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, 2023

☐ **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.)
2916 N. Miami Avenue, Suite 1000, 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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2023, was approximately $77.7 million based on the per share closing price as of March 31, 2023 quoted on the Nasdaq Capital Market for the registrant's common stock, which was $1.16.

There were 93,672,854 shares of the registrant's common stock, $0.01 par value per share outstanding on December 5, 2023.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Proxy Statement for the 2024 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, 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 our financial condition or business, our development and commercialization plans relating to our product candidates and products, including any potential development or commercialization of enobosarm initially as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a glucagon-like peptide-1 receptor agonist ("GLP-1 RA") who are at-risk for developing muscle atrophy and muscle weakness, enobosarm for certain breast cancer patients, and sabizabulin for viral-induced acute respiratory distress syndrome ("ARDS") indications, the outlook for growth in our FC2 business through telehealth customers, our portal and the global public health sector, future financial and operating results, plans, objectives, expectations and intentions, costs and expenses, royalty payments, outcome of litigation and other contingencies, financial condition, results of operations, liquidity, cost savings, our ability to continue as a going concern, future ordering patterns of our customers, objectives of management, business strategies, clinical trial timing, plans and results, the achievement of clinical and commercial milestones, the advancement of our technologies and our products and drug candidates, and other statements that are not historical facts. You can identify forward-looking statements by the use of words or phrases such as "anticipate," "believe," "could," "expect," "intend," "may," "opportunity," "plan," "predict," "potential," "estimate," "should," "will," "would" or the negative of those terms or other words of similar meaning. These statements are based upon our current plans and strategies, reflect our current assessment of the risks and uncertainties related to our 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, and the risk that such results will not support marketing approval, emergency use authorization ("EUA"), or commercialization in the United States or in any foreign country;
- potential delays in the timing of any submission to the U.S. Food and Drug Administration (the "FDA") or any other regulatory authority around the world and potential delays in, or failure to obtain, from any such regulatory authority approval of products under development, including the risk of a delay or failure in reaching agreement with the FDA on the design of any clinical trial, including any post-approval or post-authorization study, or in obtaining authorization to commence a clinical trial or commercialize a product candidate in the U.S. or elsewhere;
- potential delays in the timing of approval by the FDA or any other regulatory authority of the release of manufactured lots of approved products;
- clinical trial results supporting any potential regulatory approval or authorization of any of our products, including enobosarm initially as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness, enobosarm for breast cancer, and sabizabulin for the treatment of viral-induced ARDS, may not be replicated in clinical practice;
- 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 and to enable us to continue as a going concern;
- we need to secure significant funding to advance our drug candidates, including government grants, pharmaceutical company partnerships, or similar external sources to advance the development of sabizabulin as a treatment for viral-induced ARDS;
- we may not receive any additional payments from Blue Water Biotech Inc. formerly known as Blue Water Vaccines Inc. ("BWV") in connection with the sale of our ENTADFI assets and may not receive any value for the shares of Series A Convertible Preferred Stock of BWV we hold;
- 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;

- product demand and market acceptance of our commercial products and our products in development, if approved;
- risks related to our ability to obtain insurance reimbursement from private payors or government payors, including Medicare and Medicaid, and similar risks relating to market or political acceptance of any potential or actual pricing for any of our product candidates that, if approved, we attempt to commercialize;
- 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 and market awareness and acceptance of any telehealth platform we develop or use;
- risks related to our ability to increase sales of FC2 after significant declines in recent periods due to telehealth industry consolidation and the bankruptcy of large telehealth customers;
- 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;
- 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, manufacturing partner business changes, physical damage to our or third parties' facilities, 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, or failure to make, 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;
- risks relating to the restatement of our unaudited condensed consolidated financial statements as of and for the three and nine months ended June 30, 2023;
- the costs and other effects of litigation, governmental investigations, legal and administrative cases and proceedings, settlements and investigations;
- our ability to remediate the material weakness in our internal control over financial reporting that we have identified and the risk that we may identify additional deficiencies in the future or otherwise fail to maintain an effective system of internal controls;
- 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, out-licensing transactions, in-licensing transactions 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.

Additional factors that we do not yet know of or that we currently think are immaterial may also impair our business operations.

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.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information.

This Annual Report on Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties as well as our own estimates of potential market opportunities based on our analysis of these data, research, surveys and studies. All of the market data used in this Annual Report on Form 10-K involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunities for our product candidates include a number of key assumptions based on our industry knowledge, industry publications and third-party research, surveys and studies, which may be based on a small sample size and fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions.

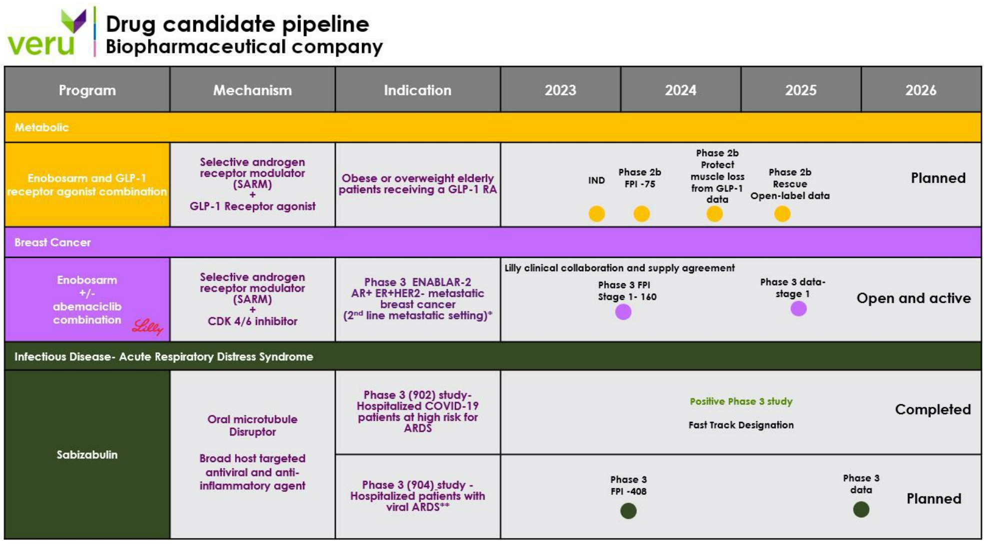
PART I

Item 1. Business

Overview

We are a late clinical stage biopharmaceutical company focused on developing novel medicines for the treatment of metabolic diseases, oncology, and ARDS. Our drug development program includes two late-stage new chemical entities, enobosarm and sabizabulin. Enobosarm, a selective androgen receptor modulator ("SARM"), is being developed for two indications: (i) enobosarm initially as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness and (ii) subject to the availability of sufficient funding, enobosarm for the treatment of androgen receptor positive (AR+), estrogen receptor positive (ER+) and human epidermal growth factor receptor 2 negative (HER2-) metastatic breast cancer in the 2nd line setting. Sabizabulin, a microtubule disruptor, is being developed for the treatment of hospitalized patients with viral-induced ARDS. We do not intend to undertake further development of sabizabulin for the treatment of viral-induced ARDS until we obtain funding from government grants, pharmaceutical company partnerships, or other similar third-party external sources. We also have an FDA-approved commercial product, the FC2 Female Condom® (Internal Condom), for the dual protection against unplanned pregnancy and sexually transmitted infections.

A chart showing our current drug candidate pipeline as of the date of this report is below. This chart is based on our current plans and is subject to change. See "Forward Looking Statements."



*Subject to availability of funds **Subject to funding from government grants, pharmaceutical company partnerships, or other similar third-party external sources

Company History

Veru is a Wisconsin corporation that is the successor to The Wisconsin Pharmacal Company, Inc. (Wisconsin Pharmacal), a company which manufactured and marketed disparate specialty chemical and branded consumer products. Wisconsin Pharmacal was originally incorporated in 1971. In 1996, we completed a series of actions which resulted in our acquisition of worldwide rights to our first-generation female condom, the divestiture of Wisconsin Pharmacal's other businesses and the change of our name to "The Female Health Company." On October 31, 2016, we completed our acquisition of Aspen Park Pharmaceuticals, Inc. (the "APP Acquisition"), which transitioned us from a single product company selling FC2 to a biopharmaceutical company with a robust drug development program. 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.

Our Strategy

Our strategy focuses primarily on the clinical development and commercialization of novel medicines for metabolic diseases, metastatic breast cancer, and viral-induced ARDS. In addition, we seek to operate and grow our sexual health program to help fund our clinical development efforts. We will need substantial capital to support our drug development and any related commercialization efforts for our drug candidates. The key elements of our strategy are:

- **Develop enobosarm for metabolic diseases.**

Our metabolic drug pipeline is focused on the clinical development of enobosarm, an oral SARM, initially as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness.

In reported third-party clinical trials evaluating currently approved GLP-1 RA in obese patients, trial participants exhibited significant weight loss composed of reductions in both fat and lean (muscle and bone) mass. Of the total weight loss reported in certain of these third-party clinical trials, 20-50% of the total weight loss reported by patients was attributable to muscle loss. Muscle is critical for metabolism, muscle strength and physical function (mobility) and prevention of injury (falls) especially in an older population. According to the Centers for Disease Control and Prevention ("CDC"), 41.5% of older adults have obesity and could benefit from weight loss medication. However, the significant amount of muscle loss which may occur when taking a currently approved GLP-1 RA has the potential to reduce a patient's muscle mass to sarcopenic, or critically low amounts. Sarcopenic obese patients, patients who have obesity and age-related low muscle mass at the same time, may experience muscle weakness leading to poor balance, decreased gait speed, mobility disability, falls, bone fractures and increased mortality. Up to 34.4% of obese patients in the United States over the age of 60 have sarcopenic obesity and are potentially at the greatest risk for developing critically low muscle mass and functional limitations when taking a currently approved GLP-1 RA for the treatment of obesity. We therefore believe there is an urgent unmet need for a drug that can both augment the fat loss and prevent the muscle loss in sarcopenic obese or overweight elderly patients receiving GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness leading to frailty.

We believe there is an urgent unmet medical need which could be addressed by a SARM, such as enobosarm, that may effectively prevent the loss of muscle mass experienced by older patients receiving a GLP-1 RA for the treatment of obesity. As demonstrated in third-party clinical trials, weight loss in patients receiving a GLP-1 receptor agonist drugs for the treatment of obesity is composed of reductions in both fat and lean (muscle and bone) mass. The muscle wasting observed with GLP-1 RA drugs places elderly overweight or obese patients with sarcopenic obesity at risk as they already have low muscle mass and may develop muscle weakness, functional limitations, mobility disability, and falls. Veru intends to conduct a Phase 2b multicenter, double-blind, placebo-controlled, randomized, and dose-finding obesity or overweight clinical study to evaluate enobosarm 3mg, enobosarm 6mg, or placebo in approximately 75 patients who qualify and will be receiving a GLP-1 RA for weight loss and are at risk for significant muscle loss.

- **Develop enobosarm for advanced breast cancer.**

Our oncology drug pipeline is focused on the clinical development of enobosarm 9mg, an oral selective androgen receptor modulator, for the treatment of AR+ ER+ HER2- metastatic breast cancer. As we have prioritized our clinical programs to focus on enobosarm for obesity, the continued clinical development of enobosarm for the treatment of metastatic breast cancer is subject to the availability of sufficient funding in excess of any funds we use for enobosarm for obesity or other uses. We completed the Stage 1a portion of our Phase 3 clinical trial in October 2023. We will not, however, begin the Stage 1b portion or otherwise advance our trial Phase 3 clinical trial until sufficient funding is available.

- **Develop sabizabulin for viral-induced ARDS subject to accessing government or pharmaceutical partnership funding.**

We are developing sabizabulin 9mg, which has both host targeted antiviral and broad anti-inflammatory properties, as a two-pronged approach to the treatment of hospitalized patients with viral lung infection at high risk for ARDS and death. We have completed positive Phase 2 and positive Phase 3 COVID-19 clinical trials, which have demonstrated that sabizabulin treatment resulted in a mortality benefit in hospitalized moderate to severe patients with COVID-19 viral lung infection at high risk for ARDS and death. The FDA granted Fast Track designation to our COVID-19 program in January 2022. On May 10, 2022, we had a pre-EUA meeting with the FDA to discuss next steps including the submission of an EUA application regarding sabizabulin for COVID-19. In June 2022, we submitted a request for FDA Emergency Use Authorization. In February 2023, the FDA declined to grant our request for Emergency Use Authorization for sabizabulin. In September 2023, we received positive feedback from the FDA on the design of a Phase 3 clinical trial to evaluate sabizabulin in viral-induced ARDS.

We currently plan to prioritize the use of our internal cash and the net proceeds of any future financings for the development of enobosarm, with a primary near-term focus on funding the proposed Phase 2b clinical trial to evaluate the safety and efficacy of enobosarm initially as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness, and to seek external funding through government grants, pharmaceutical company partnerships, or similar sources to advance the development of sabizabulin as a treatment for viral-induced ARDS. Without such external funding, we do not plan to advance the development of sabizabulin as a treatment for viral-induced ARDS and will not commence our Phase 3 clinical trial to evaluate sabizabulin in viral-induced ARDS.

- **Grow our sexual health program to invest proceeds in the clinical development of our drug pipeline.**

We remain focused on increasing revenue from FC2 in the U.S. market via our established dedicated direct to patient telemedicine and pharmacy services portal, while leveraging our relationships with telemedicine and internet pharmacy providers and distributors. We are also seeking additional commercial partnership opportunities while continuing to grow revenues in the public health sector in key U.S. and global markets via partnerships/distribution agreements with regional distributors/players.

- **Capitalize on expertise and reputation of our management team and board members.**

Our management team has significant expertise and experience in urology, oncology, endocrine, and infectious diseases 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.

Our Products and Product Candidates

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

PRODUCT	INDICATION	DEVELOPMENT PHASE
Metabolic Disease Candidate		
Enobosarm – selective androgen receptor modulator	A treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness	Planned Phase 2b
Oncology Drug Candidate – Breast		
Enobosarm – selective androgen receptor modulator with or without abemaciclib CDK 4/6 inhibitor	AR+ ER+ HER2- metastatic breast cancer (2nd line metastatic setting)	Phase 3 stage 1b ENABLAR-2 active but not currently recruiting
Viral-related ARDS		
Sabizabulin – oral microtubule disruptor, broad host targeted antiviral and anti-inflammatory agent	Hospitalized patients with mild to severe viral-induced ARDS	Planned Phase 3
Sexual Health Program Commercial Product		
FC2 Female Condom® (internal condom)	Unintended pregnancy and prevents STIs	Marketed

Our Clinical Trials Program and Our Drug Candidates

Obesity and Overweight Program - Enobosarm

Scientific Overview. In third-party clinical trials evaluating currently approved GLP-1 RA in obese patients, trial participants exhibited significant weight loss composed of reductions in both fat and lean (muscle and bone) mass. Of the total weight loss reported in certain of these third-party clinical trials, 20-50% of the total weight loss reported by patients was attributable to muscle loss. According to the CDC, 41.5% of older adults have obesity and could benefit from weight loss medication. Up to 34.4% of obese patients in the United States over the age of 60 have sarcopenic obesity. Sarcopenic obese patients are patients who have obesity and age-related low muscle mass at the same time and are potentially at the greatest risk for developing critically low muscle mass when taking a currently approved GLP-1 RA for the treatment of obesity. Patients with critically low muscle mass may experience muscle weakness leading to poor balance, decreased gait speed, mobility disability, falls, bone fractures, and increased mortality. We therefore believe there is an urgent unmet need for a drug that can ameliorate the muscle wasting effects of currently approved GLP-1 RA therapies and also allow for preferential loss of fat mass in at-risk sarcopenic obese and overweight elderly patients.

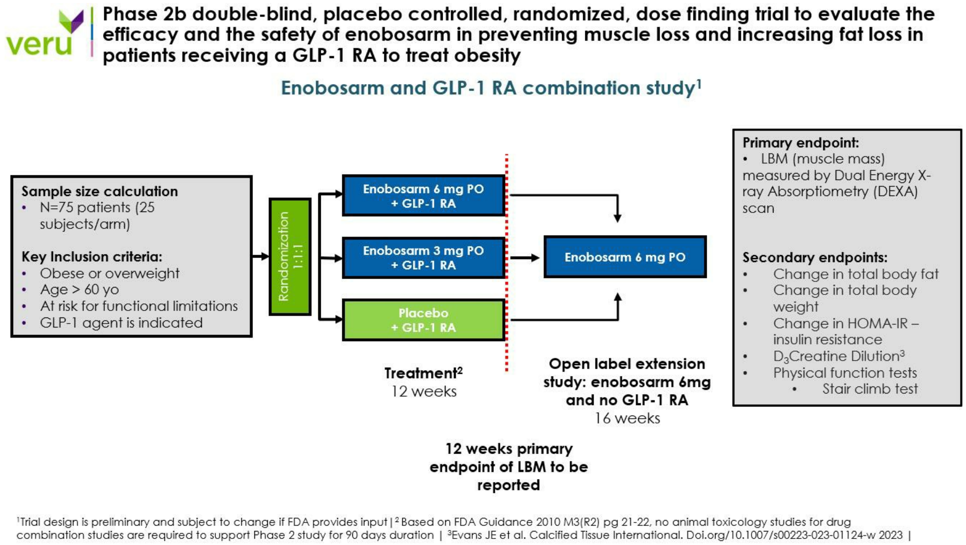
Enobosarm is an oral, novel SARM that has demonstrated tissue-selective, dose-dependent improvement in body composition with increases in muscle mass and decreases in fat mass, improves insulin resistance, has no masculinizing effects in women and has neutral prostate effects in men in third-party clinical trials. Data from certain of these third-party clinical trials also demonstrated increases in muscle mass resulting in improvement in muscle strength and physical function.

Advanced cancer can cause a “starvation state” where there is significant loss of both lean mass and fat mass. Enobosarm has been evaluated in five separate third-party clinical trials in which muscle mass measurement was a primary or co-primary endpoint. These third-party clinical trials include two Phase 2 clinical trials in healthy older or sarcopenic subjects (168 subjects) and one Phase 2b clinical trial and two Phase 3 clinical trials in subjects with muscle wasting because of cancer (800 subjects), generating muscle mass and safety data from a total of 968 patients. In certain of these trials, enobosarm demonstrated a dose-dependent improvement in body composition with increases in muscle mass and reductions in fat mass. For example, in the Phase 2 clinical trial evaluating enobosarm in 120 men over 60 years old and postmenopausal women treated for 12 weeks, patients receiving 3mg dose of enobosarm (n=24) demonstrated a statistically significant (i) increase in total lean body mass (average increase of 1.25 kg (p = < 0.001)) and (ii) decrease in total fat mass (average decrease of 0.32 kg (p=0.049)). When measuring physical function by stair climb test, patients receiving 3mg dose of enobosarm in this trial also demonstrated statistically significant improvements compared to placebo (p=0.049) using a secondary methodology of statistical analysis provided for in the trial protocol. Based on a large safety database which includes 1,581 men and women with treatment duration for up to 3 years, enobosarm has been generally well tolerated in clinical trials completed to date. However, no preclinical studies or clinical trials evaluating the combination of enobosarm and a GLP-1 RA have been completed to date. All the nonclinical and clinical efficacy and safety data on enobosarm including those generated by these five third-party clinical trials are owned by Veru pursuant to an assignment from the University of Tennessee Research Foundation.

We believe the clinical data we own that was generated from third-party clinical trials of enobosarm in both elderly patients and in patients with initial and ongoing muscle wasting caused by a starvation state (cancer induced muscle wasting), provide strong clinical rationale for the co-administration of enobosarm and a GLP-1 RA in at-risk sarcopenic obese or overweight elderly patients as the combination has the potential to ameliorate the muscle wasting effects of currently approved GLP-1 RA therapies and also allow for preferential loss of fat mass. In addition, we believe there is also clinical rationale for the administration of enobosarm to “rescue” at-risk sarcopenic obese or overweight elderly patients who may be forced to discontinue treatment with a GLP-1 RA due to the muscle loss depleting their muscle mass to critically low amounts resulting in muscle weakness and physical function limitations.

Development Plan: Planned Clinical Trials. We intend to submit an IND for enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness in the fourth quarter of 2023. Subject to receiving clearance of our IND, we plan to conduct a Phase 2b multicenter, double-blind, placebo-controlled, randomized, dose-finding clinical trial designed to evaluate the safety and efficacy of enobosarm 3mg, enobosarm 6mg, or placebo as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness, with the first data from the trial expected in the second half of 2024.

A diagram of the proposed Phase 2b clinical trial design is shown in the figure below:



We expect that the primary endpoint of the clinical trial will be change in lean muscle mass from baseline to three months and key secondary endpoints will be change from baseline to three months in total fat mass, insulin resistance (homeostatic model assessment for insulin resistance or HOMA-IR), total body weight, and physical function. Based on FDA Guidance 2010 M3(R2), in "two late stage products for which there is not adequate clinical experience with co-administration, but there are no causes for significant toxicological concern based on the available data, nonclinical combination studies generally are not recommended to support small scale, relatively short-duration clinical studies (e.g., phase 2 studies of up to 3 months' duration)." After completing the three month efficacy dose-finding portion of the clinical trial, we anticipate that participants will then continue into an open label extension trial where all patients will receive enobosarm 6mg for four months. This open label extension portion of the trial is designed to assess the safety and efficacy of enobosarm 6mg at "rescuing" patients by improving muscle loss and maintaining weight loss caused by three months of placebo + GLP-1 RA drug. We expect to measure total lean body mass, total fat mass, total muscle mass, physical function, and bone mineral density in this open label extension both compared to baseline and to the measurement at three months when treated with GLP-1 RA.

The purpose of the Phase 2b trial is to select a dose of enobosarm in combination with a GLP-1 RA at three months treatment for a Phase 3 clinical trial. The foregoing description of the proposed Phase 2b clinical trial and the indication in which we plan to develop enobosarm are preliminary and subject to update based on discussion with the FDA. There can be no assurances that the FDA will accept our proposed trial design, that we will be able to cost-effectively continue development of enobosarm, or that enobosarm will receive FDA approval or be commercialized, for this application.

Market. In the United States, 37% of adult men and 40.4% of adult women have obesity (CDC 2022). In third-party clinical trials evaluating currently approved GLP-1 RA in obese patients, trial participants exhibited significant weight loss composed of reductions in both fat and lean (muscle and bone) mass, with 20-50% of the total weight loss reported by patients attributable to muscle loss. Enobosarm is being developed to optimize weight loss by preferentially increasing fat loss and preventing loss of muscle and physical function in at risk patients taking GLP-1 receptor agonist drugs for chronic weight management. Accordingly, enobosarm is targeting at risk older obese or overweight patients who may already have low muscle mass, also known as sarcopenic obesity, and the further drop in muscle mass of all-important muscles increases risk of muscle weakness, functional limitations, mobility disability, falls, higher hospitalizations, and greater mortality. In the US, up to 41.5% of older adults (> 60 years of age) have obesity (CDC) and up to 34.4% of these patients also have sarcopenia, or low muscle reserve.

Oncology Program – Breast Cancer: Enobosarm

Scientific Overview. Breast cancer is the most commonly diagnosed cancer in women with an estimated 300,590 new cases and 43,700 deaths from breast cancer expected for 2023 in the U.S. 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. 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. Consequently, treatments that target the estrogen receptor (ER) have been the mainstay of breast cancer therapy, but unfortunately breast cancers in almost all women will eventually develop resistance to endocrine therapies with tumor progression, and alternative treatment approaches will be required including IV chemotherapy.

Targeting the AR has the potential to be the next important endocrine therapy for women with breast cancer. 1) AR is the most abundantly expressed steroid receptor in breast cancer being detected 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.

Enobosarm is a new class of endocrine therapy for advanced breast cancer. Enobosarm is an oral, new chemical entity, selective androgen receptor modulator designed to activate the AR in AR+ ER+ HER2- metastatic breast cancer and thereby suppress tumor growth without the unwanted masculinizing side effects. 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 trials in advanced breast cancer involving more than 191 patients. In one of the Phase 2 clinical trials conducted in women with AR+ ER+ HER2- metastatic breast cancer, enobosarm demonstrated significant antitumor efficacy in heavily pretreated cohorts that failed estrogen blocking agents, chemotherapy and/or CDK 4/6 inhibitors and was well tolerated with a favorable safety profile.

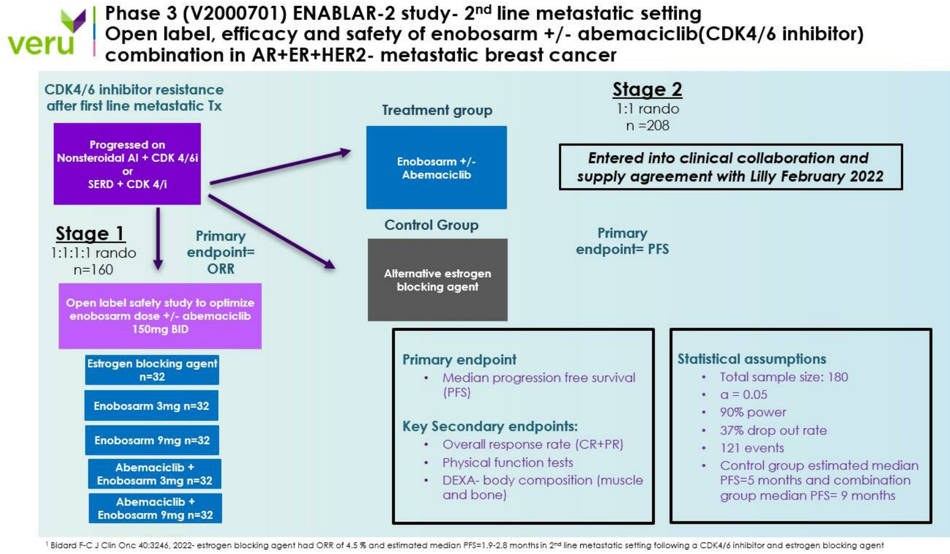
The current standard of care for first line treatment of ER+ HER2- metastatic breast cancer is treatment with a CDK 4/6 inhibitor in combination with an estrogen blocking agent. Once a patient progresses while receiving this combination therapy, the FDA-approved treatment choices are limited to another estrogen blocking agent or chemotherapy. As up to 95% of ER+ HER2- metastatic breast cancers have an androgen receptor, we are developing enobosarm as another, but different, hormone therapy for the second line treatment of ER+ HER2- metastatic breast cancer. In preclinical studies, metastatic breast cancer tissue samples taken from patients who have ER+ HER2- metastatic breast cancer that had become resistant to CDK 4/6 inhibitors and estrogen blocking agents were grown in mice. In these mice, treatment with enobosarm in combination with a CDK 4/6 inhibitor suppressed the growth of human metastatic breast cancer greater than the CDK 4/6 inhibitor alone. Further, enobosarm treatment alone was also effective in suppressing the growth of CDK 4/6 inhibitor and estrogen blocking agent resistant human metastatic breast cancer tumors in mice.

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 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 using the AR testing measure used in G200802 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 progression free survival (PFS) 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 modulator, 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, 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.

Development Plan: Current and Planned Clinical Trials. On March 30, 2023 and November 3, 2023, we met with the FDA to discuss the design of our Phase 3 clinical trial in patients with AR+ ER+ HER2- metastatic breast cancer who have tumor progression while receiving palbociclib (a CDK 4/6 inhibitor) plus an estrogen blocking agent (nonsteroidal aromatase inhibitor or selective estrogen receptor degrader). The design of the Phase 3 clinical trial was amended following our November 3, 2023 meeting with the FDA to implement the recommendations that were provided by the FDA. A diagram of the Phase 3 clinical trial is shown in the figure below:



The primary endpoint for the Stage 1 portion of the Phase 3 clinical trial is objective tumor response rates (“ORR”).

We began patient enrollment in April 2022. As of August 2023, we had completed the target enrollment of three patients in the Stage 1a portion of the Phase 3 clinical trial to assess the safety and pharmacokinetics of the combination of abemaciclib and enobosarm. There were no reported drug-to-drug interactions between abemaciclib and enobosarm or new safety findings in the three patients as of the data cutoff date. Further, the early preliminary clinical results showed two partial responses and one stable disease in the first three patients based on local assessments, and as of the cutoff date the patients were on study for 9, 11 and 12 months from first day of dosing to disease progression by blinded central assessment. We will not begin the Stage 1b portion or otherwise advance our Phase 3 clinical trial until sufficient funding is available.

Subject to the availability of sufficient funding, we expect to have topline data from Stage 1b of our Phase 3 clinical trial by early 2025. If enobosarm monotherapy or abemaciclib + enobosarm combination therapy compared to estrogen blocking agent (active control) demonstrates significant improvement in ORR, which is considered a surrogate endpoint for clinical benefit, then we may meet with the FDA to consider an accelerated approval regulatory pathway based on the clinical data from the Stage 1b portion of the Phase 3 clinical trial. Granting accelerated approval for investigational products is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for this approval pathway, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies for these designations, the FDA may, among other things, later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. There can be no assurances that the FDA will accept our proposed trial design, that we will be able to cost-effectively continue development of enobosarm, or that enobosarm will receive FDA approval or be commercialized, for this application.

In January 2022, we entered into a clinical trial collaboration and supply agreement through which Eli Lilly and Company supplies abemaciclib for the ENABLAR-2 trial.

Market. Enobosarm represents the first new class of targeted endocrine therapy in advanced breast cancer as it does not target estrogen. Enobosarm targets AR in AR+ ER+ HER2- metastatic breast cancer as a potential second line oral daily dosing endocrine therapy. Enobosarm with or without a CDK 4/6 inhibitor could be a new and important option in hormone receptor positive metastatic breast cancer patients who have exhausted endocrine therapies targeting estrogen or ER, but prior to IV chemotherapy.

Infectious Disease Program – sabizabulin for hospitalized patients with mild to severe viral-induced ARDS

We are developing sabizabulin 9mg, which has both host targeted antiviral and broad anti-inflammatory properties, as a two-pronged approach to the treatment of hospitalized patients with viral lung infection at high risk for ARDS and death. We have completed positive Phase 2 and positive Phase 3 COVID-19 clinical trials, which have demonstrated that sabizabulin treatment resulted in a mortality benefit in hospitalized moderate to severe patients with COVID-19 viral lung infection at high risk for ARDS and death. The FDA granted Fast Track designation to our COVID-19 program in January 2022. On May 10, 2022, we had a pre-EUA meeting with the FDA to discuss next steps including the submission of an EUA application regarding sabizabulin for COVID-19. In June 2022, we submitted a request for FDA Emergency Use Authorization. In February 2023, the FDA declined to grant our request for Emergency Use Authorization for sabizabulin. In September 2023, we received positive feedback from the FDA on the design of a Phase 3 clinical trial to evaluate sabizabulin in viral-induced ARDS.

However, we currently plan to prioritize the use of our internal cash and the net proceeds of any future financings for the development of enobosarm, with a primary near-term focus on funding the proposed Phase 2b clinical trial to evaluate the safety and efficacy of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness, and to seek external funding through government grants, pharmaceutical company partnerships, or similar sources to advance the development of sabizabulin as a treatment for viral-induced ARDS. Without such external funding, we do not plan to advance the development of sabizabulin as a treatment for viral-induced ARDS and will not commence our Phase 3 clinical trial to evaluate sabizabulin in viral-induced ARDS.

In October 2023, we were notified that we were not selected for participation in the planned Phase 2 ARDS clinical trial to be sponsored by the Influenza & Emerging Infectious Diseases Division of the Biomedical Advanced Research and Development Authority (BARDA).

There can be no assurances that we will be able to obtain external funding through government grants, pharmaceutical company partnerships, or similar sources, that we will be able to cost-effectively continue development of sabizabulin, or that sabizabulin will receive FDA approval or be commercialized, for this application.

Sexual Health Program

The Company's sexual health program consists of FC2, the only FDA-approved, female-controlled, hormone-free female condom indicated for the prevention of pregnancy and sexually transmitted infections, including HIV/AIDS.

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

***Product*.** FC2 is the only FDA-approved single use internal condom for the prevention of pregnancy, sexually transmitted infections (STIs), and HIV/AIDs. It comes pre-lubricated and is also the only non-hormonal, latex free contraceptive option available to women that can be used on its own or in conjunction with most other forms of contraception providing "layering" benefits. It is easy to use and covered by most insurance companies with zero out-of-pocket costs due to the Affordable Care Act.

FC2 offers several benefits over natural rubber latex, the raw material most 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 condoms without irritation. To the Company's knowledge, there is no reported allergy to the nitrile polymer. The non-latex segment of the global condom market is estimated to grow quicker than the latex segment through 2030 at a cumulative annual growth rate of 10%.

FC2 is manufactured from a nitrile polymer formulation that is proprietary 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.

In the U.S., FC2 is available by prescription through telemedicine and internet pharmacy channels as well as retail pharmacies. The Company has launched 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.

Currently, most of the Company's net revenues are derived from sales of FC2 in the commercial and public health sectors.

U.S. Market. There are approximately 54 million women between the ages of 18-49 who represent the target market due to FC2 being dually indicated for the prevention of pregnancy and/or STIs and HIV/AIDS. According to the CDC, data suggests that STIs in U.S. continued to increase in 2021 – an all-time high for the 6th straight year increasing from 2.4 million to 2.5 million.

FC2 is the only FDA approved for market female use product that protects against unintended pregnancies, the transmission of STIs and HIV/AIDs. While the market conditions are favorable for continued growth, the brand has seen decreasing sales due to lower volume from digital telemedicine customers because of consolidation in the industry. As a result, the Company has established its own dedicated direct to patient digital telemedicine (telemedicine being the remote diagnosis and treatment of patients by means of telecommunications technology) platform to bring our much-needed FC2 product to patients in a cost-effective and highly convenient manner. We remain focused on growing FC2 sales and revenues in future quarters from our dedicated telemedicine solution while leveraging opportunities that help couples better understand how FC2 can help them take control of their sexual and reproductive health.

FC2 is currently reimbursable by prescription under the Affordable Care Act (ACA). The ACA guidance requires health plans to cover at 100% payment of at least one form of contraception within each of the 16 different categories identified by the FDA in its current Birth Control Guide in which FC2 is in a standalone category of its own. 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 or are seeking the layering (i.e. STI prevention) benefits FC2 offers since it can be used with many other forms of contraception.

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. Additionally, we are executing digital and social marketing strategies intended to drive brand interest, awareness, and education; address misconceptions about the brand; and ultimately, help ensure women know they can easily access FC2 and that it is fully reimbursable.

Global Public Health Sector Market. In the global public sector, FC2 has been cleared by the World Health Organization (WHO) for purchase by U.N. agencies because it is a multipurpose prevention technology by preventing unintended pregnancy and the transmission of STIs, while protecting against HIV/AIDs. 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 since 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 that include 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. 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).

The Company has sold more than 750 million female condoms worldwide and 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 Company has distribution agreements and other arrangements with commercial partners which market FC2 as a consumer health product through distributors and retailers in several 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.

Sale of ENTADFI®

The Company had another FDA-approved product, ENTADFI® (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia that was approved by the FDA in December 2021. This product was part of the Company’s sexual health program. On April 19, 2023, the Company entered into an Asset Purchase Agreement (the “BWV Asset Purchase Agreement”) with Blue Water Biotech Inc. formerly known as Blue Water Vaccines Inc. (“BWV”) to sell substantially all of the assets related to ENTADFI. The transaction closed on April 19, 2023. The purchase price for the transaction was $20.0 million, consisting of $6.0 million paid at closing, $4.0 million payable by September 30, 2023, $5.0 million payable 12 months after closing, and $5.0 million payable by September 30, 2024, plus up to $80.0 million based on BWV’s net revenues from ENTADFI after closing (the “Milestone Payments”). The Company cannot determine the likelihood of receiving any Milestone Payments at this time.

On September 29, 2023, the Company entered into an amendment to the BWV Asset Purchase Agreement. The amendment amends the BWV Asset Purchase Agreement by providing that the note receivable for the $4.0 million installment of the purchase price due September 30, 2023, was deemed paid and fully satisfied upon (1) the payment to the Company of the sum of $1.0 million in immediately available funds on September 29, 2023, and (2) the issuance to the Company by October 3, 2023 of 3,000 shares of Series A Convertible Preferred Stock of BWV (“BWV Series A Preferred Stock”). The BWV Series A Preferred Stock may not be converted into shares of BWV common stock until one year after issuance, subject to a limit on the number of shares of BWV common stock into which the BWV Series A Preferred Stock may be converted without approval of BWV’s shareholders. The Company received payment of $1.0 million on September 29, 2023. There can be no assurance as to (1) whether and when we will receive the future installment payments of purchase price or sales milestone payments under the BWV Asset Purchase Agreement, (2) the ability of BWV to obtain the requisite approval of its shareholders for the conversion of all the shares of BWV Series A Preferred Stock, and (3) whether and when we will be able to receive any cash proceeds from the BWV Series A Preferred Stock. The Company received payment of $1.0 million on September 29, 2023 and the 3,000 shares of BWV Series A Preferred Stock on October 3, 2023. There is no market for the BWV Series A Preferred Stock and therefore, little likelihood of any liquidity in the BWV Series A Preferred Stock.

The Company determined that it was not probable, at the time of the transaction and at September 30, 2023, that substantially all of the consideration promised under the BWV Asset Purchase Agreement would be collected. Therefore, the Company recognizes the difference between the nonrefundable consideration received and the carrying amount of the assets as a gain. The gain is recorded considering only the nonrefundable consideration of $7.0 million received by the Company as of September 30, 2023. Total assets sold, consisting primarily of inventory, had a net book value of approximately $1.3 million. The Company recorded a gain of approximately $5.7 million on the transaction during fiscal 2023.

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.

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. 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.

Emergency Use Authorizations. The Secretary of Health and Human Services may authorize unapproved medical products to be manufactured, marketed, and sold in the context of an actual or potential emergency that has been designated by the government. After an emergency has been announced, the Secretary of Health and Human Services may authorize EUAs for the use of specific products based on criteria established by statute, including that the product at issue may be effective in diagnosing, treating, or preventing serious or life-threatening diseases when there are no adequate, approved, and available alternatives. An EUA is subject to additional conditions and restrictions, such as the obligation to provide fact sheets for healthcare providers administering the product and those to whom it is administered, adverse event monitoring and reporting, and recordkeeping and reporting requirements by product manufacturers. The FDA may also establish additional discretionary conditions of authorization that the FDA deems necessary or appropriate to protect the public health, including conditions related to product distribution, product administration and data collection and analysis concerning the safety and effectiveness of the product. In issuing an EUA, the FDA considers the totality of available scientific evidence regarding quality, safety and efficacy, including the known and potential risks of such products and the adequacy and availability of approved alternatives, among other factors. An EUA is not a substitute for obtaining FDA approval, licensure, or clearance for use of a product. An EUA terminates when the emergency determination underlying the EUA terminates, and EUAs can be revoked under other circumstances, the timing of which may occur unexpectedly or be difficult to predict. Following the FDA’s declination decision on the Company’s EUA application for sabizabulin as a treatment for COVID-19, the Company does not expect to apply for an EUA for any of its drug candidates currently under development.

Outside the U.S., the emergency use of medical products is subject to regulatory processes and requirements that differ from those in the U.S. These processes and requirements also vary widely from country to country, region to region, and regulatory authority to regulatory authority.

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. None of the Company’s drug candidates currently under development are expected to follow the Section 505(b)(2) approval pathway.

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

505(b)(1) Approval Process. Drug development via Section 505(b)(1) of the FDCA is typically used for novel drugs that have not previously been approved by the FDA for commercial sale in the U.S or a new indication for a drug previously approved by the FDA for commercial sale in the U.S. 505(b)(1) drug development stipulates that all of the studies required for approval are conducted by or for the Company. Enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness, enobosarm for AR+ ER+ HER2- metastatic breast cancer, and sabizabulin for certain hospitalized patients with viral-induced ARDS 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 from submission for a non-new chemical entity and ten months from filing for a new chemical entity and for a priority review is six months from submission for a non-new chemical entity and six months from filing for a new chemical entity 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 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 MSAP and ISO13485 approval by regulatory authorities which covers Australian TGA, Brazil ANVISA, Health Canada, and other jurisdictions. Also, FC2 received the CE Mark which allows it to be marketed throughout the EU.

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.

Enobosarm and Related Compounds License. Enobosarm is a new chemical entity that has not been approved for any indication anywhere in the world. We hold an exclusive worldwide license to 16 issued U.S. patents, six pending U.S. patent applications, 74 patents and patent applications in countries outside the U.S., and one pending PCT application, including issued molecule and polymorph composition of matter and method of use patents in the U.S, EU and Japan, relating to our enobosarm drug candidate and related compounds, and their use in breast cancer. Further, one of the pending patent applications is related to the use of enobosarm in combination with or following GLP-1 receptor agonists in obese and overweight adult patients to increase or preserve muscle and bone, as well as the use of SARMs generally for treatment of obesity and chronic weight management. 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, with the patent application related to the use of enobosarm in combination with or following GLP-1 receptor agonists in obese and overweight adult patients to increase or preserve muscle and bone, as well as the use of SARMs generally for treatment of obesity and chronic weight management, would expire in 2044, if issued. In the U.S., 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. In addition, as a new chemical entity, enobosarm could qualify for 10 years of regulatory market exclusivity in the European Union countries and 7.5 years of regulatory market exclusivity in Japan. Lastly, regarding the patent application related to the use of enobosarm in combination with or following GLP-1 receptor agonists in obese and overweight adult patients to increase or preserve muscle and bone, as well as the use of SARMs generally for treatment of obesity and chronic weight management, we have engaged an independent third-party search firm to perform a prior art search and this independent firm has identified no prior art likely to prevent issuance of the claims of the patent application.

Sabizabulin and Related Compounds License. We hold an exclusive worldwide license to twelve issued U.S. patents, three pending U.S. patent applications and 84 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, and oncology methods of use. This license contains provisions requiring upfront, milestone and royalty payments to the licensor (Ohio State Innovation 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 these drug candidates. The patents and applications relating to sabizabulin and related compounds have statutory expiration dates from 2029 to 2039. In the U.S., 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. In addition, as a new chemical entity, sabizabulin could qualify for 10 years of regulatory market exclusivity in Europe and 7.5 years of regulatory market exclusivity in Japan.

Uses of Sabizabulin and Related Compounds Owned by Veru Inc. Sabizabulin is a new chemical entity which has not been approved for any indication anywhere in the world. We have one U.S. patent, six U.S. applications, 44 patents and patent applications in countries outside of the United States, and two pending PCT applications from which we will enter more countries outside of the United States, including pending patents in the EU and Japan relating to the polymorphs of our sabizabulin drug candidate and non-oncology methods of use of our sabizabulin drug candidate and related compounds. The patents and patent applications relate to completed phase III and planned clinical trials to test sabizabulin for infectious and/or inflammatory diseases including viral ARDS. The patents and patent applications related to the ongoing and planned clinical trials have statutory expiration dates from 2041 to 2043. In the U.S., 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. In addition, as a new chemical entity, sabizabulin could qualify for 10 years of regulatory market exclusivity in the European Union countries and 7.5 years of regulatory market exclusivity in Japan.

Other Non-Sabizabulin Anti-tubulin Compounds License. We hold an exclusive worldwide license to one U.S. patent application and eleven patents and patent applications in countries outside the U.S. This license is relating to non-sabizabulin anti-tubulin compounds. This license contains provisions requiring diligence milestones, and upfront, 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 these drug candidates. Any patents issuing from these patents and patent applications would expire in April 2042.

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" and the FC2 Female Condom stylized logo in the U.S. The Company has filed applications in the U.S. for the trademarks "Veru" and "Veru" together with the chevron. The Company has filed applications or secured registrations in 40 countries or jurisdictions around the world to protect the various names and symbols used in marketing its Female Condoms.

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

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

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

As with other biopharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property positions for our product candidates will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, certain patent applications that we have filed or may file, or that we have licensed or may license from third parties, may not result in the issuance of corresponding patents. We also cannot predict the breadth of claims that may be allowed or enforced in our patents. Any issued patents that we may receive in the future may be challenged, invalidated or circumvented. For example, we cannot be certain of the priority of inventions covered by pending third-party patent applications. If third parties prepare and file patent applications in the United States that also claim intellectual property to which we have rights, we may have to participate in proceedings in the USPTO to determine invention rights, which could result in substantial costs to us, even if the eventual outcome is favorable to us. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate we may develop, it is possible that any related patent may remain in force for a short period following commercialization, thereby reducing any advantage of any such patent.

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

Significant Customers

The Company's two largest customers in fiscal 2023 accounted for 47% of the Company’s net revenues, including The Pill Club, which represented 24% of the Company’s net revenues. In the U.S. market, the Company has experienced fast growth in prescription sales of FC2 in prior years largely through supply agreements with leading telemedicine providers. Due to The Pill Club’s recent Chapter 11 bankruptcy and the termination of our contract with The Pill Club, we will not have any future revenues from The Pill Club.

Because FC2 is multipurpose prevention technology that provides prevention of pregnancy and transmission of STIs, including HIV/AIDS, it is an integral part of 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, 2023, the Company had 189 full-time employees, including 32 located in the U.S., 11 in the U.K., 145 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 2023 or 2022, 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. The supplier has indicated that it intends to close the facility where our specialty grade of nitrile is currently manufactured by the end of the current calendar year. We intend to move to an alternative grade of nitrile, which will require us to incur costs to formulate and test the alternative grade and seek FDA approval of the alternative grade. The supplier has stated that it will assist in providing continuity of supply while we transfer to the standardized grade of nitrile and has confirmed that it will utilize another production facility that it controls to produce the current specialty grade. Appropriate plant trials and testing have been conducted to show the new facility is capable of supplying our current nitrile grade.

Manufacturing

We manufacture and warehouse 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.

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.

Enobosarm is an oral, first-in-class, novel, selective androgen receptor modulator, that is being developed for two indications: in combination with weight loss drugs (GLP-1 receptor agonists), to increase the preferential loss of fat while preventing the loss of muscle and bone in at risk sarcopenic obese or overweight older adults and for the treatment of AR+ER+HER2- metastatic breast cancer in the 2nd line setting. No drugs are currently approved by the FDA for the indication of chronic weight management with preservation of muscle and bone, either alone or in combination with GLP-1 receptor agonists. 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; Orserdu® (elacestrant) tablets, for oral 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).

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 limited experience in obtaining regulatory approval or emergency use authorization for a drug.
- We could experience delays in our planned clinical trials.
- Our clinical trials may be suspended or discontinued.
- We could experience delays or unanticipated costs in connection with our planned Phase 2b clinical trial of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness if the FDA does not accept our trial design.
- 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 and we rely on third party manufacturers for our marketed products.
- Disruptions to or significantly increased costs associated with transportation and other distribution channels for our products may adversely affect our margins and profitability.
- 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 or our approved or authorized products.
- Our development and commercialization of sabizabulin as a treatment for ARDS will depend on our ability to secure significant funding through government grants, pharmaceutical company partnerships or similar external sources.
- 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.
- Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this Annual Report on Form 10-K for the fiscal year ended September 30, 2023.
- We will need to raise additional capital to fund our operations in the future. If we are unsuccessful in attracting new capital, we may not be able to continue operations or may be forced to sell assets to do so. Alternatively, capital may not be available to us on favorable terms, or if at all. If available, financing terms may lead to significant dilution of our stockholders' equity.
- The amount of additional financing that we will need to support our development and commercialization activities is uncertain.
- We may not receive any additional payments from BWV in connection with the sale of our ENTADFI assets and may not receive any value for the shares of BWV Series A Preferred Stock we hold.

Risks Related to Our Business

- 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 competition, especially for enobosarm as a treatment for metabolic diseases, if approved, and FC2.
- Our net revenues from sales of FC2 may not return to past levels.
- We may not be able to successfully implement our strategy to grow sales of FC2 in the U.S. market through our own portal.
- An inability to identify or complete future acquisitions could adversely affect our future growth.
- We may experience difficulties in integrating strategic acquisitions.
- We may be subject to claims or investigations relating to The Pill Club's business practices with respect to sales of FC2.
- It is unlikely that we will collect any amount of our accounts receivable with The Pill Club.
- We are subject to potential liability relating to a dispute with a supplier.
- Since we sell FC2 in foreign markets, we are subject to international business risks that could adversely affect our operating results.
- 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.
- We may incur costs or experience supply interruptions relating to our need to transition the supply of the nitrile polymer for FC2.
- 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.
- We have been named a defendant in stockholder class actions. These, and potential similar or related lawsuits or investigations, could result in substantial legal fees, fines, penalties or damages and may divert management's time and attention from our business.
- Our business and operations would suffer if we sustain cyber-attacks or other privacy or data security incidents that result in security breaches.
- 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.
- Our effective tax rate may be negatively impacted if we are unable to realize deferred tax assets or by future changes to tax laws in jurisdictions in which we operate.
- Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

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 may not have sufficient intellectual property protection for enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness.
- 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 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.
- Our common stock may be subject to delisting from the Nasdaq Capital Market if our common stock has a closing bid price of less than $1.00 per share.
- We incurred charges to earnings in fiscal 2020 and in fiscal 2023 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.
- The restatement of our prior quarterly financial statements may affect stockholder and investor confidence in us or harm our reputation, and may subject us to additional risks and uncertainties, including increased costs and the increased possibility of legal proceedings and regulatory inquiries, sanctions or investigations.
- We identified a material weakness in internal control over financial reporting, and determined that they resulted in our internal control over financial reporting and disclosure controls and procedures not being effective, as of September 30, 2023. If we are not able to remediate this material weakness, or we identify additional deficiencies in the future or otherwise fail to maintain an effective system of internal controls, including disclosure controls and procedures, this could result in material misstatements of our financial statements or cause us to fail to meet our reporting obligations.
- 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.
- 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 limited experience in obtaining regulatory approval or emergency use authorization for a drug.

We have only obtained regulatory approval for one drug, ENTADFI (tadalafil and finasteride) capsules, for oral use, which we sold to BWV in April 2023. We have never obtained an EUA in the U.S. or in any other jurisdiction. It is possible that the FDA or other regulatory authorities 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 authorization or 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 or authorization of any EUA application 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 or any EUA we submit. If any of these outcomes occur, we may be forced to abandon our planned NDAs or EUAs 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 a pandemic or other reasons.

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, a 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 could experience delays or unanticipated costs in connection with our planned Phase 2b clinical trial of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness if the FDA does not accept our trial design.

We intend to submit an IND for enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness in the fourth quarter of 2023. Subject to receiving clearance of our IND, we plan to conduct a Phase 2b multicenter, double-blind, placebo-controlled, randomized, dose-finding clinical trial designed to evaluate the safety and efficacy of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness, with the first data from the trial expected in the second half of 2024. Upon the review of our IND and clinical trial design, the FDA may require that we conduct preclinical studies or additional or earlier clinical trials or that we conduct larger and more expensive clinical trials than the planned Phase 2b clinical trial we have described in this report. FDA may also disagree with the indication we have proposed and require us to more clearly define or otherwise alter the condition we are seeking to treat. Any delays of or unanticipated changes to the planned Phase 2b clinical trial may increase our costs, slow down our product development and approval process and jeopardize our ability to develop enobosarm for and ultimately generate revenue from enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness, which may cause a change in our development strategy. Additional costs may also require us to raise additional capital, which may not be available when needed or on terms acceptable to us. As a result, we may be forced to abandon our development of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness. There can be no assurances that the FDA will accept our proposed trial design, that we will be able to cost-effectively continue development of enobosarm, or that enobosarm will receive FDA approval or be commercialized, for any application.

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 and we rely on third party manufacturers for our marketed products.

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 and products 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 or products, this process would likely cause a delay in the availability of our drug candidates or products and an increase in costs. In addition, third-party manufacturers may have a limited number of facilities in which our drug candidates or products 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 or products.

In addition, regulatory requirements could pose barriers to the manufacture of our drug candidates or marketed products. 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 and marketed products 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 and marketed products under FDA cGMPs in order to meet acceptable standards. 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 or marketed products 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 or marketed products, which could impair our ability to supply our drug candidates at the levels required for our clinical trials or commercialization and prevent or delay their successful development and commercialization.

Disruptions to or significantly increased costs associated with transportation and other distribution channels for our products may adversely affect our margins and profitability.

We expect to rely on the uninterrupted and efficient operation of third-party logistics companies to transport and deliver our products, including FC2. These third-party logistics companies may experience disruptions to the transportation channels used to distribute our products, including disruptions caused by pandemics, increased airport and shipping port congestion, a lack of transportation capacity, increased fuel expenses, and a shortage of manpower or capital or due to other business interruptions. Disruptions to the transportation channels experienced by our third-party logistics companies may result in increased costs, including the additional use of airfreight to meet demand. Disruptions to this business model or our relationship with the third party if, for example, performance fails to meet our expectations, could harm our business.

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 or our approved or authorized products.

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. Similar risks apply to Emergency Use Authorization applications in the U.S. and other jurisdictions. 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.

If we fail to commercialize any of these drug candidates, or approved or authorized products, 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.

Our development and commercialization of sabizabulin as a treatment for ARDS will depend on our ability to secure significant funding through government grants, pharmaceutical company partnerships or similar external sources.

We currently plan to prioritize the use of our internal cash and the net proceeds of any future financings to the development of enobosarm, with a primary near-term focus on funding a Phase 2b clinical trial designed to evaluate the safety and efficacy of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness, and to seek external funding through government grants, pharmaceutical company partnerships or similar sources to advance sabizabulin as a treatment for viral-induced ARDS. Such funding may not be available on a timely basis or at all, which may cause a significant delay in or the suspension of our development of sabizabulin as a treatment for viral-induced ARDS. Government funding for private sector research and development activities can be difficult to obtain and may contain limitations on its use. For example, in October 2023, we were notified that we were not selected for participation in the planned Phase 2 ARDS clinical trial to be sponsored by BARDA. There are also uncertainties regarding our ability to obtain funding through partnerships with pharmaceutical companies, including significant competition in seeking appropriate partners and the possibility that potential partners may not view sabizabulin as having the requisite potential to demonstrate safety and efficacy or adequate intellectual property protection.

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

Our marketed 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 Office of Prescription Drug Promotion (OPDP) division of the FDA 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 outside the U.S. 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. Even though the U.S. Department of Labor issued a statement on January 10, 2022, reminding plans and issuers subject to these requirements of their responsibility to fully comply with the requirements under PHS Act section 2713 and the HRSA Guidelines, challenges or future regulatory efforts to erode the contraception mandate may persist. If successful, such challenges 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.

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, marketing and promotional laws, rules, and policies, 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 marketed product, FC2, and drug candidates 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 marketed product, FC2, and drug candidates by physicians, patients and payors, will depend on a number of factors, many of which are beyond our control, including the following:

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

Even if the medical community accepts that our drug candidates are safe and efficacious for their approved indications, physicians may not immediately be receptive to the use or may be slow to adopt such products as an accepted treatment for the conditions for which they are intended. Without head-to-head comparative data, we will also not be able to promote our products as being superior to competing products. If our drug candidates, if approved, do not achieve an adequate level of acceptance by physicians and payors, we may not generate sufficient or any revenue from these products. In addition, our efforts to educate the medical community and third-party payors on the benefits of our products may require significant resources and may never be successful.

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

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

Our drug products may be subject to governmental pricing controls.

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

Third parties may obtain FDA regulatory exclusivity to our detriment.

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

Risks Related to Our Financial Position and Need for Capital

We have incurred net losses in recent fiscal years and expect to continue to incur losses for the foreseeable future.

We incurred a net loss of $93.1 million during the year ended September 30, 2023. 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.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this Annual Report on Form 10-K for the fiscal year ended September 30, 2023.

The report from our independent registered public accounting firm for the year ended September 30, 2023, includes an explanatory paragraph stating that our losses from operations and required additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern for a period of one year after the date the financial statements are issued. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all. There can be no assurance that the current operating plan will be achieved in the time frame anticipated by us, or that our cash resources will fund our operating plan for the period anticipated by the Company or that additional funding will be available on terms acceptable to us, or at all.

We will need to raise additional capital to fund our operations in the future. If we are unsuccessful in attracting new capital, we may not be able to continue operations or may be forced to sell assets to do so. Alternatively, capital may not be available to us on favorable terms, or if at all. If available, financing terms may lead to significant dilution of our stockholders' equity.

We are not profitable and have had negative cash flow from operations. We will need large amounts of capital to support our development and commercialization efforts for our drug candidates, including the Phase 2b clinical trial to evaluate the efficacy and the safety of enobosarm in preventing significant muscle wasting in obese patients receiving a GLP-1 therapeutic to treat obesity. Our existing cash and cash equivalents as of the date of this report may not be sufficient to fund our working capital needs and operating expenses. To obtain the capital necessary to fund our operations, we expect to finance our cash needs through public or private equity offerings, debt financing and/or other capital sources. Additional capital may not be available at such times or amounts as needed by us.

Even if capital is available, it might be available only on unfavorable terms. Any additional equity or convertible debt financing into which we enter could be dilutive to our existing stockholders. Any future debt financing into which we enter may impose covenants upon us that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, we may need to relinquish rights to our technologies or our products or grant licenses on terms that are not favorable to us. If access to sufficient capital is not available as and when needed, our business will be materially impaired, and we may be required to cease operations, curtail one or more product development or commercialization programs, scale back or eliminate the development of business opportunities, or significantly reduce expenses, sell assets, seek a merger or joint venture partner, file for protection from creditors or liquidate all of our assets. Any of these factors could harm our operating results.

The amount of additional financing that we will need to support our development and commercialization activities is uncertain.

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.

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.

We may not receive any additional payments from BWV in connection with the sale of our ENTADFI assets and may not receive any value for the shares of BWV Series A Preferred Stock we hold.

In April 2023, we sold our ENTADFI assets to BWV and on September 29, 2023, we entered into an amendment to the BWV Asset Purchase Agreement which provided that the promissory note for the $4 million installment of the purchase price due September 30, 2023 was deemed paid and fully satisfied upon (1) the payment to us of the sum of $1.0 million in immediately available funds on September 29, 2023, and (2) the issuance to us by October 3, 2023 of 3,000 shares of BWV Series A Preferred Stock. The BWV Series A Preferred Stock may not be converted into shares of BWV common stock until one year after issuance. Although BWV's common stock is currently traded on the Nasdaq Capital Market, there is limited trading volume and we do not have any registration rights with respect to the shares of BWV common stock issuable upon conversion of the BWV Series A Preferred Stock, which means that any sales by us of those shares may be subject to volume and other limitations pursuant to Rule 144 under the Securities Act of 1933, as amended. Under the BWV Asset Purchase Agreement, BWV is obligated to pay an additional $10 million in installments in our fiscal year 2024 pursuant to unsecured promissory notes, plus up to an additional $80 million in milestone payments based on BWV's net sales from ENTADFI business after closing. There is uncertainty as to whether and when we will receive any future installment payments of purchase price or sales milestone payments under the BWV Asset Purchase Agreement, and there is a risk of a future default by BWV in performing its payment obligations, and we do not have a security interest in any of BWV's assets and accordingly would be an unsecured creditor in the event that BWV defaulted. We received payment of $1.0 million on September 29, 2023. There can be no assurance as to (1) whether and when we will receive the future installment payments of purchase price or sales milestone payments under the BWV Asset Purchase Agreement, (2) the ability of BWV to obtain the requisite approval of its shareholders for the conversion of all the shares of BWV Series A Preferred Stock, and (3) whether and when we will be able to receive any cash proceeds from the BWV Series A Preferred Stock.

Risks Related to Our Business

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 competition, especially for enobosarm as a treatment for metabolic diseases, if approved, and FC2.

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.

The market for treatments relating to obesity, including treatments relating to muscle atrophy and muscle weakness in patients receiving a GLP-1 RA, is highly competitive and includes major pharmaceutical companies. Such competitors may 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. In addition, if we believe that a competitor’s development activities infringe on our intellectual property rights relating to enobosarm, we may lack the resources to file infringement claims, which can be expensive and time-consuming.

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 polyurethane brands from China 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.

Our net revenues from sales of FC2 may not return to past levels.

Net revenues from sales of FC2 have declined significantly in recent periods, particularly in the U.S. prescription channel. Although we are working to restore ordering and utilization patterns in future periods, net revenues from sales of FC2 may not return to past levels. Ordering patterns may not rebound or may continue to decline if our distribution partners in the telehealth sector encounter issues, we or our distribution partners are not able or willing to spend sufficient amounts to market and promote FC2, or underlying demand for FC2 decreases. In particular, sales to our largest telehealth customer, The Pill Club, have been eliminated due to The Pill Club's recent Chapter 11 bankruptcy filing and the termination of our contract with The Pill Club. In addition, we may lack resources to increase FC2 marketing efforts by an amount sufficient to grow revenues and drive awareness of our independent, FC2-dedicated direct to patient telemedicine and pharmacy services portal. Any failure to attain or sustain sales growth for FC2 in the U.S. market may have a material adverse effect on our results of operations.

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

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.

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 may be subject to claims or investigations relating to The Pill Club's business practices with respect to sales of FC2.

The Pill Club was one of our largest customers, accounting for 44% of our net revenues in fiscal 2022 and 43% of our net revenues in fiscal 2021. On February 7, 2023, the California Attorney General announced a settlement with The Pill Club over a number of alleged improper actions by The Pill Club, including alleged overbilling for FC2. Although we were not involved in the business practices that were the subject of the California Attorney General's allegations, it is possible that the California Attorney General or another governmental authority may investigate or assert claims against us in connection with The Pill Club's practices with respect to sales of FC2. Any such claims or investigations could have a material adverse effect on our reputation, business, results of operations and financial condition. Any such claims or investigations, regardless of the outcome, would be costly and time-consuming.

It is unlikely that we will collect any amount of our accounts receivable with The Pill Club.

We have a concentration of accounts receivable at The Pill Club, with $3.9 million of accounts receivable as of June 30, 2023. On April 18, 2023, The Pill Club filed for Chapter 11 bankruptcy and its assets were sold in June 2023 to satisfy a secured creditor. Our claims against The Pill Club for these receivables have been filed with The Pill Club bankruptcy estate and we will continue to pursue payment for as much of the receivables as possible but based on the amount of the claims of other unsecured creditors and the limited assets remaining in The Pill Club bankruptcy estate it is unlikely that we will recover any of these receivables. We have recorded a provision for credit losses of $3.9 million due to The Pill Club's Chapter 11 bankruptcy filing in April 2023.

We are subject to potential liability relating to a dispute with a supplier.

A supplier has claimed that we owe approximately $10 million for products and services relating to our efforts to commercialize sabizabulin under an EUA. We dispute the amount owed, but there can be no assurance as to how this matter will be resolved. While we have reserved for the full amount of the claim, any resolution of this matter may result in a significant cash obligation. In addition, this matter may become subject to litigation, which would force us to expend significant resources in the defense of such an action, and we may not prevail. Monitoring and defending against any such legal action may be time-consuming for management and may detract from our ability to fully focus our internal resources on our business activities. If we are required to pay all or substantially all of the amount claimed by our supplier with immediate effect, we may need to raise additional capital, curtail one or more product development or commercialization programs, scale back or eliminate the development of business opportunities, or significantly reduce expenses, sell assets, seek a merger or joint venture partner, file for protection from creditors or liquidate all of our assets.

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.

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, 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.

We may incur costs or experience supply interruptions relating to our need to transition the supply of the nitrile polymer for FC2.

We have relied on a sole supplier for the principal raw material for FC2. The supplier has indicated that it intends to close the facility where our specialty grade of nitrile is currently manufactured at the end of the current calendar year. We intend to move to an alternative grade of nitrile, which will require us to incur costs to formulate and test the alternative grade and seek FDA approval of the alternative grade. We are not certain of the amount of time or costs involved in this transition. In addition, the supplier has stated that it will assist in providing continuity of supply while we transfer to the standardized grade of nitrile and has confirmed that it will utilize another production facility that it controls to produce the current specialty grade. Appropriate plant trials and testing have been conducted to show the new facility is capable of supplying our current nitrile grade.

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

If general economic conditions, including continued or worsening inflation or supply chain challenges, recessionary pressures, rising interest rates, labor shortages, and rising unemployment, 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 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.

We have been named a defendant in stockholder class actions. These, and potential similar or related lawsuits or investigations, could result in substantial legal fees, fines, penalties or damages and may divert management's time and attention from our business.

On December 5, 2022, a putative securities class action complaint was filed in federal district court for the Southern District of Florida against us certain of our current officers and directors. The amended complaint alleges that certain public statements about sabizabulin as a treatment for COVID-19 between March 1, 2021 and March 2, 2023 violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, and seeks monetary damages. We and certain of our offices and directors are also parties to four derivative actions asserting state law claims primarily in connection with the issues and claims asserted in the securities class action.

These legal proceedings and any other similar or related legal proceedings are subject to inherent uncertainties, and the actual costs to be incurred relating to these matters will depend upon many unknown factors. The outcome of these legal proceedings is uncertain, and we could be forced to expend significant resources in the defense of these actions, and we may not prevail. Although we have insurance coverage for these actions, we have a $5 million retention amount, which means that we are responsible for the first $5 million of costs or damages relating to these actions, and as a result must pay for any defense costs ourselves up to such retention amount before any insurance coverage will apply. Monitoring and defending against legal actions is time-consuming for management and detracts from our ability to fully focus our internal resources on our business activities. In addition, we may incur substantial legal fees and costs in connection with these matters. We are also generally obligated, to the extent permitted by law, to indemnify our current and former directors and officers who are named as defendants in these and similar actions. We are not currently able to estimate the possible cost to us from these matters, as these actions are currently at an early stage and we cannot be certain how long it may take to resolve these matters or the possible amount of any damages that we may be required to pay. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. Decisions adverse to our interests in these actions could result in the payment of substantial damages, and could have a material adverse effect on our cash flow, results of operations and financial position. These and additional legal proceedings may also increase the costs of, or result in adverse changes in, our director and officer insurance coverage, and if we are unable in the future to obtain an acceptable level of director and officer insurance coverage we may face challenges in recruiting or retaining qualified independent directors or officers.

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, 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.

Our effective tax rate may be negatively impacted if we are unable to realize deferred tax assets or by future changes to tax laws in jurisdictions in which we operate.

We are subject to income taxes in the U.S., the U.K. and other global jurisdictions. Our effective tax rate could be adversely affected by changes in the valuation of deferred tax assets and liabilities. We recognize deferred tax assets and liabilities based on the differences between the consolidated financial statement carrying amounts and the tax basis of assets and liabilities. Significant judgment is required in determining our provision for income taxes. We regularly review our deferred tax assets for recoverability and establish a valuation allowance if it is more likely than not that some portion or all of a deferred tax asset will not be realized. If we are unable to generate sufficient future taxable income, if there is a material change in the actual effective tax rates, or if there is a change to the time period within which the underlying temporary differences become taxable or deductible, we could be required to increase our valuation allowance against our deferred tax assets, which could result in a material increase in our effective tax rate. Changes in tax laws or tax rulings could have a material impact on our effective tax rate. Jurisdictions in which we operate, including the U.S. and the UK, may consider changes to existing tax laws. Such changes could increase our tax obligations in those countries where we do business. Any changes in the taxation of our activities in such jurisdictions may result in a material increase in our effective tax rate.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of September 30, 2023, we had federal and state net operating loss carryforwards of approximately \$140.5 million and \$62.4 million, respectively, of which \$29.7 million and \$35.2 million, respectively, if not utilized to offset taxable income in future periods, will begin to expire in 2024 and will completely expire in 2043. Under the Internal Revenue Code of 1986, as amended (the “Code”) and the regulations promulgated thereunder, including, without limitation, the consolidated income tax return regulations, various corporate ownership changes could limit our ability to use our net operating loss carryforwards and other tax attributes to offset our income.

An “ownership change” (generally a 50% change in equity ownership over a three-year period) under Section 382 of the Code could limit our ability to offset, post-change, our U.S. federal taxable income. Section 382 of the Code imposes an annual limitation on the amount of post-ownership change taxable income a corporation may offset with pre-ownership change net operating loss carryforwards and certain recognized built-in losses.

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 may not have sufficient intellectual property protection for enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness.

The value of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness will depend in part on our ability to obtain and maintain intellectual property rights to this drug candidate as well as successfully defend these rights against third party challenges. We have existing composition of matter and polymorph composition of matter issued patents with the last patent terms expiring in 2028 and 2029 as well as a pending provisional patent method of use application related to the use of enobosarm in weight management, with the longest patent term, if issued, being for the method of use application which would expire in 2044, if issued. This method of use patent application may fail to result in an issued patent, may be challenged, or may result in patent protection that may be too narrow to exclude competitors from developing or designing around any issued patent. 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.

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 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 December 5, 2023, our executive officers and directors collectively beneficially owned approximately 21.7% of the outstanding shares of our common stock, including approximately 10.0% beneficially owned by Mitchell Steiner, M.D., our Chairman, President and Chief Executive Officer, and 9.4% 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.

Our common stock may be subject to delisting from the Nasdaq Capital Market if our common stock has a closing bid price of less than $1.00 per share.

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. Although we have not had such a period of 30 consecutive trading days with the closing bid price of our common stock below $1.00 per share, our common stock has had a closing bid price below $1.00 for a number of recent days. If our stock price continues to trade below $1.00 per share, it may in the future be subject to delisting. If Nasdaq delists our shares of common stock or warrants from trading on its exchange for failure to meet Nasdaq’s listing standards, we and our stockholders could face significant material adverse consequences including:

- a limited availability of market quotations for our shares;
- reduced liquidity for our shares;
- a determination that our common stock is a “penny stock” which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our shares;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

We incurred charges to earnings in fiscal 2020 and in fiscal 2023 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. Impairment of goodwill, among other factors, could result in material charges that would cause our financial results to be negatively impacted:

The restatement of our prior quarterly financial statements may affect stockholder and investor confidence in us or harm our reputation, and may subject us to additional risks and uncertainties, including increased costs and the increased possibility of legal proceedings and regulatory inquiries, sanctions or investigations.

Subsequent to the filing of our Form 10-Q for the quarter ended June 30, 2023 on August 10, 2023 (the "Original Form 10-Q"), we reached a determination to restate certain financial information and related footnote disclosures in our previously issued consolidated financial statements in the Original Form 10-Q. As a result of the restatement, we have incurred, and may continue to incur, unanticipated costs for accounting and legal fees in connection with, or related to, such restatement. In addition, such restatement could subject us to a number of additional risks and uncertainties, including the increased possibility of legal proceedings and inquiries, sanctions or investigations by the SEC or other regulatory authorities. Any of the foregoing may adversely affect our reputation, the accuracy and timing of our financial reporting, or our business, results of operations, liquidity and financial condition, or cause stockholders, investors, members and customers to lose confidence in the accuracy and completeness of our financial reports or cause the market price of our common stock to decline.

We identified a material weakness in internal control over financial reporting, and determined that they resulted in our internal control over financial reporting and disclosure controls and procedures not being effective, as of September 30, 2023. If we are not able to remediate this material weakness, or we identify additional deficiencies in the future or otherwise fail to maintain an effective system of internal controls, including disclosure controls and procedures, this could result in material misstatements of our financial statements or cause us to fail to meet our reporting obligations.

SEC rules define a material weakness as a deficiency, or a combination of control deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a registrant's financial statements will not be prevented or detected on a timely basis. We are required to annually provide management's attestation on internal control over financial reporting. We are also required to disclose significant changes made to our internal control procedures on a quarterly basis and any material weaknesses identified by our management in our internal control over financial reporting during the course of related assessments.

Subsequent to the filing of the Original Form 10-Q, in connection with the restatement, management identified a material weakness in the Company's internal control over financial reporting related to its controls over applying technical accounting guidance to nonrecurring events and transactions, specific to the evaluation of information that was known or knowable at the time of the transaction or event. Management determined that such material weakness resulted in the Company's internal control over financial reporting and disclosure controls and procedures not being effective as of September 30, 2023.

Effective internal controls are necessary for us to provide reliable financial statements and prevent or detect fraud. The material weakness in internal control over financial reporting described above, any new deficiencies identified in the future or any deficiencies in our disclosure controls and procedures, if not timely remediated, could limit our ability to prevent or detect a misstatement of our accounts or disclosures that could result in a material misstatement of our annual or interim financial statements. We are in the process of implementing a remediation plan to remediate the material weakness we identified, which is designed to improve our internal control over financial reporting. We can provide no assurance that the measures we have taken to-date and any actions that we may take in the future will be sufficient to remediate this control deficiency, or that such remediation measures will be effective at preventing or avoiding potential future significant deficiencies or material weaknesses in our internal controls.

If we identify any new deficiencies in the future or are not able to successfully remediate the material weakness we have identified and related deficiencies in our disclosure controls and procedures, the accuracy and timing of our financial reporting may be adversely affected, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, we could be subject to sanctions or investigations by the SEC, or other regulatory authorities, and we may not be able to source external financing for our capital needs on acceptable terms or at all. Each of the foregoing items could adversely affect our business, results of operations, financial condition, and the market price and volatility of our common stock. In addition, we have expended, and expect to continue to expend, significant resources, including accounting-related costs and significant management oversight, in order to assess, implement, maintain, remediate and improve the effectiveness of our internal control over financial reporting and our general control environment.

In addition, as a result of the material weakness described above and other matters raised or that may in the future be raised by the SEC, we face the potential for litigation or other disputes which may include, among others, claims invoking the federal and state securities laws, contractual claims or other claims arising from the deficiencies in our internal control over financial reporting described above, the preparation of our financial statements and the restatement described above. Any such litigation or dispute, whether successful or not, could have a material adverse effect on our business, results of operations, liquidity and financial condition.

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;
- attacks by short sellers or substantial short interest in our common stock; or
- other economic or external factors.

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

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, shares of common stock we may issue under our current common stock purchase agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"), including 3,025,000 shares of common stock that we have issued under our current common stock purchase agreement with Lincoln Park through the date of this report, and shares of common stock we may issue under our Open Market Sales Agreement℠ with Jefferies LLC. 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 12,000 square feet of office space. The Company executed the lease for this office space in June 2021. The lease is for an eight-year term, which commenced on March 1, 2022 and ends on February 28, 2030.

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.

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 had an option to extend the term of the lease for a period of three years, which was executed so that the lease is effective through August 31, 2025. 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.

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

Item 3. Legal Proceedings.

For a description of our material pending legal proceedings, see Litigation in Note 13, Contingent Liabilities, to the financial statements included in this report and incorporated herein by reference.

Item 4. Mine Safety Disclosures

Not Applicable

PART II

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

Shares of our common stock trade on the Nasdaq Capital Market under the symbol "VERU". The number of record holders of our common stock on December 5, 2023 was approximately 153.

Item 6. Reserved

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

Overview

We are a late clinical stage biopharmaceutical company focused on developing novel medicines for the treatment of metabolic diseases, oncology, and ARDS. Our drug development program includes two late-stage new chemical entities, enobosarm and sabizabulin. Enobosarm, a selective androgen receptor modulator ("SARM"), is being developed for two indications: (i) enobosarm initially as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness and (ii) subject to the availability of sufficient funding, enobosarm for the treatment of androgen receptor positive (AR+), estrogen receptor positive (ER+) and human epidermal growth factor receptor 2 negative (HER2-) metastatic breast cancer in the 2nd line setting. Sabizabulin, a microtubule disruptor, is being developed for the treatment of hospitalized patients with viral-induced ARDS. We do not intend to undertake further development of sabizabulin for the treatment of viral-induced ARDS until we obtain funding from government grants, pharmaceutical company partnerships, or other similar third-party external sources. We also have an FDA-approved commercial product, the FC2 Female Condom® (Internal Condom), for the dual protection against unplanned pregnancy and sexually transmitted infections.

Obesity and Overweight Program

Our metabolic drug pipeline is focused on the clinical development of enobosarm, an oral SARM, initially as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness.

In third-party clinical trials evaluating currently approved GLP-1 RA in obese patients, trial participants exhibited significant weight loss composed of reductions in both fat and lean (muscle and bone) mass. Of the total weight loss reported in certain of these third-party clinical trials, 20-50% of the total weight loss reported by patients was attributable to muscle loss. According to the CDC, 41.5% of older adults have obesity and could benefit from weight loss medication. Up to 34.4% of obese patients in the United States over the age of 60 have sarcopenic obesity. Sarcopenic obese patients are patients who have obesity and age-related low muscle mass at the same time and are potentially at the greatest risk for developing critically low muscle mass when taking a currently approved GLP-1 RA for the treatment of obesity. Patients with critically low muscle mass may experience muscle weakness leading to poor balance, decreased gait speed, mobility disability, falls, bone fractures, and increased mortality. We therefore believe there is an urgent unmet need for a drug that can ameliorate the muscle wasting effects of currently approved GLP-1 RA therapies and also allow for preferential loss of fat mass in at-risk sarcopenic obese or overweight elderly patients.

Enobosarm is an oral, novel SARM that has demonstrated tissue-selective, dose-dependent improvement in body composition with increases in muscle mass and decreases in fat mass, improves insulin resistance, has no masculinizing effects in women, and has neutral prostate effects in men in third-party clinical trials. Data from certain of these third-party clinical trials also demonstrated increases in muscle mass resulting in improvement in muscle strength and physical function.

Advanced cancer can cause a “starvation state” where there is significant loss of both lean mass and fat mass. Enobosarm has been evaluated in five separate third-party clinical trials in which muscle mass measurement was a primary or co-primary endpoint. These third-party clinical trials include two Phase 2 clinical trials in healthy older or sarcopenic subjects (168 subjects) and one Phase 2b clinical trial and two Phase 3 clinical trials in subjects with muscle wasting because of cancer (800 subjects), generating muscle mass and safety data from a total of 968 patients. In certain of these trials, enobosarm demonstrated a dose-dependent improvement in body composition with increases in muscle mass and reductions in fat mass. For example, in the Phase 2 clinical trial evaluating enobosarm in 120 men over 60 years old and postmenopausal women treated for 12 weeks, patients receiving 3mg dose of enobosarm (n=24) demonstrated a statistically significant (i) increase in total lean body mass (average increase of 1.25 kg (p = < 0.001)) and (ii) decrease in total fat mass (average decrease of 0.32 kg (p=0.049)). When measuring physical function by stair climb test, patients receiving 3mg dose of enobosarm in this trial also demonstrated statistically significant improvements compared to placebo (p=0.049) using a secondary methodology of statistical analysis provided for in the trial protocol. Based on a large safety database which includes 1,581 men and women with treatment duration for up to 3 years, enobosarm has been generally well tolerated in clinical trials completed to date. However, no preclinical studies or clinical trials evaluating the combination of enobosarm and a GLP-1 RA have been completed to date. All the nonclinical and clinical efficacy and safety data on enobosarm including those generated by these five third-party clinical trials are owned by Veru pursuant to an assignment from the University of Tennessee Research Foundation.

We believe the clinical data we own that was generated from third-party clinical trials of enobosarm in both elderly patients and in patients with initial and ongoing muscle wasting caused by a starvation state (cancer induced muscle wasting), provide strong clinical rationale for the co-administration of enobosarm and a GLP-1 RA in at-risk sarcopenic obese or overweight elderly patients as the combination has the potential to ameliorate the muscle wasting effects of currently approved GLP-1 RA therapies and also allow for preferential loss of fat mass. In addition, we believe there is also clinical rationale for the administration of enobosarm to “rescue” at-risk sarcopenic obese or overweight elderly patients who may be forced to discontinue treatment with a GLP-1 RA due to the muscle loss depleting their muscle mass to critically low amounts resulting in muscle weakness and physical function limitations.

We intend to submit an IND for enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness in the fourth quarter of 2023. Subject to receiving clearance of our IND, we plan to conduct a Phase 2b multicenter, double-blind, placebo-controlled, randomized, dose-finding clinical trial designed to evaluate the safety and efficacy of enobosarm 3mg, enobosarm 6mg, or placebo as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness, with the first data from the trial expected in the second half of 2024.

We expect that the primary endpoint of the clinical trial will be change in lean muscle mass from baseline to three months and key secondary endpoints will be change from baseline to three months in total fat mass, insulin resistance (homeostatic model assessment for insulin resistance or HOMA-IR), total body weight, and physical function. Based on FDA Guidance 2010 M3(R2), in “two late stage products for which there is not adequate clinical experience with co-administration, but there are no causes for significant toxicological concern based on the available data, nonclinical combination studies generally are not recommended to support small scale, relatively short-duration clinical studies (e.g., phase 2 studies of up to 3 months’ duration).” After completing the three month efficacy dose-finding portion of the clinical trial, we anticipate that participants will then continue into an open label extension trial where all patients will receive enobosarm 6mg for four months. This open label extension portion of the trial is designed to assess the safety and efficacy of enobosarm 6mg at “rescuing” patients by improving muscle loss and maintaining weight loss caused by three months of placebo + GLP-1 RA drug. We expect to measure total lean body mass, total fat mass, total muscle mass, physical function, and bone mineral density in this open label extension both compared to baseline and to the measurement at three months when treated with GLP-1 RA.

The purpose of the Phase 2b trial is to select a dose of enobosarm in combination with a GLP-1 RA at three months treatment for a Phase 3 clinical trial. The foregoing description of the proposed Phase 2b clinical trial and the indication in which we plan to develop enobosarm are preliminary and subject to update based on discussion with the FDA. There can be no assurances that the FDA will accept our proposed trial design, that we will be able to cost- effectively continue development of enobosarm, or that enobosarm will receive FDA approval or be commercialized, for this application.

Oncology Program

Our oncology drug pipeline is focused on the clinical development of enobosarm, an oral selective androgen receptor modulator, for the treatment of metastatic breast cancer. As we have prioritized our clinical programs to focus on enobosarm for obesity, the continued clinical development of enobosarm for the treatment of metastatic breast cancer is subject to the availability of sufficient funding. We completed the Stage 1a portion of our Phase 3 clinical trial in October 2023. We will not, however, begin the Stage 1b portion or otherwise advance our trial Phase 3 clinical trial until sufficient funding is available.

Enobosarm is a new class of endocrine therapy for advanced breast cancer. Enobosarm is an oral, new chemical entity, selective androgen receptor modulator designed to activate the AR in AR+ ER+ HER2- metastatic breast cancer and thereby suppress tumor growth without the unwanted masculinizing side effects. 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 trials in advanced breast cancer involving more than 191 patients. In one of the Phase 2 clinical trials conducted in women with AR+ ER+ HER2- metastatic breast cancer, enobosarm demonstrated significant antitumor efficacy in heavily pretreated cohorts that failed estrogen blocking agents, chemotherapy and/or CDK 4/6 inhibitors and was well tolerated with a favorable safety profile.

The current standard of care for first line treatment of ER+ HER2- metastatic breast cancer is treatment with a CDK 4/6 inhibitor in combination with an estrogen blocking agent. Once a patient progresses while receiving this combination therapy, the FDA-approved treatment choices are limited to another estrogen blocking agent or chemotherapy. As up to 95% of ER+ HER2- metastatic breast cancers have an androgen receptor, we are developing enobosarm as another, but different, hormone therapy for the second line treatment of ER+ HER2- metastatic breast cancer. In preclinical studies, metastatic breast cancer tissue samples taken from patients who have ER+ HER2- metastatic breast cancer that had become resistant to CDK 4/6 inhibitors and estrogen blocking agents were grown in mice. In these mice, treatment with enobosarm in combination with a CDK 4/6 inhibitor suppressed the growth of human metastatic breast cancer greater than the CDK 4/6 inhibitor alone. Further, enobosarm treatment alone was also effective in suppressing the growth of CDK 4/6 inhibitor and estrogen blocking agent resistant human metastatic breast cancer tumors in mice.

On March 30, 2023 and November 3, 2023, we met with the FDA to discuss the design of our Phase 3 clinical trial in patients with AR+ ER+ HER2- metastatic breast cancer who have tumor progression while receiving palbociclib (a CDK 4/6 inhibitor) plus an estrogen blocking agent (nonsteroidal aromatase inhibitor or selective estrogen receptor degrader). The design of the Phase 3 clinical trial was amended following our November 3, 2023 meeting with the FDA to implement the recommendations that were provided by the FDA.

The primary endpoint for the Stage 1 portion of the Phase 3 clinical trial is objective tumor response rates (“ORR”). We are currently producing clinical supply of 3mg and 6mg enobosarm capsules for the additional dose optimization arms, which is expected to be available in the fourth quarter of calendar year 2023.

We began patient enrollment in April 2022. As of August 2023, we had completed the target enrollment of three patients in the Stage 1a portion of the Phase 3 clinical trial to assess the safety and pharmacokinetics of the combination of abemaciclib and enobosarm. There were no reported drug-to-drug interactions between abemaciclib and enobosarm or new safety findings in the three patients as of the data cutoff date. Further, the early preliminary clinical results showed two partial responses and one stable disease in the first three patients based on local assessments, and as of the cutoff date the patients were on study for 9, 11 and 12 months from first day of dosing to disease progression by blinded central assessment.

Subject to the availability of sufficient funding, we expect to have topline data from Stage 1b of our Phase 3 clinical trial by early 2025. If enobosarm monotherapy or abemaciclib + enobosarm combination therapy compared to estrogen blocking agent (active control) demonstrates significant improvement in ORR, which is considered a surrogate endpoint for clinical benefit, then we may meet with the FDA to consider an accelerated approval regulatory pathway based on the clinical data from the Stage 1b portion of the Phase 3 clinical trial. Granting accelerated approval for investigational products is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for this approval pathway, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies for these designations, the FDA may, among other things, later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. There can be no assurances that the FDA will accept our proposed trial design, that we will be able to cost-effectively continue development of enobosarm, or that enobosarm will receive FDA approval or be commercialized, for this application.

In January 2022, we entered into a clinical trial collaboration and supply agreement through which Eli Lilly and Company supplies abemaciclib for the ENABLAR-2 trial.

Infectious Disease Program

We are developing sabizabulin 9mg, which has both host targeted antiviral and broad anti-inflammatory properties, as a two-pronged approach to the treatment of hospitalized patients with viral lung infection at high risk for ARDS and death. We have completed positive Phase 2 and positive Phase 3 COVID-19 clinical trials, which have demonstrated that sabizabulin treatment resulted in a mortality benefit in hospitalized moderate to severe patients with COVID-19 viral lung infection at high risk for ARDS and death. The FDA granted Fast Track designation to our COVID-19 program in January 2022. On May 10, 2022, we had a pre-EUA meeting with the FDA to discuss next steps including the submission of an EUA application regarding sabizabulin for COVID-19. In June 2022, we submitted a request for FDA Emergency Use Authorization. In February 2023, the FDA declined to grant our request for Emergency Use Authorization for sabizabulin. In September 2023, we received positive feedback from the FDA on the design of a Phase 3 clinical trial to evaluate sabizabulin in viral-induced ARDS.

However, we currently plan to prioritize the use of our internal cash and the net proceeds of any future financings for the development of enobosarm, with a primary near-term focus on funding the proposed Phase 2b clinical trial to evaluate the safety and efficacy of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness, and to seek external funding through government grants, pharmaceutical company partnerships, or similar sources to advance the development of sabizabulin as a treatment for viral-induced ARDS. Without such external funding, we do not plan to advance the development of sabizabulin as a treatment for viral-induced ARDS and will not commence our Phase 3 clinical trial to evaluate sabizabulin in viral- induced ARDS.

In October 2023, we were notified that we were not selected for participation in the planned Phase 2 ARDS clinical trial to be sponsored by the Influenza & Emerging Infectious Diseases Division of the Biomedical Advanced Research and Development Authority (BARDA).

There can be no assurances that we will be able to obtain external funding through government grants, pharmaceutical company partnerships, or similar sources, that we will be able to cost-effectively continue development of sabizabulin, or that sabizabulin will receive FDA approval or be commercialized, for this application.

Sexual Health Program

Our sexual health program consists of FC2, the only FDA-approved, female controlled, hormone free female condom indicated for the dual protection against unplanned pregnancy and sexually transmitted infections, including HIV/AIDS.

We sell FC2 in both the U.S. commercial sector and in the public health sector both in the U.S. and globally.

In the U.S. commercial sector, FC2 is available by prescription through multiple telehealth and internet pharmacy channels as well as retail pharmacies. Over this past year, there were changes in the business status of two of our major telehealth contraception partners, which has led to the consolidation of these businesses as follows: The Pill Club filed for bankruptcy and its assets were transferred to telehealth contraception businesses, Thirty Madison and Twentyeight Health, and Simple Health ceased operations and its telehealth platform was transferred to Twentyeight Health.

While there has been consolidation in the telehealth industry, we continue to believe that telehealth will be an important commercial strategy in the U.S. for access to birth control products, including FC2, given both healthcare industry dynamics and our product's profile. In order to maximize its reach and to have more direct control of the promotion, distribution, and sales of FC2, we made the decision last year to launch our own independent, FC2-dedicated direct to patient telehealth and pharmacy services portal.

Having taken the time to refine our marketing, drive operational improvements, and enhance the patient experience during the initial launch phase over the last year, there are increasing new prescriptions being written and filled through our FC2 telehealth portal. During the year ended September 30, 2023, we saw more than 14,000 additional new women receive an FC2 prescription, as well as marked improvements in refill rates for those women who already had an existing FC2 prescription. With growth each quarter demonstrating high demand for FC2, we plan to continue to grow and deepen our investment in a profitable way by further expanding our presence both in social media channels and online search.

On the basis of our experience to date, we expect revenue from our U.S. FC2 prescription business to demonstrate growth both from our dedicated FC2 telehealth portal and from the addition of new telehealth and other commercial distribution relationships. Furthermore, we intend to continue leveraging partnerships with entities in the U.S. public health sector such as state departments of health and 501(c)(3) organizations to generate the strong unit sales growth we have seen in fiscal 2023 from this channel.

In the global public health sector outside the U.S., we market 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. After the COVID-19 pandemic, there has been an increase in interest to resume distribution of FC2 in the global public sector. We are currently supplying a large multi-year South African tender for female condoms, which is expected to continue until 2025 and have seen sales grow in the current year as the current tender launched. We also believe a formal Brazil tender process may commence in calendar year 2024.

Sale of ENTADFI

The Company had another FDA-approved product, ENTADFI® (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia that was approved by the FDA in December 2021. This product was part of the Company's sexual health program. On April 19, 2023, the Company entered into the BWV Asset Purchase Agreement with BWV to sell substantially all of the assets related to ENTADFI. The transaction closed on April 19, 2023. The purchase price for the transaction was $20.0 million, consisting of $6.0 million paid at closing, $4.0 million payable by September 30, 2023, $5.0 million payable 12 months after closing, and $5.0 million payable by September 30, 2024, plus up to $80.0 million based on BWV's net revenues from ENTADFI after closing. The Company cannot determine the likelihood of receiving any Milestone Payments at this time.

On September 29, 2023, the Company entered into an amendment to the BWV Asset Purchase Agreement. The amendment amends the BWV Asset Purchase Agreement by providing that the note receivable for the $4.0 million installment of the purchase price due September 30, 2023, was deemed paid and fully satisfied upon (1) the payment to the Company of the sum of $1.0 million in immediately available funds on September 29, 2023, and (2) the issuance to the Company by October 3, 2023 of 3,000 shares of BWV Series A Preferred Stock. The BWV Series A Preferred Stock may not be converted into shares of BWV common stock until one year after issuance, subject to a limit on the number of shares of BWV common stock into which the BWV Series A Preferred Stock may be converted without approval of BWV's shareholders. The Company received payment of $1.0 million on September 29, 2023. There can be no assurance as to (1) whether and when we will receive the future installment payments of purchase price or sales milestone payments under the BWV Asset Purchase Agreement, (2) the ability of BWV to obtain the requisite approval of its shareholders for the conversion of all the shares of BWV Series A Preferred Stock, and (3) whether and when we will be able to receive any cash proceeds from the BWV Series A Preferred Stock. The Company received payment of $1.0 million on September 29, 2023 and the 3,000 shares of BWV Series A Preferred Stock on October 3, 2023. There is no market for the BWV Series A Preferred Stock and therefore, little likelihood of any liquidity in the BWV Series A Preferred Stock.

The Company determined that it was not probable, at the time of the transaction and at September 30, 2023, that substantially all of the consideration promised under the BWV Asset Purchase Agreement would be collected. Therefore, the Company recognizes the difference between the nonrefundable consideration received and the carrying amount of the assets as a gain. The gain is recorded considering only the nonrefundable consideration of $7.0 million received by the Company as of September 30, 2023. Total assets sold, consisting primarily of inventory, had a net book value of approximately $1.3 million. The Company recorded a gain of approximately $5.7 million on the transaction during fiscal 2023.

Consolidated Operations

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

The Company has shifted the focus for its FC2 business to growing its prescription business through an internal telehealth solution following the loss of its two largest telehealth providers. Its aim is to use its own telehealth portal to recover lost revenues from its primary customer base, telehealth providers in the U.S. who sell into the prescription channel. Additionally, the Company is seeking to continue generating revenue from global public health sector agencies who purchase and distribute FC2 for HIV/AIDS prevention and family planning. Through partnership collaborations, the Company has experienced revenue growth from the U.S. public sector and this collaborative strategy will continue to be a focus for future growth opportunities.

The Pill Club had historically been our largest telehealth customer for FC2, accounting for 24% of our net revenues (including 67% of our U.S. prescription channel revenue) in fiscal 2023 and 44% of our net revenues (including 58% of our U.S. prescription channel revenue) in fiscal 2022. We sold FC2 to The Pill Club at a wholesale price pursuant to purchase orders received from The Pill Club from time to time. The Pill Club took title to FC2 and then acted as a distributor of FC2. The Pill Club was solely responsible for its interactions with health care providers and patients (including, without limitation, the conduct of the telehealth physician-patient interactions), pricing of the FC2 products that it distributed, and legal and regulatory compliance. We had no oversight of The Pill Club's operations.

On February 7, 2023, the California Attorney General announced a settlement with The Pill Club over a number of alleged improper actions by The Pill Club, including alleged overbilling for FC2. Notwithstanding the statements in the California Attorney General's press release, California's allegations against The Pill Club, according to the publicly available Settlement Agreement executed as of January 18, 2023, involved not only billing related to FC2 but also billing related to emergency contraceptives, improper coding of asynchronous telemedicine visits, and billing for prescriptions sent to California patients by a Texas pharmacy not then-licensed to provide pharmacy services to California patients.

While the California Attorney General's allegations included The Pill Club's practices with respect to sales of FC2 by The Pill Club, we were not involved in such business practices and no claims against Veru have been made by the California Attorney General.

We also had a concentration of accounts receivable with The Pill Club, which totaled $3.9 million as of September 30, 2023. In March 2023, the Company recorded a provision for credit losses for the entire amount of these receivables, due to the uncertainty as to whether or when The Pill Club would pay these amounts. The Pill Club filed for Chapter 11 bankruptcy on April 18, 2023 and its assets have been sold to satisfy a secured creditor. Our claims against The Pill Club for these receivables, and an additional claim of $1.4 million for contractual damages, have been filed with The Pill Club bankruptcy estate. It is uncertain at this time what assets will be available to satisfy unsecured creditors such as Veru.

Due to The Pill Club's recent Chapter 11 bankruptcy and the termination of our contract with The Pill Club, we will not have any future revenues from The Pill Club.

In February 2022, the Company received a tender award to supply 57% of a tender covering up to 120 million female condoms over three years in the Republic of South Africa (the "2022 South Africa Tender"). The Company began shipping units under the 2022 South Africa Tender in the second quarter of fiscal 2023.

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.

The Company relies on supply for its principal raw material for FC2 from one supplier who is a technical market leader in synthetic polymers. The supplier has indicated that it intends to close the facility where our specialty grade of nitrile is currently manufactured at the end of the current calendar year. We intend to move to an alternative grade of nitrile, which will require us to incur costs to formulate and test the alternative grade and seek FDA approval of the alternative grade. The supplier has stated that it will assist in providing continuity of supply while we transfer to the standardized grade of nitrile and has confirmed that it will utilize another production facility that it controls to produce the current specialty grade. Appropriate plant trials and testing have been conducted to show the new facility is capable of supplying our current nitrile grade.

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 increases in the cost of the nitrile polymer used to produce FC2, as well as transportation costs, and may also experience increases in other material costs due to the impact of inflation. Moreover, the Company's decision to adopt an internal telehealth solution means that the expenses associated with acquiring new FC2 users are expected to increase. Consequently, there may be an unfavorable effect on the Company's selling expenses and income from operations if it cannot pass through these cost escalations to its customers.

Conducting research and development is central to our oncology, obesity and overweight, and infectious disease programs. The Company has several products under development 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 $51.1 million and $70.6 million for fiscal 2023 and 2022, respectively. We expect to continue this trend of investing significant resources in research and development due to advancement of our drug candidates.

Results of Operations

YEAR ENDED SEPTEMBER 30, 2023 COMPARED TO YEAR ENDED SEPTEMBER 30, 2022

The Company generated net revenues of $16.3 million and net loss of $93.1 million, or $(1.10) per basic and diluted common share, in fiscal 2023, compared to net revenues of $39.4 million and net loss of $83.8 million, or $(1.05) per basic and diluted common share, in fiscal 2022. Net revenues decreased 59% year over year.

Most of the Company's net revenues were derived from sales of FC2 in the U.S. prescription channel and global public health sector. In the U.S. prescription channel, the Company's customers include primarily telemedicine providers. In the global public health sector, 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. The Company had net revenues from the U.S. prescription channel of $5.8 million and $30.2 million in fiscal 2023 and fiscal 2022, respectively and net revenues from the global public health sector of $10.5 million and $9.1 million in fiscal 2023 and fiscal 2022, respectively. There was a change in the sales mix with the U.S. prescription channel representing 36% of total FC2 net revenues in the current year compared to 77% in the prior year and the global public health sector representing 64% of total FC2 net revenues in the current year compared to 23% in the prior year.

The decrease in FC2 net revenues in the U.S. prescription channel is primarily due to lower volume from telemedicine customers. Specifically, net revenues from The Pill Club were $3.9 million in the current year compared to $17.4 million in the prior year, which represented 67% and 58% of net revenues from the U.S. prescription channel in the current and prior year, respectively. We have recorded a provision for credit losses for the gross accounts receivable balance at September 30, 2023, due to The Pill Club's Chapter 11 bankruptcy filing in April 2023. Net revenues from another prescription channel customer were $11.4 million in the prior year period and zero in the current year period. We are working to increase net revenues in future periods based on growing awareness and demand through increased FC2 marketing efforts, using our telehealth platform, and discussions with potential new distribution partners in the telehealth sector.

The increase in FC2 net revenues in the global public health sector is primarily due to increases in the U.S. public sector. Significant 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 also currently seeing pressure on pricing for FC2 by large global agencies and governments that donate to those global agencies. As a result, the Company may continue to experience challenges for revenue from sales of FC2 in the global public health sector.

Cost of sales was $8.7 million in fiscal 2023, which is comparable to $8.8 million in fiscal 2022. There was a decrease in units sold, partially offset by a higher cost per unit sold, due to reduced production volume.

Gross profit decreased to $7.6 million in fiscal 2023 from $30.6 million in fiscal 2022. Gross profit margin for fiscal 2023 was 46% of net revenues, compared to 78% of net revenues in fiscal 2022. The decrease in gross profit and gross profit margin is primarily due to the decrease in FC2 net revenues in the U.S. prescription channel, which have higher profit margins, and reduced production, which results in a higher cost per unit.

Research and development expenses were $51.1 million in fiscal 2023 compared with $70.6 million in fiscal 2022. Increased research and development expenses in the second half of fiscal 2022 and the first half of fiscal 2023 were mainly related to sabizabulin for COVID-19 and the Company's emergency use authorization application. In the second half of fiscal 2023, research and development expense has decreased due to the Company's updated strategy to refocus development efforts on those drug candidates which it believes have the best opportunity to lead to long-term success and shareholder value creation.

Selling, general and administrative expenses increased to $48.1 million in fiscal 2023 from $43.2 million in fiscal 2022. The increase is due primarily to an increase in share-based compensation costs of $13.8 million in the current year compared to $8.2 million in the prior year, resulting from an increased number of unvested stock options for which the Company recognizes expense over a three year period. Additionally, the Company incurred commercialization costs of $13.4 million in the current year compared to $9.3 million in the prior year related to preparation for the potential launch of sabizabulin for COVID-19 prior to the FDA's declination decision on the Company's EUA application. These increases were partially offset by a decrease in the Company's bonus compensation expense of $2.8 million, due to management's decision not to pay bonuses in fiscal 2023.

The Company recorded a provision for credit losses of $3.9 million in fiscal 2023 for the total amount of receivables due from The Pill Club due to their Chapter 11 bankruptcy (see Note 5 to the financial statements included in this report for additional information). There was no provision for credit losses recorded in fiscal 2022.

In March 2023, the Company recorded an impairment charge of $3.9 million related to IPR&D assets recorded for sabizabulin for prostate cancer and zuclomiphene, as a result of the Company's strategic decision to refocus its drug development efforts on those drug candidates that it believes have the best opportunity to lead to long-term success and shareholder value creation. There was no impairment charge recorded in fiscal 2022.

The Company recorded a pre-tax gain of $5.7 million on the sale of the Company's ENTADFI assets in fiscal 2023. See Note 15 to the financial statements included in this report for additional information.

Interest expense, which is related to the accretion of the liability for the Residual Royalty Agreement, was $2.4 million in fiscal 2023, which is a decrease from $4.4 million in fiscal 2022. The decrease relates to a decrease in actual and projected FC2 sales.

The gain associated with the change in fair value of the embedded derivatives related to Residual Royalty Agreement was $3.0 million in fiscal 2023 compared to $3.6 million in fiscal 2022. The liabilities associated with embedded derivatives represent the fair value of the change of control provision in the Residual Royalty Agreement. The decrease in the fair value of the embedded derivates is due to a decrease in projected FC2 net revenues in future periods. See Note 3 and Note 9 to the financial statements included in this report for additional information.

Income tax expense in fiscal 2023 was $0.5 million, compared to income tax expense of $0.2 million in fiscal 2022. The change in income tax expense is primarily due to an increase of $0.4 million in tax expense recorded in the current year due to an increase in income recognized by our U.K. and Malaysia subsidiaries, partially reduced by a benefit recorded for the reduction of deferred tax liabilities upon the impairment of the IPR&D assets and a reduction in U.S. state income tax expense of $0.1 million. The U.S. continues to have a full valuation allowance on its deferred tax assets; therefore, activity in the U.S. does not have a material effect on income tax expense.

Liquidity and Sources of Capital

Liquidity

Our cash and cash equivalents on hand at September 30, 2023 was $9.6 million, compared to $80.2 million at September 30, 2022. At September 30, 2023, the Company had working capital of $3.2 million and stockholders' equity of $17.8 million compared to working capital of $63.3 million and stockholders' equity of $80.8 million as of September 30, 2022. The decrease in working capital is primarily due to the decrease in cash on hand, related to our increased spend on research and development and drug commercialization costs related to the infectious disease program, partially offset by a decrease in accounts payable and accrued expenses.

The Company is not profitable and has had negative cash flow from operations. We will need substantial capital to support our drug development and any related commercialization efforts for our drug candidates. Based upon the Company's current operating plan, it estimates that its cash and cash equivalents as of the issuance date of the financial statements included in this report are insufficient for the Company to fund operating, investing and financing cash flow needs for the twelve months subsequent to the issuance date of the financial statements included in this report. To obtain the capital necessary to fund our operations, we expect to finance our cash needs through public or private equity offerings, debt financing transactions and/or other capital sources. Additional capital may not be available at such times and in such amounts as needed by us to fund our activities on a timely basis.

These uncertainties raise substantial doubt regarding our ability to continue as a going concern for a period of twelve months subsequent to the issuance date of the financial statements included in this report. Certain elements of our operating plan to alleviate the conditions that raise substantial doubt, including but not limited to our ability to secure equity financing or other financing alternatives, are outside of our control and cannot be included in management's evaluation under the requirement of ASC 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least twelve months subsequent to the issuance date of the financial statements included in this report.

Operating activities

Our operating activities used cash of $88.0 million in fiscal 2023. Cash used in operating activities included net loss of $93.1 million, adjustments to reconcile net loss to net cash used in operating activities totaling an increase of $20.3 million and changes in operating assets and liabilities totaling a decrease of $15.2 million. Adjustments to net loss primarily consisted of share-based compensation of $17.9 million, a provision for credit losses of $3.9 million, and an impairment of intangible assets of $3.9 million, partially offset by the gain on the sale of ENTADFI assets of $5.7 million. The decrease in cash from changes in operating assets and liabilities included a decrease in accrued expenses and other current liabilities of $13.6 million, a decrease in accounts payable of $7.4 million, and an increase in accounts receivable of $4.2 million, partially offset by a decrease in prepaid expenses and other assets of $10.0 million.

Our operating activities used cash of $47.5 million in fiscal 2022. Cash used in operating activities included net loss of $83.8 million, adjustments to reconcile net loss to net cash used in operating activities totaling an increase of $10.4 million and changes in operating assets and liabilities of $25.9 million. Adjustments to net loss primarily consisted of share-based compensation of $11.2 million and noncash interest expense of $1.7 million, partially offset by a decrease in the fair value of derivative liabilities of $3.6 million. The increase in cash from changes in operating assets and liabilities included an increase in accounts payable of $18.6 million, an increase in accrued expenses and other current liabilities of $8.7 million, and a decrease in accounts receivable of $4.5 million, partially offset by an increase in inventory of $3.1 million and an increase in prepaid expenses and other assets of $2.4 million.

Investing activities

Net cash from investing activities was $6.3 million in fiscal 2023, attributed to $7.0 million received from the sale of the Company's ENTADFI® assets, partially offset by $0.7 million in capital expenditures for manufacturing equipment and leasehold improvements.

Net cash from investing activities was $4.3 million in fiscal 2022, attributed to $5.0 million received on notes receivable from the sale of the Company's PREBOOST® business, partially offset by $0.7 million in capital expenditures for manufacturing and office equipment.

Financing activities

Net cash provided by financing activities in fiscal 2023 was $11.1 million and primarily consisted of proceeds from the sale of shares under common stock purchase agreements of $4.8 million, proceeds from the sale of shares in a private investment in public equity of $5.0 million, and proceeds from the sale of shares pursuant to the Jefferies Sales Agreement of $1.0 million.

Net cash provided by financing activities in fiscal 2022 was $1.1 million and primarily consisted of proceeds from stock option exercises of $1.1 million.

Sources of Capital

SWK Credit Agreement and Residual Royalty 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. 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. The Agent has released its security interest in Company collateral previously pledged to secure its 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 Residual Royalty Agreement, or (ii) mutual agreement of the parties.

The Company made total payments under the Residual Royalty Agreement of $0.6 million and $2.6 million during the year ended September 30, 2023 and 2022, respectively. The Company currently estimates the aggregate amount of quarterly revenue-based payments payable during the 12-month period subsequent to September 30, 2023 will be approximately $0.9 million under the Residual Royalty Agreement.

Aspire Capital Purchase Agreement

On June 26, 2020, the Company entered into a common stock purchase agreement (the “Aspire Purchase Agreement”) with Aspire Capital Fund, LLC (“Aspire Capital”) which provided that, upon the terms and subject to the conditions and limitations set forth therein, the Company had the right, from time to time in its sole discretion during the 36-month term of the Aspire 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 Aspire Purchase Agreement, the Company issued and sold to Aspire Capital under the Aspire 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 Aspire Purchase Agreement and the initial sale of 1,644,737 shares of common stock, the Company had no obligation to sell any shares of common stock pursuant to the Aspire Purchase Agreement and the timing and amount of any such sales were in the Company's sole discretion subject to the conditions and terms set forth in the Aspire Purchase Agreement.

During the year ended September 30, 2023, prior to the expiration of the Aspire Purchase Agreement on June 26, 2023, we sold 2,779,713 shares of common stock to Aspire Capital under the Aspire Purchase Agreement, resulting in proceeds to the Company of $3.4 million. During the 36-month term of the Aspire Purchase Agreement, we sold 4,424,450 shares of common stock to Aspire Capital resulting in proceeds to the Company of $8.4 million. On June 26, 2023, the term of the Aspire Purchase Agreement expired and no additional shares of common stock will be sold under the agreement.

Private Investment in Public Equity

On April 12, 2023, the Company entered into a stock purchase agreement (the “Stock Purchase Agreement”) with Frost Gamma Investments Trust (“FGI”), pursuant to which, on the date thereof, the Company issued and sold 5,000,000 shares of the Company’s common stock to FGI at a price of $1.00 per share, for a total investment of $5,000,000, through a private investment in public equity financing. The shares of common stock issued to FGI pursuant to the Stock Purchase Agreement were not registered under the Securities Act. The Company filed a registration statement under the Securities Act to register the resale of the shares of common stock issued to FGI, which was declared effective on May 24, 2023.

Lincoln Park Capital Fund, LLC Purchase Agreement

On May 2, 2023, the Company entered into a common stock purchase agreement (the "Lincoln Park Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right, but not the obligation, to sell to Lincoln Park up to $100.0 million of shares (the "Purchase Shares") of the Company's common stock over the 36-month term of the Lincoln Park Purchase Agreement. On the date the Company executed the Lincoln Park Purchase Agreement, we also issued 800,000 shares of the Company's common stock to Lincoln Park as an initial fee for Lincoln Park's commitment to purchase shares of the Company's common stock under the Lincoln Park Purchase Agreement, and we are obligated to issue $1.0 million of shares of the Company's common stock at the time Lincoln Park's purchases cumulatively reach an aggregate amount of $50.0 million (such shares, collectively, the "Commitment Shares"). The Purchase Shares and Commitment Shares under the Lincoln Park Purchase Agreement have been registered pursuant to the Company's effective shelf registration statement on Form S-3 (File No. 333-270606), and a related prospectus supplement that was filed with the SEC on May 3, 2023. During the year ended September 30, 2023, we sold 1,225,000 shares of common stock to Lincoln Park under the Lincoln Park Purchase Agreement, resulting in proceeds to the Company of $1.4 million. Subsequent to September 30, 2023, we sold 1,800,000 shares of common stock to Lincoln Park under the Lincoln Park Purchase Agreement, resulting in proceeds to the Company of $1.7 million.

Open Market Sale Agreement with Jefferies LLC

On May 12, 2023, the Company entered into an Open Market Sale Agreement^{SM} (the "Jefferies Sales Agreement") with Jefferies LLC ("Jefferies"), as sales agent, pursuant to which we may issue and sell, from time to time, through Jefferies, shares of the Company's common stock, with an aggregate value of up to $75 million (not to exceed the lesser of 39,609,072 shares of common stock or the number of authorized, unissued and available shares of common stock at any time).

The Company is not obligated to sell any shares of common stock under the Jefferies Sales Agreement. Subject to the terms and conditions of the Jefferies Sales Agreement, Jefferies will use commercially reasonable efforts consistent with its normal trading and sales practices, to sell shares of common stock from time to time based upon the Company's instructions, including any price, time or size limits specified by the Company. Upon delivery of a placement notice, and subject to our instructions in that notice, and the terms and conditions of the Jefferies Sales Agreement generally, Jefferies may sell the Company's common stock by any method permitted by law deemed to be an "at the market offering" as defined by Rule 415(a)(4) promulgated under the Securities Act. Under the terms of the Sales Agreement, the Company cannot cause or request Jefferies to sell shares of common stock exceeding the number of shares of common stock authorized, unissued and available for issuance at any time. The Company will pay Jefferies a commission of 3% of the aggregate gross proceeds from each sale of common stock and has agreed to provide Jefferies with customary indemnification and contribution rights, including liabilities under the Securities Act and the Securities Exchange Act of 1934, as amended. The Company has also agreed to reimburse Jefferies for certain specified expenses. During the year ended September 30, 2023, we sold 1,277,259 shares of common stock under the Jefferies Sales Agreement, resulting in net proceeds to the Company of $1.0 million.

Shares of common stock will be offered and sold pursuant to the Jefferies Sale Agreement, the Company's effective shelf registration statement on Form S-3 (File No. 333-270606), and a related prospectus supplement that was filed with the SEC on May 12, 2023.

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 2023 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 $19.9 million should be recorded against the U.S. deferred tax assets related to federal and state net operating loss carryforwards as of September 30, 2023. 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. 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. Veru Biopharma UK Limited has a full valuation allowance of $0.3 million.

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

Our effective tax rates have differed from the statutory rate primarily due to the tax impact of foreign operations, state taxes and 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 may be subject to the examination of our income tax returns by the IRS and other tax authorities. We 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, 2023, 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 values of these liabilities were estimated based on unobservable inputs (Level 3 measurement), which requires highly subjective judgment and assumptions. The Company estimates the fair value of the embedded derivative within the Residual Royalty Agreement using a scenario-based method, whereby different scenarios are valued and probability weighted. The scenario-based valuation model incorporates transaction details such as the contractual terms of the instrument and assumptions including projected FC2 revenues, expected cash outflows, probability and estimated dates of a change of control, risk-free interest rates and applicable credit risk. 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, 2023 was $1.3 million compared to $4.3 million at September 30, 2022. The Company recognized non-operating income of $3.0 million to adjust the fair value of these instruments. The decrease in the fair value of the embedded derivates is due primarily to a decrease in projected FC2 net revenues in future periods.

Goodwill and Intangible Assets

The Company has $6.9 million recorded as goodwill at September 30, 2023 and 2022 and $6,000 and $4.0 million recorded as intangible assets at September 30, 2023 and 2022, respectively. The Company evaluates the carrying value of its goodwill and indefinite-lived intangible assets, which consisted 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. The Company's goodwill is assigned to the Research and Development reporting unit, which has a negative carrying amount as of September 30, 2023.

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.

In March 2023, the Company announced its strategic decision to refocus its drug development efforts on those drug candidates that it believes have the best opportunity to lead to long-term success and shareholder value creation. As part of this strategic decision, the Company has indefinitely ceased development of sabizabulin for prostate cancer and zuclomiphene. The Company has no current plans that would invest funds in the development of these two assets or that would lead to the Company deriving value from these two assets, which has met the criteria for abandonment under the accounting standards. This resulted in writing off the carrying amount of these two acquired in-process research and development assets and recording an impairment charge of $3.9 million for the year ended September 30, 2023.

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.

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

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Annual Report on Form 10-K, the Company carried out an evaluation, under the supervision and with the participation of the Company’s management, including the Company’s Chief Executive Officer and the Company’s Chief Financial Officer, of the effectiveness of the design and operation of the Company’s disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Based on this evaluation, the Company’s Chief Executive Officer and Chief Financial Officer concluded that the Company’s disclosure controls and procedures were not effective as of September 30, 2023, due to the material weakness in internal control over financial reporting described below.

Material Weakness in Internal Control Over Financial Reporting

A material weakness is defined as a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

Management identified a material weakness in the Company’s internal control over financial reporting as of September 30, 2023 related to its controls over applying technical accounting guidance to nonrecurring events and transactions, specific to the evaluation of information that was known or knowable at the time of the transaction or event.

With respect to nonrecurring events and transactions, specific to the evaluation of information that was known or knowable at the time of the transaction or event, our internal controls were not designed to adequately accumulate and evaluate all information that was known or knowable at the time and apply that information to the applicable accounting guidance. This resulted in a restatement of our financial statements as of and for the three and nine months ended June 30, 2023.

As a result of the identified material weakness, our management directed a comprehensive review of this complex, nonrecurring transaction to assess the possibility of further material misstatements that may remain unidentified. As a result of such review, and notwithstanding the material weakness described above, our management, including our Chief Executive Officer and Chief Financial Officer, believe that the audited consolidated financial statements contained in this Form 10-K as of and for the year ended September 30, 2023, fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented in conformity with U.S. GAAP.

Remediation Activities

We have implemented additional controls and review procedures to enhance our internal control over financial reporting with respect to complex and nonrecurring transactions as follows:

- enhanced the design of our review procedures and controls with respect to any new complex and nonrecurring transactions; and
- implemented additional review procedures with respect to accumulation and evaluation of information that is known or knowable to the Company at the time in which a complex and nonrecurring transaction is executed, including development of a review checklist, to ensure that we will apply that information to the applicable accounting guidance.

The actions that we are taking are subject to ongoing senior management review as well as Audit Committee oversight. We are committed to maintaining a strong internal control environment and believe that we have made progress toward remediation. We continue to implement our remediation plan for the current material weakness in internal control over financial reporting. We will consider the material weakness remediated after the applicable controls operate for a sufficient period of time and management has concluded that the controls are operating effectively.

Changes in Internal Control over Financial Reporting

As discussed above, we identified a material weakness in our control over financial reporting for the period covered by this Annual Report on Form 10-K and are implementing a plan of remediation to strengthen the design and operation of our control environment. Other than as described above, 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 period covered by this Annual Report on Form 10-K 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 did not maintain effective internal control over financial reporting as of September 30, 2023, based on criteria in "Internal Control - Integrated Framework" issued by the COSO in 2013 due to the material weakness in internal control over financial reporting described above.

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 2024 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 29, 2024. 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 2023 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 29, 2024.

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 2024 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 29, 2024.

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” the Company’s Proxy Statement for the 2024 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 29, 2024.

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 2024 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 29, 2024. 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 2024 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 29, 2024.

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 2024 Annual Meeting of Shareholders, which will be filed with the SEC on or before January 29, 2024.

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, 2023 and 2022

Consolidated Statements of Operations for the Years Ended September 30, 2023 and 2022

Consolidated Statements of Stockholders' Equity for the Years Ended September 30, 2023 and 2022

Consolidated Statements of Cash Flows for the Years Ended September 30, 2023 and 2022

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.

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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).
2.2	Asset Purchase Agreement, dated as of April 19, 2023, between the Company and Blue Water Vaccines Inc. (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on April 20, 2023).
2.3	Amendment to Asset Purchase Agreement, dated as of September 29, 2023, between the Company and Blue Water Biotech Inc. (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on October 2, 2023).
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	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 308,000,000 shares (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on July 28, 2023).
3.10	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, 3.8, and 3.9).
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	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). *
10.2	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). *
10.3	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). *
10.4	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). *
10.5	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). *
10.6	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).*
10.7	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).*
10.8	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). *
10.9	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). *
10.10	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). *

10.11	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). *
10.12	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). *
10.13	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). *
10.14	Veru Inc. 2018 Equity Incentive Plan (as amended and restated effective March 29, 2022) (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on March 31, 2022). *
10.15	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). *
10.16	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).
10.17	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).
10.18	Veru Inc. 2022 Employment Inducement Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q (File No. 1-13602) filed with the SEC on August 11, 2022).
10.19	Stock Purchase Agreement, dated as of April 12, 2023, between the Company and Frost Gamma Investments Trust (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on April 13, 2023).
10.20	Purchase Agreement, dated May 2, 2023, between the Company and Lincoln Park 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 May 3, 2023).
10.21	Registration Rights Agreement, dated May 2, 2023, between the Company and Lincoln Park 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 May 3, 2023).
10.22	Open Market Sale Agreement, dated May 12, 2023, between the Company and Jefferies LLC (incorporated by reference to Exhibit 1.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on May 12, 2023).
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). **, ***
97.1	Veru Inc. Clawback Policy. **
101	The following materials from the Company's Annual Report on Form 10-K for the year ended September 30, 2023, 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).

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

Item 16. Form 10-K Summary

Not Applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: December 8, 2023

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 8, 2023
/s/ Michele Greco Michele Greco	Chief Financial Officer and Chief Administrative Officer (Principal Accounting and Financial Officer)	December 8, 2023
/s/ Mario Eisenberger Mario Eisenberger	Director	December 8, 2023
/s/ Harry Fisch Harry Fisch	Vice Chairman of the Board and Director	December 8, 2023
/s/ Grace S. Hyun Grace S. Hyun	Director	December 8, 2023
/s/ Lucy Lu Lucy Lu	Director	December 8, 2023
/s/ Michael L. Rankowitz Michael L. Rankowitz	Director	December 8, 2023

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, 2023 and 2022, 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, 2023 and 2022, 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.

Emphasis of Matter Regarding Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company is not profitable, has recorded negative cash flows from operations, and will need substantial capital to support its drug development operations. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Valuation Allowance for Deferred Tax Assets

As described in Note 14 to the financial statements, the Company has recorded net deferred tax assets totaling approximately $12.7 million at September 30, 2023. The Company has recorded a valuation allowance of approximately $65.6 million at September 30, 2023 against its deferred tax assets in the United States and certain deferred tax assets in the United Kingdom (UK). The Company has approximately $12.7 million of net deferred tax assets in the UK 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, and forecasts of future taxable income. In determining future taxable income, management makes assumptions to forecast US federal and state, UK, 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 asset 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 UK 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 UK.

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

- We evaluated the reasonableness of management’s forecasted revenue and pre-tax income, including revenue growth rates and margins, by comparing the projections to historic results, and by comparing management’s prior forecasts to historical results for the UK.

- 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.

Gain on Sale of ENTADFI Assets

As described in Note 15 to the financial statements, the Company has recorded a gain on the sale of ENTADFI assets of approximately $5.7 million during the year ended September 30, 2023. On April 19, 2023, the Company entered into an asset purchase agreement to sell substantially all of the assets related to ENTADFI capsules for oral use. The purchase price for the transaction was $20.0 million, consisting of $6.0 million paid at closing, $4.0 million payable by September 30, 2023, $5.0 million payable 12 months after closing, and $5.0 million payable by September 30, 2024, plus up to $80.0 million based on net revenues from ENTADFI after closing (Milestone Payments). The Company determined that it was not probable, at the time of the transaction and at September 30, 2023, that substantially all of the consideration promised under the asset purchase agreement would be collected. Therefore, the Company recognized the difference between the nonrefundable consideration received and the carrying amount of the assets over which it has transferred control as a gain.

We identified the gain on sale of ENTADFI assets as a critical audit matter because of the assumptions management makes in determining whether the contract criteria had been met, specifically, whether it is probable the Company will collect substantially all of the consideration to which it is entitled in exchange for the ENTADFI assets. Auditing management’s analysis of the amount of consideration considered to be collectible involved a high degree of subjectivity and auditor judgment as changes in the assumptions could have a significant impact on the determination of whether the contract criteria had been met, and the resulting impact on the calculated gain on sale of ENTADFI assets.

Our audit procedures related to the assessment of whether the contract criteria had been met included the following, among others:

- We evaluated management's assessment of the variable consideration, including the future payments due, when determining the amount of total consideration.
- We evaluated management's assessment of the collectability of the notes receivable, based on the third party's intent and ability to pay the notes as they come due by evaluating public information related to the acquirer and expected timing of commercialization.
- We tested the receipt of the nonrefundable consideration.

/s/ RSM US LLP

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

Chicago, Illinois
December 8, 2023

VERU INC.
CONSOLIDATED BALANCE SHEETS
AS OF SEPTEMBER 30, 2023 AND 2022

	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 9,625,494	$ 80,190,675
Accounts receivable, net	4,506,508	3,550,895
Inventories, net	6,697,117	8,618,944
Prepaid research and development costs	1,579,086	10,444,587
Prepaid expenses and other current assets	1,097,851	1,964,373
Total current assets	23,506,056	104,769,474
Plant and equipment, net	1,652,732	1,185,766
Operating lease right-of-use asset	4,332,473	4,786,915
Deferred income taxes	12,707,419	12,965,985
Intangible assets, net	5,952	3,977,381
Goodwill	6,878,932	6,878,932
Other assets	1,512,361	1,561,564
Total assets	$ 50,595,925	$ 136,126,017
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 14,576,624	$ 22,003,394
Accrued research and development costs	853,987	9,071,503
Accrued compensation	990,609	5,986,557
Accrued expenses and other current liabilities	1,956,075	2,249,995
Residual royalty agreement, short-term portion (Note 9)	864,623	1,169,095
Operating lease liability, short-term portion	1,036,590	957,085
Total current liabilities	20,278,508	41,437,629
Residual royalty agreement, long-term portion (Note 9)	8,870,136	9,656,441
Operating lease liability, long-term portion	3,634,114	4,093,667
Deferred income taxes	—	81,067
Other liabilities	29,948	18,577
Total liabilities	32,812,706	55,287,381
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock, no shares issued and outstanding at September 30, 2023 and 2022, respectively	—	—
Common stock, par value $0.01 per share; 308,000,000 and 154,000,000 shares authorized, 93,966,402 and 82,692,598 shares issued and 91,782,698 and 80,508,894 shares outstanding at September 30, 2023 and 2022, respectively	939,664	826,926
Additional paid-in-capital	283,894,830	253,974,032
Accumulated other comprehensive loss	(581,519)	(581,519)
Accumulated deficit	(258,663,151)	(165,574,198)
Treasury stock, 2,183,704 shares, at cost	(7,806,605)	(7,806,605)
Total stockholders' equity	17,783,219	80,838,636
Total liabilities and stockholders' equity	$ 50,595,925	$ 136,126,017

See notes to consolidated financial statements.

VERU INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED SEPTEMBER 30, 2023 AND 2022

	2023	2022
Net revenues	$ 16,296,958	$ 39,354,352
Cost of sales	8,731,030	8,762,964
Gross profit	7,565,928	30,591,388
Operating expenses:		
Research and development	51,138,480	70,646,103
Selling, general and administrative	48,057,834	43,177,345
Provision for (recovery of) credit losses	3,911,714	(8,500)
Impairment of intangible assets	3,900,000	—
Total operating expenses	107,008,028	113,814,948
Gain on sale of ENTADFI® assets	5,723,623	—
Operating loss	(93,718,477)	(83,223,560)
Non-operating income (expenses):		
Interest expense	(2,427,041)	(4,368,798)
Change in fair value of derivative liabilities	2,963,000	3,557,000
Other income, net	573,771	495,735
Total non-operating income (expenses)	1,109,730	(316,063)
Loss before income taxes	(92,608,747)	(83,539,623)
Income tax expense	480,206	236,397
Net loss	$ (93,088,953)	$ (83,776,020)
Net loss per basic and diluted common shares outstanding	$ (1.10)	$ (1.05)
Basic and diluted weighted average common shares outstanding	84,973,382	80,122,526

See notes to consolidated financial statements.

VERU INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED SEPTEMBER 30, 2023 AND 2022

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Treasury Stock, at Cost	Total
	Shares	Amount					
Balance at September 30, 2021	82,153,452	$ 821,535	$ 241,658,711	$ (581,519)	$ (81,798,178)	$ (7,806,605)	$ 152,293,944
Share-based compensation	—	—	11,242,423	—	—	—	11,242,423
Issuance of shares pursuant to share-based awards	539,146	5,391	1,072,898	—	—	—	1,078,289
Net loss	—	—	—	—	(83,776,020)	—	(83,776,020)
Balance at September 30, 2022	82,692,598	826,926	253,974,032	(581,519)	(165,574,198)	(7,806,605)	80,838,636
Share-based compensation	—	—	17,918,603	—	—	—	17,918,603
Issuance of shares pursuant to share-based awards	191,832	1,918	387,140	—	—	—	389,058
Shares issued in connection with common stock purchase agreement	800,000	8,000	1,000,000	—	—	—	1,008,000
Sale of shares under common stock purchase agreements	4,004,713	40,047	4,806,644				4,846,691
Issuance of shares pursuant to Jefferies Sales Agreement, net of commission and costs	1,277,259	12,773	1,027,548	—	—	—	1,040,321
Amortization of deferred costs			(138,182)				(138,182)
Issuance of shares in a Private Investment in Public Equity, net of costs	5,000,000	50,000	4,919,045	—	—	—	4,969,045
Net loss	—	—	—	—	(93,088,953)	—	(93,088,953)
Balance at September 30, 2023	93,966,402	$ 939,664	$ 283,894,830	$ (581,519)	$ (258,663,151)	$ (7,806,605)	$ 17,783,219

See notes to consolidated financial statements.

VERU INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED SEPTEMBER 30, 2023 AND 2022

	2023	2022
OPERATING ACTIVITIES		
Net loss	$ (93,088,953)	$ (83,776,020)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	269,874	209,595
Impairment of intangible assets	3,900,000	—
Provision for credit losses	3,911,714	(8,500)
Gain on sale of ENTADFI® assets	(5,723,623)	—
Noncash change in right-of-use assets	741,257	594,398
Noncash interest expense, net of interest paid	1,872,223	1,748,189
Share-based compensation	17,918,603	11,242,423
Deferred income taxes	177,499	76,206
Provision for obsolete inventory	185,499	82,019
Change in fair value of derivative liabilities	(2,963,000)	(3,557,000)
Other	290	1,723
Changes in operating assets and liabilities:		
(Increase) decrease in accounts receivable	(4,153,327)	4,537,829
Decrease (increase) in inventories	648,628	(3,126,710)
Decrease (increase) in prepaid expenses and other assets	10,004,978	(2,352,547)
(Decrease) increase in accounts payable	(7,426,770)	18,593,623
(Decrease) increase in accrued expenses and other current liabilities	(13,621,843)	8,698,314
Decrease in operating lease liabilities	(666,863)	(468,546)
Net cash used in operating activities	(88,013,814)	(47,505,004)
INVESTING ACTIVITIES		
Cash proceeds from sale of ENTADFI® assets	7,000,000	—
Cash proceeds from sale of PREBOOST® business	—	5,000,000
Capital expenditures	(665,700)	(733,052)
Net cash provided by investing activities	6,334,300	4,266,948
FINANCING ACTIVITIES		
Proceeds from stock option exercises	389,058	1,078,289
Proceeds from sale of shares pursuant to Jefferies Sales Agreement, net of commissions and costs	1,040,321	—
Proceeds from sale of shares under common stock purchase agreements	4,846,691	—
Payment of deferred equity financing issuance costs	(263,757)	—
Proceeds from sale of shares in a private investment in public equity, net of costs	4,969,045	—
Proceeds from premium finance agreement	1,425,174	—
Installment payments on premium finance agreement	(1,292,199)	—
Cash paid for debt portion of finance lease	—	(9,093)
Net cash provided by financing activities	11,114,333	1,069,196
Net (decrease) increase in cash and cash equivalents	(70,565,181)	(42,168,860)
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	80,190,675	122,359,535
CASH AND CASH EQUIVALENTS AT END OF YEAR	$ 9,625,494	$ 80,190,675
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 247,361	$ 422,135
Cash paid for interest	$ 554,818	$ 2,620,609
Schedule of non-cash investing and financing activities:		
Shares issued in connection with common stock purchase agreement	$ 1,008,000	$ —
Amortization of deferred costs related to common stock purchase agreement	$ 138,182	$ —
Right-of-use assets recorded in exchange for lease liabilities	$ 286,815	$ 4,411,474

See notes to consolidated financial statements.

VERU INC.
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, Veru International Holdco Inc., 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"); The Female Health Company (UK) plc's wholly owned subsidiary, The Female Health Company (M) SDN.BHD (the "Malaysia subsidiary"); and Veru International Holdco Inc.'s wholly owned subsidiaries, Veru Biopharma UK Limited, Veru Biopharma Europe Limited, and Veru Biopharma Netherlands B.V. All significant intercompany transactions and accounts have been eliminated in consolidation. The Company is a late clinical stage biopharmaceutical company focused on developing novel medicines for the treatment of metabolic diseases (obesity), oncology, and acute respiratory distress syndrome (ARDS). Our drug development program includes enobosarm, a selective androgen receptor modulator, for preferential loss of fat while preventing the loss of muscle and bone, in combination with weight loss drugs, and for the management of advanced breast cancer and sabizabulin, a microtubule disruptor, for the treatment of hospitalized patients with viral induced ARDS. The Company also has the FC2 Female Condom/FC2 Internal Condom® (FC2), an FDA-approved commercial product for the dual protection against unplanned pregnancy and sexually transmitted infections. The Company had ENTADFI® (finasteride and tadalafil) capsules for oral use (ENTADFI), a new treatment for benign prostatic hyperplasia that was approved by the FDA in December 2021. We sold substantially all of the assets related to ENTADFI on April 19, 2023. See Note 15 for additional information. Most of the Company's net revenues during fiscal 2023 and 2022 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 various countries through distributors, public health programs, and/or retailers and in the U.S. by prescription.

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.

Segments: We regularly review our operating segments and the approach used by management to evaluate performance and allocate resources. The Company operates as a single operating segment. Our determination that we operate as a single segment is consistent with the financial information regularly reviewed by the chief operating decision maker (CODM) for purposes of evaluating performance, allocating resources, setting incentive compensation targets, and planning and forecasting for future periods. Our CODM allocates resources and assesses financial performance on a consolidated basis.

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 credit losses based on a review of all outstanding amounts on a periodic basis.

Inventories: 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.

The Company capitalizes inventory costs associated with its drug products following regulatory approval when future commercialization is considered probable and the future economic benefit is expected to be realized. Prior to an initial regulatory approval for our drug products under clinical development, we expense costs relating to the production of inventory as research and development expense in the Company's consolidated statements of operations, in the period incurred.

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 reporting unit that is expected to benefit from the synergies of a business combination. The Company has identified two reporting units within its single operating 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 second quarter of fiscal 2023, the Company recorded an impairment charge of $3.9 million related to IPR&D. The charge was primarily a result of the Company's strategic decision to refocus its drug development efforts on those drug candidates that it believes to have the best opportunity to lead to long-term success and shareholder value creation, which led the Company to indefinitely cease development of sabizabulin for prostate cancer and zuclomiphene. See Note 8 for additional information. The Company's intangible asset balance for IPR&D at September 30, 2023, after the impairment charge was recorded, is zero.

<u>Deferred financing costs</u>: Costs incurred in connection with the common stock purchase agreements and the at-the-market sale agreement discussed in Note 10 have been included in other assets on the accompanying consolidated balance sheets at September 30, 2023 and 2022. When shares of the Company's common stock are sold under the common stock purchase agreement or at-the market sale agreement, a pro-rata portion of the deferred costs is recorded to additional paid-in-capital.

<u>Fair value measurements</u>: 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 the residual royalty agreement liabilities, taking into consideration the related derivative instruments, is estimated to approximate fair value.

<u>Derivative instruments</u>: 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.

<u>Revenue recognition</u>: 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.

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, 2023.

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 $0.9 million and $0.6 million for the years ended September 30, 2023 and 2022, respectively.

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, 2023 and September 30, 2022. Assets located outside of the U.S. totaled approximately $10.5 million and $10.8 million at September 30, 2023 and September 30, 2022, 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 2023 and 2022, comprehensive income (loss) is equivalent to the reported net income (loss).

Recent accounting pronouncements not yet adopted: In November 2023, the FASB issued Accounting Standards Update (ASU) 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. The ASU expands public entities' segment disclosures by requiring disclosure of significant segment expenses that are regularly reviewed by the CODM and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment's profit or loss and assets. The ASU also allows, in addition to the measure that is most consistent with U.S. GAAP, the disclosure of additional measures of segment profit or loss that are used by the CODM in assessing segment performance and deciding how to allocate resources. All disclosure requirements under ASU 2023-07 are also required for public entities with a single reportable segment. The ASU is effective for the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2025, and subsequent interim periods, with early adoption permitted. The Company is currently evaluating the impact of adopting this ASU on its consolidated financial statements and disclosures.

We have reviewed all other recently issued accounting pronouncements and have determined that such standards that are not yet effective will not have a material impact on our financial statements or do not otherwise apply to our operations.

Note 2 – Going Concern

The Company is not profitable and has had negative cash flow from operations. We will need substantial capital to support our drug development and any related commercialization efforts for our drug candidates. Based upon the Company's current operating plan, it estimates that its cash and cash equivalents as of the issuance date of these financial statements are insufficient for the Company to fund operating, investing and financing cash flow needs for the twelve months subsequent to the issuance date of these financial statements. To obtain the capital necessary to fund our operations, we expect to finance our cash needs through public or private equity offerings, debt financing transactions and/or other capital sources. Additional capital may not be available at such times and in such amounts as needed by us to fund our activities on a timely basis.

These uncertainties raise substantial doubt regarding our ability to continue as a going concern for a period of twelve months subsequent to the issuance date of these financial statements. Certain elements of our operating plan to alleviate the conditions that raise substantial doubt, including but not limited to our ability to secure equity financing or other financing alternatives, are outside of our control and cannot be included in management's evaluation under the requirement of ASC 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least twelve months subsequent to the issuance date of these financial statements.

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 2023 and 2022.

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 second quarter of fiscal 2023, we recognized an impairment charge of $3.9 million associated with IPR&D intangible assets due to their meeting the criteria for abandonment under the accounting standards. See Note 8 for additional information.

As of September 30, 2023 and 2022, 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, 2023 and 2022:

	2023	2022
Beginning balance	$ 4,294,000	$ 7,851,000
Change in fair value of derivative liabilities	(2,963,000)	(3,557,000)
Ending balance	$ 1,331,000	$ 4,294,000

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 Residual Royalty Agreement. See Note 9 for additional information. There is no current observable market for these types of derivatives. The Company estimates the fair value of the embedded derivative within the Residual Royalty Agreement by using a scenario-based method, whereby different scenarios are valued and probability weighted. The scenario-based valuation model incorporates transaction details such as the contractual terms of the instrument and assumptions including projected FC2 revenues, expected cash outflows, probability and estimated dates of a change of control, risk-free interest rates and applicable credit risk. 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 decrease in the fair value of derivative liabilities in fiscal 2023 was driven by a decrease in the expected cash outflows under the Residual Royalty Agreement, due to decreases in projected FC2 net revenues in future periods, and increases in the discount rates used, due primarily to external market factors. The decrease in the fair value of derivative liabilities in fiscal 2022 was driven by a decrease in the expected cash outflows under the Residual Royalty Agreement, due to decreases in projected FC2 net revenues in future periods, and increases in the discount rates used, due primarily to external market factors.

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, 2023 and 2022:

Valuation Methodology	Significant Unobservable Input	2023	2022
Scenario-Based	Estimated change of control dates	December 2024 to December 2026	September 2023 to September 2025
	Discount rate	14.1% to 15.1%	13.6% to 14.2%
	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 primarily 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 ENTADFI through the date the ENTADFI assets were sold on April 19, 2023. The following table presents net revenues by product and sector for the years ended September 30, 2023 and 2022:

	2023	2022
FC2		
U.S. prescription channel	$ 5,823,921	$ 30,223,079
Global public health sector	10,460,024	9,128,858
Total FC2	16,283,945	39,351,937
Other	13,013	2,415
Net revenues	$ 16,296,958	$ 39,354,352

The following table presents net revenue by geographic area for the years ended September 30, 2023 and 2022:

	2023	2022
United States	$ 8,370,202	$ 31,430,235
South Africa	1,941,678	*
Other	5,985,078	7,924,117
Net revenues	$ 16,296,958	$ 39,354,352

*Less than 10% of total net revenues

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 $105,000 and $342,000 at September 30, 2023 and 2022, respectively.

The amount of revenue recognized that was included in the contract liabilities and unearned revenues balance at the beginning of the period was $330,000 and $130,000 during the years ended September 30, 2023 and 2022, 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 Company classified approximately $0.7 million of trade receivables with its distributor in Brazil as long-term as of September 30, 2022, because payment was expected in greater than one year. The long-term portion of trade receivables is included in other assets on the accompanying consolidated balance sheet. The Company has $1.4 million of trade receivables as of September 30, 2023 due from its distributor in Brazil for sales recognized in fiscal 2021, which the Company expects to be paid within one year.

The components of accounts receivable consist of the following at September 30, 2023 and 2022:

	2023	2022
Trade receivables, gross	$ 8,445,370	$ 4,289,892
Less: allowance for credit losses	(3,923,857)	(12,143)
Less: allowance for sales returns and payment term discounts	(15,005)	(12,854)
Less: long-term trade receivables*	—	(714,000)
Accounts receivable, net	$ 4,506,508	$ 3,550,895

*Included in other assets on the accompanying consolidated balance sheets.

No customer had a current accounts receivable balance that represented 10% of current assets at September 30, 2023 and 2022.

At September 30, 2023, three customers had an accounts receivable balance greater than 10% of net accounts receivable, representing 71% of net accounts receivable in the aggregate. At September 30, 2022, two customers had an accounts receivable balance greater than 10% of net accounts receivable and long-term trade receivables, representing 83% of the Company's net accounts receivable and long-term trade receivables in the aggregate.

For the year ended September 30, 2023, there were two customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 47% of the Company's net revenues in the aggregate, including The Pill Club that represented 24% of the Company's net revenues. For the year ended September 30, 2022, there were two customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 73% of the Company's net revenues in the aggregate, including The Pill Club that represented 44% of the Company's net revenues.

The Company maintains an allowance for credit losses for estimated losses resulting from the inability of its customers to make required payments on accounts receivable. Management determines the allowance for credit losses 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. During the year ended September 30, 2023, the Company recorded a provision for credit losses of $3.9 million related to the total amount of receivables due from The Pill Club due to their Chapter 11 bankruptcy, filed on April 18, 2023.

The table below summarizes the change in the allowance for credit losses on trade receivables for the years ended September 30, 2023 and 2022:

	2023	2022
Beginning balance	$ 12,143	$ 20,643
Charge-offs (recoveries), net	3,911,714	(8,500)
Ending balance	$ 3,923,857	$ 12,143

Recoveries of accounts receivable previously charged-off are recorded when received. In the global public health sector, 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. In the U.S. prescription channel, the Company's customers include primarily telemedicine providers.

Note 6 – Inventories

Inventories consisted of the following at September 30, 2023 and September 30, 2022

	2023	2022
Raw material	$ 1,854,810	$ 1,662,712
Work in process	112,799	872,596
Finished goods	4,913,295	6,099,343
Inventories, gross	6,880,904	8,634,651
Less: inventory reserves	(183,787)	(15,707)
Inventories, net	$ 6,697,117	$ 8,618,944

The Company had ENTADFI inventory of $1.1 million, which was included in the sale of ENTADFI assets, and was included in the inventories balance at September 30, 2022. See Note 15 for additional information.

Note 7 – Property and Equipment

Property and equipment consisted of the following at September 30, 2023 and 2022:

	Estimated Useful Life	2023	2022
Property and equipment:			
Manufacturing equipment	5 - 8 years	$ 3,008,122	$ 2,902,715
Office equipment, furniture and fixtures	3 - 10 years	1,471,870	1,440,475
Leasehold improvements	3 - 8 years	960,694	484,460
Total property and equipment		5,440,686	4,827,650
Less: accumulated depreciation and amortization		(3,787,954)	(3,641,884)
Property and equipment, net		$ 1,652,732	$ 1,185,766

Depreciation expense for the years ended September 30, 2023 and 2022 was approximately $198,000 and $138,000, respectively. Property and equipment included $214,000 and $276,000 at September 30, 2023 and 2022, respectively, for deposits on equipment, furniture, and leasehold improvements, which have not been placed into service; therefore, the Company has not started to record depreciation expense.

Note 8 –Intangible Assets and Goodwill

Intangible Assets

Intangible assets includes IPR&D and covenants not-to-compete.

The gross carrying amounts and net book value of intangible assets are as follows at September 30, 2023:

	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Intangible asset with finite life:			
Covenants not-to-compete	$ 500,000	$ 494,048	$ 5,952
Indefinite-lived intangible assets:			
Acquired in-process research and development assets	—	—	—
Total intangible assets	$ 500,000	$ 494,048	$ 5,952

The gross carrying amounts and net book value of intangible assets are as follows at September 30, 2022:

	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Intangible asset with finite life:			
Covenants not-to-compete	$ 500,000	$ 422,619	$ 77,381
Indefinite-lived intangible assets:			
Acquired in-process research and development assets	3,900,000	—	3,900,000
Total intangible assets	$ 4,400,000	$ 422,619	$ 3,977,381

Amortization is recorded 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 $71,000 for the years ended September 30, 2023 and 2022. Based on finite-lived intangible assets recorded as of September 30, 2023, the estimated future amortization expense is approximately $6,000 in fiscal 2024.

In March 2023, the Company announced its strategic decision to refocus its drug development efforts on those drug candidates that it believes have the best opportunity to lead to long-term success and shareholder value creation. As part of this strategic decision, the Company has indefinitely ceased development of sabizabulin for prostate cancer and zuclomiphene. The Company has no current plans that would invest funds in the development of these two assets or that would lead to the Company deriving value from these two assets, which has met the criteria for abandonment under the accounting standards. This resulted in writing off the carrying amount of these two acquired in-process research and development assets and recording an impairment charge of $3.9 million for the year ended September 30, 2023.

Goodwill

The carrying amount of goodwill at September 30, 2023 and 2022 was $6.9 million. There was no change in the balance during the years ended September 30, 2023 and 2022. The Company's goodwill is assigned to the Research and Development reporting unit, which had a negative carrying amount as of September 30, 2023.

Note 9 – Debt

SWK 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. 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. The Agent has released its security interest in Company collateral previously pledged to secure its 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. 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 Residual Royalty 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 Residual Royalty Agreement, equal to the fair value of the change of control provision, was allocated to an embedded derivative liability. The derivative liability is adjusted to fair market value at each reporting period.

At September 30, 2023 and 2022, the Residual Royalty Agreement liability consisted of the following:

	2023	2022
Residual royalty agreement liability, fair value at inception	$ 346,000	$ 346,000
Add: accretion of liability using effective interest rate	12,377,949	9,950,908
Less: cumulative payments	(4,320,190)	(3,765,372)
Residual royalty agreement liability, excluding embedded derivative liability	8,403,759	6,531,536
Add: embedded derivative liability at fair value (see Note 3)	1,331,000	4,294,000
Total residual royalty agreement liability	9,734,759	10,825,536
Residual royalty agreement liability, short-term portion	(864,623)	(1,169,095)
Residual royalty agreement liability, long-term portion	$ 8,870,136	$ 9,656,441

As the Company has repaid the original principal of $10.0 million advanced in connection with the Credit Agreement and the Residual Royalty Agreement, payments under the Residual Royalty Agreement are classified as interest payments and included in operating activities on the accompanying consolidated statements of cash flows. 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 the balance sheet dates.

Interest expense on the accompanying consolidated statements of operations relates to the accretion of the liability for the Residual Royalty Agreement. The accretion of the liability is based on projected FC2 revenues.

Premium Finance Agreement

On November 1, 2022, the Company entered into an agreement to finance $1.4 million of its directors and officers liability insurance premium at an annual percentage rate of 6.3%. The financing agreement was payable in eleven monthly installments of principal and interest, which began on December 1, 2022. The balance of the insurance premium liability is $0.1 million as of September 30, 2023 and is included in accrued expenses and other current liabilities on the accompanying consolidated balance sheet.

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, 2023 and September 30, 2022. 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, 2023 and September 30, 2022.

Common Stock

We are authorized to issue up to 308,000,000 shares of common stock, $0.01 par value per share. Following approval by stockholders at the Company's annual meeting of stockholders held on July 24, 2023, the Company filed an amendment to its articles of incorporation to increase the number of authorized shares of common stock from 154,000,000 to 308,000,000. Holders are entitled to one vote for each share of common stock.

Shelf Registration Statement

In March 2023, the Company filed a shelf registration statement on Form S-3 (File No. 333-270606) with a capacity of $200 million, which was declared effective by the Securities and Exchange Commission ("SEC") on April 14, 2023. At September 30, 2022, $23.0 million remains available under that shelf registration statement. The Company's prior shelf registration statement on Form S-3 (File No. 333-239493) expired on July 1, 2023.

Aspire Capital Purchase Agreement

On June 26, 2020, the Company entered into a common stock purchase agreement (the “Aspire Purchase Agreement”) with Aspire Capital Fund, LLC (“Aspire Capital”) which provided that, upon the terms and subject to the conditions and limitations set forth therein, the Company had the right, from time to time in its sole discretion during the 36-month term of the Aspire Purchase Agreement, to direct Aspire Capital to purchase up to $23.9 million of the Company’s common stock in the aggregate.

During the year ended September 30, 2023, we sold 2,779,713 shares of common stock to Aspire Capital under the Aspire Purchase Agreement resulting in proceeds to the Company of $3.4 million. As a result of these sales, we recorded approximately $105,000 of deferred costs to additional paid-in capital.

During the 36-month term of the Aspire Purchase Agreement, we sold 4,424,450 shares of common stock to Aspire Capital resulting in proceeds to the Company of $8.4 million. On June 26, 2023, the term of the Aspire Purchase Agreement expired and no additional shares of common stock will be sold under the agreement.

In consideration for entering into the Aspire Purchase Agreement, concurrently with the execution of the Aspire 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. The unamortized amount of deferred costs related to the Aspire Purchase Agreement remaining when the agreement terminated was $473,000 and was expensed at the time of termination. It is included in selling, general and administrative expenses on the accompanying consolidated statement of operations for the year ended September 30, 2023. The unamortized amount of deferred costs related to the Aspire Purchase Agreement of $578,000 at September 30, 2022 is included in other assets on the accompanying consolidated balance sheet.

Private Investment in Public Equity

On April 12, 2023, the Company entered into a stock purchase agreement (the “Stock Purchase Agreement”) with Frost Gamma Investments Trust (“FGI”), pursuant to which, on the date thereof, the Company issued and sold 5,000,000 shares of the Company’s common stock to FGI at a price of $1.00 per share, for a total investment of $5.0 million, through a private investment in public equity financing. Proceeds were recorded net of issuance costs of $31,000. The shares of common stock issued to FGI pursuant to the Stock Purchase Agreement were not registered under the Securities Act. The Company filed a registration statement under the Securities Act to register the resale of the shares of common stock issued to FGI, which was declared effective by the SEC on May 24, 2023.

Lincoln Park Capital Fund LLC Purchase Agreement

On May 2, 2023, the Company entered into a purchase agreement (the “Lincoln Park Purchase Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”), which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company may sell to Lincoln Park up to $100.0 million of shares (the “Purchase Shares”) of the Company’s common stock over the 36 month term of the Lincoln Park Purchase Agreement. The Lincoln Park Purchase Agreement may be terminated by the Company at any time, at its sole discretion, without any cost or penalty, by giving one business day notice to Lincoln Park. Lincoln Park has covenanted not to in any manner whatsoever enter into or effect, directly or indirectly, any short selling or hedging of the Company’s common stock. The issuance of shares of common stock pursuant to the Lincoln Park Purchase Agreement have been registered pursuant to the Company’s effective shelf registration statement on Form S-3 (File No. 333-270606), and a related prospectus supplement that was filed with the SEC on May 3, 2023.

Under the Lincoln Park Purchase Agreement, the Company has the right, but not the obligation, on any business day selected by the Company (the "Purchase Date"), provided that on such day the closing sale price per share of the Company's common stock is above the Floor Price, as defined in the Lincoln Park Purchase Agreement, to require Lincoln Park to purchase up to 225,000 shares of the Company's common stock (the "Regular Purchase Amount") at the Purchase Price (as defined below) per purchase notice (each such purchase, a "Regular Purchase") provided, however, that (1) the limit on the Regular Purchase Amount will be increased to 250,000 shares, if the closing sale price of the Company's common stock on the applicable Purchase Date is not below $6.00 and to 275,000 shares, if the closing sale price of the Company's common stock on the applicable Purchase Date is not below $8.00. Lincoln Park's committed obligation under each Regular Purchase shall not exceed $2,500,000 or 2,000,000 Purchase Shares per each Regular Purchase. The purchase price for Regular Purchases (the "Purchase Price") shall be equal to the lesser of: (i) the lowest sale price of the Company's common stock during the Purchase Date, or (ii) the average of the three lowest closing sale prices of the Company's common stock on the 10 consecutive business days ending on the business day immediately preceding such Purchase Date. The Company shall have the right to submit a Regular Purchase notice to Lincoln Park as often as every business day. A Regular Purchase notice is delivered to Lincoln Park after the market has closed (i.e., after 4:00 P.M. Eastern Time) so that the Purchase Price is always fixed and known at the time the Company elects to sell shares to Lincoln Park.

In addition to Regular Purchases and provided that the Company has directed a Regular Purchase in full, the Company in its sole discretion may require Lincoln Park on each Purchase Date to purchase on the following business day ("Accelerated Purchase Date") up to the lesser of (i) three (3) times the number of shares purchased pursuant to such Regular Purchase or (ii) 30% of the trading volume on the Accelerated Purchase Date (the "Accelerated Purchase") at a purchase price equal to the lesser of 97% of (i) the closing sale price on the Accelerated Purchase Date, or (ii) the Accelerated Purchase Date's volume weighted average price (the "Accelerated Purchase Price"). The Company may also direct Lincoln Park, on any business day on which an Accelerated Purchase has been completed and all of the shares to be purchased thereunder have been properly delivered to Lincoln Park in accordance with the Lincoln Park Purchase Agreement, to make additional purchases upon the same terms as an Accelerated Purchase (an "Additional Accelerated Purchase").

The purchase price of Regular Purchases, Accelerated Purchases and Additional Accelerated Purchases and the minimum closing sale price for a Regular Purchase will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction occurring during the business days used to compute the purchase price. The aggregate number of shares that the Company can sell to Lincoln Park under the Lincoln Park Purchase Agreement may in no case exceed 17,678,502 shares (subject to adjustment as described above) of the Company's common stock (which is equal to approximately 19.99% of the shares of the Company's common stock outstanding immediately prior to the execution of the Lincoln Park Purchase Agreement) (the "Exchange Cap"), unless (i) shareholder approval is obtained to issue Purchase Shares above the Exchange Cap, in which case the Exchange Cap will no longer apply, or (ii) the average price of all applicable sales of the Company's common stock to Lincoln Park under the Lincoln Park Purchase Agreement equals or exceeds $1.26 per share (subject to adjustment as described above) (which represents the Minimum Price, as defined under Nasdaq Listing Rule 5635(d), on the Nasdaq Capital Market immediately preceding the signing of the Lincoln Park Purchase Agreement, such that the transactions contemplated by the Lincoln Park Purchase Agreement are exempt from the Exchange Cap limitation under applicable Nasdaq rules).

In consideration for entering into the Lincoln Park Purchase Agreement, concurrently with the execution of the Lincoln Park Purchase Agreement, the Company issued 800,000 shares of the Company's common stock to Lincoln Park. The shares of common stock issued as consideration were valued at $1.0 million, 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 $57,000, which total approximately $1.1 million, were recorded as deferred costs. We are obligated to issue $1.0 million of shares of the Company's common stock at the time Lincoln Park's purchases cumulatively reach an aggregate amount of $50.0 million of Purchase Shares.

During the year ended September 30, 2023, we sold 1,225,000 shares of common stock to Lincoln Park under the Lincoln Park Purchase Agreement resulting in proceeds to the Company of $1.4 million. As a result of these sales, we recorded approximately $30,000 of deferred costs to additional paid-in capital. The unamortized amount of deferred costs related to the Lincoln Park Purchase Agreement is $1.0 million at September 30, 2023 and is included in other assets on the accompanying consolidated balance sheet. Subsequent to September 30, 2023, we sold 1,800,000 shares of common stock to Lincoln Park under the Lincoln Park Purchase Agreement, resulting in proceeds to the Company of $1.7 million.

At-the-Market Sale Agreement

On May 12, 2023, the Company entered into an Open Market Sale Agreement℠ (the "Jefferies Sales Agreement") with Jefferies LLC ("Jefferies"), as sales agent, pursuant to which the Company may issue and sell, from time to time, through Jefferies, shares of the Company's common stock, with an aggregate value of up to $75 million (not to exceed the lesser of 39,609,072 shares of common stock or the number of authorized, unissued and available shares of common stock at any time). Shares of common stock offered and sold pursuant to the Jefferies Sale Agreement have been registered pursuant to the Company's effective shelf registration statement on Form S-3 (File No. 333-270606), and a related prospectus supplement that was filed with the SEC on May 12, 2023.

The Company is not obligated to sell any shares of common stock under the Jefferies Sales Agreement. Subject to the terms and conditions of the Jefferies Sales Agreement, Jefferies will use commercially reasonable efforts consistent with its normal trading and sales practices, to sell shares of common stock from time to time based upon the Company's instructions, including any price, time or size limits specified by the Company. Upon delivery of a placement notice, and subject to our instructions in that notice, and the terms and conditions of the Jefferies Sales Agreement generally, Jefferies may sell the Company's common stock by any method permitted by law deemed to be an "at the market offering" as defined by Rule 415(a)(4) promulgated under the Securities Act. Under the terms of the Sales Agreement, the Company cannot cause or request Jefferies to sell shares of common stock exceeding the number of shares of common stock authorized, unissued and available for issuance at any time. The Company will pay Jefferies a commission of 3% of the aggregate gross proceeds from each sale of common stock and has agreed to provide Jefferies with customary indemnification and contribution rights, including liabilities under the Securities Act and the Securities Exchange Act of 1934, as amended. The Company has also agreed to reimburse Jefferies for certain specified expenses. The Company incurred issuance costs of $207,000, which were recorded as deferred costs.

During the year ended September 30, 2023, we sold 1,277,259 shares of common stock under the Jefferies Sales Agreement resulting in net proceeds to the Company of $1.0 million. As a result of these sales, we recorded approximately $3,000 of deferred costs to additional paid-in capital. The unamortized amount of deferred costs related to the Jefferies Sales Agreement is $0.2 million at September 30, 2023 and is included in other assets on the accompanying consolidated balance sheet. Subsequent to September 30, 2023, we sold 90,156 shares of common stock under the Jefferies Sales Agreement, resulting in proceeds to the Company of $67,000.

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 $4.0 million and $2.5 million in fiscal 2023 and 2022, respectively. For fiscal 2023 and 2022, we recorded share-based compensation expenses as follows:

	2023	2022
Cost of sales	$ 361,843	$ 328,225
Selling, general and administrative	13,785,067	8,151,505
Research and development	3,771,693	2,762,693
	$ 17,918,603	$ 11,242,423

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 June 2022, the Company's board of directors adopted the Company's 2022 Employment Inducement Equity Incentive Plan (the "Inducement Plan"). The Inducement Plan is a non-shareholder approved stock plan adopted pursuant to the "inducement exception" provided under Nasdaq listing rules. The Inducement Plan is used exclusively for the issuance of equity awards to new hires who satisfy the requirements to be granted inducement grants under Nasdaq listing rules as an inducement material to the individual's entry into employment with the Company. The terms of the Inducement Plan are substantially similar to the terms of our 2018 Plan. The Company has reserved 4,000,000 shares of common stock under the Inducement Plan and as of September 30, 2023, 3,901,250 shares remain available for issuance.

In March 2018, the Company's stockholders approved the Company's 2018 Equity Incentive Plan (the "2018 Plan"). On March 29, 2022, the Company's stockholders approved an increase in the number of shares that may be issued under the 2018 Plan to 18.5 million. As of September 30, 2023, 2,593,491 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, 2023, 398,105 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 Company recognized a reduction in share-based compensation expense of $1.9 million during the year ended September 30, 2023. The reduction in share-based compensation expense during the year ended September 30, 2022 was immaterial.

The following table outlines the weighted average assumptions for options granted during fiscal 2023 and 2022:

	2023	2022
Weighted Average Assumptions:		
Expected Volatility	101.37%	84.53%
Expected Dividend Yield	0.00%	0.00%
Risk-free Interest Rate	3.92%	2.17%
Expected Term (in years)	6.0	6.0
Fair Value of Options Granted	$ 5.55	$ 7.10

During the years ended September 30, 2023 and 2022, 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, 2023:

		Weighted Average		
	Number of Shares	Exercise Price Per Share	Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2022	14,263,470	$ 5.00		
Granted	4,934,955	6.92		
Exercised	(191,832)	2.03		
Forfeited	(1,638,950)	8.19		
Outstanding at September 30, 2023	17,367,643	$ 5.28	7.10	$ —
Exercisable at September 30, 2023	9,759,441	$ 3.54	5.76	$ —

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, 2023 of $0.72, less the respective weighted average exercise price per share at period end.

The total intrinsic value of options exercised was approximately $0.5 million and $8.1 million during the years ended September 30, 2023 and 2022, respectively. Cash received from options exercised was $0.4 million and $1.1 million in the years ended September 30, 2023 and 2022, respectively.

As of September 30, 2023, the Company had unrecognized compensation expense of approximately $29.5 million related to unvested stock options. This expense is expected to be recognized over a weighted average period of 1.8 years.

During fiscal 2023 and 2022, the Company modified stock options held by certain optionees upon termination of their employment by the Company. As permitted under the 2018 Plan, 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 was approximately $25,000 and $1.0 million during the years ended September 30, 2023 and 2022, respectively.

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, 2023 and 2022, 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

In June 2021, the Company executed a lease for its new corporate headquarters in Miami, Florida. The Company is leasing approximately 12,000 square feet of office space for an eight year term, which commenced on March 1, 2022. The space replaced the Company's previous corporate headquarters in Miami, Florida when the lease terminated at the end of February 2022. Annual base rent payments are $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, 2023 and 2022.

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 ended August 2023. The monthly sublease payment was subject to annual increases in September of each year and increased to approximately $17,300 per month in the final year of the sublease. Sublease income was recognized as a reduction to operating lease costs as the sublease was 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 continued to be responsible for performance under the lease until it expired on October 31, 2023.

International Leases

The Company leases approximately 6,400 square feet of office space located in London, England. The lease was effective in August 2020 with a five year term and a tenant's option to cancel after three years with no penalty to the Company. At the time the lease was commenced, it was reasonably certain that the Company will exercise that option. The option to exercise required 6 months notice on February 28, 2023. At that time, the Company determined that it would not exercise the option to cancel and recorded an adjustment of $265,000 to its lease liabilities and right-of-use asset to reflect the additional lease term. The Company maintains a security deposit of approximately $58,000. The lease requires quarterly payments of approximately $41,100.

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 had an option to extend the term of the lease for a period of three years, which was executed so that the lease is effective through August 31, 2025. 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 years ended September 30, 2023 and 2022:

	2023	2022
Finance lease cost:		
Amortization of right-of-use assets	$ —	$ 3,631
Interest on lease liabilities	—	403
Operating lease cost	1,117,463	883,928
Short-term lease cost	42,809	46,117
Variable lease cost	186,904	211,840
Sublease income	(179,378)	(179,378)
Total lease cost	$ 1,167,798	$ 966,541

The Company paid cash of $860,000 and $680,000 for amounts included in the measurement of operating lease liabilities during the year ended September 30, 2023 and 2022, 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, 2023 and 2022.

Other information related to the Company's leases as of September 30, 2023 and 2022 was as follows:

	2023	2022
Operating Leases		
Weighted-average remaining lease term	6.1	6.8
Weighted-average discount rate	7.7%	7.6%

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, 2023, maturities of lease liabilities were as follows:

		Operating Leases
Fiscal year ended September 30,		
2024	$	1,085,368
2025		1,034,855
2026		800,693
2027		814,311
2028		832,997
Thereafter		1,217,797
Total lease payments		5,786,021
Less imputed interest		(1,115,317)
Total lease liabilities	$	4,670,704

The Company does not have any leases that have not yet commenced as of September 30, 2023.

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 $10.0 million.

Litigation

On December 5, 2022, a putative class action complaint was filed in federal district court for the Southern District of Florida (Ewing v. Veru Inc., et al., Case No. 1:22-cv-23960) against the Company and Mitchell Steiner, its Chairman, CEO and President, and Michele Greco, its CFO (the "Ewing Lawsuit"). The First Amended Class Action Complaint, filed on September 15, 2023 by purported stockholders Dr. Myo Thant and Karen Brounstein, alleges that certain public statements about sabizabulin as a treatment for COVID-19 between March 1, 2021 and March 2, 2023 violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, and seeks monetary damages. The Defendants intend to vigorously defend the lawsuit. There can be no assurance that the defense will be successful. At this time, the Company is unable to estimate potential losses, if any, related to the lawsuit.

On July 7, 2023, Anthony Maglia, a purported stockholder, filed a derivative action in the Circuit Court for the Eleventh Judicial Circuit, Miami-Dade County, Florida (Maglia v. Steiner et al., Case No. 2023-019406-CA-01), against the Company as a nominal defendant, and Company officers and directors Mitchell S. Steiner, Michele Greco, Harry Fisch, Mario Eisenberger, Grace S. Hyun, Lucy Lu and Michael L. Rankowitz (the "Maglia Lawsuit"). The Maglia lawsuit asserts claims for breach of fiduciary duty, waste of corporate assets, and unjust enrichment primarily in connection with the issues and claims asserted in the Ewing Lawsuit. The Maglia Lawsuit seeks to direct the Company to improve its corporate governance and internal procedures, and also seeks monetary damages, injunctive relief, restitution, and an award of reasonable fees and expenses. The Defendants intend to vigorously defend the lawsuit. There can be no assurance that the defense will be successful. At this time, the Company is unable to estimate potential losses, if any, related to the Maglia Lawsuit.

On September 1, 2023, Anthony Franchi, a purported stockholder, filed a derivative action in the United States District Court for the Eastern District of Wisconsin (Franchi v. Steiner et al., Case No. 2:23-CV-01164), against the Company as a nominal defendant, and Company officers and directors Mitchell S. Steiner, Mario Eisenberger, Harry Fisch, Michael L. Rankowitz, Grace Hyun, Lucy Lu, and Michele Greco (the "Franchi Lawsuit"). The Franchi lawsuit asserts claims for breach of fiduciary duty and unjust enrichment primarily in connection with the issues and claims asserted in the Ewing Lawsuit. The Franchi Lawsuit seeks to direct the Company to improve its corporate governance and internal procedures, and also seeks monetary damages, restitution, and an award of reasonable fees and expenses. On November 8, 2023, this action was consolidated with the Renbarger action, discussed below. The Defendants intend to vigorously defend the lawsuit. There can be no assurance that the defense will be successful. At this time, the Company is unable to estimate potential losses, if any, related to the Franchi Lawsuit.

On September 28, 2023, Philip Renbarger, a purported stockholder, filed a derivative action in the United States District Court for the Eastern District of Wisconsin (Renbarger v. Steiner et al., Case No. 2:23-CV-01291), against the Company as a nominal defendant, and Company officers and directors Mitchell Steiner, Mario Eisenberger, Harry Fisch, Michael L. Rankowitz, Grace S. Hyun, Lucy Lu, and Michele Greco (the "Renbarger Lawsuit"). The Renbarger lawsuit asserts claims for breach of fiduciary duty, aiding and abetting, gross mismanagement, waste of corporate assets, and unjust enrichment primarily in connection with the issues and claims asserted in the Ewing Lawsuit. The Renbarger Lawsuit seeks to direct the Company to improve its corporate governance and internal procedures, and also seeks monetary damages and an award of reasonable fees and expenses. On November 8, 2023, the Renbarger Lawsuit was consolidated with the Franchi Lawsuit, discussed above. The Defendants intend to vigorously defend the lawsuit. There can be no assurance that the defense will be successful. At this time, the Company is unable to estimate potential losses, if any, related to the Renbarger Lawsuit.

On October 9, 2023, Mohamed Alshourbagy, a purported stockholder, filed a derivative action in the United States District Court for the Southern District of Florida (Alshourbagy v. Steiner et al., Case No. 1:23-cv-23846), against the Company as a nominal defendant, and Company officers and directors Mitchell S. Steiner, Mario A. Eisenberger, Harry D. Fisch, Michael L. Rankowitz, Grace S. Hyun, Lucy Lu, and Michele J. Greco (the "Alshourbagy Lawsuit"). The Alshourbagy lawsuit asserts claims for breach of fiduciary duty and contribution primarily in connection with the issues and claims asserted in the Ewing Lawsuit. The Alshourbagy Lawsuit seeks to direct the Company to improve its corporate governance and internal procedures, and also seeks monetary damages, injunctive relief, restitution, and an award of reasonable fees and expenses. The Defendants intend to vigorously defend the lawsuit. There can be no assurance that the defense will be successful. At this time, the Company is unable to estimate potential losses, if any, related to the Alshourbagy Lawsuit.

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.

Collaborative Arrangements

On January 31, 2022, the Company entered into a Clinical Trial Collaboration and Supply Agreement (the "Lilly Agreement") with Eli Lilly and Company ("Lilly"). Under the Lilly Agreement, the Company is sponsoring a clinical trial in which both the Company's enobosarm compound and Lilly's compound are being dosed in combination. The ENABLAR-2 clinical trial is active but not currently recruiting. The Company is conducting the research at its own cost and Lilly is contributing its compound towards the study at no cost to the Company. The parties will continue to hold exclusive rights to all intellectual property relating solely to their own respective compounds. The Company will provide to Lilly copies of clinical data relating to the clinical trial and certain rights to use the clinical data. Veru maintains full exclusive, global commercialization rights to the enobosarm compound.

The terms of the Lilly Agreement meet the criteria under ASC Topic 808, Collaborative Arrangements ("ASC 808"), as both parties are active participants in the activity and are exposed to the risks and rewards dependent on the commercial success of the activity. ASC 808 does not provide guidance on how to account for the activities under the collaboration, and the Company determined that Lilly did not meet the definition of a customer under ASC 606, Revenue from Contracts with Customers. The Company has concluded that ASC 730, Research and Development, should be applied by analogy. There is no financial statement impact for the Lilly Agreement as the value of the drug supply received from Lilly is offset against the drug supply cost within research and development expense.

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. The Company had a cumulative pretax loss in the U.S. for fiscal 2023 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, 2023. The valuation allowance against U.S. deferred tax assets was increased by $19.9 million during the year ended September 30, 2023. As of September 30, 2023 and 2022 respectively, the Company has recorded a valuation allowance of $62.1 million and $42.2 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 as of September 30, 2023 and 2022. The operating U.K. subsidiary, The Female Health Company (UK) plc does not have a valuation allowance due to projections of future taxable income. The Company projects that the deferred tax assets of The Female Health Company (UK) plc will be realized over a significant period of time, which may exceed 20 years. Veru Biopharma UK Limited has a full valuation allowance of $0.3 million.

As of September 30, 2023, the Company had U.S. federal and state NOL carryforwards of approximately $140.5 million and $62.4 million, respectively, for income tax purposes with $29.7 million and $35.2 million, respectively, expiring in fiscal years 2024 to 2043 and $110.8 million and $27.2 million, respectively, which can be carried forward indefinitely. The Company also has U.S. federal research and development tax credit carryforwards of $8.3 million, expiring in fiscal years 2038 to 2043. The Company's U.K. subsidiary and Veru Biopharma UK Limited have U.K. NOL carryforwards of approximately $63.0 million as of September 30, 2023, which can be carried forward indefinitely to be used to offset future U.K. taxable income.

The Tax Cuts and Jobs Act of 2017, which was signed into U.S. law in December 2017, eliminated the option to immediately deduct research and development expenditures in the year incurred under Section 174 of the Internal Revenue Code ("Section 174") effective for the Company October 1, 2022. The amended provision under Section 174 requires us to capitalize and amortize these expenditures over five years, for U.S.-based research, and over 15 years, for foreign-based research. As of September 30, 2023, we recorded a decrease to income tax benefit and an increase to deferred tax assets, before applying a valuation allowance, of approximately $9.8 million as a result of the amended provision under Section 174. Because the Company has a full valuation allowance recorded against U.S. deferred tax assets, the net impact to income tax benefit and deferred tax assets from the amended provision under Section 174 is zero.

Loss before income taxes was taxed by the following jurisdictions for the years ended September 30, 2023 and 2022:

	2023	2022
Domestic	$ (90,458,648)	$ (82,186,464)
Foreign	(2,150,099)	(1,353,159)
Total	$ (92,608,747)	$ (83,539,623)

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

	2023		2022	
	Amount	Tax Rate	Amount	Tax Rate
Income tax benefit at U.S. federal statutory rates	$ (19,447,837)	21.0%	$ (17,543,321)	21.0 %
State income tax benefit, net of federal benefits	(1,505,818)	1.6	(1,358,354)	1.6
Non-deductible expenses	330,281	(0.3)	76,913	(0.1)
U.S. research and development tax credit	178,378	(0.2)	(5,720,374)	6.9
Effect of foreign income tax rates	454,808	(0.5)	409,048	(0.5)
Effect of common stock options exercised	180,847	(0.2)	(1,580,756)	1.9
Effect of global intangible low-taxed income	(24,691)	(0.0)	24,691	(0.0)
Change in valuation allowance	20,191,386	(21.8)	25,792,441	(30.9)
Other, net	122,852	(0.1)	136,109	(0.2)
Income tax expense	$ 480,206	(0.5) %	$ 236,397	(0.3)%

The federal and state income tax expense (benefit) for the years ended September 30, 2023 and 2022 is summarized below:

	2023	2022
Deferred – U.S.	$ (63,426)	$ —
Deferred – U.K.	262,612	(42,089)
Deferred – Malaysia	(21,687)	118,295
Subtotal	177,499	76,206
Current – U.S.	(8,624)	126,079
Current – Malaysia	311,331	34,112
Subtotal	302,707	160,191
Income tax expense	$ 480,206	$ 236,397

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

	2023	2022
Deferred tax assets:		
Federal net operating loss carryforwards	$ 29,510,855	$ 23,627,461
State net operating loss carryforwards	3,354,274	2,850,956
Foreign net operating loss carryforwards – U.K.	15,749,809	15,773,497
Foreign capital allowance – U.K.	174,748	128,490
Share-based compensation – U.K.	217,821	265,631
U.S. research and development tax credit carryforward	8,303,411	8,481,789
U.S. research and development expense	9,758,373	—
Accrued compensation	190,397	1,227,290
Share-based compensation	7,896,221	4,325,354
Interest expense	2,602,890	2,206,484
U.S. credit loss provision	885,562	—
Change in fair value of derivative liability	—	220,607
Other, net – Malaysia	4,046	—
Other, net – U.K.	2,500	—
Other, net – U.S.	71,509	81,507
Gross deferred tax assets	78,722,416	59,189,066
Valuation allowance for deferred tax assets	(65,563,838)	(45,372,452)
Net deferred tax assets	13,158,578	13,816,614
Deferred tax liabilities:		
Change in fair value of derivative liability	(449,812)	—
In process research and development	—	(882,427)
Covenant not-to-compete	(1,347)	(17,508)
Other, net – Malaysia	—	(17,641)
Other	—	(14,120)
Net deferred tax liabilities	(451,159)	(931,696)
Net deferred tax asset	$ 12,707,419	$ 12,884,918

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

	2023	2022
Long-term deferred tax asset – U.K.	$ 12,703,373	$ 12,965,985
Long-term deferred tax asset – Malaysia	4,046	—
Total long-term deferred tax asset	$ 12,707,419	$ 12,965,985
Long-term deferred tax liability – U.S.	$ —	$ (63,426)
Long-term deferred tax liability – Malaysia	—	(17,641)
Total long-term deferred tax liability	$ —	$ (81,067)

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 or 3 years after an NOL is utilized. The U.S. open tax years are for fiscal 2004 through 2007, fiscal 2015 through fiscal 2019, and fiscal 2022, for which the Company is carrying forward NOLs, which expire in years 2024 through 2038 or are being carried forward indefinitely with no expiration.

- 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 2018 through 2022, which expire on December 31, 2023 through 2027.
- 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 2022, which expires in 2024.

The fiscal 2023 tax returns for all jurisdictions have not been filed as of the date of this filing. As of September 30, 2023 and 2022, 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 material expense for interest and penalties was recognized for the years ended September 30, 2023 and 2022.

Note 15 – Sale of ENTADFI

On April 19, 2023, the Company entered into an asset purchase agreement (the “BWV Asset Purchase Agreement”) to sell substantially all of the assets related to ENTADFI® (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia that was approved by the FDA in December 2021, with Blue Water Biotech Inc. formerly known as Blue Water Vaccines Inc. (“BWV”). The transaction closed on April 19, 2023. The purchase price for the transaction was $20.0 million, consisting of $6.0 million paid at closing, $4.0 million payable by September 30, 2023, $5.0 million payable 12 months after closing, and $5.0 million payable by September 30, 2024, plus up to $80.0 million based on BWV’s net revenues from ENTADFI after closing (the “Milestone Payments”). The Company cannot determine the likelihood of receiving any Milestone Payments at this time.

On September 29, 2023, the Company entered into an Amendment to the BWV Asset Purchase Agreement providing that the promissory note for the $4.0 million installment of the purchase price due September 30, 2023 would be deemed paid and fully satisfied upon (1) the payment to the Company of the sum of $1.0 million in immediately available funds on September 29, 2023 and (2) the issuance to the Company by October 3, 2023 of 3,000 shares of Series A Convertible Preferred Stock of BWV. The Company received payment of $1.0 million on September 29, 2023 and the 3,000 Series A Convertible Preferred Stock on October 3, 2023. There is no market for the Series A Convertible Preferred Stock and therefore, little likelihood of any liquidity in the Series A Preferred Stock.

The Company determined that it was not probable, at the time of the transaction and at September 30, 2023, that substantially all of the consideration promised under the BWV Asset Purchase Agreement would be collected. Therefore, the Company recognizes the difference between the nonrefundable consideration received and the carrying amount of the assets as a gain. The gain is recorded considering only the nonrefundable consideration of $7.0 million received by the Company as of September 30, 2023. Total assets sold, consisting primarily of inventory, had a net book value of approximately $1.3 million. The Company recorded a gain of approximately $5.7 million on the transaction during fiscal 2023. The gain calculation will be updated if additional consideration is received in future periods or when it is deemed probable that substantially all of the consideration promised will be collected. The Company will continue to evaluate the collectability of the notes receivable.

Note 16 – Loss per Share

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing net income by the weighted average number of common shares outstanding during the period after giving effect to all dilutive potential common shares that were outstanding during the period. Dilutive potential common shares consist of the incremental common shares issuable upon the exercise of stock options and stock appreciation rights as determined under the treasury stock method. Due to our net loss for the periods presented, all potentially dilutive instruments were excluded because their inclusion would have been anti-dilutive. See Note 11 for a discussion of our potentially dilutive common shares.

Note 17 – 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 6% of included compensation. Company contributions to the 401(k) plan were approximately $616,000 and $461,000 for the years ended September 30, 2023 and 2022, 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 $29,000 and $41,000 for the years ended September 30, 2023 and 2022, respectively.

Exhibit 4.3

DESCRIPTION OF CAPITAL STOCK

The following is a summary description of the material terms of the common stock and preferred stock of Veru Inc. (the "Company," "we," "us" or "our"). It may not contain all the information that is important to you. For additional information, you should look at our amended and restated articles of incorporation, as amended, and our amended and restated by-laws, copies of which are on file with the SEC as exhibits to our periodic reports and are incorporated by reference.

Our common stock is the only class of securities of the Company registered under Section 12 of the Securities Exchange Act of 1934.

Common Stock

We are authorized to issue up to 308,000,000 shares of common stock, $0.01 par value per share.

Dividend Rights.

Subject to limitations under Wisconsin law and the rights of any outstanding shares of preferred stock, holders of our common stock are entitled to ratably receive dividends or other distributions when and if declared by our board of directors out of funds legally available for that purpose.

Voting Rights.

Each outstanding share of our common stock is entitled to one vote per share held of record on all matters to be voted upon by shareholders, including the election of our directors and other corporate matters. At a meeting of shareholders at which a quorum is present, for all matters other than the election of directors, a matter is approved if the votes cast favoring the matter exceed the votes cast opposing the matter unless the matter is one upon which a different vote is required by our amended and restated articles of incorporation, as amended, our amended and restated by-laws or the Wisconsin Business Corporation Law. Directors are elected by a plurality of the votes cast by the shares entitled to vote in the election at a meeting at which a quorum is present. There is no cumulative voting with respect to the election of directors or any other matter. Under the Wisconsin Business Corporation Law, the affirmative vote of shareholders holding at least two-thirds of the shares entitled to vote is generally required to approve (i) a merger to which we are a party, (ii) the sale, lease, exchange or other disposition of all or substantially all of our assets, (iii) an amendment to our amended and restated articles of amendment, as amended, which requires a shareholder vote, and (iv) our dissolution.

Liquidation, Dissolution or Winding Up.

If we liquidate, dissolve or wind up, subject to the rights of any outstanding shares of preferred stock, the holders of our common stock are entitled to share ratably in all assets legally available for distribution to our shareholders after the payment of all of our debts and other liabilities.

Rights and Preferences.

Holders of our common stock have no preemptive, conversion or subscription rights. There are no redemption or sinking fund provisions applicable to shares of our common stock.

Miscellaneous.

All outstanding shares of our common stock are fully paid and not liable to further calls or assessments by us.

Transfer Agent and Registrar.

Computershare serves as the registrar and transfer agent for our common stock.

Stock Exchange Listing.

Our common stock is listed on the NASDAQ Capital Market under the trading symbol "VERU".

Preferred Stock

The Company is authorized to issue 5,000,000 shares of Class A preferred stock with a par value of $0.01 per share.

Our board of directors has the authority, without further action by our shareholders, to issue Class A preferred stock in one or more series and to fix from time to time the number of shares to be included in each such series and the designation of such series, and to fix the relative rights and preferences of the shares of any such series, but only with respect to:

- the rate of dividend;
- the price at and the terms and conditions on which shares may be redeemed;
- the amount payable upon shares in the event of voluntary or involuntary liquidation;
- sinking fund provisions for the redemption or purchase of shares; and
- the terms and conditions on which shares may be converted into shares of any other class or series.

Except as to the matters expressly set forth in the bullet points above, all series of Class A preferred stock, whenever designated and issued, must have the same preferences, limitations and relative rights and will rank equally, share ratably and be identical in all respects as to all matters.

Unless otherwise provided by Wisconsin law, each holder of Class A preferred stock will have one vote per share and will vote with the holders of common stock together as a single class.

Our board of directors may authorize the issuance of Class A preferred stock with rights that could adversely affect the rights of the holders of our common stock. The purpose of authorizing our board of directors to issue Class A preferred stock and determine its rights and preferences is to eliminate delays associated with a shareholder vote on specific issuances. The issuance of Class A preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of the Company and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. It is not possible to state the actual effect of the issuance of any shares of Class A preferred stock on the rights of holders of our common stock until our board of directors determines the specific rights attached to that Class A preferred stock.

Wisconsin Anti-Takeover Provisions

Under Section 180.1150 of the Wisconsin Business Corporation Law, unless the board of directors otherwise specifies, the voting power of shares of a "resident domestic corporation," such as us, which are held by any person holding in excess of 20% of the voting power of our stock will be limited to 10% of the full voting power of the shares. This statutory voting restriction does not apply to shares acquired directly from us, acquired in a transaction incident to which our shareholders vote to restore the full voting power of the shares and under other circumstances more fully described in Section 180.1150.

Sections 180.1141 through 180.1144 of the Wisconsin Business Corporation Law provide that a "resident domestic corporation," such as us, may not engage in a "business combination" with a person beneficially owning 10% or more of the voting power of our outstanding stock (an "interested stockholder") for three years after the date the interested shareholder acquired his 10% or greater interest, unless the business combination or the acquisition of the 10% or greater interest was approved before the stock acquisition date by our Board of Directors. After the three-year period, a business combination that was not so approved can be completed only if it is approved by a majority of the outstanding voting shares not held by the interested shareholder or is made at a specified price intended to provide a fair price for the shares held by noninterested shareholders.

Sections 180.1130 through 180.1132 of the Wisconsin Business Corporation Law provide that a "resident domestic corporation," such as us, may not engage in a "business combination" with a person beneficially owning 10% or more of the voting power of our outstanding stock (a "significant stockholder") unless the business combination either satisfies certain fair price criteria or the business combination is approved by at least 80% of the voting power of our stock and at least two-thirds of the voting power of our stock not beneficially owned by the significant stockholder.

Requirements for Advance Notification of Shareholder Nominations and Proposals

Our amended and restated by-laws establish advance notice procedures with respect to shareholder proposals to be brought before a shareholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Exhibit 21

Subsidiaries of Veru Inc. (1)

The subsidiaries of Veru Inc. are as follows:

Name	**Jurisdiction of Organization**
Aspen Park Pharmaceuticals, Inc.	Delaware
Badger Acquisition Sub, Inc.	Delaware
The Female Health Company Limited	United Kingdom
The Female Health Company (UK) Plc.	United Kingdom
The Female Health Company (M) SDN.BHD	Malaysia
Veru International Holdco Inc.	Delaware
Veru Biopharma UK Limited	United Kingdom
Veru Biopharma Europe Limited	Ireland
Veru Biopharma Netherlands B.V.	Netherlands

(1) All subsidiaries are wholly owned, directly or indirectly, by Veru Inc.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (No.333-154252) on Form S-8, the Registration Statement (No. 333-222513) on Form S-8, the Registration Statement (No. 333-228789) on Form S-8, the Registration Statement (No. 333-231489) on Form S-8, the Registration Statement (No. 333-238218) on Form S-8, the Registration Statement (No. 333-264877) on Form S-8, the Registration Statement (No. 333-266791) on Form S-8, the Registration Statement (No. 333-271891) on Form S-3, and the Registration Statement (No. 333-270606) on Form S-3 of Veru Inc. of our report dated December 8, 2023, relating to the consolidated financial statements of Veru Inc., appearing in this Annual Report on Form 10-K of Veru Inc. for the year ended September 30, 2023.

/s/ RSM US LLP

Chicago, Illinois
December 8, 2023

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mitchell S. Steiner, certify that:

1. I have reviewed this annual report on Form 10-K of Veru Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 8, 2023

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

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michele Greco, certify that:

1. I have reviewed this annual report on Form 10-K of Veru Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 8, 2023

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

Exhibit 32.1

Certification of Periodic Financial Report
Pursuant to 18 U.S.C. Section 1350

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned officers of Veru Inc. (the "Company") certifies that the Annual Report on Form 10-K of the Company for the year ended September 30, 2023 fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934 and information contained in that Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: December 8, 2023	/s/Mitchell S. Steiner Mitchell S. Steiner Chairman, President and Chief Executive Officer
Date: December 8, 2023	/s/Michele Greco Michele Greco Chief Financial Officer and Chief Administrative Officer

This certification is made solely for purpose of 18 U.S.C. Section 1350, subject to the knowledge standard contained therein, and not for any other purpose.

Exhibit 97.1

VERU INC.
CLAWBACK POLICY
(adopted as of November 30, 2023)

Introduction

The Board of Directors (the “Board”) of Veru Inc. (the “Company”) believes that it is in the best interests of the Company and its shareholders to create and maintain a culture that emphasizes integrity and accountability and that reinforces the Company's pay-for-performance compensation philosophy. The Board has therefore adopted this policy (this “Policy”) which provides for the recoupment of certain executive compensation in the event of an accounting restatement resulting from material noncompliance with financial reporting requirements under securities laws. This Policy is designed to comply with Section 10D of the Securities Exchange Act of 1934 and any applicable rules or standards adopted by the Securities and Exchange Commission (the “SEC”) or any national securities exchange on which the Company's securities are listed (collectively, the “Applicable Rules”).

Administration

This Policy shall be administered by the Board or, if so designated by the Board, the Compensation Committee, in which case references herein to the Board shall be deemed references to the Compensation Committee. Any determinations made by the Board shall be final and binding on all affected individuals.

Covered Executives

This Policy applies to the Company's current and former executive officers, as determined by the Board in accordance with the Applicable Rules (the “Covered Executives”). This Policy applies to any Covered Executive who receives Incentive Compensation after such Covered Executive began service as an executive officer and who served as an executive officer at any time during the performance period for the Incentive Compensation.

Recoupment; Accounting Restatement

In the event the Company is required to prepare an accounting restatement of its financial statements due to the Company's material noncompliance with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period, the Board will require reimbursement or forfeiture of any excess Incentive Compensation received by any Covered Executive during the three completed fiscal years immediately preceding the date on which the Company is required to prepare an accounting restatement. Such recoupment shall be made reasonably promptly after the Company is required to prepare such an accounting restatement.

For these purposes, the date the Company is required to prepare an accounting restatement will be the earlier of:

- the date the Company's board of directors, a committee of the board of directors, or the officer or officers of the Company authorized to take such action if board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an accounting restatement; or

- the date a court, regulator, or other legally authorized body directs the Company to prepare an accounting restatement.

Incentive Compensation

For purposes of this Policy, Incentive Compensation means any compensation that is granted, earned or vested based wholly or in part on the attainment of a Financial Reporting Measure, and may include the following:

- Annual bonuses and other short- and long-term cash incentives.

- Stock options.

- Stock appreciation rights.

- Restricted stock.

- Restricted stock units.

- Performance shares.

- Performance units.

Financial Reporting Measures are measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures. A financial reporting measure need not be presented within the financial statements or included in a filing with the SEC. Examples of Financial Reporting Measures include:

- Company stock price.

- Total shareholder return.

- Revenues.

- Net income.

- Earnings before interest, taxes, depreciation, and amortization (EBITDA).

- Funds from operations.
- Liquidity measures such as working capital or operating cash flow.
- Return measures such as return on invested capital or return on assets.
- Earnings measures such as earnings per share.

Excess Incentive Compensation: Amount Subject to Recovery

The amount to be recovered will be the excess of the Incentive Compensation paid to the Covered Executive based on the erroneous data over the Incentive Compensation that would have been paid to the Covered Executive had it been based on the restated results, computed without regard to any taxes paid , as determined by the Board.

If the Board cannot determine the amount of excess Incentive Compensation received by the Covered Executive directly from the information in the accounting restatement, then it will make its determination based on a reasonable estimate of the effect of the accounting restatement.

The Company will maintain documentation of the determination of the amount to be recovered.

Method of Recoupment

The Board will determine, in its sole discretion, the method for recouping Incentive Compensation hereunder which may include, without limitation:

- requiring reimbursement of cash Incentive Compensation previously paid;
- seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards;
- offsetting the recouped amount from any compensation otherwise owed by the Company to the Covered Executive;
- cancelling outstanding vested or unvested equity awards; and/or
- taking any other remedial and recovery action permitted by law, as determined by the Board.

No Indemnification

The Company shall not indemnify any Covered Executives against the loss of any incorrectly awarded Incentive Compensation.

Interpretation

The Board is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy. It is intended that this Policy be interpreted in a manner that is consistent with the requirements of the Applicable Rules.

Effective Date

This Policy shall be effective as of October 2, 2023 (the "Effective Date") and shall apply to Incentive Compensation that is approved, awarded or granted to Covered Executives on or after that date.

Amendment; Termination

The Board may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary to reflect any changes in the Applicable Rules. The Board may terminate this Policy at any time.

Other Recoupment Rights

The Board intends that this Policy will be applied to the fullest extent of the law. The Board may require that any employment agreement, equity award agreement, or similar agreement entered into on or after the Effective Date shall, as a condition to the grant of any benefit thereunder, require a Covered Executive to agree to abide by the terms of this Policy. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any similar policy in any employment agreement, equity award agreement, or similar agreement and any other legal remedies available to the Company.

Impracticability

The Board shall recover any excess Incentive Compensation in accordance with this Policy unless such recovery would be impracticable, as determined by the Board in accordance with the Applicable Rules.

Successors

This Policy shall be binding and enforceable against all Covered Executives and their beneficiaries, heirs, executors, administrators or other legal representatives.