veru

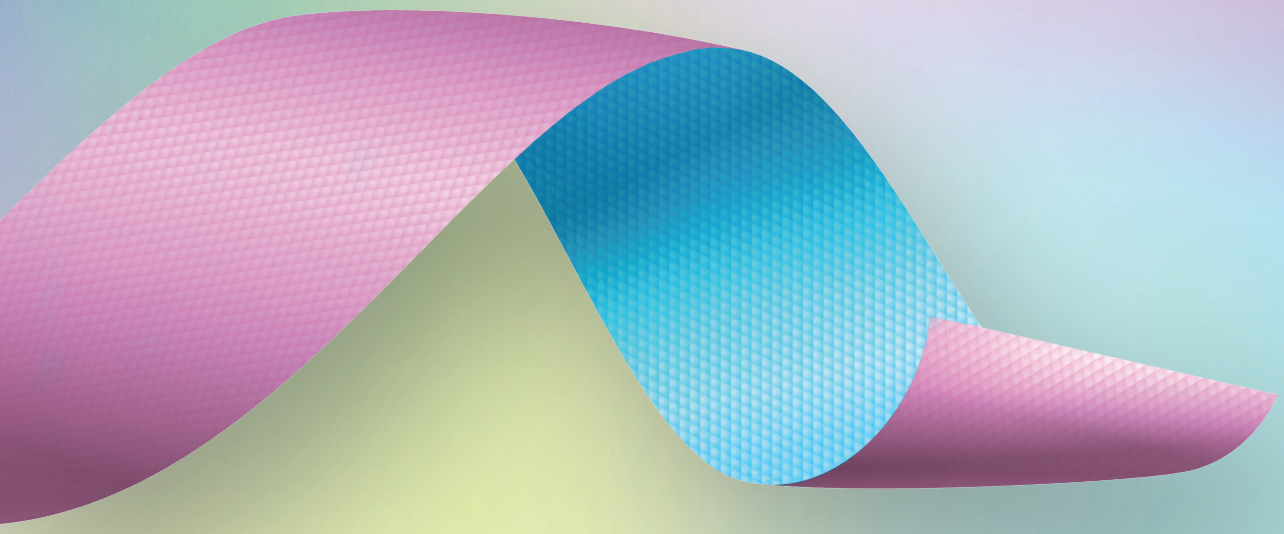
2021 Annual Report

Understanding your risk

1 IN 8 WOMEN*
will be diagnosed with
BREAST CANCER
in HER lifetime

1 IN 8 MEN*
will be diagnosed with
PROSTATE CANCER
in HIS lifetime

** Source: American Cancer Society*



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

DEAR SHAREHOLDERS,

Fiscal year 2021 was an exciting and very productive year for Veru. We have successfully transformed our Company into a late-stage oncology biopharmaceutical company. We are developing novel medicines for the management of two of the most prevalent cancers, breast cancer and prostate cancer. One of our anticancer drugs, sabizabulin, has dual antiviral and anti-inflammatory effects and is also being developed for the potential treatment of hospitalized COVID-19 patients at high risk for acute respiratory distress syndrome (ARDS), which remains a global unmet medical need. With our recent FDA approval in December 2021, our commercial Sexual Health Division now has two products—the newly approved drug ENTADFI™ (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia, and the FC2 Female Condom® (Internal Condom), an FDA-approved product for the dual protection against unplanned pregnancy and the transmission of sexually transmitted infections. Revenue from the Sexual Health Division is being used to largely fund the clinical development of our late-stage drug candidate assets which aim to address multi-billion dollar, premium market opportunities.

This was the year we initiated our metastatic breast cancer program with two of our drug candidates, enobosarm and sabizabulin. We are developing treatments against both hormone receptor positive and triple negative metastatic breast cancers. Enobosarm is an oral selective androgen receptor (AR) targeted agonist, which has shown efficacy in a heavily pretreated hormone receptor positive metastatic breast cancer patient population and demonstrated an excellent safety profile without causing unwanted masculinizing adverse side effects. We have identified that patients who have greater than 40% androgen receptor expression in their breast cancer tissue are most likely to respond to enobosarm. Based on this observation, the FDA has recommended that we develop a companion diagnostic test to determine the patient's AR expression status. Consequently, we are partnering with Roche/Ventana Diagnostics, a world leader in oncology companion diagnostic tests, who will develop and, if approved, will be responsible for commercializing the companion diagnostic AR test. Enobosarm represents the first new and novel hormone therapeutic approach to breast cancer in decades. Our second drug candidate, sabizabulin, is an oral cytoskeleton disruptor that targets unique binding sites and crosslinks microtubules, a well-validated cancer target, resulting in promising efficacy and potentially a better safety profile without clinically relevant neurotoxicity, neutropenia, or alopecia. We also have learned that chronic oral daily administration of sabizabulin is feasible.

Our clinical development strategy allows us to potentially become an important treatment option for large market opportunities in both hormone receptor positive and triple negative metastatic breast cancer. In the 3rd line treatment setting for hormone receptor positive metastatic breast cancer, we have 2 clinical studies based on the patient's AR expression level in their breast cancer tissue. In patients with ≥ 40% AR expression, we are actively enrolling a global Phase 3 ARTEST registration study to evaluate enobosarm monotherapy. In patients with <40% AR expression, we have a planned Phase 2b study which will start soon to evaluate sabizabulin monotherapy. We are also moving enobosarm earlier in the treatment sequence to the 2nd line treatment of AR+ER+HER2- metastatic breast cancer by targeting patients with AR breast cancer expression ≥ 40% in the Phase 3 ENABLAR-2 clinical study which will also start soon to evaluate an enobosarm + abemaciclib combination agent. Finally, in metastatic triple negative breast cancer patients who have failed at least 2 chemotherapy treatments, we will be conducting a Phase 2 single arm study evaluating an enobosarm + sabizabulin combination. Therefore, in FY 2022, we plan to conduct 4 late-stage clinical studies for the treatment of different large and important populations of metastatic breast cancer.

Our prostate cancer program has also made great progress this year. The Phase 3 VERACITY registration trial evaluating sabizabulin in men who have metastatic castration and androgen receptor targeting agent resistant prostate cancer, but prior to IV chemotherapy, is enrolling in over 45 clinical sites. VERU-100, a GnRH antagonist 3-month depot formulation, is completing a Phase 2 dose-finding clinical study for the treatment of hormone sensitive advanced prostate cancer. Once completed, and if positive, we will start the Phase 3 registration study. Finally, based on the

positive Phase 2 clinical study evaluating zuclomiphene for the treatment of hot flashes caused by androgen deprivation therapy, we decided that because of the excellent safety profile of zuclomiphene, we should further optimize the dose to determine if we can have even better efficacy in a Phase 2b clinical study. Therefore, in FY 2022, we plan to conduct 3 late-stage clinical studies for the management of metastatic prostate cancer.

We discovered that sabizabulin, which is being developed for cancer indications, also has both broad anti-inflammatory and antiviral properties. We hypothesized that based on this mechanism of drug action, sabizabulin may serve as a two-pronged approach to the treatment of COVID-19 viral infection, and the subsequent debilitating inflammatory effects that can lead to ARDS and death. In February 2021, we reported positive Phase 2 clinical study results where sabizabulin treatment demonstrated an 82% relative reduction of mortality in hospitalized patients with moderate to severe COVID-19 symptoms who were at high risk for developing ARDS. Currently, we are enrolling a global Phase 3 COVID-19 clinical registration trial evaluating sabizabulin 9mg versus placebo in moderate to severe COVID-19 hospitalized subjects who are at high risk for developing ARDS, which remains a significant unmet medical need. The Company anticipates having results for the Phase 3 clinical trial in 1H calendar year 2022.

Veru has a base commercial Sexual Health Division which now includes two commercial products, the FC2, an FDA-approved product for the dual protection against unplanned pregnancy and the transmission of sexually transmitted infections, and the drug, ENTADFI™, a new treatment for benign prostatic hyperplasia that was approved by the FDA in December 2021.

For FC2, we have built the infrastructure to allow for broad access to the product across the US. As a result, FC2 is now available through multiple sales channels. In particular, we have partnered with fast-growing, highly reputable telemedicine platform companies to bring our FC2 product to patients in a cost-effective and highly convenient manner. Our strategy to continue to drive robust FC2 sales is to seek additional telemedicine and pharmacy service partners as well as creating our own dedicated "direct to patient" telemedicine and telepharmacy services platform to drive further growth in sales.

ENTADFI™ has been developed to treat benign prostatic hyperplasia, or an enlarged prostate gland. The co-administration of tadalafil and finasteride has been shown to be more effective for the treatment of benign prostatic hyperplasia than finasteride alone without causing sexual adverse effects. We plan to market and distribute ENTADFI™ by our own "direct to patient" telemedicine and telepharmacy platform. We have also partnered with GoodRx, a digital resource for healthcare, to reach their almost 20 million monthly visitors, which include both consumers and healthcare providers, and offer a unique cash price to ensure our treatment is more affordable and accessible. We will augment our marketing and sales efforts by seeking partners in the US and ex-US. Commercialization activities are already underway and we expect to achieve first commercial sale in the first half of 2022.

In summary, we have evolved into an oncology biopharmaceutical company dedicated to developing treatments for breast cancer and prostate cancer. Also, with ENTADFI, we have now achieved our first NDA drug approval, a key milestone for any biopharmaceutical company. Our strategy to advance the clinical development of our drug candidates by investing revenues generated by our Sexual Health Division is working. Our base Sexual Health Division, as a stand-alone business, is valuable, profitable, and growing, which provides optionality for Veru's shareholders. I am proud of the hardworking, dedicated, and talented team we have assembled to execute on our clinical and commercial strategy. We are committed to driving shareholder value by developing and commercializing novel medicines addressing significant unmet medical needs for the management of breast cancer and prostate cancer and being opportunistic by developing sabizabulin for hospitalized COVID-19 patients at high risk for acute respiratory distress syndrome and death.

Sincerely,

Mitchell Steiner, MD FACS
Chairman, President and Chief Executive Officer

We encourage you to read our Annual Report on Form 10-K for the fiscal year ended September 30, 2021 which accompanies this letter, including the sections captioned "Risk Factors" and "Forward Looking Statements" for a description of the substantial risks and uncertainties related to the forward looking statements included herein.

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, 2021

☐ **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, 2021, was approximately $689.5 million based on the per share closing price as of March 31, 2021 quoted on the NASDAQ Capital Market for the registrant's common stock, which was $10.78.

There were 80,029,748 shares of the registrant's common stock, $0.01 par value per share outstanding on November 29, 2021.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Proxy Statement for the 2022 Annual Meeting of the Shareholders of the Registrant are incorporated by reference into Part III of this report.

VERU INC.
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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.

All trademarks, service marks or trade names appearing in this report are the property of their respective owners. We do not intend the use or display of other companies’ trade names, trademarks, or service marks to imply a relationship with, or endorsement or sponsorship of or by, any of these other companies

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, plans and results, 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 or other reasons, 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 potential delays in, or failure to obtain, 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 or commercialize a product candidate in the U.S.;
- 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 sabizabulin 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 any of our product candidates to market, and risks related to efforts of our collaborators such as in the development of a companion diagnostic for enobosarm;
- 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 still in development 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 and the possibility that as vaccines become widely distributed the need for new COVID-19 treatment candidates may be reduced or eliminated;
- government entities may take actions that directly or indirectly have the effect of limiting opportunities for sabizabulin as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments;
- product demand and market acceptance of our commercial product and our products in development, if approved;
- some of our products are in development and we may fail to successfully commercialize such products;
- risks related to any potential new telehealth platform developed or used by us in commercializing our current product or potential future products, including potential regulatory uncertainty around such platforms;

- 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 as well as potential healthcare reform measures;
- the risk that we will be affected by regulatory and legal developments, including a reclassification of products or repeal or modification of part or all 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 or other governmental actions, and the duration and impact of any such disruptions;
- our reliance on major customers and risks related to delays in payment of accounts receivable by major customers;
- risks from rising costs of raw materials and our ability to pass along increased costs to our 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 to realize any potential benefits of such transactions or 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

Overview

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

Our breast cancer development portfolio includes:

- Enobosarm, a selective androgen receptor targeting agonist; and
- Sabizabulin, a cytoskeleton disruptor.

Our prostate cancer development portfolio includes:

- Sabizabulin,
- VERU-100, a long-acting GnRH antagonist; and
- Zuclomiphene citrate, an oral nonsteroidal estrogen receptor agonist.

One of our anticancer drugs, sabizabulin, also has dual antiviral and anti-inflammatory effects and is also being developed for the potential treatment of hospitalized COVID-19 patients at high risk for acute respiratory distress syndrome (ARDS).

We also have a commercial Sexual Health Division which includes a drug candidate, ENTADFI™ (tadalafil 5mg and finasteride 5mg capsule), for the treatment of benign prostatic hyperplasia (BPH) with a December 2021 PDUFA date, and a commercial product, the FC2 Female Condom® (Internal Condom) (FC2), an FDA-approved product for the dual protection against unplanned pregnancy and the transmission of sexually transmitted infections, which is sold in the U.S. and globally.

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 an oncology biopharmaceutical company with a focus on developing novel medicines for the management of breast and prostate cancers; an antiviral/anti-inflammatory drug development program for treatment of hospitalized COVID-19 patients at high risk for acute respiratory distress syndrome (ARDS); and, a commercial Sexual Health Division which includes a drug candidate, ENTADFI™, for the treatment of benign prostatic hyperplasia (BPH) and a commercial product, the FC2 Female Condom® (Internal Condom). 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.

Our Strategy

Our strategy focuses primarily on the clinical development and commercialization of oncology drugs initially for the management of two of the most prevalent cancers globally – breast cancer and prostate cancer – while at the same time being opportunistic in exploring additional new indications or disease areas. In addition, we seek to operate and grow our Sexual Health Division to help fund our oncology and other clinical development efforts. The key elements of our strategy are:

- **Develop and launch high value, novel biopharmaceutical products for breast cancer.**

  Breast cancer is the most commonly diagnosed cancer in women with an estimated 284,200 new cases and 44,130 deaths expected for 2021 in the U.S. It is expected that 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 estrogen receptor (ER) have been 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 triple negative breast cancer. Triple negative breast cancer does not have ER or a progesterone receptor (PR) and does not make human epidermal growth factor receptor 2 (HER2). As a consequence, triple negative breast cancer is an endocrine resistant, aggressive cancer that grows and spreads faster than ER+ and/or HER2+ breast cancers. Triple negative breast cancer also eventually develops resistance to currently used chemotherapy drugs like taxanes and anthracyclines, and as such, treatment options for triple negative breast cancer are limited.

  Our breast cancer pipeline includes enobosarm and sabizabulin.

  Enobosarm is an oral, first-in-class, new chemical entity, selective androgen receptor agonist that targets the AR in AR+ ER+ HER2- metastatic breast cancer without unwanted masculinizing 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 patients and was well tolerated with a favorable safety profile.

  Sabizabulin is an oral, first-in-class, new chemical entity that uniquely targets and crosslinks microtubules which are critical components of the cytoskeleton and a well-validated target for anticancer drugs. Sabizabulin has been evaluated initially in Phase 1b/2 clinical studies in 80 patients with advanced prostate cancer. Sabizabulin was well-tolerated and had promising evidence of antitumor activity. Sabizabulin is ready to be evaluated in advanced breast cancer.

  We have developed an extensive breast cancer program with 4 late-stage clinical studies to evaluate enobosarm and/or sabizabulin in metastatic breast cancer. Global revenues for current oral therapies for advanced breast cancer are over $14 billion.

- **Develop and launch high value, novel biopharmaceutical products for prostate cancer management.**

  Prostate cancer is the most commonly diagnosed cancer in men with an estimated 248,530 new cases and 34,130 deaths expected for 2021 in the U.S. It is expected that one in eight 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.

  Our prostate cancer pipeline includes sabizabulin, VERU-100, and zuclomiphene citrate – each of which seeks to address unmet medical needs in potentially large markets relating to advanced prostate cancer and prostate cancer supportive care.

- **Continue to grow our Sexual Health Division to invest proceeds in the clinical development of our drug pipeline with the goal of accessing large premium oncology markets in breast and prostate cancer.**

    - ENTADFI™ (tadalafil 5mg and finasteride 5mg capsule) is being developed to treat urinary tract symptoms caused by BPH. The NDA was submitted in February 2021 and filed by the FDA in April 2021 with a PDUFA date in December 2021. If approved by the FDA, ENTADFI is expected to be marketed and distributed by telemedicine (telemedicine being the remote diagnosis and treatment of patients by means of telecommunications technology) and telepharmacy channels in U.S. We also intend to secure partnership opportunities to commercialize ENTADFI outside the U.S.

    - We expect to continue revenue growth from FC2 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. Further, the Company is establishing its own dedicated direct to patient telemedicine and pharmacy services portal to continue to drive sales growth.

- **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 matters, marketing and sales, and business development which we believe facilitates effective management of our preclinical studies and clinical trials of drug candidates, potential launch planning, effective collaboration activity 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 potential new products.

- **Be opportunistic.** We discovered that sabizabulin, which is being developed for cancer indications, also has both broad anti-inflammatory and antiviral properties. We hypothesized that based on this mechanism of drug action, sabizabulin may serve as a two-pronged approach to the treatment of COVID-19 viral infection, and the subsequent debilitating inflammatory effects that can lead to ARDS and death. In February 2021, we reported positive Phase 2 clinical study results where sabizabulin treatment demonstrated an 82% relative reduction of mortality in hospitalized patients with moderate to severe COVID-19 symptoms who were at high risk for developing ARDS. We are enrolling a global Phase 3 COVID-19 clinical registration trial which is a double-blind randomized (2:1) placebo-controlled trial evaluating daily oral doses of 9 mg sabizabulin for 21 days versus placebo in moderate to severe COVID-19 hospitalized subjects who are at high risk for developing ARDS, which remains an unmet medical need. The Company anticipates having results for the Phase 3 clinical trial in the first half of calendar year 2022.

Our Products and Product Candidates

The following table summarizes the Company's current product and development portfolio:

PRODUCT	INDICATION	DEVELOPMENT PHASE
Oncology Drug Candidates - Breast		
Enobosarm – selective androgen receptor agonist	AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% (3rd line metastatic setting)	Phase 3 ARTEST ongoing
Sabizabulin – oral targeted cytoskeleton disruptor	AR+ ER+ HER2- metastatic breast cancer with AR < 40% (3rd line metastatic setting)	Planned Phase 2b
Enobosarm + abemaciclib combination therapy – selective androgen receptor agonist plus CDK 4/6 inhibitor	AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% (2nd line metastatic setting)	Planned Phase 3 ENABLAR-2
Sabizabulin + enobosarm combination therapy – oral targeted cytoskeleton disruptor plus selective androgen receptor agonist	Metastatic triple negative breast cancer after two systemic chemotherapies	Planned Phase 2

Oncology Drug Candidates - Prostate		
Sabizabulin – oral targeted cytoskeleton disruptor	Metastatic castration and androgen receptor targeting agent resistant prostate cancer prior to IV chemotherapy	Phase 2 ongoing, Phase 3 VERACITY ongoing
VERU-100 – long-acting GnRH antagonist peptide subcutaneous 3-month depot injection	Advanced hormone sensitive prostate cancer	Phase 2 ongoing
Zuclomiphene citrate – oral, non-steroidal, estrogen receptor agonist	Hot flashes in men on ADT with advanced prostate cancer	Phase 2 completed Planned Phase 2b
COVID-19 Drug Candidate		
Sabizabulin – oral cytoskeleton disruptor with dual antiviral and anti-inflammatory activities	Moderate to severe COVID-19 in hospitalized patients at risk for ARDS	Phase 3 COVID-19 ongoing
Sexual Health Division		
Drug Candidate		
ENTADFI™ – tadalafil 5mg and finasteride 5mg capsule	Initial treatment of men with lower urinary tract symptoms from an enlarged prostate	NDA filed, PDUFA date 12/2021
Commercial Product		
FC2 Female Condom® (internal condom)	Unintended pregnancy and prevents STIs	Marketed

Our Clinical Trials Program and Our Drug Candidates

Oncology Drug Candidates- Breast Cancer: enobosarm and sabizabulin

Scientific Overview. In the U.S., breast cancer is the most commonly diagnosed cancer in women with an estimated 284,200 new cases and 44,130 deaths expected for 2021 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 progesterone receptor (PR), as well as HER2 status. Up to 85% of breast cancers are ER+, and consequently, estrogen is one of the main drivers of breast cancer proliferation, tumor progression, and metastasis. Treatments that target the ER have been 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. Metastatic triple negative breast cancer is an aggressive form of breast cancer that occurs in approximately 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 drug resistance and have tumor progression.

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 in between 70 to 95% of breast cancer specimens; 2) Androgen receptor agonists inhibit cellular proliferation and have antitumor 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.

Further, 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 advanced breast cancer. 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 (CBR) at 6 months (CR+PR+SD) 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 masculinization, increase in hematocrit, liver toxicity, and inability to source the drugs.

Enobosarm is an oral, first-in-class, new chemical entity that is a member of a new class of endocrine drugs called selective androgen receptor agonists, 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+ HER2- 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 improve physical function, as well as reduce fat, in clinical studies involving elderly subjects and patients with cancer cachexia including breast cancer. Furthermore, the tissue selectivity of enobosarm results in a favorable side effect profile with no masculinizing adverse effects (facial hair and acne), no increase in hematocrit, and no liver toxicity. Enobosarm has extensive nonclinical and clinical experience having been evaluated in 25 separate clinical studies in approximately 1,450 subjects dosed, including three Phase 2 clinical studies in advanced AR+ ER+ HER2- metastatic breast cancer involving more than 250 patients.

Sabizabulin 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, sabizabulin causes apoptosis, or cell death by cleaving poly ADP ribose polymerase (PARP) which is important for DNA repair in cancer cells. Sabizabulin 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. Sabizabulin 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.

Enobosarm for the treatment of AR+ ER+ HER2- metastatic breast cancer. 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 CBR 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 masculinization, no increase in hematocrit, 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 AR+ ER+ HER2- metastatic breast cancer. The patients in this study were also heavily pretreated having failed an average of 3.7 endocrine treatments, 90% had received prior chemotherapy, and 12% had prior treatment with CDK4/6 inhibitor. Enobosarm showed efficacy with a CBR 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). A post-hoc AR expression subset analysis was also performed in this population with known AR status and measurable disease (n=84). Objective tumor responses correlated with the degree of % AR staining. Using a 40% AR staining cutoff, CBR at 24 weeks for ≥40% AR was 52% and <40% AR was 14% ($p<0.0004$). Overall response rate in subjects with ≥40% AR staining was 34% and <40% AR was 2.7% ($p=0.0003$). Median radiographic progression free survival (rPFS) for ≥40% AR was 5.47 months (95% CI 2.83-11.13) versus <40% AR was 2.73 months (95% CI 2.63 – 2.80) ($p<0.001$). Enobosarm treatment was well tolerated with significant positive effects on quality-of-life measurements. The 9 mg group had a slightly better safety profile than the 18 mg group.

In summary, treatment with enobosarm, a novel oral selective androgen receptor agonist, resulted in clinically significant objective tumor responses, improvement in quality of life, and favorable safety profile in a heavily pretreated population of women with AR+ER-HER2- metastatic breast cancer. Higher % AR nuclei staining correlated with a greater antitumor activity. By targeting and activating AR in breast cancer tumors with sufficient AR expression (≥40% AR nuclei staining), women with metastatic breast cancer may be identified who are most likely to respond to enobosarm therapy. Overall, these studies of enobosarm clearly establish the clinical relevance of targeting the AR with a selective AR agonist. Enobosarm introduces a novel endocrine therapy to patients with breast cancer that have exhausted endocrine therapies targeting ER, but prior to IV chemotherapy.

Sabizabulin and enobosarm for the treatment of AR+ metastatic triple negative breast cancer. Over expression of P-glycoprotein is a common mechanism that results in taxane and other chemotherapy treatment resistance in triple negative breast cancer. Sabizabulin is not a substrate for P-glycoprotein drug resistance protein. Preclinical studies in human triple negative breast cancer grown in animal models demonstrate that sabizabulin significantly inhibits cancer proliferation, migration, metastases, and invasion of triple negative breast cancer cells and tumors that have become resistant to paclitaxel (taxane). Furthermore, an enobosarm + pembrolizumab combination Phase 2 study in 18 heavily pretreated women with AR+ metastatic triple negative breast cancer demonstrated that enobosarm was well tolerated and resulted in promising preliminary efficacy of 25% clinical benefit rate (CR+PR+SD) at 16 weeks and objective tumor responses (1 CR and 1 PR). Thus, the combination of two oral agents, sabizabulin + enobosarm, may provide a new treatment option for women who have AR+ metastatic triple negative breast cancer.

Development Plan: Current and Planned Clinical Trials.

- ***Phase 3 clinical study – Enobosarm as a 3rd line treatment of AR+ER+HER2- metastatic breast cancer (AR nuclei staining ≥40%).*** We are enrolling the Phase 3 multicenter, international, open label, and randomized (1:1) ARTEST registration clinical trial design to evaluate the efficacy and safety of enobosarm monotherapy versus physician's choice of either exemestane ± everolimus or a SERM as the active comparator for the treatment of AR+ ER+ HER2- metastatic breast cancer in approximately 210 patients with AR nuclei staining ≥40% in their breast cancer tissue who had tumor progression on a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor. We have identified that patients who have greater than 40% androgen receptor nuclei staining in their breast cancer tissue are most likely to respond to enobosarm. Based on the recommendation of the FDA to have a companion diagnostic test to determine the patient's AR status, we are partnering with Roche/Ventana Diagnostics, a global oncology diagnostics company, who will develop and commercialize a companion diagnostic AR test.

- ***Phase 2b clinical study – Sabizabulin as a 3rd line treatment of AR+ER+HER2- metastatic breast cancer (AR nuclei staining <40%).*** We also intend to conduct a Phase 2b clinical study of sabizabulin, a novel oral cytoskeleton disruptor, for the treatment of AR+ ER+ HER2- metastatic breast cancer in patients with an AR nuclei staining <40%. The Phase 2b clinical trial will be an open label, multicenter, and randomized (1:1) study evaluating the efficacy and safety of sabizabulin 32mg monotherapy versus active comparator (exemestane ± everolimus or a SERM, physician's choice) for the treatment of ER+ HER2- metastatic breast cancer in approximately 200 patients with AR nuclei staining <40% in their breast cancer tissue who had tumor progression on a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor. The Phase 2b study is expected to commence during the first quarter of calendar year 2022.

- ***Phase 3 clinical study – Enobosarm + abemaciclib combination as a 2nd line treatment of AR+ER+HER2- metastatic breast cancer (AR nuclei staining ≥40%).*** We intend to also conduct a Phase 3 multicenter, open label, randomized (1:1), active control clinical study, named ENABLAR-2 to evaluate the efficacy and safety of enobosarm plus abemaciclib combination therapy versus an alternative estrogen blocking agent (fulvestrant or an aromatase inhibitor) in subjects with AR+ ER+ HER2- metastatic breast cancer who have failed first line palbociclib (a CDK 4/6 inhibitor) plus an estrogen blocking agent (non-steroidal aromatase inhibitor or fulvestrant) and have an AR nuclei staining ≥ 40% in their breast cancer tissue. We plan to enroll approximately 186 subjects in this Phase 3 clinical study which is expected to commence during the first quarter of calendar year 2022.

- ***Phase 2b clinical study - Sabizabulin + enobosarm combination therapy for the treatment of patients who have AR+ metastatic triple negative breast cancer and who have tumor progression after receiving at least 2 systemic chemotherapies.*** The Company plans to commence a single arm, sabizabulin plus enobosarm combination therapy Phase 2b clinical study in the first quarter of calendar year 2022 in approximately 111 women.

Market. Enobosarm represents the first new class of targeted endocrine therapy in advanced breast cancer in decades. Enobosarm targets AR in AR+ ER+ HER2- metastatic breast cancer as a potential second line and/or third line oral daily dosing endocrine therapy. Oral sabizabulin could provide a non-endocrine oral therapy. Both enobosarm and sabizabulin could be an option in hormone receptor positive metastatic breast cancer patients that have exhausted endocrine therapies targeting ER, but prior to IV chemotherapy. We believe that the global annual market for an oral agent in an ER endocrine resistant setting would be similar to that for CDK 4/6 inhibitor drugs which is an $18 billion dollar market. In addition, the number of new U.S. breast cancer cases in 2021 with triple negative breast cancer is approximately 42,630 patients. The annual U.S. market for chemotherapy resistant metastatic triple negative breast cancer is over $1 billion annually.

Oncology Drug Candidates – Prostate Cancer: sabizabulin, VERU-100 and zuclomiphene citrate

Sabizabulin, an oral, first-in-class cytoskeleton disruptor small molecule for the treatment of prechemotherapy metastatic castration resistant and androgen receptor targeting agent resistant prostate cancer.

Scientific Overview. In 2021, there were an estimated 248,539 new cases and 34,130 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 androgen deprivation therapy (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 acetate) 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.

Sabizabulin 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, sabizabulin causes apoptosis, or cell death by cleaving poly ADP ribose polymerase (PARP) which is important for DNA repair in cancer cells. Sabizabulin 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. Sabizabulin 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, sabizabulin 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 is developing sabizabulin 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 (prechemotherapy). In September 2018, the Company completed a pre-Investigational New Drug Application (IND) meeting with the FDA for sabizabulin 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 prior taxane IV chemotherapy. Based on the Phase 1b clinical study, the recommended Phase 2 dose is 63mg oral daily continuous dosing 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 41 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 the Phase1b/2 clinical studies, there was evidence of both cytotoxic and cytostatic antitumor efficacy including PSA declines and objective tumor responses (partial and complete responses), and sabizabulin was well tolerated with no reported clinically relevant neutropenia or neurotoxicity. The safety profile appears to be similar to what has been reported in the FDA package inserts for an androgen receptor targeting agent, enzalutamide or abiraterone.

In July 2020, the Company had a meeting with the FDA and received positive input from the FDA on the pivotal Phase 3 trial design for sabizabulin. The Phase 3 VERACITY clinical study is an open label, randomized (2:1), multicenter, registration study evaluating sabizabulin 32mg daily dosing versus an alternative androgen receptor targeting agent as the active control in men who have metastatic castration resistant prostate cancer and who had tumor progression while taking at least one androgen receptor targeting agent, but prior to IV chemotherapy. The Phase 3 VERACITY study has a primary endpoint of median radiographic progression-free survival and is currently enrolling, and we expect to enroll 245 men from approximately 45 clinical sites across the U.S.

Current and Planned Clinical Trials

- ***Phase 1b/2 clinical studies to determine maximum tolerated dose and recommended dosing of sabizabulin.*** We are completing the Phase 1b open label clinical trial of sabizabulin in 39 men with metastatic castration resistant and androgen receptor targeting agent resistant prostate cancer ± taxane chemotherapy and the Phase 2 clinical study in 41 men with metastatic castration resistant prostate cancer who have also become resistant to at least one androgen receptor targeting agent, but prior to proceeding to IV taxane chemotherapy. In the Phase 1b/2 studies, sabizabulin was both well tolerated and demonstrated promising preliminary efficacy data.

- ***Phase 3 VERACITY clinical study.*** We are currently enrolling the Phase 3 VERACITY registration study evaluating sabizabulin 32mg in approximately 245 men who have metastatic castration resistant prostate cancer and who had tumor progression while receiving at least one androgen receptor targeting agent, but prior to IV chemotherapy.

Market. Sabizabulin 32mg is being developed for metastatic castration resistant and androgen receptor targeting agent resistant prostate cancer prior to IV chemotherapy. The potential U.S. market for oral cancer therapies in advanced prostate cancer is expected to be over $6.5 billion in 2022. Furthermore, sabizabulin may be a candidate for further development for the 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 subcutaneous injection formulation for androgen deprivation therapy for advanced hormone sensitive prostate cancer.

Scientific Overview. Androgen deprivation therapy remains the mainstay primary first line therapy for advanced prostate cancer, but current androgen deprivation therapy products, such as LUPRON DEPOT® (leuprolide acetate for depot suspension), for injection; ELIGARD® (leuprolide acetate), for injectable suspension, for subcutaneous use; FIRMAGON® (degarelix for injection), for subcutaneous use; and ZOLADEX® (goserelin implant) have several important clinical 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. ORGOVYX® (relugolix tablets), an oral GnRH antagonist may potentially have compliance concerns through a patient's reluctance or failure to take oral medicine as prescribed. There are no GnRH antagonist depot formulations commercially approved beyond a one-month duration injection. In contrast, VERU-100 is designed to address a number of these important clinical shortfalls of currently marketed androgen deprivation therapy products: VERU-100 is a long-acting GnRH antagonist designed to be administered as a small volume 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. As VERU-100 is a long-acting injected depot, there are no concerns with patient compliance while on treatment. Furthermore, as a class, GnRH antagonists have been shown to have fewer cardiovascular adverse events than LHRH agonists in men on androgen deprivation therapy.

Development Plan. The Company had a Pre-IND meeting with the FDA in May 2019 clarifying the requirements for full regulatory development pathway. The FDA agreed to an expedited regulatory development pathway for VERU-100. The Company is conducting a single Phase 2 dose finding, open label, multicenter clinical study of VERU 100 in men with advanced prostate cancer (n=35) for a single three-month injection. Phase 2 clinical results are expected in early 2022. FDA has agreed to the design of the registration study which will be a Phase 3-open label single arm clinical study in men with advanced prostate cancer (n=100) using the achievement and maintenance of castration levels of testosterone as the primary endpoint.

Current and Planned Clinical Trials

- ***Phase 2 dose finding clinical study.*** Currently enrolling study to determine optimal dose of VERU-100 in men with advanced hormone sensitive prostate cancer. Phase 2 clinical results are expected in early calendar year 2022.

- ***Phase 3 registration clinical study.*** If the Phase 2 trial is successful, and as discussed with and agreed upon by the FDA, the Phase 3 clinical trial will be a single arm, multicenter, open-label study in approximately 100 men with hormone sensitive advanced prostate cancer using the achievement and maintenance of castration levels of testosterone as the primary endpoint. The Phase 3 registration study is planned to initiate in the first half of calendar year 2022.

Market. VERU-100 is a long-acting GnRH antagonist for androgen deprivation therapy 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 androgen deprivation therapy drugs in 2022 are estimated to be greater than $2.9 billion.

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

Scientific Overview. The estimated prevalence of prostate cancer in the U.S. is 3 million cases for which over one-third are on androgen deprivation therapy. Androgen deprivation therapy 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), ORGOVYX® (relugolix tablets), as well as the newer agents approved to treat advanced prostate cancer such as ZYTIGA® (abiraterone), XTANDI® (enzalutamide), ERLEADA® (apalutamide), and NUBEQA® (darolutamide). Up to 80% of men on androgen deprivation therapy complain of hot flashes with 30-40% having moderate to severe hot flashes. Patients on androgen deprivation therapy 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 androgen deprivation therapy.

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 ES® (megesterol acetate suspension), 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 androgen deprivation therapy 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.

Zuclomiphene citrate 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. Upon review of the Phase 2 clinical data, we believe a higher dose of zuclomiphene may be more efficacious against hot flashes with acceptable safety. Consequently, the Company plans to further optimize the dosing of zuclomiphene citrate in a Phase 2b clinical trial in men with advanced prostate cancer who experience moderate to severe hot flashes.

Planned Clinical Trial

- ***Phase 2b zuclomiphene citrate clinical study.*** The Company reported positive dose finding Phase 2 study in January 2020. The Company plans to further optimize the dosing schedule of zuclomiphene citrate in a Phase 2b study.

Market. Hot flashes are the most common side effect of prostate cancer hormone therapy, with hot flashes occurring in approximately 80% of men receiving one of the common forms of androgen deprivation therapy, including like LUPRON® and ELIGARD® (leuprolide), FIRMAGON® (degarelix), ZOLADEX® (goserelin), ORGOVYX® (relugolix tablets), as well as the newer agents approved to treat advanced prostate cancer such as ZYTIGA® (abiraterone), XTANDI® (enzalutamide), ERLEADA® (apalutamide), and NUBEQA® (darolutamide, and about up to 40% of such men experience moderate to severe hot flashes. The potential patient population for zuclomiphene citrate is the approximately 480,000 men annually in the U.S. who suffer from ADT-induced hot flashes. There are currently no FDA-approved therapies for hot flashes associated with prostate cancer hormonal therapies.

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

Sabizabulin 9mg for the treatment of hospitalized moderate to severe COVID-19 patients at high risk for acute respiratory distress syndrome (ARDS)

Scientific Overview. Drugs like sabizabulin 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. Sabizabulin provides a two-pronged approach to the treatment of COVID-19 viral 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 virus particles 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. In February 2021, we reported positive Phase 2 clinical study results where sabizabulin treatment demonstrated an 82% relative reduction of mortality in hospitalized patients with moderate to severe COVID-19 symptoms who were at high risk for developing ARDS.

Development Plan. Sabizabulin 9mg is a novel once-a-day orally dosed small molecule that has both broad anti-inflammatory and anti-viral properties which may serve as a two-pronged approach to the treatment of COVID-19 virus infection and the subsequent debilitating inflammatory effects that can lead to ARDS and death.

Current Clinical Trial

- ***Phase 3 COVID-19 registration clinical study.*** We are enrolling patients into a double-blind randomized (2:1) placebo-controlled Phase 3 COVID-19 registration clinical trial evaluating daily oral doses of sabizabulin 9mg for 21 days versus placebo in moderate to severe COVID-19 hospitalized subjects who are at high risk for developing ARDS, which remains an unmet medical need. The primary efficacy endpoint will be proportion of patients alive at Day 60. Secondary endpoints will include the proportion of patients alive without respiratory failure, days in ICU, days on mechanical ventilations, days in the hospital, and viral load. The Company will enroll 300 subjects from clinical sites in the U.S., Brazil, Argentina, Colombia, Mexico, and Bulgaria. The Company anticipates completion of enrollment of the Phase 3 trial early in calendar year 2022.

Market. Approximately 20% of symptomatic cases require hospitalization with 5% ending up in the ICU. According to U.S. Centers for Disease Control and Prevention, there have been approximately 48 million confirmed COVID cases and approximately 777,000 deaths in the U.S. as of November 28, 2021. While many factors go into the market analysis such as the prevalence of vaccination as well as both the development and the severity of virus mutations, the Company believes that the market opportunity for the indication, if approved, is greater than $1 billion in the US.

Sexual Health Division

The Company's Sexual Health Division includes a drug candidate, ENTADFI™ (tadalafil 5mg and finasteride 5mg capsule), for the treatment of benign prostatic hyperplasia (BPH) and a commercial product, the FC2 Female Condom® (internal condom) (FC2), an FDA-approved product for the dual protection against unplanned pregnancy and the transmission of sexually transmitted infections.

Drug Candidate

ENTADFI™ (tadalafil 5mg and finasteride 5mg capsule) for the treatment of benign prostatic hyperplasia (BPH)

Scientific Overview. Tadalafil and finasteride combination product in capsules is a new, proprietary formulation for the treatment of lower urinary tract symptoms because of an enlarged prostate, also known as BPH. CIALIS® (tadalafil) tablets and PROSCAR® (finasteride 5mg) co-administration is indicated for the initial treatment of BPH for up to 26 weeks. Tadalafil 5mg is a phosphodiesterase 5 (PDE5) inhibitor and 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. ENTADFI (tadalafil 5mg and finasteride 5mg capsule) is being developed to treat urinary tract symptoms caused by BPH. The co-administration of tadalafil and finasteride has been shown to be more effective for the treatment of BPH than finasteride alone with no adverse effects on sexual function. The NDA was submitted in February 2021, filed by the FDA in April 2021 with a PDUFA date in December 2021. If approved, ENTADFI™ is expected to be marketed and distributed by telemedicine (telemedicine being the remote diagnosis and treatment of patients by means of telecommunications technology) and telepharmacy channels. The Company's Sexual Health Business segment will include future revenues for ENTADFI, if approved. Costs associated with the development of ENTADFI™ are currently included in our Research and Development segment.

Market. The worldwide prevalence of BPH lower urinary symptoms is estimated to be 10-25% of the male population. ENTADFI, if approved, would be the first combination of tadalafil and finasteride approved by the FDA. ENTADFI would treat BPH with low potential for adverse sexual side effects, and we believe that ENTADFI being one single pill would help increase drug compliance whereas poor compliance with a BPH medicine could lead to an increased chance of acute urinary retention, urosepsis, and death. If approved, ENTADFI is expected to be marketed and distributed by telemedicine (telemedicine being the remote diagnosis and treatment of patients by means of telecommunications technology) and telepharmacy channels. The Company's Sexual Health Business segment will include future revenues for ENTADFI, if approved.

Commercial product

FC2 Female Condom for dual protection against unintended pregnancy and transmission of sexually transmitted infections

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. FC2 was approved for market by the FDA in 2009.

The Company sells FC2 in both the commercial sector and in the public health sector in the U.S. and globally. In the U.S., FC2 is available by prescription through multiple telemedicine and internet pharmacy channels as well as retail pharmacies. The Company is currently working to establish its own dedicated direct to patient telemedicine and pharmacy services portal to continue to drive sales growth. FC2 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.

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

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, has been rapidly growing. FC2 is currently reimbursable by prescription under the Affordable Care Act (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 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, universities, direct purchase and 340B qualified health care clinics, and directly to the public health sector without distributors. In particular, we have also partnered with fast-growing, highly reputable telemedicine platform companies (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. Finally, the Company is establishing its own dedicated direct to patient telemedicine and pharmacy services portal/platform to continue to drive sales growth.

Global Public Health Sector Market. FC2's primary use is for dual protection against unplanned pregnancy and the transmission of sexually transmitted infections. Within the global public health sector, various governments and 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. 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 through 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 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, local sexual health 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 male condoms is estimated to be worth up to $9.4 billion annually. The female condom market represents a very small portion of the total global condom market, yet 53% of individuals living with HIV/AIDS are women. Consequently, 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 23 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.

Sale of PREBOOST® Business

On December 8, 2020, the Company entered into an Asset Purchase Agreement, pursuant to which the Company sold substantially all of the assets related to the Company's PREBOOST® business. PREBOOST® is a 4% benzocaine medicated individual wipe for the treatment of premature ejaculation and was a commercial product in the Company's Sexual Health Division during fiscal 2020 and in fiscal 2021 through the date the transaction closed. 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.

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 condom 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 sexual transmitted 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, which 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. In August 2021, the Company's supplier of sheaths needed for the production of FC2 experienced a fire at its manufacturing facility and once repaired, the facility will undergo inspections, and resume manufacturing activities. Additionally, we have completed new accreditation under the European Medical Devices Directive with a new notified body and are awaiting final certification, which we expect by the end of calendar year 2021.

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) or independent data monitoring committee (IDMC), 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, ENTADFI, 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.

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. Sabizabulin for metastatic castration and androgen receptor targeting agent resistant prostate cancer and sabizabulin for taxane resistant metastatic triple negative breast cancer, as well as enobosarm for ER+ HER2- metastatic breast cancer, are 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 ceased on December 31, 2020. We have completed new accreditation under the European Medical Devices Directive with a new notified body and are awaiting final certification, which we expect by the end of calendar year 2021. There was no material impact on our business in fiscal 2021 and we do not believe that this will have a material impact on our business in fiscal 2022.

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.

Sabizabulin and Related Compounds License. We hold an exclusive worldwide license to ten issued U.S. patents, nine pending U.S. patent applications and 90 patents and patent applications in countries outside the United States, including issued patents in the EU and Japan, relating to our sabizabulin 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 sabizabulin 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 three U.S. patent applications, a European patent allowance 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, European 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 sixteen issued U.S. patents, four pending U.S. patent applications and 63 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. The Company has also filed a trademark application for ENTADFI in the U.S.

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 two largest customers in fiscal 2021 accounted for 75% of the Company’s net revenues. In the U.S. market, the Company has experienced fast growth in prescription sales of FC2 in recent years largely through supply agreements with leading telemedicine providers.

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 Foreign, Commonwealth and Development Office (FCDO), DKT 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.

Human Capital Management

As of October 31, 2021, the Company had 252 full-time employees, including 39 located in the U.S., 11 in the U.K., 201 in Malaysia, and one in another country 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.

Our key human capital management objectives are to identify, recruit, integrate, retain and motivate our new and existing employees. We are committed to fostering an environment where all employees can grow and thrive. A diverse workforce results in a broader range of perspectives, helping drive our commitment to growth. We believe that our compensation and benefit programs are appropriately designed to attract and retain qualified talent. To create and maintain a successful work environment, we offer an annual base salary and a comprehensive package of additional benefits that support the physical and mental health and wellness of all of our employees and their families. Additionally, we may also grant equity awards to attract and promote employee retention, with such awards presently vesting over a three-year period, and to allow for employees to share in the performance of the Company.

We are committed to a safe workplace for our employees and have implemented health and safety management processes into our operations. In response to the COVID-19 pandemic, we have implemented additional safety measures for the protection of our employees, including work-from-home measures for applicable employees and additional cleaning and protective measures.

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 2021 or 2020, 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 biocompatibility 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.

On August 7, 2021, the Company learned that a fire had occurred at the manufacturing site used by our supplier to produce component sheaths for FC2. The supplier has informed the Company that full production of the sheaths is expected to commence in December 2021 and the supplier has been prioritizing repairs on this line. We have robust levels of inventory of FC2 in our U.S. warehouses and of FC2 and component sheaths in our facility in Malaysia. As a result, this supply disruption had no significant impact on sales of FC2 in the fourth quarter of fiscal 2021 and, based on historic ordering and our forecasts, we believe the current loss of production of the sheaths will not have a significant impact on sales of FC2 in the first quarter of fiscal 2022. Given our inventory position, and the updated guidance given to us by our supplier at this stage, we expect any impact from this temporary disruption would be limited to the global public health sector market outside of the U.S. and have no impact on sales in the U.S. market.

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 Germany-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 increases use of female as well as male condoms. Male condoms cost less and can 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. We are not currently aware of any other female condoms currently in 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, especially in the EU. 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 outside the U.S. 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.

Sabizabulin is a first-in-class oral therapy that targets and crosslinks both alpha and beta tubulin and will be initially developed for breast and prostate cancers. Sabizabulin is first-in-class with this unique targeting and crosslinking of microtubules, which appears to have favorable results in efficacy and safety that is different from other tubulin targeting agents that do not crosslink. All currently available tubulin targeting agents are chemotherapies that are given IV and include Vinca Alkaloids such as VELBAN® (VinBLAStine Sulfate) injection, for intravenous use; ONCOVIN® (vincristine sulfate injection, solution); and NAVELBINE® (vinrelbine) injection, for intravenous use. 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) injection, for intravenous use; TAXOTERE® (docetaxel) injection, for intravenous use; and JEVTANA® (cabazitaxel) injection, for intravenous use 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-hziy) for injection, for intravenous use; PARP inhibitors, LYNPARZA® (olaparib) tablets, for oral use and TALZENNA® (talazoparib) capsules, for oral use, capecitabine, TECENTRIQ® (atezolizumab) injection, for intravenous use and ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound), for intravenous use and platinum-based chemotherapies including cisplatin and PARAPLATIN® (carboplatin) injection are indicated for advanced breast cancers such as triple negative breast cancer.

VERU-100 is a long-acting GnRH antagonist subcutaneous injection formulation for androgen deprivation therapy 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 administered by depot injection that provide castration beyond one month, making VERU-100, if approved, the only commercially available GnRH antagonist three-month depot that would provide castration for such three-month period.

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) tablets, for oral use and ARIMIDEX® (anastrozole) tablet, for oral use; irreversible steroidal inhibitors including AROMASIN® (exemestane) tablets, for oral use; selective estrogen receptor degraders including FASLODEX® (fulvestrant) injection, for intramuscular use; and CDK 4/6 inhibitors including IBRANCE® (palbociclib) capsules, for oral use, KISQUALI® (ribociclib) tablets, for oral use, 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 hydrochloride) injection, solution for intravenous use, ELLENCE® (epirubicin hydrochloride) injection, solution for intravenous use, capecitabine, CYTOXAN® (cyclophosphamide) capsules, for oral use 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) capsules, for oral use and anticonvulsants like NEURONTIN® (gabapentin) capsules, for oral use or tablets, for oral use 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) and AVODART® (dutasteride). 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), HYTRIN® (terazosin), UROXATRAL® (alfuzosin), CARDURA® (doxazosin), and RAPAFLO® (silodosin) as well as Phosphodiesterase 5 (PDE5) inhibitors like CIALIS ® (tadalafil). One class of drugs combines a drug that shrinks and another that relaxes the prostate called JALYN® (dutasteride/tamsulosin combination).

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

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 more detailed discussion of these highlighted risks, which discussion immediately follows this summary. A summary of the material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, those relating to:

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

- We have no experience in obtaining regulatory approval for a drug.
- We could experience delays in our planned clinical trials.
- Our clinical trials may be suspended or discontinued.
- We may be subject to risks relating to collaboration with third parties.
- We intend to rely on CROs to conduct our research and development activities.
- We expect to rely on third party manufacturers for our drug candidates.
- Changes in law could have a negative impact on the approval of our drug candidates.
- We may fail or elect not to commercialize our drug candidates, including ENTADFI, if approved.
- 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.
- 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.
- 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.
- Government entities may take actions that directly or indirectly have the effect of limiting opportunities for sabizabulin as a COVID-19 treatment.
- We are subject to extensive and costly governmental regulation, including healthcare reform measures that may negatively impact sales of FC2.
- We could experience misconduct by our employees.
- Coverage and reimbursement may not be available for our products.
- We may not be able to gain and retain market acceptance for our drug candidates.
- Our drug products may be subject to governmental pricing controls.
- Third parties may obtain FDA regulatory exclusivity to our detriment.

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.
- Additional financing may be needed to support our development activities.
- COVID-19 and its impact on the economic environment and capital markets could adversely affect our access to capital when needed.
- 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.

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

- 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.
- We may experience intense competition.
- We may not be able to successfully implement our strategy to grow sales of FC2 in the U.S. market.
- We may not be able to sustain price levels for sales of FC2 in the U.S. market.
- An inability to identify or complete future acquisitions could adversely affect our future growth.
- We may experience difficulties in integrating strategic acquisitions.
- We depend on two major customers for a significant portion of our net revenues.
- Since we sell FC2 in foreign markets, we are subject to international business risks that could adversely affect our operating results.
- Disruptions from an exit of the United Kingdom from the European Union could 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.
- Currency exchange rate fluctuations could increase our expenses.
- We rely on a single facility to manufacture FC2, which subjects us to the risk of supply disruptions.
- Uncertainty and adverse changes in the general economic conditions may negatively affect our business.
- Material adverse or unforeseen legal judgments, fines, penalties, or settlements could have an adverse impact on our profits and cash flows.
- Our business and operations would suffer if we sustain cyber-attacks or other privacy or data security incidents that result in security breaches.
- 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.
- 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.
- 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.

Risks Relating to Our Intellectual Property

- We may be unable to protect the proprietary nature of the intellectual property covering our products.
- 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.
- We are dependent in part on some license relationships.
- 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.
- We must submit patent certifications in connection with the 505(b)(2) FDA regulatory pathway.
- We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of our competitors.
- We may need to file lawsuits or take other actions to protect or enforce our intellectual property rights.
- We may fail to protect the confidentiality of commercially sensitive information.

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.
- 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.
- 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.
- 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.

- There are provisions in our charter documents, Wisconsin law and our residual royalty agreement that might prevent or delay a change in control of our company.
- The trading price of our common stock has been volatile, and investors in our common stock may experience substantial losses.
- If our stock price declines, our common stock may be subject to delisting from the NASDAQ Capital Market.
- A substantial number of shares may be sold in the market, which may depress the market price for 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.

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

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

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

Although our President and Chief Executive Officer 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 any of the 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 or IDMC, 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;
- delays resulting from negative or equivocal findings of DSMB or IDMC for a trial; or
- delays resulting from shutdowns or quarantines or staffing shortages relating to COVID-19.

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, IDMC 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 or to develop companion diagnostics for 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 or may require more time to achieve the planned goals of any such collaboration, if they are achieved at all. For companion diagnostics, any such collaborator may be unsuccessful in obtaining regulatory approval for the planned diagnostic and, even if approved, may not be successful in commercializing the diagnostic or achieving widespread adoption of the diagnostic by physicians. 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 do not have the resources to independently conduct research and development activities. Therefore, we intend to and do 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 and do 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, including ENTADFI, if approved.

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, or if we are unable to obtain any required state and local distribution licenses or similar authorizations, 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.

We submitted an NDA for ENTADFI™ to the FDA in April 2021 with a PDUFA date in December 2021. If approved, ENTADFI is expected to be marketed and distributed by telemedicine (telemedicine being the remote diagnosis and treatment of patients by means of telecommunications technology) and telepharmacy channels. We or our collaboration partners in any potential commercial launch of ENTADFI may not be successful in achieving widespread patient or physician awareness or acceptance of ENTADFI. Also, we may be subject to pricing pressures from competitive products that could make it difficult or impossible for us to commercialize ENTADFI successfully.

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 February 2021, we reported positive Phase 2 results in a study of sabizabulin in hospitalized patients with COVID-19 and are currently enrolling patients in a Phase 3 COVID study. 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 or by drug products to treat COVID-19 being developed by other companies that receive approval. 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 sabizabulin 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. Many states and local governments require distribution licenses or similar authorizations to sell products in their jurisdictions. 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.

The ACA mandates coverage of FC2 by U.S. health insurance plans. The ACA is periodically subject to legal challenges and a continuing political effort to limit its scope or even potentially repeal it. We do not expect any imminent such modifications or repeal under the Biden Administration, but we can offer no assurance that the political situation regarding the ACA will not change in ways in the future that could have a material adverse effect on our ability to commercialize FC2 as a prescription product in the U.S.

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, including the inability to market a product in certain state or local jurisdictions; 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, including ENTADFI, 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, including ENTADFI if approved, 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 and $12.0 million during the years ended September 30, 2020 and 2019, 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 may 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 time and cost involved in developing any required companion diagnostics for any of our product candidates, including enobosarm;
- the terms and timing of any potential future collaborations, licensing or other arrangements we may establish;
- cash requirements of any future acquisitions, in-licenses 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.

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 certain 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.

Large international agencies and government health agencies which purchase and distribute FC2 for use in family planning and HIV/AIDS prevention programs have historically purchased significant quantities of FC2. 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-qualification 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-qualification is required to sell female condoms to U.N. agencies. The FDA's 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. There are other polyethurane brands from China (Ormelle, Sensitex) that have CE-certification. 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 and HIV-prevention and treatment methods 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 through fiscal 2021 largely through a small number of current telemedicine providers, we may not be able to achieve sales growth by adding additional telemedicine providers, which could cause us to be dependent on our current telemedicine providers and could limit our growth in this market. In fact, U.S. prescription channel sales of FC2 in fiscal 2021 and 2020 exceeded those of FC2 global public health sector sales in the respective fiscal years. 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 are currently working to establish our own dedicated direct to patient telemedicine and pharmacy services portal to continue to drive sales growth for FC2. We have never developed a telemedicine platform before. The cost and regulatory complexity required for launching this platform, including costs with collaborators who are helping us develop the platform, who will help us in our efforts to market the platform and FC2 and who will provide telehealth physician consultations, may outweigh any increased sales resulting from this effort. Similarly, any subsidies that we may offer to patients may be disallowed by regulators at any time. Any of these risks could harm patient acceptance of the platform and our ability to continue to grow FC2 sales.

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. Similarly, any use of our equity or a convertible debt security in any acquisition would be dilutive to our stockholders and may affect the market price of our shares.

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 two major customers for a significant portion of our net revenues.

The Company's two largest customers in fiscal 2021 accounted for 75% 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;
- currency fluctuations;
- global pandemics, as governments reallocate their health or development budgets to other health areas;
- changes in international regulatory requirements, import duties, or export restrictions, including limitations on the repatriation of earnings;
- disruptions and price increases 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 that ended 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 change in Notified Body suspended all CE marked sales in the EU from December 31, 2020 until new accreditations are completed. MHRA allowed us to continue to operate in the U.K. until December 31, 2021. We have completed the steps required for new accreditation under the Medical Devices Directive with a new notified body and are awaiting final certification, which should be available by the end of calendar year 2021. There was no material impact on our business in fiscal 2021 and we do not expect this will have a material impact on our business in fiscal 2022. 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. We have seen a global shortage of a key ingredient used to manufacture FC2 lubricant, which may give future pricing pressure and stock availability. Strategic supply stocks have been ordered to mitigate this risk, but our supply may not be sufficient to meet demand for FC2 globally or in any particular market.

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, supply chain problems, inflation, political instability, 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.

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 sabizabulin 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 our 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 November 29, 2021, our executive officers and directors collectively beneficially owned approximately 23.1% of the outstanding shares of our common stock, including approximately 10.8% beneficially owned by Mitchell Steiner, M.D., our Chairman, President and Chief Executive Officer, and 10.6% 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 residual royalty 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 residual royalty 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 residual royalty 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. 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.

In June 2021, the Company executed a lease for its new corporate headquarters in Miami, Florida. The Company will be leasing approximately 12,000 square feet of office space for an eight-year term commencing on the later of March 1, 2022 or the date the landlord substantially completes tenant improvements. The space will replace the Company's current corporate headquarters in Miami, Florida when the existing lease terminates at the end of February 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 Division 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 Division 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 November 29, 2021 was approximately 159.

Item 6. Reserved

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

Overview

Veru is principally an oncology biopharmaceutical company with a focus on developing novel medicines for the management of breast and prostate cancers. One of our anticancer drugs, sabizabulin, also has dual antiviral and anti-inflammatory effects and is also being developed for the treatment of hospitalized COVID-19 patients at high risk for acute respiratory distress syndrome (ARDS). The Company has a commercial Sexual Health Division which includes a drug candidate, ENTADFI™, for the treatment of benign prostatic hyperplasia (BPH) and a commercial product, the FC2 Female Condom® (Internal Condom) (FC2), an FDA-approved product for the dual protection against unplanned pregnancy and the transmission of sexually transmitted infections.

The Biopharmaceutical Business:

The Company's breast cancer drug pipeline has four clinical development programs for two drugs: enobosarm, oral selective androgen receptor agonist, and sabizabulin, oral cytoskeleton disruptor.

Hormone receptor positive HER2- metastatic breast cancer:

Phase 3 clinical study – Enobosarm as a 3rd line treatment of AR+ER+HER2- metastatic breast cancer (AR nuclei staining ≥40%). We are enrolling the Phase 3 multicenter, international, open label, and randomized (1:1) ARTEST registration clinical trial design to evaluate the efficacy and safety of enobosarm monotherapy versus physician's choice of either exemestane ± everolimus or a SERM as the active comparator for the treatment of AR+ ER+ HER2- metastatic breast cancer in approximately 210 patients with AR nuclei staining ≥40% in their breast cancer tissue who had tumor progression on a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor. We have identified that patients who have greater than 40% androgen receptor nuclei staining in their breast cancer tissue are most likely to respond to enobosarm. Based on the recommendation of the FDA to have a companion diagnostic test to determine the patient's AR status, we are partnering with Roche/Ventana Diagnostics, a global oncology diagnostics company, who will develop and commercialize a companion diagnostic AR test.

Phase 2b clinical study – Sabizabulin as a 3rd line treatment of AR+ER+HER2- metastatic breast cancer (AR nuclei staining <40%). We also intend to conduct a Phase 2b clinical study of sabizabulin, a novel oral cytoskeleton disruptor, for the treatment of AR+ ER+ HER2- metastatic breast cancer in patients with an AR nuclei staining <40%. The Phase 2b clinical trial will be an open label, multicenter, and randomized (1:1) study evaluating the efficacy and safety of sabizabulin 32mg monotherapy versus physician's choice of either exemestane ± everolimus or a SERM as the active comparator for the treatment of ER+ HER2- metastatic breast cancer in approximately 200 patients with AR nuclei staining <40% in their breast cancer tissue who had tumor progression on a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor. The Phase 2b study is expected to commence during the first quarter of calendar year 2022.

Phase 3 clinical study – Enobosarm + abemaciclib combination as a 2nd line treatment of AR+ER+HER2- metastatic breast cancer (AR nuclei staining ≥40%). We intend to conduct a Phase 3 multicenter, open label, randomized (1:1), active control clinical study, named ENABLAR-2 to evaluate the efficacy and safety of enobosarm plus abemaciclib combination therapy versus an alternative estrogen blocking agent (fulvestrant or an aromatase inhibitor) in subjects with AR+ ER+ HER2- metastatic breast cancer who have failed first line palbociclib (a CDK4/6 inhibitor) plus an estrogen blocking agent (non-steroidal aromatase inhibitor or fulvestrant) and have an AR nuclei staining ≥ 40% in their breast cancer tissue. We plan to enroll approximately 186 subjects in this Phase 3 clinical study which is expected to commence during the first quarter of calendar year 2022.

Metastatic triple negative breast cancer:

Phase 2b clinical study - Sabizabulin + enobosarm combination therapy for the treatment of patients who have AR+ metastatic triple negative breast cancer and who have tumor progression after receiving at least 2 systemic chemotherapies. The Company plans to commence a single arm, sabizabulin plus enobosarm combination therapy Phase 2b clinical study in the first quarter of calendar year 2022 in approximately 111 women.

The Company's prostate cancer drug pipeline includes sabizabulin, VERU-100 and zuclomiphene citrate.

Sabizabulin 32mg for the treatment of metastatic castration resistant and androgen receptor targeting agent resistant prostate cancer-

Phase 1b/2 clinical studies to determine maximum tolerated dose and recommended dosing of sabizabulin. We are completing the Phase 1b open label clinical trial of sabizabulin in 39 men with metastatic castration resistant and androgen receptor targeting agent resistant prostate cancer ± taxane chemotherapy and the Phase 2 clinical study in 41 men with metastatic castration resistant prostate cancer who have also become resistant to at least one androgen receptor targeting agent, but prior to proceeding to IV chemotherapy. In the Phase 1b/2 studies, sabizabulin was both well tolerated and demonstrated promising preliminary efficacy data.

Phase 3 VERACITY clinical study. We are currently enrolling the Phase 3 VERACITY registration study evaluating sabizabulin 32mg in men approximately 245 men who have metastatic castration resistant prostate cancer and who had tumor progression while receiving at least one androgen receptor targeting agent, but prior to IV chemotherapy.

VERU-100, long acting GnRH antagonist subcutaneous depot, for the treatment of advanced hormone sensitive prostate cancer-

Phase 2 dose finding clinical study. Currently enrolling study to determine optimal dose of VERU-100 in men with advance hormone sensitive prostate cancer. Phase 2 clinical results are expected in early 2022.

Phase 3 registration clinical study. If the Phase 2 trial is successful, and as discussed with and agreed upon by the FDA, the Phase 3 clinical trial will be a single arm, multicenter, open-label study in approximately 100 men with hormone sensitive advanced prostate cancer using the achievement and maintenance of castration levels of testosterone as the primary endpoint. The Phase 3 registration study is planned to initiate in the first half of calendar year 2022.

Zuclomiphene citrate, estrogen receptor agonist, for the treatment of hot flashes caused by prostate cancer hormonal therapies in men with advanced prostate cancer-

Phase 2b zuclomiphene clinical study. The Company reported positive dose finding Phase 2 study in January 2020. The Company plans to further optimize the dosing schedule of zuclomiphene citrate in a Phase 2b study.

The Company is opportunistically developing sabizabulin 9mg, which has both broad anti-inflammatory and anti-viral properties as a two-pronged approach to the treatment of COVID-19 virus infection.

Phase 3 COVID-19 registration trial: Sabizabulin 9mg for the treatment of hospitalized moderate to severe COVID-19 patients at high risk for acute respiratory distress syndrome- We are enrolling a global Phase 3 COVID-19 clinical registration trial which is a double-blind randomized (2:1) placebo-controlled trial evaluating daily oral doses of 9 mg sabizabulin for 21 days versus placebo in approximately 300 moderate to severe COVID-19 hospitalized subjects who are at high risk for developing ARDS, which remains an unmet medical need. The Company anticipates having results for Phase 3 clinical trial in the first half of calendar year 2022.

Sexual Health Division

The Company's Sexual Health Division includes a drug candidate, ENTADFI™, for the treatment of benign prostatic hyperplasia (BPH) and a commercial product, the FC2 Female Condom® (internal condom) (FC2), an FDA-approved product for the dual protection against unplanned pregnancy and the transmission of sexually transmitted infections.

ENTADFI™ (tadalafil 5mg and finasteride 5mg capsule) is being developed to treat urinary tract symptoms caused by BPH. The co-administration of tadalafil and finasteride has been shown to be more effective for the treatment of BPH than finasteride alone with no adverse effects on sexual function. The NDA was submitted in February 2021, filed by the FDA in April 2021 with a PDUFA date in December 2021. If approved, ENTADFI™ is expected to be marketed and distributed by telemedicine (telemedicine being the remote diagnosis and treatment of patients by means of telecommunications technology) and telepharmacy channels. The Company's Sexual Health Business segment will include future revenues for ENTADFI, if approved. Costs associated with the development of ENTADFI™ are currently included in our Research and Development segment.

The Company sells FC2 in both the commercial sector and in the public health sector both in the U.S. and globally. In the U.S., FC2 is available by prescription through multiple telemedicine and internet pharmacy channels as well as retail pharmacies. The Company is establishing its own dedicated direct to patient telemedicine and pharmacy services portal/platform to continue to drive sales growth. FC2 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.

All 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 and in fiscal 2021 through the date the transaction closed. 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 from time to time 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.

To date, COVID-19 has not impacted the Company's ability to supply product demand for FC2. We have experienced, and continue to experience, some temporary disruptions to our manufacturing facility due to the implementation of government policies. 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 with continued social distancing requirements on May 4, 2020. On June 1, 2021, the Malaysian government issued a nationwide lockdown order placing limitations on social and economic activity in the country. The Company was able to secure the required approvals, as a health product, to continue to partially operate by reducing the number of employees physically allowed in the facilities to 60% of the total workforce. On July 3, 2021, the lockdown was strengthened in the region in which the Company operates and the Company entered into a two-week period ceasing all operations, in common with similar manufacturing businesses. On July 19, 2021, after allowing some time for staff testing, operations resumed at the required levels of 60% of the total workforce. The Company has partially mitigated the disruption to production by changing staffing patterns. From time to time, we have temporarily paused operations as part of our contact tracing protocols and to allow for cleaning and disinfection of our production facility.

The Company has enrolled manufacturing staff in a vaccination program. More than 95% of the staff have received two doses of vaccination. This has allowed shift patterns to return to normal and the facility is allowed to operate at 100% capacity under the current Malaysia control orders.

The Company has had and believes it continues to have a sufficient quantity of FC2 inventory both inside and outside of Malaysia to satisfy expected customer demand. The recent closure and reduced operating capacity did not have a material impact to the Company's consolidated operating results in fiscal 2021 and we do not expect them to have a material impact on the Company's consolidated operating results in foreseeable future periods. The Company continues to operate enhanced health and safety protocols 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 is subject to future government mandates to counter COVID-19 or 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 also produces surgical gloves and has at times prioritized their production 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 reduced capacity, and the Company may also encounter issues shipping product into key markets or through freight or other carriers. To mitigate these factors, the Company continues to build strategic stock to ensure supply is available during a period of potential disruption. 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 channel 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 fiscal 2021.

To protect the health and safety of our workforce, we closed our offices in the United States and the United Kingdom temporarily. Offices have reopened but non-essential staff and our personnel have largely continued to work 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 as a result of uncertainties, including the extent and rate of the spread of the virus that continue to fluctuate, the potential for additional peaks in infection rates, and the timing and availability of vaccines, treatments or cures to slow and eventually stop the spread. 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 global 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 accessing fast-growing, highly reputable telemedicine firms 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. The Company is establishing its own dedicated direct to patient telemedicine and pharmacy services portal to continue to drive sales growth.

FC2 Global Public Health Sector. FC2's use is for the prevention of HIV/AIDS and the transmission of other sexually transmitted diseases and prevention of unplanned pregnancies, and the global public health sector has been an important 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 unplanned 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 through 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 the World Health Organization, 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 tender was extended until January 2022. The Company began shipping units under this tender award in the third quarter of fiscal 2019 and we have shipped approximately 16.1 million units through September 30, 2021. In October 2020, the Company was awarded up to 20 million units through its distributor in Brazil under the new Brazil female condom tender. These units are expected to be delivered over two years. The Company began shipping units under this tender award in the first quarter of fiscal 2021 and we have shipped approximately 9.7 million units through September 30, 2021.

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

Period	2021	2020	2019	2018	2017
October 1 – December 31	12,318,988	10,070,700	7,382,524	4,399,932	6,389,320
January 1 – March 31	8,189,552	6,884,472	9,792,584	4,125,032	4,549,020
April 1 – June 30	11,201,588	10,532,048	10,876,704	10,021,188	8,466,004
July 1 - September 30	6,095,332	5,289,908	9,842,020	6,755,124	6,854,868
Total	37,805,460	32,777,128	37,893,832	25,301,276	26,259,212

Revenues. The Company's revenues are primarily derived from sales of FC2 in the U.S. prescription channel and global public health sector. The Company also had revenues from sales of PREBOOST® (Roman Swipes) through the date the PREBOOST® business was sold on December 8, 2020. 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.

We have recently seen an increase in the cost of the nitrile polymer used to produce FC2 and may experience increases in other material costs due to the impact of COVID-19 and increased inflation. Our costs of sales and gross margins may be adversely impacted if we are unable to pass along cost increases to our customers.

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 $32.7 million and $16.9 million for fiscal 2021 and 2020, respectively. In fiscal 2022, 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, 2021 COMPARED TO YEAR ENDED SEPTEMBER 30, 2020

The Company generated net revenues of $61.3 million and net income of $7.4 million, or $0.10 per basic common share and $0.09 per diluted common share, in fiscal 2021, compared to net revenues of $42.6 million and net loss of $19.0 million, or $(0.28) per basic and diluted common share, in fiscal 2020. Net revenues increased 44% year over year.

FC2 net revenues increased 49% year over year. There was a 15% increase in total FC2 unit sales and an increase in FC2 average sales price per unit of 29%. 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 77% of total FC2 net revenues in fiscal 2021 compared to 67% of total FC2 net revenues in fiscal 2020. The Company experienced an increase of 71% in FC2 net revenues in the U.S. prescription channel and an increase of 4% in FC2 net revenues in the global public health sector.

Cost of sales increased to $13.3 million in fiscal 2021 from $11.8 million in fiscal 2020 primarily due to an increase in unit sales. An increase in cost of raw materials was substantially offset by decreases in labor, transportation, and equipment maintenance costs.

Gross profit increased to $47.9 million in fiscal 2021 from $30.8 million in fiscal 2020. Gross profit margin for fiscal 2021 was 78% of net revenues, compared to 72% of net revenues for fiscal 2020. In fiscal 2021, 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 and gross profit margin.

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 $32.7 million in fiscal 2021 from $16.9 million in fiscal 2020. The increase is primarily due to increased costs associated with the multiple in-process research and development projects and increased personnel costs. In fiscal 2021, the Company initiated two Phase 3 clinical trials and one Phase 2 clinical trial with additional clinical trial initiations planned to soon commence. This ongoing clinical trial activity has resulted in increased costs. Additionally, in fiscal 2020, research and development expenses were reduced by $0.1 million due to the funds received under the Paycheck Protection Program. See Note 15 to the financial statements included in this report for additional information related to the Paycheck Protection Program.

Selling, general and administrative expenses increased to $20.7 million in fiscal 2021 from $14.5 million in fiscal 2020. The increase is primarily due to increased personnel costs, drug commercialization costs, and insurance costs. Additionally, in fiscal 2020, selling, general, and administrative costs were reduced by $0.4 million due to the funds received under the Paycheck Protection Program. See Note 15 to the financial statements included in this report for additional information related to the Paycheck Protection Program.

During the first quarter of fiscal 2021, we recorded a pre-tax gain on sale of the Company's PREBOOST® business of $18.4 million. See Note 2 to the financial statements included in this report for additional information.

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, 2021 and 2020. There was no impairment charge recorded in fiscal 2021.

Interest expense, which primarily consists of items related to the Credit Agreement and Residual Royalty Agreement, was $4.9 million in fiscal 2021, increased from $4.6 million in fiscal 2020. The increase is due to an increase in the accretion of the Residual Royalty Agreement, for which payments began during fiscal 2021, partially offset by decreases in the amortization of discounts and deferred issuance costs related to the Credit Agreement.

Expense associated with the change in fair value of the embedded derivatives related to the Credit Agreement and Residual Royalty Agreement was $3.7 million in fiscal 2021 compared to expense of $0.6 million in fiscal 2020. The liabilities associated with embedded derivatives represent the fair value of the change of control provisions in the Credit Agreement and Residual Royalty Agreement. The increase in the fair value of the embedded derivates is due to an increase in projected FC2 net revenues in future periods and decrease in the discount rates used, driven by external market factors. See Note 3 and Note 9 to the financial statements included in this report for additional information.

The income tax benefit in fiscal 2021 was $3.1 million, compared to the income tax benefit of $1.1 million in fiscal 2019. The increase in the income tax benefit of $2.0 million is primarily due an increase in the income tax benefit of $2.4 million for the change in U.K. tax rates, $3.8 million due to the exercise of stock options and warrants, and $2.8 million in R&D credits, partially offset by the increase in income tax expense of $5.5 million resulting from the increase in income before income taxes and $1.3 million from the increase in the valuation allowance.

Liquidity and Sources of Capital

Liquidity

Our cash and cash equivalents on hand on September 30, 2021 was $122.4 million, compared to $13.6 million on September 30, 2020. On September 30, 2021, the Company had working capital of $136.0 million and stockholders' equity of $152.3 million compared to working capital of $12.3 million and stockholders' equity of $30.1 million as of September 30, 2020. The increase in working capital is primarily due to the increase in cash on hand and an increase in prepaid research and development costs.

We anticipate that we will continue to consume cash 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 or the conditions for raising capital are favorable, the Company 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) or under a new registration statement.

Operating activities

Our operating activities used cash of $15.6 million in fiscal 2021. Cash used in operating activities included net income of $7.4 million, adjustments to reconcile net income to net cash provided by operating activities totaling a reduction of $15.7 million and changes in operating assets and liabilities of $7.3 million. Adjustments to net income primarily consisted of $18.4 million for the gain on sale of the PREBOOST® business, $3.6 million of interest paid in excess of interest expense, and $3.6 million of deferred income taxes, partially offset by share-based compensation of $5.1 million and an increase in the fair value of derivative liabilities of $3.7 million. The decrease in cash from changes in operating assets and liabilities included an increase in accounts receivable of $3.6 million and an increase in prepaid expenses and other assets of $8.6 million, partially offset by a decrease in accrued expenses and other current liabilities of $4.2 million.

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.

Investing activities

Net cash from investing activities was $14.6 million in fiscal 2021, attributed to $15.0 million received from the sale of the Company's PREBOOST® business, partially offset by $0.4 million in capital expenditures for manufacturing and office equipment.

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

Financing activities

Net cash provided by financing activities in fiscal 2021 was $109.7 million and primarily consisted of proceeds from the underwritten public offering of the Company's common stock, net of fees and costs paid through September 30, 2021, of $108.0 million (see discussion below) and proceeds from stock option exercises of $1.8 million.

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.

Sources of Capital

Common Stock Offering

On February 22, 2021, we completed an underwritten public offering of 7,419,354 shares of our common stock, which included the exercise in full of the underwriters' option to purchase additional shares, at a public offering price of $15.50 per share. Net proceeds to the Company from this offering were $108.0 million after deducting underwriting discounts and commissions and costs incurred by the Company. All of the shares sold in the offering were by the Company. The offering was made pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-239493).

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 was 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 Company repaid the loan and return premium specified in the Credit Agreement in August 2021, and as a result has no further obligations under the Credit Agreement.

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, which continues after the repayment of the loan and return premium under the Credit Agreement. The Residual Royalty Agreement will terminate upon (i) a change of control or sale of the FC2 business and the payment by the Company of the amount due in connection therewith pursuant to the Credit Agreement, or (ii) mutual agreement of the parties.

The Company made total payments under the Credit Agreement of $7.3 million and $4.7 million during fiscal 2021 and 2020, respectively. The Company began making payments under the Residual Royalty Agreement during fiscal 2021, totaling $1.1 million during the year. The Company currently estimates the aggregate amount of quarterly revenue-based payments payable during the 12-month period subsequent to September 30, 2021 will be approximately $3.2 million under the Residual Royalty Agreement.

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. As of September 30, 2021, there was $18.9 million remaining under the 2020 Purchase Agreement, which is registered under the Company's shelf registration statement on Form S-3 (File No. 333-239493). Effective June 26, 2020, upon the execution of the 2020 Purchase Agreement, the Company's prior purchase agreement with Aspire Capital was terminated.

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 $4.7 million should be recorded against the U.S. deferred tax assets related to federal and state net operating loss carryforwards as of September 30, 2021. 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 $3.2 million, which increased by $0.8 million due to the change in U.K. tax rates (see below). 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 June 10, 2021, the U.K. Finance Act 2021 was enacted increasing the U.K. tax rate from 19% to 25% effective April 1, 2023. The increase in the tax rate increased the value of the deferred tax assets in the U.K. by $3.7 million with a corresponding valuation allowance of $0.8 million, which resulted in a net income tax benefit of $3.0 million.

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, 2021, the Company's financial liabilities measured at fair value on a recurring basis, which consisted of embedded derivatives, represents the fair value of the change of control provisions in the Residual Royalty Agreement. See Note 9 to the financial statements included in this report.

The fair value of these liabilities were estimated based on unobservable inputs (Level 3 measurement), which requires highly subjective judgment and assumptions. The Company determined the fair values of the embedded derivatives using a Monte Carlo simulation model. This valuation model incorporates the contractual terms of the instruments and assumptions including projected FC2 revenues over a 10-year period, expected cash outflows, probability and estimated dates of a change of control, expected volatility, and risk-free interest rates and applicable credit risk. 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.

The fair value of the embedded derivatives at September 30, 2021 was $7.9 million compared to $4.2 million at September 30, 2020. The Company recognized non-operating expense of $3.7 million to adjust the fair value of these instruments. The increase in the fair value of the embedded derivates is due to an increase in projected FC2 net revenues in future periods and decreases in the discount rates, resulting from external market factors.

Goodwill and Intangible Assets

The Company has $6.9 million recorded as goodwill at September 30, 2021 and 2020 and $4.0 million and $5.8 million in intangible assets at September 30, 2021 and 2020, respectively. 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. 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, 2021, based on criteria in “Internal Control - Integrated Framework” issued by the COSO in 2013.

Report of Independent Registered Public Accounting Firm

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

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information with respect to this item is incorporated herein by reference to the discussion under the headings "Proposal 1: Election of Directors," "Executive Officers," "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 2022 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 28, 2022. 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 2022 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 28, 2022.

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 Lucy Lu, M.D. (Chairperson), Michael L. Rankowitz and Mario Eisenberger, M.D.

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 2022 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 28, 2022.

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" and "Equity Compensation Plan Information" in the Company's Proxy Statement for the 2022 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 28, 2022.

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 2022 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 28, 2022. 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 2022 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 28, 2022.

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 2022 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 28, 2022.

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, 2021 and 2020

Consolidated Statements of Operations for the Years Ended September 30, 2021 and 2020

Consolidated Statements of Stockholders' Equity for the Years Ended September 30, 2021 and 2020

Consolidated Statements of Cash Flows for the Years Ended September 30, 2021 and 2020

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	Asset Purchase Agreement, dated as of December 8, 2020, between the Company and Roman Health Ventures Inc (incorporated by reference to Exhibit 2.2 to the Company's Form 10-K (File No. 1-13602) filed with the SEC on December 10, 2020).
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 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). *

10.3 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). *

10.4 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). *

10.5 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). *

10.6 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). *

10.7 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).*

10.8 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).*

10.9 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). *

10.10 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). *

10.11 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). *

10.12 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). *

10.13 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). *

10.14	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). *
10.15	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. *
10.16	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). *
10.17	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).
10.18	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).
10.19	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).
10.20	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).
10.21	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). **, ***
101	The following materials from the Company's Annual Report on Form 10-K for the year ended September 30, 2021, formatted in iXBRL (Inline 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.
104	Cover Page Interactive Data File (formatted as iXBRL and contained in Exhibit 101).

*	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 2, 2021

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 Mitchell S. Steiner	Chairman of the Board, Chief Executive Officer, President and Director (Principal Executive Officer)	December 2, 2021
/s/ Michele Greco Michele Greco	Chief Financial Officer and Chief Administrative Officer (Principal Accounting and Financial Officer)	December 2, 2021
/s/ Mario Eisenberger Mario Eisenberger	Director	December 2, 2021
/s/ Harry Fisch Harry Fisch	Vice Chairman of the Board and Director	December 2, 2021
/s/ Grace S. Hyun Grace S. Hyun	Director	December 2, 2021
/s/ Lucy Lu Lucy Lu	Director	December 2, 2021
/s/ Michael L. Rankowitz Michael L. Rankowitz	Director	December 2, 2021

Veru Inc.

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the 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, 2021 and 2020, 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, 2021 and 2020, 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Valuation Allowance for Deferred Tax Assets

As described in Note 14 to the consolidated financial statements, the Company has recorded net deferred tax assets totaling approximately $13.0 million and net deferred tax liabilities totaling approximately $63,000 at September 30, 2021. The Company has recorded a valuation allowance of approximately $19.6 million at September 30, 2021 against its deferred tax assets in the United States and certain deferred tax assets in the United Kingdom. The Company has approximately $12.9 million of net deferred tax assets in the United Kingdom (U.K.) for which there is no valuation allowance. Management assesses the need for valuation allowances at least annually. Deferred tax assets are reduced by a tax valuation allowance when, in the opinion of management, it is more likely than not that some portion of the deferred tax assets will not be realized. In evaluating the Company's ability to realize its deferred tax assets, management considers all available positive and negative evidence on a country-by-country basis, including past operating results, forecasts of future taxable income and the potential Section 382 limitation on the net operating loss (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.

We identified the deferred tax valuation allowance as a critical audit matter because of the assumptions management makes in determining the estimate which consists of forecasting future taxable income by jurisdiction. Auditing management's forecast of future taxable income in the U.K. involved a high degree of subjectivity and auditor judgment as changes in the assumptions could have a significant impact on the realization of the deferred tax assets in the U.K.

Our audit procedures related to the realization of the Company's deferred tax assets included the following, among others:

- We evaluated management's ability to accurately forecast revenue and taxable income by comparing management's prior forecasts to historical results for the U.K.
- We evaluated the reasonableness of management's forecasted revenue and taxable income, including revenue growth rates and margins, by comparing the projections to historic results and industry expectations.
- We evaluated the reasonableness of management's forecasted revenue by comparing the projections and assumptions utilized to evidence obtained in other areas of the audit.
- With the assistance of tax specialists, we compared tax rates and remaining lives of NOLs utilized by management to regulations in effect.
- We tested the mathematical accuracy of the calculation.

/s/ RSM US LLP

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

Chicago, Illinois
December 2, 2021

VERU INC.
CONSOLIDATED BALANCE SHEETS
AS OF SEPTEMBER 30, 2021 AND 2020

	2021	2020
Assets		
Current assets:		
Cash and cash equivalents	$ 122,359,535	$ 13,588,778
Accounts receivable, net	8,794,224	5,227,237
Notes receivable	5,000,000	—
Inventory, net	5,574,253	6,704,134
Prepaid research and development costs	9,174,586	613,274
Prepaid expenses and other current assets	850,889	881,267
Total current assets	151,753,487	27,014,690
Property and equipment, net	592,603	312,691
Operating lease right-of-use asset	969,839	1,352,315
Deferred income taxes	13,024,550	9,466,800
Intangible assets, net	4,048,810	5,752,127
Goodwill	6,878,932	6,878,932
Other assets	878,502	766,120
Total assets	$ 178,146,723	$ 51,543,675
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,409,771	$ 2,812,673
Accrued research and development costs	2,020,445	934,110
Accrued compensation	4,986,058	2,274,396
Accrued expenses and other current liabilities	1,615,922	1,177,126
Credit agreement liability (Note 9)	—	5,841,874
Residual royalty agreement, short-term portion (Note 9)	3,237,211	1,100,193
Operating lease liability, short-term portion	497,903	586,769
Total current liabilities	15,767,310	14,727,141
Residual royalty agreement, long-term portion (Note 9)	9,397,136	5,617,494
Operating lease liability, long-term portion	609,921	990,020
Deferred income taxes	63,426	74,724
Other liabilities	14,986	22,980
Total liabilities	25,852,779	21,432,359
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock, no shares issued and outstanding at September 30, 2021 and 2020, respectively	—	—
Common stock, par value $0.01 per share; 154,000,000 shares authorized, 82,153,452 and 72,047,385 shares issued and 79,969,748 and 69,863,681 shares outstanding at September 30, 2021 and 2020, respectively	821,535	720,474
Additional paid-in-capital	241,658,711	126,971,518
Accumulated other comprehensive loss	(581,519)	(581,519)
Accumulated deficit	(81,798,178)	(89,192,552)
Treasury stock, 2,183,704 shares, at cost	(7,806,605)	(7,806,605)
Total stockholders' equity	152,293,944	30,111,316
Total liabilities and stockholders' equity	$ 178,146,723	$ 51,543,675

See notes to consolidated financial statements.

VERU INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED SEPTEMBER 30, 2021 AND 2020

	2021	2020
Net revenues	$ 61,259,528	$ 42,592,060
Cost of sales	13,332,305	11,805,202
Gross profit	47,927,223	30,786,858
Operating expenses:		
Research and development	32,694,405	16,935,222
Selling, general and administrative	20,670,319	14,498,330
Total operating expenses	53,364,724	31,433,552
Gain on sale of PREBOOST® business	18,410,158	—
Impairment of intangible assets	—	(14,100,000)
Operating income (loss)	12,972,657	(14,746,694)
Non-operating expenses:		
Interest expense	(4,886,054)	(4,621,422)
Change in fair value of derivative liabilities	(3,669,000)	(557,000)
Other expense, net	(152,367)	(126,860)
Total non-operating expenses	(8,707,421)	(5,305,282)
Income (loss) before income taxes	4,265,236	(20,051,976)
Income tax benefit	(3,129,138)	(1,078,441)
Net income (loss)	$ 7,394,374	$ (18,973,535)
Net income (loss) per basic common share outstanding	$ 0.10	$ (0.28)
Basic weighted average common shares outstanding	76,272,853	66,753,450
Net income (loss) per diluted common share outstanding	$ 0.09	$ (0.28)
Diluted weighted average common shares outstanding	83,802,420	66,753,450

See notes to consolidated financial statements.

VERU INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED SEPTEMBER 30, 2021 AND 2020

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Treasury Stock,	
	Shares	Amount	Capital	Loss	Deficit	at Cost	Total
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
Share-based compensation	—	—	5,050,389	—	—	—	5,050,389
Shares issued in connection with public offering of common stock, net of fees and costs	7,419,354	74,194	107,888,104	—	—	—	107,962,298
Issuance of shares pursuant to share-based awards	1,112,102	11,121	1,764,446	—	—	—	1,775,567
Issuance of shares pursuant to common stock purchase warrants	1,574,611	15,746	(15,746)	—	—	—	—
Net income	—	—	—	—	7,394,374	—	7,394,374
Balance at September 30, 2021	82,153,452	$ 821,535	$ 241,658,711	$ (581,519)	$ (81,798,178)	$ (7,806,605)	$ 152,293,944

See notes to consolidated financial statements.

VERU INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED SEPTEMBER 30, 2021 AND 2020

	2021	2020
OPERATING ACTIVITIES		
Net income (loss)	$ 7,394,374	$ (18,973,535)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	211,394	462,741
Impairment of intangible assets	—	14,100,000
Noncash change in right-of-use assets	382,476	320,900
Noncash interest expense, net of interest paid	(3,594,214)	4,306,927
Share-based compensation	5,050,389	2,646,246
Gain on sale of PREBOOST® business	(18,410,158)	—
Deferred income taxes	(3,569,048)	(1,255,012)
Provision for obsolete inventory	583,503	244,823
Change in fair value of derivative liabilities	3,669,000	557,000
Other	(6,182)	6,091
Changes in operating assets and liabilities:		
Increase in accounts receivable	(3,561,987)	(87,790)
Decrease (increase) in inventory	546,378	(3,301,551)
(Increase) decrease in prepaid expenses and other assets	(8,643,316)	621,777
Increase (decrease) in accounts payable	597,098	(312,078)
Increase (decrease) in accrued expenses and other current liabilities	4,248,234	(946,390)
Decrease in operating lease liabilities	(468,965)	(320,244)
Net cash used in operating activities	(15,571,024)	(1,930,095)
INVESTING ACTIVITIES		
Cash proceeds from sale of PREBOOST® business	15,000,000	—
Capital expenditures	(376,649)	(105,760)
Net cash provided by (used in) investing activities	14,623,351	(105,760)
FINANCING ACTIVITIES		
Proceeds from sale of shares in public offering, net of fees	108,099,988	—
Payment of costs related to public offering	(137,690)	—
Installment payments on SWK credit agreement	—	(4,421,915)
Proceeds from sale of shares under common stock purchase agreement	—	13,399,999
Payment of costs related to common stock purchase agreement	—	(50,284)
Proceeds from stock option exercises	1,775,567	415,464
Proceeds from premium finance agreement	1,061,442	836,780
Installment payments on premium finance agreement	(1,061,442)	(836,780)
Cash paid for debt portion of finance lease	(19,435)	(13,783)
Net cash provided by financing activities	109,718,430	9,329,481
Net increase in cash and cash equivalents	108,770,757	7,293,626
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	13,588,778	6,295,152
CASH AND CASH EQUIVALENTS AT END OF YEAR	$ 122,359,535	$ 13,588,778
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 248,746	$ 362,060
Cash paid for interest	$ 8,480,268	$ 314,495
Schedule of non-cash investing and financing activities:		
Notes receivable for sale of PREBOOST® business	$ 5,000,000	$ —
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

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 breast and prostate cancers. The Company has two operating segments: the Research and Development segment and the Sexual Health Business segment. The Company has multiple drug products under clinical development. Activities related to these potential drug products are included in the Research and Development segment. 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, 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 2 for additional information. Most of the Company's net revenues during fiscal 2021 and 2020 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. The fair value of the reporting unit is compared with its carrying amount and an impairment charge would be recognized for the amount by which the carrying value exceeds the reporting unit's fair value.

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, 2021 and 2020. 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 credit agreement liability on the accompanying consolidated balance sheet at September 30, 2020. These issuance costs were amortized using the effective interest method over the repayment period of the debt. The debt was repaid in August 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 material capitalized nonrefundable advance payments as of September 30, 2021 and September 30, 2020.

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, 2021 and 2020.

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, 2021 and September 30, 2020. Assets located outside of the U.S. totaled approximately $8.5 million and $9.2 million at September 30, 2021 September 30, 2020, 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 2021 and 2020, comprehensive income (loss) is equivalent to the reported net income (loss).

Recently adopted accounting pronouncements: In June 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-13, Financial Instruments—Credit Losses (Topic 326). This ASU introduces a new accounting model, the Current Expected Credit Losses model (CECL), which could result in earlier recognition of credit losses and additional disclosures related to credit risk. The CECL model requires the Company to use a forward-looking expected credit loss impairment methodology for the recognition of credit losses for financial instruments at the time the financial asset is originated or acquired. The expected credit losses are adjusted each period for changes in expected lifetime credit losses. This model replaces the multiple existing impairment models in current U.S. GAAP, which generally require that a loss be incurred before it is recognized. The new standard also applies to receivables arising from revenue transactions such as accounts receivable. The Company adopted ASU 2016-13 on a modified-retrospective basis effective October 1, 2020. The adoption of ASU 2016-13 did not impact our consolidated financial statements and related disclosures.

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. The Company adopted ASU 2017-04 on a prospective basis effective October 1, 2020. The adoption of ASU 2017-04 did not impact our consolidated financial statements and related disclosures.

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. The Company adopted ASU 2018-13 on a retrospective basis effective October 1, 2020. The adoption of ASU 2018-13 did not impact our financial position, results of operations, or cash flows as it modified disclosure requirements only.

Recent accounting pronouncements not yet adopted: 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 – Sale of PREBOOST® Business

On December 8, 2020, the Company entered into an Asset Purchase Agreement, pursuant to which the Company sold substantially all of the assets related to the Company's PREBOOST business. PREBOOST is a 4% benzocaine medicated individual wipe for the treatment of premature ejaculation and was a commercial product in the Company's Sexual Health Division until the date of the sale. 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, a $2.5 million note receivable due 12 months after closing and a $2.5 million note receivable due 18 months after closing. Total assets sold, consisting of intangible assets, had a net book value of approximately $1.6 million, resulting in a pre-tax gain on sale of approximately $18.4 million. The Company had income before income taxes of $327,000 and $1.2 million during fiscal 2021 and 2020, respectively, related to the PREBOOST business before the sale.

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 2021 and 2020.

Amounts capitalized as IPR&D are subject to impairment testing until the completion or abandonment of the associated research and development efforts. We use 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 impairment, if any. 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. See Note 8 for additional information.

As of September 30, 2021 and 2020, the Company's financial liabilities measured at fair value on a recurring basis, which consisted of embedded derivatives, are also 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, 2021 and 2020:

	2021	2020
Beginning balance	$ 4,182,000	$ 3,625,000
Change in fair value of derivative liabilities	3,669,000	557,000
Ending balance	$ 7,851,000	$ 4,182,000

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 the contractual terms of the instruments and assumptions including projected FC2 revenues, expected cash outflows, expected repayment dates, probability and estimated dates of a change of control, expected volatility, and risk-free interest rates and applicable credit risk. 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 2021 was driven by decreases in the discount rates used, due primarily to external market factors, and an increase in the expected cash outflows under the Residual Royalty Agreement, due to increases in projected FC2 net revenues in future periods. The increase in fiscal 2020 was driven by changes in the estimated change of control dates and 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, 2021 and 2020:

		Weighted Average (range, if applicable)	
Valuation Methodology	**Significant Unobservable Input**	**2021**	**2020**
Monte Carlo Simulation	Estimated change of control dates	September 2022 to September 2025	December 2021 to June 2022
	Discount rate	6.6% to 7.9%	14.1% to 16.0%
	Probability of change of control	20% to 90%	20% 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 through the date the PREBOOST® business was sold on December 8, 2020. The following table presents net revenues from these three categories for the years ended September 30, 2021 and 2020:

	2021	2020
FC2		
U.S. prescription channel	$ 46,470,448	$ 27,124,462
Global public health sector	13,926,249	13,432,356
Total FC2	60,396,697	40,556,818
PREBOOST®	862,831	2,035,242
Net revenues	$ 61,259,528	$ 42,592,060

The following table presents net revenue by geographic area for the years ended September 30, 2021 and 2020:

	2021	2020
United States	$ 48,938,821	$ 30,338,115
Other	12,320,707	12,253,945
Net revenues	$ 61,259,528	$ 42,592,060

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 $132,000 and $6,000 at September 30, 2021 and 2020, respectively.

The amount of revenue recognized that was included in the contract liabilities and unearned revenues balance at the beginning of the period was $6,000 and $249,000 during the years ended September 30, 2021 and 2020, 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 90 days subsequent to clearance of the product by the Ministry of Health in Brazil.

The components of accounts receivable consist of the following at September 30, 2021 and 2020:

	2021	2020
Trade receivables, gross	$ 8,938,849	$ 5,332,786
Less: allowance for doubtful accounts	(20,643)	(25,643)
Less: allowance for sales returns and payment term discounts	(123,982)	(79,906)
Accounts receivable, net	$ 8,794,224	$ 5,227,237

No customer had a current accounts receivable balance that represented 10% of current assets at September 30, 2021 and 2020.

At September 30, 2021, three customers had an accounts receivable balance greater than 10% of net accounts receivable, representing 90% of net accounts receivable in the aggregate. At September 30, 2020, three customers had an accounts receivable balance greater than 10% of net accounts receivable, representing 89% of the Company's net accounts receivable in the aggregate.

For the year ended September 30, 2021, there were two customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 75% of the Company's net revenues 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.

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, 2021 and 2020:

	2021	2020
Beginning balance	$ 25,643	$ 33,143
Charge-offs, net of recoveries	(5,000)	(7,500)
Ending balance	$ 20,643	$ 25,643

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, 2021 and 2020:

	2021	2020
FC2		
Raw material	$ 1,371,133	$ 962,860
Work in process	112,915	106,272
Finished goods	4,547,690	5,634,612
FC2, gross	6,031,738	6,703,744
Less: inventory reserves	(457,485)	(29,331)
FC2, net	5,574,253	6,674,413
PREBOOST®		
Finished goods	—	29,721
Inventory, net	$ 5,574,253	$ 6,704,134

Note 7 – Property and Equipment

Property and equipment consisted of the following at September 30, 2021 and 2020:

	Estimated Useful Life	2021	2020
Property and equipment:			
Manufacturing equipment	5 - 8 years	$ 2,875,744	$ 2,752,854
Office equipment, furniture and fixtures	3 - 10 years	991,146	803,484
Leasehold improvements	3 - 8 years	298,886	298,886
Total property and equipment		4,165,776	3,855,224
Less: accumulated depreciation and amortization		(3,573,173)	(3,542,533)
Property and equipment, net		$ 592,603	$ 312,691

Depreciation expense for the years ended September 30, 2021 and 2020 was approximately $98,000 and $146,000, respectively.

The Company has a finance lease for office equipment, furniture, and fixtures. The value of the assets under finance lease was $44,000 at September 30, 2021 and 2020 and is included in office equipment, furniture and fixtures above.

Note 8 –Intangible Assets and Goodwill

Intangible Assets

Intangible assets includes 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, 2021:

	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Intangible asset with finite life:			
Covenants not-to-compete	$ 500,000	$ 351,190	$ 148,810
Indefinite-lived intangible assets:			
Acquired in-process research and development assets	3,900,000	—	3,900,000
Total intangible assets	$ 4,400,000	$ 351,190	$ 4,048,810

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

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. 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 was 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 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.

As discussed in Note 2, the Company sold its intangible assets related to PREBOOST® as part of the sale of the PREBOOST® business on December 8, 2020. The remaining net book value of the PREBOOST® technology, acquired in the acquisition of APP, was $1.6 million on the date of the sale. 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 $113,000 and $316,000, for the years ended September 30, 2021 and 2020, respectively. Based on finite-lived intangible assets recorded as of September 30, 2021, the estimated future amortization expense is approximately $71,000 per year through fiscal 2023 and $6,000 in fiscal 2024.

Goodwill

The carrying amount of goodwill at September 30, 2021 and 2020 was $6.9 million. There was no change in the balance during the years ended September 30, 2021 and 2020.

Note 9 – Debt

SWK Credit Agreement and Residual Royalty Agreement

On March 5, 2018, the Company entered into a Credit Agreement (the "Credit Agreement") with the financial institutions party thereto from time to time (the "Lenders") and SWK Funding LLC, as agent for the Lenders (the "Agent"), for a synthetic royalty financing transaction. On and subject to the terms of the Credit Agreement, the Lenders 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 were 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 paid 176.5% of the aggregate amount advanced to the Company under the Credit Agreement. The Company repaid the loan and return premium specified in the Credit Agreement in August 2021, and as a result has no further obligations under the Credit Agreement.

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, which commenced after the Company paid 175% of the aggregate amount advanced to the Company under the Credit Agreement based on a calculation of revenue-based payments under the Credit Agreement. The Residual Royalty Agreement will terminate upon (i) a change of control or sale of the FC2 business and the payment by the Company of the amount due in connection therewith pursuant to the Credit Agreement, or (ii) mutual agreement of the parties. If a change of control or sale of the FC2 business occurs, 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.

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, were 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 were presented as a reduction of the Credit Agreement obligation and were amortized to interest expense over the expected term of the loan using the effective interest method.

At September 30, 2021 and 2020, the Credit Agreement liability consisted of the following:

	2021	2020
Aggregate repayment obligation	$ 17,650,000	$ 17,650,000
Less: cumulative payments	(17,650,000)	(10,314,495)
Remaining repayment obligation	—	7,335,505
Less: unamortized discounts	—	(1,459,330)
Less: unamortized deferred issuance costs	—	(34,301)
Credit agreement liability	$ —	$ 5,841,874

The Company made its final payment to repay the original principal of $10.0 million during the quarter ended September 30, 2020. Remaining quarterly payments under the Credit Agreement were classified as interest payments, consistent with the terms of the Credit Agreement.

At September 30, 2021 and 2020, the Residual Royalty Agreement liability consisted of the following:

	2021	2020
Residual royalty agreement liability, fair value at inception	$ 346,000	$ 346,000
Add: accretion of liability using effective interest rate	5,582,110	2,189,687
Less: cumulative payments	(1,144,763)	—
Residual royalty agreement liability, excluding embedded derivative liability	4,783,347	2,535,687
Add: embedded derivative liability at fair value (see Note 3)	7,851,000	4,182,000
Total residual royalty agreement liability	12,634,347	6,717,687
Residual royalty agreement liability, short-term portion	(3,237,211)	(1,100,193)
Residual royalty agreement liability, long-term portion	$ 9,397,136	$ 5,617,494

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, 2021.

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, 2021 and 2020, interest expense related to the Credit Agreement and Residual Royalty Agreement was as follows:

	2021	2020
Amortization of discounts	$ 1,459,330	$ 3,131,644
Accretion of residual royalty agreement	3,392,423	1,416,169
Amortization of deferred issuance costs	34,301	73,609
Interest expense	$ 4,886,054	$ 4,621,422

Premium Finance Agreement

On November 1, 2020, the Company entered into an agreement to finance $1.1 million of its directors and officers liability insurance premium at an annual percentage rate of 3.94%. The financing agreement was payable in three quarterly installments of principal and interest, which began on January 1, 2021. The last payment was made in June 2021 and there was no balance outstanding as of September 30, 2021

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 in July 2020 and there was 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, 2021 or September 30, 2020. 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, 2021 or September 30, 2020 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. 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. At September 30, 2021, $16.1 million remains available under that shelf registration statement.

Common Stock Offering

On February 22, 2021, we completed an underwritten public offering of 7,419,354 shares of our common stock, which included the exercise in full of the underwriters' option to purchase additional shares, at a public offering price of $15.50 per share. Net proceeds to the Company from this offering were approximately $108.0 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 shelf registration statement on Form S-3 (File No. 333-239493).

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 had 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 fiscal 2021, Financial Advisor Warrants to purchase 2,326,841 shares of the Company's common stock were exercised using the cashless exercise feature, resulting in the issuance of 1,574,611 shares of common stock. During fiscal 2020, Financial Advisor Warrants to purchase 258,538 shares of the Company's common stock were exercised using the cashless exercise feature, resulting in the issuance of 109,143 shares of common stock. As of September 30, 2021, there were no outstanding common stock purchase 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, 2021, 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. There was no activity under the 2020 Purchase Agreement in fiscal 2021. The unamortized amount of deferred costs related to the 2020 Purchase Agreement of $578,000 at September 30, 2021 and 2020 is included in other assets on the accompanying consolidated balance sheets. As of September 30, 2021, the amount remaining under the 2020 Purchase Agreement is $18.9 million.

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 shares of common stock to Aspire Capital under the 2017 Purchase Agreement during the year ended September 30, 2020 resulting in proceeds to the Company of $8.4 million. As a result of these sales, we recorded approximately $238,000 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 were amortized to additional paid-in capital as shares under the agreement were sold.

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 $1.1 million and $599,000 in fiscal 2021 and 2020, respectively. For fiscal 2021 and 2020, we recorded share-based compensation expenses as follows:

	2021	2020
Cost of sales	$ 65,165	$ 52,267
Selling, general and administrative	3,629,732	1,905,192
Research and development	1,355,492	688,787
	$ 5,050,389	$ 2,646,246

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, 2021, 2,872,354 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, 2021, 18,433 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, 2021 and 2020:

	2021	2020
Weighted Average Assumptions:		
Expected Volatility	69.68%	63.13%
Expected Dividend Yield	0.00%	0.00%
Risk-free Interest Rate	0.67%	1.63%
Expected Term (in years)	5.9	5.9
Fair Value of Options Granted	$ 3.58	$ 1.14

During the years ended September 30, 2021 and 2020, 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, 2021:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2020	8,599,000	$ 1.67		
Granted	3,568,625	5.62		
Exercised	(1,112,102)	1.60		
Forfeited	(454,843)	5.78		
Outstanding at September 30, 2021	10,600,680	$ 2.84	7.70	$ 64,473,535
Exercisable at September 30, 2021	5,924,444	$ 1.65	6.83	$ 40,743,351

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, 2021 of $8.53, less the respective weighted average exercise price per share at period end.

The total intrinsic value of options exercised was approximately $9.2 million and $1.1 million during the years ended September 30, 2021 and 2020, respectively. Cash received from options exercised was $1.8 million and $415,000 in the years ended September 30, 2021 and 2020, respectively. During the year ended September 30, 2020, options to purchase 223,415 shares of common stock were exercised using the cashless exercise feature available under the 2017 Plan and 2018 Plan, which resulted in the issuance of 143,958 shares of common stock. There were no options exercised using the cashless exercise feature during the year ended September 30, 2021.

As of September 30, 2021, the Company had unrecognized compensation expense of approximately $9.2 million related to unvested stock options. This expense is expected to be recognized over a weighted average period of 1.6 years.

During fiscal 2021, the Company modified stock options held by certain optionees upon termination of their employment by the Company or resignation from the board of directors. As permitted under the 2018 Plan and with the approval of the Compensation Committee of the Board of Directors, the stock options were primarily modified to accelerate vesting or to allow for continued vesting. The aggregate amount of expense recognized in connection with these modifications for the year ended September 30, 2021 was approximately $550,000.

Stock Appreciation Rights

In fiscal 2017, the Company issued stock appreciation rights based on 50,000 shares of the Company's common stock to an employee that vested on October 31, 2018. The stock appreciation rights have a ten-year term and an exercise price per share of $0.95. Upon exercise, the stock appreciation rights will be settled in common stock issued under the 2017 Plan. As of September 30, 2021 and 2020, 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.

Corporate Headquarters

On June 20, 2019, the Company executed a lease for its 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.

In June 2021, the Company executed a lease for its new corporate headquarters in Miami, Florida. The Company will be leasing approximately 12,000 square feet of office space for an eight year term commencing on the later of March 1, 2022 or the date the landlord substantially completes tenant improvements. The space will replace the Company's current corporate headquarters in Miami, Florida when the existing lease terminates at the end of February 2022. Annual base rent payments will be $58.00 per square foot and are subject to a 3% annual escalation. Based on the terms of the lease agreement, the Company paid a security deposit of approximately $117,000, which is included in other assets on the accompanying consolidated balance sheet as of September 30, 2021.

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, 2021:

	2021	2020
Finance lease cost:		
Amortization of right-of-use assets	$ 8,731	$ 8,713
Interest on lease liabilities	2,765	5,189
Operating lease cost	542,751	496,803
Short-term lease cost	44,347	7,452
Variable lease cost	178,527	153,852
Sublease income	(179,378)	(179,915)
Total lease cost	$ 597,743	$ 492,094

The Company paid cash of $650,000 and $479,000 for amounts included in the measurement of operating lease liabilities during the year ended September 30, 2021 and 2020, respectively. 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, 2021 and 2020. The Company's finance lease ROU asset was $25,000 and $34,000 as of September 30, 2021 and 2020, respectively, and is included in property and equipment, net on the accompanying consolidated balance sheet. The current finance lease liability as of September 30, 2021 was $9,000 and 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, 2021 and 2020 was as follows:

	2021	2020
Operating Leases		
Weighted-average remaining lease term	2.9	3.6
Weighted-average discount rate	11.5%	11.5%
Finance Leases		
Weighted-average remaining lease term	0.4	1.4
Weighted average discount rate	13.9%	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, 2021, maturities of lease liabilities were as follows:

	Operating Leases	Finance Leases	Sublease Income
Fiscal year ended September 30,			
2022	$ 527,213	$ 9,496	$ 203,584
2023	417,345	—	190,749
2024	196,005	—	—
2025	168,579	—	—
2026	—	—	—
Thereafter	—	—	—
Total lease payments	1,309,142	9,496	$ 394,333
Less imputed interest	(201,318)	(403)	
Total lease liabilities	$ 1,107,824	$ 9,093	

As of September 30, 2021, we have additional operating lease commitments that have not yet commenced of approximately $5.9 million for our new corporate headquarters with a lease term of 8 years.

The lease liabilities presented above do not include variable lease payments for common area maintenance, real estate taxes, and insurance or based on usage for the office equipment leases. These amounts are 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 $20.0 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.

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 2021 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 our analysis, concluded that a full valuation allowance should be recorded related to federal and state NOL carryforwards as of September 30, 2021. The valuation allowance against U.S. deferred tax assets was increased by $4.7 million during the year ended September 30, 2021. As of September 30, 2021 and 2020 respectively, the Company has recorded a valuation allowance of $16.4 million and $11.7 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 $3.2 million and $2.4 million as of September 30, 2021 and 2020, respectively. The increase in the valuation allowance for The Female Health Company Limited is due to the increase in the U.K. tax rate. The operating U.K. subsidiary, The Female Health Company (UK) plc does not have a valuation allowance due to projections of future taxable income.

As of September 30, 2021, the Company had U.S. federal and state NOL carryforwards of approximately $39.1 million and $24.9 million, respectively, for income tax purposes with $30.5 million and $22.5 million, respectively, expiring in fiscal years 2022 to 2040 and $8.6 million and $2.4 million, respectively, which can be carried forward indefinitely. The Company also has U.S. federal research and development tax credit carryforwards of $2.8 million, expiring in fiscal years 2040 to 2041. The Company's U.K. subsidiary has U.K. NOL carryforwards of approximately $63.5 million as of September 30, 2021, 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, 2021 and 2020:

	2021	2020
Domestic	$ 4,822,626	$ (20,008,999)
Foreign	(557,390)	(42,977)
Total	$ 4,265,236	$ (20,051,976)

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

	2021		2020	
	Amount	Tax Rate	Amount	Tax Rate
Income tax expense (benefit) at U.S. federal statutory rates	$ 895,699	21.0 %	$ (4,210,916)	21.0 %
State income tax expense (benefit), net of federal benefits	69,353	1.6	(326,045)	1.6
Effect of change in U.K. tax rate	(3,746,247)	(87.8)	(1,337,263)	6.7
Non-deductible expenses – other	137,003	3.2	114,699	(0.6)
U.S. research and development tax credit	(2,761,415)	(64.7)	—	—
Effect of foreign income tax rates	461,177	10.8	238,645	(1.2)
Effect of common stock options and warrants exercised	(3,848,412)	(90.2)	—	—
Effect of Paycheck Protection Program funds	(113,442)	(2.7)	—	—
Effect of global intangible low-taxed income	219,167	5.1	143,219	(0.7)
Change in valuation allowance	5,505,271	129.1	4,244,531	(21.2)
Other, net	52,708	1.2	54,689	(0.2)
Income tax benefit	$ (3,129,138)	(73.4)%	$ (1,078,441)	5.4 %

On June 10, 2021, the U.K. Finance Act 2021 was enacted increasing the U.K. tax rate from 19% to 25% effective April 1, 2023. The increase in the tax rate increased the value of the deferred tax assets in the U.K. by $3.7 million with a corresponding valuation allowance of $0.7 million, which resulted in a net income tax benefit of $3.0 million.

The federal and state income tax (benefit) expense for the years ended September 30, 2021 and 2020 is summarized below:

	2021	2020
Deferred – U.S.	$ —	$ (229,313)
Deferred – U.K.	(3,457,096)	(1,033,131)
Deferred – Malaysia	(111,952)	7,432
Subtotal	(3,569,048)	(1,255,012)
Current – U.S.	51,880	(10,484)
Current – Malaysia	388,030	187,055
Subtotal	439,910	176,571
Income tax benefit	$ (3,129,138)	$ (1,078,441)

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

	2021	2020
Deferred tax assets:		
Federal net operating loss carryforwards	$ 8,209,224	$ 8,759,589
State net operating loss carryforwards	1,646,827	1,682,104
Foreign net operating loss carryforwards – U.K.	15,875,889	11,655,853
Foreign capital allowance – U.K.	117,709	113,522
U.K. bad debts	2,500	1,900
Share-based compensation – U.K.	80,844	91,839
U.S. research and development tax credit carryforward	2,761,415	—
U.S. deferred rent	31,034	40,236
Share-based compensation	2,071,838	1,255,983
Interest expense	1,368,042	850,248
Change in fair value of derivative liability	1,025,425	195,265
Other, net – Malaysia	100,654	—
Other, net – U.S.	172,203	139,441
Gross deferred tax assets	33,463,604	24,785,980
Valuation allowance for deferred tax assets	(19,580,011)	(14,074,740)
Net deferred tax assets	13,883,593	10,711,240
Deferred tax liabilities:		
In process research and development	(882,427)	(882,427)
Developed technology	—	(369,237)
Covenant not-to-compete	(33,671)	(49,832)
Other, net – Malaysia	—	(11,297)
Other	(6,371)	(6,371)
Net deferred tax liabilities	(922,469)	(1,319,164)
Net deferred tax asset	$ 12,961,124	$ 9,392,076

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

	2021	2020
Long-term deferred tax asset – U.K.	$ 12,923,896	$ 9,466,800
Long-term deferred tax asset – Malaysia	100,654	—
Total long-term deferred tax asset	$ 13,024,550	$ 9,466,800
Long-term deferred tax liability – U.S.	$ (63,426)	$ (63,427)
Long-term deferred tax liability – Malaysia	—	(11,297)
Total long-term deferred tax liability	$ (63,426)	$ (74,724)

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 2018 through 2020, which expire in years 2022 through 2024, 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 2016 through 2020, which expire on December 31, 2021 through 2025.

- 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 2020, which expires in 2022.

The fiscal 2021 tax returns for all jurisdiction have not been filed as of the date of this filing. As of September 30, 2021 and 2020, 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, 2021 and 2020.

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 Income (Loss) Per Share

Basic net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period. Diluted net income (loss) per share is computed by dividing net income (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 common stock purchase warrants as determined under the treasury stock method.

The following table provides a reconciliation of the net income (loss) per basic and diluted common share outstanding:

	2021	2020
Net income (loss)	$ 7,394,374	$ (18,973,535)
Basic weighted average common shares outstanding	76,272,853	66,753,450
Net effect of dilutive instruments:		
Stock options	7,151,070	—
Stock appreciation rights	44,291	—
Common stock purchase warrants	334,206	—
Total net effect of dilutive instruments	7,529,567	—
Diluted weighted average common shares outstanding	83,802,420	66,753,450
Net income (loss) per basic common share outstanding	$ 0.10	$ (0.28)
Net income (loss) per diluted common share outstanding	$ 0.09	$ (0.28)

For the year ended September 30, 2021, approximately 1.2 million potentially dilutive instruments were excluded from the computation of net income per diluted weighted average common share outstanding because their effect would have been antidilutive. Due to our net loss for the year ended September 30, 2020, all potentially dilutive instruments were excluded because their inclusion would have been anti-dilutive. See Notes 10 and 11 for a discussion of these potentially dilutive instruments.

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 product, FC2. The Sexual Health Business also included PREBOOST® before the sale of the business in December 2020. 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 ENTADFI™, if approved. Costs associated with the development of ENTADFI 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:

	2021	2020
Sexual health business	$ 44,015,921	$ 26,495,126
Research and development	(33,390,115)	(16,871,057)
Corporate	2,346,851	(24,370,763)
Operating income (loss)	$ 12,972,657	$ (14,746,694)

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 are included in the Research and Development segment. The gain on sale of the PREBOOST business, 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 $207,000 and $119,000 for the years ended September 30, 2021 and 2020, 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 $40,000 and $33,000 for the years ended September 30, 2021 and 2020, respectively.

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CORPORATE INFORMATION

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Mitchell S. Steiner, M.D., F.A.C.S.
Chairman, 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
Senior Vice President of Finance

Gary Bird, Ph.D.
Executive Vice President–
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Robert Getzenberg, Ph.D.
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Kevin Gilbert, J.D., CPA
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Philip Greenberg, J.D.
Executive Vice President–
Deputy General Counsel

Phillip Kuhn, MBA
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Michael J. Purvis, J.D.
Executive Vice President–
General Counsel, Corporate
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Alistair Rawson, LLB, MBA
Executive Vice President–
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Domingo Rodriguez, M.D.
Executive Vice President–
Clinical Operations

Martin Tayler
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FC2 Global Operations

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President and Chief Executive Officer
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Chief Corporate Officer
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