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 provided the Company with a term loan of $10.0 million, which was advanced to the Company on the date of the Credit Agreement. 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 $10.0 million loan under 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 176.5% of the aggregate amount advanced to the Company under the Credit Agreement. If product revenue from net sales of FC2 for the 12-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 12-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 follows: (i) as it relates to each quarter during the 2019 calendar year, the sum of 12.5% 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 5% of product revenue from net sales of FC2 greater than $12.5 million in the Elapsed Period, (ii) as it relates to each quarter during the 2020 calendar year, the sum of 25% of product revenue from net sales of FC2 up to and including $12.5 million in the Elapsed Period, plus 10% of product revenue from net sales of FC2 greater than $12.5 million in the Elapsed Period, and (iii) as it relates to each quarter during the 2021 calendar year and thereafter, the sum of 30% of product revenue from net sales of FC2 up to and including $12.5 million in the Elapsed Period, plus 20% 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 176.5% of the aggregate amount advanced to the Company under the Credit Agreement less the amounts previously paid by the Company from product revenue. The payment requirements described above reflect an amendment to the Credit Agreement dated May 13, 2019 (the "Second Amendment") which included a reduction to the percentages to be used to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar year 2019, a return to the original percentages to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar year 2020 and an increase to the percentages to be used to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar year 2021 and thereafter until the loan has been repaid.

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) 176.5% of the aggregate amount advanced to the Company under the Credit Agreement less the amounts previously paid by the Company from product revenue from net sales of FC2, 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 (as amended, the "Residual Royalty Agreement"), which provides for an ongoing royalty payment of 5% of product revenue from net sales of FC2 commencing after the Company would have paid 175% of the aggregate amount advance to the Company under the Credit Agreement based on a calculation of revenue-based payments under the Credit Agreement without taking into account the amendments to the payment requirements under the Credit Agreement effected by the Second Amendment. 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 or sale of the FC2 business occurs prior to payment in full of the Credit Agreement, there will be no further payment due with respect to the Residual Royalty Agreement. If a change of control or sale of the FC2 business occurs after 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 Female Health Company Limited, a wholly-owned U.K. subsidiary.

For accounting purposes, the $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 are adjusted to fair market value at each 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 $11.3 million, 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 of the Credit Agreement obligation and are being amortized to interest expense over the expected term of the loan using the effective interest method. The Second Amendment was accounted for as a debt modification, which resulted in prospective adjustment to the effective interest rate.

At September 30, 2020 and 2019, the Credit Agreement liability consisted of the following:

| | 2020 | 2019 |
|---|---|---|
| Aggregate repayment obligation | $ 17,650,000 | $ 17,650,000 |
| Less: cumulative payments | (10,314,495) | (5,578,085) |
| Remaining repayment obligation | 7,335,505 | 12,071,915 |
| Less: unamortized discounts | (1,459,330) | (4,590,974) |
| Less: unamortized deferred issuance costs | (34,301) | (107,910) |
| Credit agreement, excluding embedded derivative liability, net | 5,841,874 | 7,373,031 |
| Add: embedded derivative liability at fair value (see Note 3) | — | 899,000 |
| Credit agreement, net | 5,841,874 | 8,272,031 |
| Credit agreement, short-term portion | (5,841,874) | (5,385,649) |
| Credit agreement, long-term portion | $ — | $ 2,886,382 |

The Company currently estimates the remaining repayment obligation will be paid during the 12-month period subsequent to September 30, 2020.

At September 30, 2020 and 2019, the Residual Royalty Agreement liability consisted of the following:

| | 2020 | 2019 |
|---|---|---|
| Residual royalty agreement liability, fair value at inception | $ 346,000 | $ 346,000 |
| Add: accretion of liability using effective interest rate | 2,189,687 | 773,518 |
| Residual royalty agreement liability, excluding embedded derivative liability | 2,535,687 | 1,119,518 |
| Add: embedded derivative liability at fair value (see Note 3) | 4,182,000 | 2,726,000 |
| Total residual royalty agreement liability | 6,717,687 | 3,845,518 |
| Residual royalty agreement liability, short-term portion | (1,100,193) | — |
| Residual royalty agreement liability, long-term portion | $ 5,617,494 | $ 3,845,518 |

The short-term portion of the Residual Royalty Agreement liability represents the aggregate of the estimated quarterly royalty payments payable during the 12-month period subsequent to September 30, 2020.

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 years ended September 30, 2020 and 2019, interest expense related to the Credit Agreement and Residual Royalty Agreement was as follows:

| | 2020 | 2019 |
|---|---|---|
| Amortization of discounts | $ 3,131,644 | $ 4,037,320 |
| Accretion of residual royalty agreement | 1,416,169 | 572,293 |
| Amortization of deferred issuance costs | 73,609 | 96,443 |
| Interest expense | $ 4,621,422 | $ 4,706,056 |

Premium Finance Agreement

On November 1, 2019, the Company entered into an agreement to finance $837,000 of its directors and officers liability insurance premium at an annual percentage rate of 4.18%. The financing agreement was payable in three quarterly installments of principal and interest, which began on January 1, 2020. The last payment was made on July 1, 2020 and there is no balance outstanding as of September 30, 2020.

**Note 10 – Stockholders' Equity**

Preferred Stock

The Company has 5,000,000 shares designated as Class A Preferred Stock with a par value of $0.01 per share. There are 1,040,000 shares of Class A Preferred Stock – Series 1 authorized; 1,500,000 shares of Class A Preferred Stock – Series 2 authorized; 700,000 shares of Class A Preferred Stock – Series 3 authorized; and 548,000 shares of Class A Preferred Stock – Series 4 authorized. There were no shares of Class A Preferred Stock of any series issued and outstanding at September 30, 2020 or September 30, 2019, and there was no activity during the years then ended. 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, 2020 or September 30, 2019, and there was no activity during the years then ended.

Common Stock

We are authorized to issue up to 154,000,000 shares of common stock, $0.01 par value per share. On March 27, 2019, following approval by stockholders at the Company's annual meeting of stockholders held on March 26, 2019, the Company filed an amendment to its articles of incorporation to increase the number of authorized shares of common stock from 77,000,000 to 154,000,000 shares. Holders are entitled to one vote for each share of common stock.

Shelf Registration Statements

In June 2020, the Company filed a shelf registration statement on Form S-3 (File No. 333-239493) with a capacity of $150 million, which was declared effective by the Securities and Exchange Commission ("SEC") on July 1, 2020. In August 2020, the Company terminated its shelf registration statement on Form S-3 (File No. 333-221120) originally filed in 2017, and as a result no additional securities will be sold under that registration statement.

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. Net proceeds to the Company from this offering were $9.1 million after deducting underwriting discounts and commissions and costs paid by the Company. All of the shares sold in the offering were by the Company. The offering was made pursuant to the Company's 2017 shelf registration statement on Form S-3 (File No. 333-221120).

Common Stock Purchase Warrants

In connection with the closing of the APP Acquisition, the Company issued warrants 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 Warrants"). The Financial Advisor Warrants have a five-year term expiring October 31, 2021, a cashless exercise feature and an exercise price equal to $1.93 per share. The Financial Advisor Warrants vested upon issuance. During the third quarter of fiscal 2020, one of the Financial Advisor Warrants to purchase 258,538 shares of the Company's common stock was exercised using the cashless exercise feature, resulting in the issuance of 109,143 shares of common stock. As of September 30, 2020, an aggregate of 2,326,841 shares of common stock remain available for purchase under the Financial Advisor Warrants.

Aspire Capital Purchase Agreements

On June 26, 2020, the Company entered into a common stock purchase agreement (the "2020 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 2020 Purchase Agreement, to direct Aspire Capital to purchase up to $23.9 million of the Company's common stock in the aggregate. Concurrently with entering into the 2020 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 one or more 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 2020 Purchase Agreement.

Under the 2020 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 equal to up to 30% of the aggregate shares of the common stock traded on its principal market on the next trading day (the "VWAP Purchase Date"), subject to a maximum number of shares the Company may determine. The purchase price per share pursuant to such VWAP Purchase Notice is generally 97% of the volume-weighted average price for the Company's common stock traded on its principal market on the VWAP Purchase Date.

In consideration for entering into the 2020 Purchase Agreement, concurrently with the execution of the 2020 Purchase Agreement, the Company issued to Aspire Capital 212,130 shares of the Company's common stock. The shares of common stock issued as consideration were valued at $681,000, based on the closing price per share of the Company's common stock on the date the shares were issued. This amount and related expenses of $50,000, which total approximately $731,000, were recorded as deferred costs. As of September 30, 2020, the amount remaining under the 2020 Purchase Agreement was $18.9 million, which is registered under the Company's 2020 shelf registration statement on Form S-3 (File No. 333-239493).

Upon execution of the 2020 Purchase Agreement, the Company issued and sold 1,644,737 shares of common stock to Aspire Capital under the 2020 Purchase Agreement, resulting in proceeds to the Company of $5 million. As a result of this sale, we recorded approximately $153,000 of deferred costs to additional paid-in capital. The unamortized amount of deferred costs related to the 2020 Purchase Agreement of $578,000 at September 30, 2020 is included in other assets on the accompanying consolidated balance sheet.

Effective June 26, 2020, upon the execution of the 2020 Purchase Agreement, the Company's prior purchase agreement with Aspire Capital dated December 29, 2017 (the "2017 Purchase Agreement") was terminated. Under the 2017 Purchase Agreement, the Company had the right, upon the terms and subject to the conditions and limitations set forth therein, from time to time in its sole discretion during the 36-month term of the 2017 Purchase Agreement, to direct Aspire Capital to purchase up to $15.0 million of the Company's common stock in the aggregate. As of the date of termination of the 2017 Purchase Agreement, the Company had sold an aggregate of 6,214,343 shares of common stock to Aspire Capital resulting in proceeds to the Company of $15.0 million.

We sold 2,497,333 and 2,000,000 shares of common stock to Aspire Capital under the 2017 Purchase Agreement during the years ended September 30, 2020 and 2019, respectively, resulting in proceeds to the Company of $8.4 million and $3.6 million, respectively. As a result of these sales, we recorded approximately $238,000 and $102,000, respectively, of deferred costs to additional paid-in capital.

In consideration for entering into the 2017 Purchase Agreement, concurrently with the execution of the 2017 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, based on the closing price per share of the Company's common stock on the date the shares were issued. This amount and related expenses of approximately $78,000, which total approximately $425,000, were recorded as deferred costs. All deferred costs related to the 2017 Purchase Agreement have been amortized to additional paid-in capital as of June 30, 2020. The unamortized amount of deferred costs related to the 2017 Purchase Agreement of $238,000 at September 30, 2019 is included in other assets on the accompanying consolidated balance sheet.

**Note 11 – Share-based Compensation**

We allocate share-based compensation expense to cost of sales, selling, general and administrative expense and research and development expense based on the award holder's employment function. We recorded income tax benefits for share-based compensation expense of approximately $599,000 and $431,000 in fiscal 2020 and 2019, respectively. For fiscal 2020 and 2019, we recorded share-based compensation expenses as follows:

| | 2020 | 2019 |
|---|---|---|
| Cost of sales | $ 52,267 | $ 38,026 |
| Selling, general and administrative | 1,905,192 | 1,471,391 |
| Research and development | 688,787 | 396,681 |
| | $ 2,646,246 | $ 1,906,098 |

We have issued share-based awards to employees and non-executive directors under the Company's approved equity plans. Upon the exercise of share-based awards, new shares are issued from authorized common stock.

Equity Plans

In March 2018, the Company's stockholders approved the Company's 2018 Equity Incentive Plan (the "2018 Plan"). On March 24, 2020, the Company's stockholders approved an increase in the number of shares that may be issued under the 2018 Plan to 11.0 million. As of September 30, 2020, 5,901,322 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, 2020, 103,247 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 closing price per share 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, 2020 and 2019:

| | 2020 | 2019 |
|---|---|---|
| Weighted Average Assumptions: | | |
| Expected Volatility | 63.13% | 65.85% |
| Expected Dividend Yield | 0.00% | 0.00% |
| Risk-free Interest Rate | 1.63% | 2.36% |
| Expected Term (in years) | 5.9 | 5.9 |
| Fair Value of Options Granted | $ 1.14 | $ 0.93 |

During the years ended September 30, 2020 and 2019, 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, 2020:

| | Number of Shares | Weighted Average Exercise Price Per Share | Weighted Average Remaining Contractual Term (years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding at September 30, 2019 | 7,027,989 | $ 1.58 | | |
| Granted | 2,228,827 | 1.97 | | |
| Exercised | (441,548) | 1.67 | | |
| Forfeited | (216,268) | 1.59 | | |
| Outstanding at September 30, 2020 | 8,599,000 | $ 1.67 | 7.76 | $ 8,174,898 |
| Exercisable at September 30, 2020 | 4,565,615 | $ 1.52 | 6.93 | $ 5,036,148 |

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, 2020 of $2.62, less the respective weighted average exercise price per share at period end.

The total intrinsic value of options exercised was approximately $1.1 million and $274,000 during the years ended September 30, 2020 and 2019, respectively. Cash received from options exercised was $415,000 and $333,000 in the years ended September 30, 2020 and 2019, respectively. During the years ended September 30, 2020 and 2019, options to purchase 223,415 and 120,716 shares of common stock, respectively, were exercised using the cashless exercise feature available under the 2017 Plan and 2018 Plan, which resulted in the issuance of 143,958 and 36,208 shares of common stock, respectively.

As of September 30, 2020, the Company had unrecognized compensation expense of approximately $2.7 million related to unvested stock options. This expense is expected to be recognized over approximately 3 years.

During fiscal 2019, 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 stock options were primarily modified to accelerate vesting to the date of termination or retirement. The aggregate amount of expense recognized in connection with these modifications for the year ended September 30, 2019 was approximately $53,000.

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 vested on October 31, 2018. The stock appreciation rights have a ten-year term and an exercise price per share of $0.95, which was the closing price of a share of the Company's common stock as quoted on NASDAQ on the trading day immediately preceding the date of the completion of the APP Acquisition. Upon exercise, the stock appreciation rights will be settled in common stock issued under the 2017 Plan. During the year ended September 30, 2019, stock appreciation rights based on 140,000 shares of the Company's common stock were exercised resulting in the issuance of 77,559 shares of common stock. As of September 30, 2020 and 2019, vested stock appreciation rights based on 50,000 shares of common stock remain outstanding.

**Note 12 – Leases**

The Company has operating leases for its office, manufacturing and warehouse space, and office equipment. The Company has a finance lease for office equipment, furniture, and fixtures. The Company does not have any leases that have not yet commenced as of September 30, 2020.

Corporate Headquarters

On June 20, 2019, the Company executed a lease for its new corporate headquarters in Miami, Florida. Under the terms of the lease, which was amended on August 13, 2019, the Company is leasing approximately 4,640 square feet of office space for a 30-month term commencing on September 1, 2019 and ending on February 27, 2022. Annual base rent payments are $33.00 per square foot and are subject to a 2.9% annual escalation on September 1 of each subsequent year. Based on the terms of the lease agreement, the Company paid a security deposit of approximately $12,000. The lease included a finance lease for office equipment, furniture, and fixtures.

Under the lease for the Company's former headquarters in Miami, Florida, the Company leased approximately 3,900 square feet of office space for a three-year term commencing on November 1, 2016 and ending on October 31, 2019. The Company executed the lease for this office space effective October 31, 2016 and amended the lease in June 2017. Effective with the June 2017 amendment, annual base rent payments were $36.00 per square foot and were subject to a 4% annual escalation on November 1 of each subsequent year. The lease also required payment of related expenses, including real estate taxes, common area maintenance and insurance. The Company had two renewal options to extend the term for a period of three years each. The Company did not renew the lease agreement and it terminated on October 31, 2019.

Chicago Lease

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. Annual 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 paid 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 increases in September of each year and will increase to approximately $17,300 per month in the final year of the sublease. Sublease income is recognized as a reduction to operating lease costs as the sublease is outside of the Company's normal business operations. This is consistent with the Company's recognition of sublease income prior to the adoption of FASB ASC Topic 842. 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.

International Leases

The Company leases approximately 6,400 square feet of office space located in London, England. The Company executed this lease in June 2010, for a ten-year term, which ended in June 2020 and was extended through August 2020. The lease required quarterly payments of approximately $24,100. Based on the terms of the lease agreement, the Company paid a security deposit of approximately $58,000. The lease was renewed effective August 2020 with a five year term and a tenant's option to cancel after three years with no penalty to the Company. It is reasonably certain that the Company will exercise that option. The renewed lease requires quarterly payments of approximately $41,100. The security deposit under the original lease did not change.

The Company leases 45,800 square feet of manufacturing and warehouse space in Selangor D.E., Malaysia. The Company executed the lease for this space in August 2019, for a three-year term commencing September 1, 2019 and ending August 31, 2022. The Company has an option to extend the term of the lease for a period of three years and it is reasonably certain that the Company will exercise that option. The lease requires monthly payments of approximately $15,400. Based on the terms of the lease agreement, the Company maintains a security deposit of approximately $46,000.

Certain of our lease agreements include variable lease payments for common area maintenance, real estate taxes, and insurance or based on usage for the office equipment leases. The components of the Company's lease cost were as follows for the year ended September 30, 2020:

| | 2020 |
|---|---|
| Finance lease cost: | |
| Amortization of right-of-use assets | $ 8,713 |
| Interest on lease liabilities | 5,189 |
| Operating lease cost | 496,803 |
| Short-term lease cost | 7,452 |
| Variable lease cost | 153,852 |
| Sublease income | (179,915) |
| Total lease cost | $ 492,094 |

The Company paid cash of $479,000 for amounts included in the measurement of operating lease liabilities during the year ended September 30, 2020. The Company's operating lease ROU assets and related lease liabilities are presented as separate line items on the accompanying consolidated balance sheet as of September 30, 2020. The Company's finance lease ROU asset was $34,000 as of September 30, 2020 and is included in property and equipment, net on the accompanying unaudited condensed consolidated balance sheet. The current and long-term finance lease liabilities were $21,000 and $8,000, respectively, and are included in accrued expenses and other current liabilities and other liabilities, respectively, on the accompanying consolidated balance sheet as of September 30, 2020.

Other information related to the Company's leases as of September 30, 2020 was as follows:

| | 2020 |
|---|---|
| **Operating Leases** | |
| Weighted-average remaining lease term | 3.6 |
| Weighted-average discount rate | 11.5% |
| **Finance Leases** | |
| Weighted-average remaining lease term | 1.4 |
| Weighted average discount rate | 13.9% |

The Company's lease agreements do not provide a readily determinable implicit rate. Therefore, the Company estimates its incremental borrowing rate based on information available at lease commencement in order to discount lease payments to present value.

As of September 30, 2020, maturities of lease liabilities were as follows:

| | Operating Leases | Finance Leases | Sublease Income |
|---|---|---|---|
| **Fiscal year ended September 30,** | | | |
| 2021 | $ 621,661 | $ 22,200 | $ 198,668 |
| 2022 | 520,086 | 9,496 | 203,583 |
| 2023 | 424,152 | — | 190,749 |
| 2024 | 196,963 | — | — |
| 2025 | 169,577 | — | — |
| Thereafter | — | — | — |
| Total lease payments | 1,932,439 | 31,696 | $ 593,000 |
| Less imputed interest | (355,650) | (3,168) | |
| Total lease liabilities | $ 1,576,789 | $ 28,528 | |

Under FASB ASC 840, the lease accounting guidance prior to the Company's adoption of FASB ASC 842, the Company recognized operating lease expense of approximately $683,000 for the year ended September 30, 2019. The Company had net capital lease assets of $43,000 included in property and equipment, net and a related capital lease obligation of $42,000 included in accrued expenses and other current liabilities and other liabilities on the accompanying consolidated balance sheet as of September 30, 2019.

Under FASB ASC 840, future minimum payments under operating leases consist of the following as of September 30, 2019:

| | Operating Leases | Sublease Income | Net Total |
|---|---|---|---|
| 2020 | $ 469,002 | $ 193,753 | $ 275,249 |
| 2021 | 433,751 | 198,668 | 235,083 |
| 2022 | 337,456 | 203,584 | 133,872 |
| 2023 | 114,493 | 190,749 | (76,256) |
| 2024 | 11,238 | — | 11,238 |
| Total minimum lease payments | $ 1,365,940 | $ 786,754 | $ 579,186 |

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 13 – 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

From time to time we may be involved in litigation or other contingencies arising in the ordinary course of business. Based on the information presently available, management believes there are no contingencies, claims or actions, pending or threatened, the ultimate resolution of which will have a material adverse effect on our financial position, liquidity or results of operations.

In accordance with FASB ASC 450, Contingencies, we accrue loss contingencies including costs of settlement, damages and defense related to litigation to the extent they are probable and reasonably estimable. Otherwise, we expense these costs as incurred. If the estimate of a probable loss is a range and no amount within the range is more likely, we accrue the minimum amount of the range.

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 future milestones is not reasonably estimable, we have not recorded a liability in the accompanying consolidated financial statements for any of these contingencies.

**Note 14 – 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 (NOL) 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.

The Tax Act repealed the alternative minimum tax (AMT) for corporations. The law provided that AMT carryovers could be utilized to reduce or eliminate the tax liability in subsequent years or to obtain a tax refund. The Company had $0.5 million of its AMT credit carryovers in prepaid expenses and other current assets and other assets due to the expectation that the AMT credits will be refundable over the next several years as of September 30, 2019. The Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), which was enacted on March 27, 2020, accelerated the ability to claim a refund of the entire refundable credit to 2018, with an election when filing. The Company received the refund of $0.5 million in August 2020.

The Tax Act also limited the annual net interest deduction to 30% of the Company's adjusted taxable income (ATI), beginning in 2018. Any excess may be carried over and offset taxable income in a future year within the allowable limit. The CARES Act raised the limit on business interest deductions from 30% of ATI to 50% of ATI for the 2019 and 2020 tax years. However, the Tax Act also provided an exemption for qualified small businesses or businesses with average gross receipts of $25 million or less for the three previous tax years. The Company was not subject to the limitation in prior years because it qualified as a small business. Beginning fiscal 2020, the Company no longer qualifies for the exemption and recorded a deferred tax asset for $0.9 million.

In the U.K., the corporation tax rate was scheduled to decline from 19% to 17% commencing April 1, 2020. In March 2020, the U.K. government announced the U.K. tax rate would remain at 19%, which was enacted in July 2020 upon Royal Assent of the Finance Act 2020. The increase in the tax rate increased the value of the deferred tax assets in the U.K. to the newly enacted tax rate, which resulted in a $1.3 million income tax benefit for the year ended September 30, 2020.

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 NOL 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. From fiscal 2006 through fiscal 2015, the Company generated taxable income on a consolidated basis. However, the Company had a cumulative pretax loss in the U.S. for fiscal 2020 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 pretax losses in the U.S. driven by the investment in research and development, and based on their analysis concluded that an additional valuation allowance of $4.1 million should be recorded against the U.S. deferred tax assets related to federal and state NOL carryforwards as of September 30, 2020. As of September 30, 2020 and 2019 respectively, the Company has recorded a valuation allowance of $11.7 million and $7.6 million against U.S. deferred tax assets. In addition, the Company's U.K. holding company for the non-U.S. operating companies, The Female Health Company Limited, continues to have a full valuation allowance of $2.4 million. 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.

The Tax Act caused NOLs generated in taxable years ending after December 31, 2017 to have an indefinite carryforward period. Indefinite-lived intangibles such as the IPR&D assets that are recorded as U.S. deferred tax liabilities or "naked credits" could be utilized as a source of taxable income against those NOLs. The U.S. has a full valuation allowance except to the extent the naked credits are expected to reverse and generate indefinite-lived NOLs. The Company had $18 million in IPR&D assets that represented $4.1 million in deferred tax liabilities as of September 30, 2019. The $14.1 million impairment of the IPR&D assets recognized in the year ended September 30, 2020 resulted in additional tax expense and in increase in the valuation allowance of $3.2 million as of September 30, 2020. The IPR&D deferred tax liability balance as of September 30, 2020 is $0.9 million.

As of September 30, 2020, the Company had U.S. federal and state NOL carryforwards of approximately $41.7 million and $25.7 million, respectively, for income tax purposes with $13.5 million and $19.8 million, respectively, expiring in years 2022 to 2038 and $28.2 million and $5.9 million, respectively, which can be carried forward indefinitely. The Company's U.K. subsidiary has U.K. NOL carryforwards of approximately $61.3 million as of September 30, 2020, which can be carried forward indefinitely to be used to offset future U.K. taxable income.

Income (loss) before income taxes was taxed by the following jurisdictions for the years ended September 30, 2020 and 2019:

| | 2020 | 2019 |
|---|---|---|
| Domestic | $ (20,008,999) | $ (12,838,076) |
| Foreign | (42,977) | 516,777 |
| Total | $ (20,051,976) | $ (12,321,299) |

A reconciliation between the effective tax rate and the U.S. statutory rate and the related income tax benefit is as follows:

| | 2020 | | 2019 | |
|---|---|---|---|---|
| | Amount | Tax Rate | Amount | Tax Rate |
| Income tax benefit at U.S. federal statutory rates | $ (4,210,916) | 21.0 % | $ (2,587,472) | 21.0 % |
| State income tax benefit, net of federal benefits | (326,045) | 1.6 | (200,385) | 1.6 |
| Effect of change in U.K. tax rate | (1,337,263) | 6.7 | — | — |
| Non-deductible expenses – other | 114,699 | (0.6) | 8,171 | (0.1) |
| Effect of foreign income tax rates | 238,645 | (1.2) | 67,637 | (0.5) |
| Effect of global intangible low-taxed income | 143,219 | (0.7) | 99,514 | (0.8) |
| Effect of change in state tax rate | — | — | 57,981 | (0.5) |
| Other | 54,689 | (0.2) | 51,490 | (0.4) |
| Change in valuation allowance | 4,244,531 | (21.2) | 2,199,131 | (17.8) |
| Income tax benefit | $ (1,078,441) | 5.4 % | $ (303,933) | 2.5 % |

The federal and state income tax (benefit) expense for the years ended September 30, 2020 and 2019 is summarized below:

| | 2020 | 2019 |
|---|---|---|
| Deferred – U.S. | $ (229,313) | $ (552,018) |
| Deferred – U.K. | (1,033,131) | 76,246 |
| Deferred – Malaysia | 7,432 | 37,708 |
| Subtotal | (1,255,012) | (438,064) |
| | | |
| Current – U.S. | (10,484) | (2,728) |
| Current – Malaysia | 187,055 | 136,859 |
| Subtotal | 176,571 | 134,131 |
| | | |
| Income tax benefit | $ (1,078,441) | $ (303,933) |

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

| | 2020 | 2019 |
|---|---|---|
| **Deferred tax assets:** | | |
| Federal net operating loss carryforwards | $ 8,759,589 | $ 8,971,569 |
| State net operating loss carryforwards | 1,682,104 | 1,689,536 |
| AMT credit carryforward | — | 35,180 |
| Foreign net operating loss carryforwards – U.K. | 11,655,853 | 10,486,476 |
| Foreign capital allowance – U.K. | 113,522 | 103,400 |
| U.K. bad debts | 1,900 | 1,700 |
| Share-based compensation – U.K. | 91,839 | 49,081 |
| U.S. deferred rent | 40,236 | 43,558 |
| Share-based compensation | 1,255,983 | 804,378 |
| Interest expense | 850,248 | — |
| Other, net – U.S. | 334,706 | 356,026 |
| Gross deferred tax assets | 24,785,980 | 22,540,904 |
| Valuation allowance for deferred tax assets | (14,074,740) | (9,830,209) |
| Net deferred tax assets | 10,711,240 | 12,710,695 |
| **Deferred tax liabilities:** | | |
| In process research and development | (882,427) | (4,072,740) |
| Developed technology | (369,237) | (424,657) |
| Covenant not-to-compete | (49,832) | (65,993) |
| Other, net – Malaysia | (11,297) | (3,865) |
| Other | (6,371) | (6,376) |
| Net deferred tax liabilities | (1,319,164) | (4,573,631) |
| **Net deferred tax asset** | $ 9,392,076 | $ 8,137,064 |

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

| | 2020 | 2019 |
|---|---|---|
| Long-term deferred tax asset – U.K. | $ 9,466,800 | $ 8,433,669 |
| Total long-term deferred tax asset | $ 9,466,800 | $ 8,433,669 |
| | | |
| Long-term deferred tax liability – U.S. | $ (63,427) | $ (292,740) |
| Long-term deferred tax liability – Malaysia | (11,297) | (3,865) |
| Total long-term deferred tax liability | $ (74,724) | $ (296,605) |

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 2017 through 2019, which expire in years 2021 through 2023, 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 2015 through 2019, which expire on December 31, 2020 through 2024.

- 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 2019, which expires in 2021.

The fiscal 2020 tax returns for all jurisdiction have not been filed as of the date of this filing. As of September 30, 2020 and 2019, 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, 2020 and 2019.

**Note 15 – Paycheck Protection Program**

The CARES Act established the Paycheck Protection Program (PPP) administered by the U.S. Small Business Administration (SBA), which authorized forgivable loans to small businesses. Pursuant to the CARES Act, PPP loans will be fully forgiven if the funds are used for payroll costs, rent and utilities, subject to certain conditions, including maintaining employees and maintaining salary levels. In April 2020, the Company applied for a PPP loan and received funding of approximately $540,000. The Company expended the funds received under the PPP in full on qualifying expenses, and maintained the conditions set forth by the PPP. The Company submitted its application for forgiveness in September 2020 and the SBA approved the forgiveness of the full amount of the loan and the related interest on November 10, 2020. For accounting purposes, the Company treated the PPP loan as a government grant. As a result, the Company recorded a reduction to selling, general and administrative expenses of approximately $420,000 and a reduction to payroll-related research and development expenses of approximately $120,000 related to these funds within the consolidated statement of operations for the year ended September 30, 2020.

**Note 16 – 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. See Notes 10 and 11 for a discussion of these potentially dilutive instruments. Due to our net loss for the periods presented, all potentially dilutive instruments were excluded because their inclusion would have been anti-dilutive. Therefore, the number of shares used to calculate basic net loss per common share is also used for the diluted net loss per share calculation.

**Note 17 – Industry Segments**

The Company currently operates in two reporting segments: Sexual Health Business and Research and Development. The Sexual Health Business segment consists of the Company's commercial products: FC2 and PREBOOST®. Historically, this segment was referred to as the Commercial segment. The Research and Development segment consists of multiple drug products under clinical development. The Company's Sexual Health Business segment will include future revenues for TADFYN®. Costs associated with the development of TADFYN® are currently included in the Research and Development segment. 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.

The Company's operating income (loss) by segment is as follows:

| | 2020 | 2019 |
|---|---|---|
| Sexual health business | $ 26,495,126 | $ 16,699,875 |
| Research and development | (16,871,057) | (13,973,938) |
| Corporate | (24,370,763) | (9,161,831) |
| Operating loss | $ (14,746,694) | $ (6,435,894) |

All of our net revenues, which are primarily derived from the sale of FC2, are attributed to our Sexual Health Business reporting segment. See Note 4 for additional information regarding our net revenues. Costs related to the office located in London, England are fully dedicated to FC2 and are presented as a component of the Sexual Health Business segment. Drug commercialization costs, which were previously included in the Commercial segment, are now included in the Research and Development segment to reflect the changes to the Company's internal organization, and prior period results have been reclassified to conform to the current period presentation. The impairment of intangible assets and 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 18 – 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 $119,000 and $121,000 for the years ended September 30, 2020 and 2019, respectively.

In March 2014, the Company elected to contribute 3% of eligible employee compensation into the personal pension schemes of certain senior U.K. employees. Effective January 1, 2019, this contribution amount was increased to 4%. Company contributions were approximately $33,000 and $29,000 for the years ended September 30, 2020 and 2019, respectively.

**Note 19 – Related Party Transactions**

K. Gary Barnette, the Company's Chief Scientific Officer, holds a 25% equity interest in a company from which APP purchased intellectual property assets relating to our Tamsulosin DRS drug candidate in 2016. We have notified the company of our intention to cease development work on Tamsulosin DRS and we do not expect to make any payments to this company in the future. We did not make any payments to this company during the years ended September 30, 2020 and 2019.

**Note 20 – Subsequent Events**

On December 8, 2020 the Company entered into an Asset Purchase Agreement with Roman Health Ventures Inc. to sell its PREBOOST® business. The transaction closed on December 8, 2020. The purchase price was $20.0 million, consisting of $15.0 million paid at closing, $2.5 million payable 12 months after closing and $2.5 million payable 18 months after closing. The Company expects to record an after-tax gain of approximately $18.3 million on the transaction. The Company intends to use the net proceeds from the sale for working capital and general corporate purposes, which will include research and development, and clinical trial activities for our drug candidates.

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# CORPORATE INFORMATION

## OFFICERS

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

Michele Greco, CPA
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

Aaftine Antillon
Vice President of Finance

Gary Bird, Ph.D.
Executive Vice President–
Quality and Regulatory Affairs

Robert Getzenberg, Ph.D.
Executive Vice President–
Medical Affairs

Kevin Gilbert, J.D., CPA
Executive Vice President–
Corporate Development

Philip Greenberg, J.D.
Executive Vice President–
Legal and Secretary

Phillip Kuhn, MBA
Executive Vice President–
Strategy and Commercialization

Alistair Rawson, LLB, MBA
Executive Vice President–
Operations, GPS Sales

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

Martin Tayler
Executive Vice President–
FC2 Global Operations

## BOARD OF DIRECTORS

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President and Chief Executive Officer
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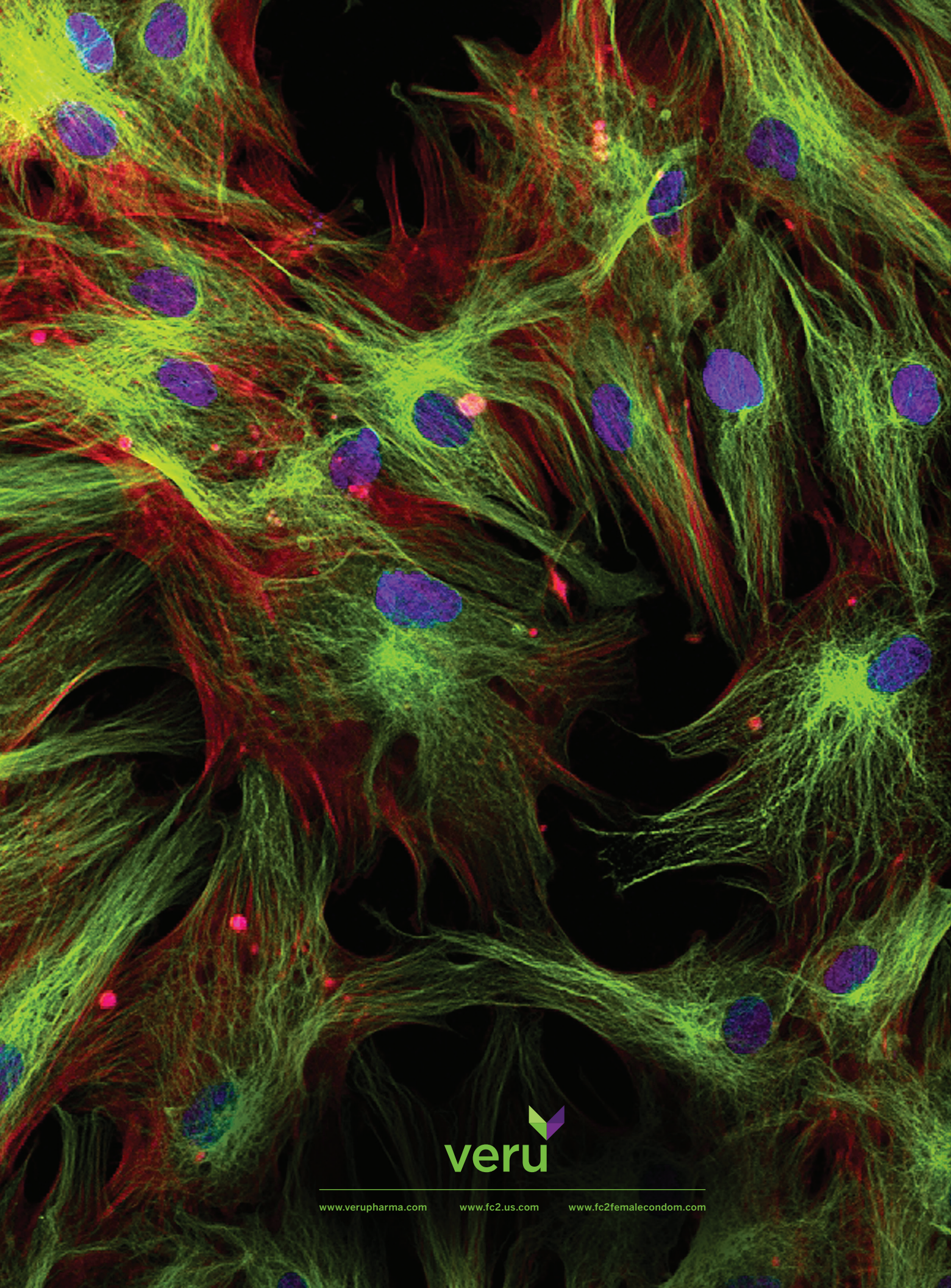
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