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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended March 31, 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.

(Exact Name of Registrant as Specified in its Charter)

Wisconsin	**39-1144397**
(State of Incorporation)	(I.R.S. Employer Identification No.)
2916 N. Miami Avenue, Suite 1000, Miami, FL	**33127**
(Address of Principal Executive Offices)	(Zip Code)

305-509-6897
(Registrant's Telephone Number, Including Area Code)

N/A
(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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 per share	VERU	Nasdaq Capital Market

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 (§232.405 of this chapter) 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 ☐
Non-accelerated filer ☒

Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as determined by Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of May 9, 2023, the registrant had 89,236,732 shares of $0.01 par value common stock outstanding.

VERU INC.
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FORWARD LOOKING STATEMENTS

Certain statements included in this quarterly report on Form 10-Q 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 sabizabulin for certain COVID-19 patients and other acute respiratory distress syndrome (ARDS) indications and of enobosarm for certain breast cancer patients, future financial and operating results, plans, objectives, expectations and intentions, costs and expenses, royalty payments, outcome of contingencies, financial condition, results of operations, liquidity, cost savings, 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. Forward-looking statements can be identified by the use of forward-looking words or phrases such as "anticipate," "believe," "could," "expect," "intend," "may," "opportunity," "plan," "predict," "potential," "estimate," "should," "will," "would" or the negative of these terms or other words of similar meaning. These statements are based upon the Company's current plans and strategies and reflect the Company's current assessment of the risks and uncertainties related to its business and are made as of the date of this report. These statements are inherently subject to known and unknown risks and uncertainties. You should read these statements carefully because they discuss our future expectations or state other "forward-looking" information. There may be events in the future that we are not able to accurately predict or control and our actual results may differ materially from the expectations we describe in our forward-looking statements. Factors that could cause actual results to differ materially from those currently anticipated include the following:

- potential delays in the timing of and results from clinical trials and studies, including potential delays in the recruitment of patients and their ability to effectively participate in such trials and studies, and the risk that such results will not support marketing approval, emergency use authorization, 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 or approval of any emergency use authorization applications the Company may submit for sabizabulin for certain COVID-19 patients, 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 sabizabulin for the treatment of certain COVID-19 patients, 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, including our ability to secure timely grant or other funding to develop, manufacture or distribute sabizabulin as a potential COVID-19 treatment;
- risks related to the development of our product portfolio, including clinical trials, regulatory approvals and time and cost to bring any of our product candidates to market, and risks related to efforts of our collaborators such as in the development of a companion diagnostic for enobosarm;
- our pursuit of a COVID-19 treatment candidate is still in development and we may be unable to develop a drug that successfully treats the virus in a timely manner, if at all;
- risks related to our commitment of financial resources and personnel to the development of a COVID-19 treatment which may cause delays in or otherwise negatively impact our other development programs or our working capital, despite uncertainties about the longevity and extent of COVID-19 as a global health concern and the possibility that as vaccines and other treatments become widely distributed the need for new COVID-19 treatment candidates may be reduced or eliminated;
- risks related to our ability to scale up and manufacture sabizabulin in sufficient quantities as a COVID-19 treatment if we receive an emergency use authorization in the U.S. or elsewhere;

- government entities may take actions that directly or indirectly have the effect of limiting opportunities for sabizabulin as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments;
- government entities in the U.S. or elsewhere have and may continue to declare the COVID-19 pandemic emergency over and, if sabizabulin is authorized in the U.S. or elsewhere for the treatment of certain COVID-19 patients under an Emergency Use Authorization or similar regime outside the U.S., such termination of the pandemic emergency may affect our ability to continue to market sabizabulin;
- 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, for our approved or authorized products, including, if authorized, sabizabulin for the treatment of certain COVID-19 patients, and similar risks relating to market or political acceptance of any potential or actual pricing for any such products;
- some of our products are in development and we may fail to successfully commercialize such products;
- risks related to any potential new telehealth platform developed or used by us in commercializing our current product or potential future products, including potential regulatory uncertainty around such platforms;
- risks related to intellectual property, including the uncertainty of obtaining intellectual property protections and in enforcing them, the possibility of infringing a third party's intellectual property, and licensing risks;
- competition from existing and new competitors including the potential for reduced sales, pressure on pricing and increased spending on marketing;
- risks related to compliance and regulatory matters, including costs and delays resulting from extensive government regulation and reimbursement and coverage under healthcare insurance and regulation as well as potential healthcare reform measures;
- the risk that we will be affected by regulatory and legal developments, including a reclassification of products or repeal or modification of part or all of the Patient Protection and Affordable Care Act;
- 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;
- the costs and other effects of litigation, governmental investigations, legal and administrative cases and proceedings, settlements and investigations;
- government contracting risks, including the appropriations process and funding priorities, potential bureaucratic delays in awarding contracts, process errors, politics or other pressures, and the risk that government tenders and contracts may be subject to cancellation, delay, restructuring or substantial delayed payments;
- a governmental tender award indicates acceptance of the bidder's price rather than an order or guarantee of the purchase of any minimum number of units, and as a result government ministries or other public health sector customers may order and purchase fewer units than the full maximum tender amount;
- our ability to identify, successfully negotiate and complete suitable acquisitions, out-licensing transactions, in-licensing transactions or other strategic initiatives and to realize any potential benefits of such transactions or initiatives;
- our ability to successfully integrate acquired businesses, technologies or products; and
- our ability to achieve the necessary shareholder vote to increase the number of authorized shares of our common stock.

All forward-looking statements in this report should be considered in the context of the risks and other factors described above, in Part II, Item 1A, “Risk Factors” below in this report, and in Part I, Item 1A, “Risk Factors,” in the Company’s Annual Report on Form 10-K for the fiscal year ended September 30, 2022. The Company undertakes no obligation to make any revisions to the forward-looking statements contained in this report or to update them to reflect events or circumstances occurring after the date of this report except as required by applicable law.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2023	September 30, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 23,498,371	$ 80,190,675
Accounts receivable, net	4,205,967	3,550,895
Inventories, net	7,665,194	8,618,944
Prepaid research and development costs	5,787,224	10,444,587
Prepaid expenses and other current assets	2,131,521	1,964,373
Total current assets	43,288,277	104,769,474
Plant and equipment, net	1,519,789	1,185,766
Operating lease right-of-use assets	4,675,739	4,786,915
Deferred income taxes	13,070,469	12,965,985
Intangible assets, net	41,667	3,977,381
Goodwill	6,878,932	6,878,932
Other assets	778,697	1,561,564
Total assets	$ 70,253,570	$ 136,126,017
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 17,237,474	$ 22,003,394
Accrued research and development costs	13,786,241	9,071,503
Accrued compensation	2,986,624	5,986,557
Accrued expenses and other current liabilities	2,811,453	2,249,995
Residual royalty agreement liability, short-term portion	1,354,823	1,169,095
Operating lease liability, short-term portion	1,083,183	957,085
Total current liabilities	39,259,798	41,437,629
Residual royalty agreement liability, long-term portion	10,257,325	9,656,441
Operating lease liability, long-term portion	3,987,612	4,093,667
Deferred income taxes	—	81,067
Other liabilities	32,933	18,577
Total liabilities	53,537,668	55,287,381
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock; no shares issued and outstanding at March 31, 2023 and September 30, 2022	—	—
Common stock, par value $0.01 per share; 154,000,000 shares authorized, 84,760,736 and 82,692,598 shares issued and 82,577,032 and 80,508,894 shares outstanding at March 31, 2023 and September 30, 2022, respectively	847,607	826,926
Additional paid-in-capital	265,465,702	253,974,032
Accumulated other comprehensive loss	(581,519)	(581,519)
Accumulated deficit	(241,209,283)	(165,574,198)
Treasury stock, 2,183,704 shares, at cost	(7,806,605)	(7,806,605)
Total stockholders' equity	16,715,902	80,838,636
Total liabilities and stockholders' equity	$ 70,253,570	$ 136,126,017

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended March 31,		Six Months Ended March 31,	
	2023	2022	2023	2022
Net revenues	$ 6,585,967	$ 13,028,394	$ 9,093,761	$ 27,163,526
Cost of sales	2,493,892	1,853,116	4,299,631	4,146,166
Gross profit	4,092,075	11,175,278	4,794,130	23,017,360
Operating expenses:				
Research and development	22,864,633	15,541,104	41,608,982	25,622,265
Selling, general and administrative	12,834,494	7,401,138	30,380,359	14,126,344
Provision for (recovery of) credit losses	3,911,714	(2,000)	3,911,714	(4,000)
Impairment of intangible assets	3,900,000	—	3,900,000	—
Total operating expenses	43,510,841	22,940,242	79,801,055	39,744,609
Operating loss	(39,418,766)	(11,764,964)	(75,006,925)	(16,727,249)
Non-operating income (expenses):				
Interest expense	(697,693)	(1,212,702)	(1,570,923)	(2,371,384)
Change in fair value of derivative liabilities	1,200,000	(1,229,000)	530,000	(1,438,000)
Other income, net	56,994	1,386	277,926	66,002
Total non-operating income (expenses)	559,301	(2,440,316)	(762,997)	(3,743,382)
Loss before income taxes	(38,859,465)	(14,205,280)	(75,769,922)	(20,470,631)
Income tax (benefit) expense	(66,559)	(27,450)	(134,837)	87,205
Net loss	$ (38,792,906)	$ (14,177,830)	$ (75,635,085)	$ (20,557,836)
Net loss per basic and diluted common shares outstanding	$ (0.48)	$ (0.18)	$ (0.94)	$ (0.26)
Basic and diluted weighted average common shares outstanding	80,834,453	80,052,504	80,695,046	80,037,675

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Treasury Stock, at Cost	Total
	Shares	Amount					
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	—	—	4,845,269	—	—	—	4,845,269
Issuance of shares pursuant to share-based awards	114,234	1,142	255,990	—	—	—	257,132
Net loss	—	—	—	—	(36,842,179)	—	(36,842,179)
Balance at December 31, 2022	82,806,832	828,068	259,075,291	(581,519)	(202,416,377)	(7,806,605)	49,098,858
Share-based compensation	—	—	3,837,598	—	—	—	3,837,598
Issuance of shares pursuant to share-based awards	33,891	339	79,139	—	—	—	79,478
Sale of shares under common stock purchase agreement	1,920,013	19,200	2,552,351	—	—	—	2,571,551
Amortization of deferred costs	—	—	(78,677)	—	—	—	(78,677)
Net loss	—	—	—	—	(38,792,906)	—	(38,792,906)
Balance at March 31, 2023	84,760,736	$ 847,607	$ 265,465,702	$ (581,519)	$ (241,209,283)	$ (7,806,605)	$ 16,715,902
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	—	—	1,880,428	—	—	—	1,880,428
Issuance of shares pursuant to share-based awards	79,334	793	209,076	—	—	—	209,869
Net loss	—	—	—	—	(6,380,006)	—	(6,380,006)
Balance at December 31, 2021	82,232,786	822,328	243,748,215	(581,519)	(88,178,184)	(7,806,605)	148,004,235
Share-based compensation	—	—	2,124,941	—	—	—	2,124,941
Issuance of shares pursuant to share-based awards	17,267	173	46,924	—	—	—	47,097
Net loss	—	—	—	—	(14,177,830)	—	(14,177,830)
Balance at March 31, 2022	82,250,053	$ 822,501	$ 245,920,080	$ (581,519)	$ (102,356,014)	$ (7,806,605)	$ 135,998,443

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Six Months Ended March 31,	
	2023	2022
OPERATING ACTIVITIES		
Net loss	$ (75,635,085)	$ (20,557,836)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	128,843	90,289
Impairment of intangible assets	3,900,000	—
Provision for credit losses	3,911,714	(4,000)
Noncash change in right-of-use assets	376,072	229,767
Noncash interest expense, net of interest paid	1,316,612	882,305
Share-based compensation	8,682,867	4,005,369
Deferred income taxes	(185,551)	5,165
Change in fair value of derivative liabilities	(530,000)	1,438,000
Provision for obsolete inventory	192,135	12,552
Changes in current assets and liabilities:		
Increase in accounts receivable	(3,852,786)	(764,466)
Decrease (increase) in inventories	761,615	(853,762)
Decrease (increase) in prepaid expenses and other assets	4,480,405	(1,358,084)
(Decrease) increase in accounts payable	(4,765,920)	4,108,300
Increase in accrued expenses and other current liabilities	1,374,233	378,567
Decrease in operating lease liabilities	(244,853)	(216,635)
Net cash used in operating activities	(60,089,699)	(12,604,469)
INVESTING ACTIVITIES		
Cash proceeds from sale of PREBOOST® business	—	2,500,000
Capital expenditures	(427,152)	(487,434)
Net cash (used in) provided by investing activities	(427,152)	2,012,566
FINANCING ACTIVITIES		
Proceeds from stock option exercises	336,610	256,966
Proceeds from sale of shares under common stock purchase agreement	2,571,551	—
Proceeds from premium finance agreement	1,425,174	—
Installment payments on premium finance agreement	(508,788)	—
Cash paid for debt portion of finance lease	—	(9,093)
Net cash provided by financing activities	3,824,547	247,873
Net decrease in cash	(56,692,304)	(10,344,030)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	80,190,675	122,359,535
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 23,498,371	$ 112,015,505
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 254,311	$ 1,489,079
Schedule of non-cash investing and financing activities:		
Right-of-use asset recorded in exchange for lease liabilities	$ 264,896	$ 4,392,583
Amortization of deferred costs related to common stock purchase agreement	$ 78,677	$ —

See notes to unaudited condensed consolidated financial statements.

VERU INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1 – Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements for Veru Inc. ("we," "our," "us," "Veru" or the "Company") have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) for reporting of interim financial information. Pursuant to these rules and regulations, certain information and footnote disclosures normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) have been condensed or omitted, although the Company believes that the disclosures made are adequate to make the information not misleading. Accordingly, these statements do not include all the disclosures normally required by U.S. GAAP for annual financial statements and should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations contained in this report and the audited financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended September 30, 2022. The accompanying condensed consolidated balance sheet as of September 30, 2022 has been derived from our audited financial statements. The unaudited condensed consolidated statements of operations and cash flows for the three and six months ended March 31, 2023 are not necessarily indicative of the results to be expected for any future period or for the fiscal year ending September 30, 2023.

The preparation of our unaudited interim condensed consolidated financial statements in conformity with 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.

In the opinion of management, the accompanying unaudited interim condensed consolidated financial statements contain all adjustments (consisting of only normally recurring adjustments) necessary to present fairly the financial position and results of operations as of the dates and for the periods presented.

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 breast cancer and for SARS-Cov-2 and other viral ARDS-related diseases. Our drug development program includes sabizabulin, a microtubule disrupter, for the treatment of hospitalized COVID-19 patients at high risk for ARDS and other viral-related ARDS, and enobosarm, a selective androgen receptor targeting agonist, for the management of advanced breast cancer. 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 the transmission of 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 the three and six months ended March 31, 2023 and 2022 were derived from sales of FC2.

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 unaudited condensed consolidated balance sheets, these items, along with net loss, are components of other comprehensive loss. For the three and six months ended March 31, 2023 and 2022, comprehensive loss is equivalent to the reported net loss.

Recent accounting pronouncements not yet adopted: We have reviewed all 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 – Liquidity

The Company anticipates that we will continue to consume cash and incur losses as we develop and commercialize our drug candidates. Because of the numerous risks and uncertainties associated with the development of pharmaceutical products, the Company is unable to estimate the exact amounts of capital outlays and operating expenditures necessary to fund development of our drug candidates and obtain regulatory approvals. The Company's future capital requirements will depend on many factors.

The Company believes its current cash position, cash expected to be generated from sales of FC2, cash to be received from the sale of ENTADFI (see note 15), and its ability to secure equity financing or other financing alternatives will be adequate to fund planned operations of the Company for the next 12 months. To the extent the Company may need additional capital for its operations or the conditions for raising capital are favorable, the Company may access financing alternatives that may include debt financing, common stock offerings, or financing involving convertible debt or other equity-linked securities and may include financings under the Company's current effective shelf registration statements on Form S-3 (File No. 333-239493 and File No. 333-270606) or under a new registration statement. The Company intends to be opportunistic when pursuing equity or debt financing, which could include selling common stock under its common stock purchase agreement with Aspire Capital Fund, LLC (see Note 9) or its common stock purchase agreement with Lincoln Park Capital Fund, LLC (see note 15).

Note 3 – Fair Value Measurements

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

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

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

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

Level 3 – Instruments with primarily unobservable value drivers.

As of March 31, 2023 and September 30, 2022, the Company's financial liabilities measured at fair value on a recurring basis, which consisted of embedded derivatives, were classified within Level 3 of the fair value hierarchy.

The 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) as of March 31, 2023 and 2022:

	Six Months Ended March 31,	
	2023	**2022**
Beginning balance	$ 4,294,000	$ 7,851,000
Change in fair value of derivative liabilities	(530,000)	1,438,000
Ending balance	$ 3,764,000	$ 9,289,000

The expense associated with the change in fair value of the embedded derivatives is included as a separate line item on the accompanying unaudited condensed consolidated statements of operations.

The liabilities associated with embedded derivatives represent the fair value of the change of control provision in the Residual Royalty Agreement. See Note 8 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. A significant increase in projected FC2 revenues or a significant increase in the probability or acceleration of the timing of a change of control event, in isolation, would result in a significantly higher fair value measurement of the liability associated with the embedded derivative.

The following tables present 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 March 31, 2023 and September 30, 2022:

Valuation Methodology	Significant Unobservable Input	March 31, 2023	September 30, 2022
Scenario-Based	Estimated change of control dates	June 2024 to June 2026	September 2023 to September 2025
	Discount rate	11.9% to 12.7%	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 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. The following table presents net revenues from these three categories:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2023	2022	2023	2022
FC2				
U.S. prescription channel	$ 4,146,160	$ 11,590,466	$ 4,309,164	$ 23,164,732
Global public health sector	2,434,287	1,437,928	4,771,284	3,998,794
Total FC2	6,580,447	13,028,394	9,080,448	27,163,526
ENTADFI	5,520	—	13,313	—
Net revenues	$ 6,585,967	$ 13,028,394	$ 9,093,761	$ 27,163,526

The following table presents net revenues by geographic area:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2023	2022	2023	2022
United States	$ 4,787,258	$ 11,846,960	$ 5,596,635	$ 23,755,485
South Africa	1,328,400	*	1,329,678	*
Other	470,309	1,181,434	2,167,448	3,408,041
Net revenues	$ 6,585,967	$ 13,028,394	$ 9,093,761	$ 27,163,526

*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 unaudited condensed consolidated balance sheets, were approximately $335,000 and $342,000 at March 31, 2023 and September 30, 2022, respectively.

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 are affected by the mix of purchasers within the period. As is typical in the Company's business, extended credit terms may occasionally be offered as a sales promotion or for certain sales. 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 unaudited condensed consolidated balance sheet.

The components of accounts receivable consisted of the following at March 31, 2023 and September 30, 2022:

	March 31, 2023	September 30, 2022
Trade receivables, gross	$ 8,141,573	$ 4,289,892
Less: allowance for credit losses	(3,923,857)	(12,143)
Less: allowance for sales returns and payment term discounts	(11,749)	(12,854)
Less: long-term trade receivables*	—	(714,000)
Accounts receivable, net	$ 4,205,967	$ 3,550,895

*Included in other assets on the accompanying unaudited condensed consolidated balance sheets

At March 31, 2023 and at September 30, 2022, no customers had a current accounts receivable balance that represented greater than 10% of current assets.

At March 31, 2023, three customers had an accounts receivable balance greater than 10% of net accounts receivable, representing 84% of net accounts receivable and long-term trade receivables 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 net accounts receivable and long-term trade receivables in the aggregate.

For the three months ended March 31, 2023, there were two customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 75% of the Company's net revenues in the aggregate, including The Pill Club that represented 59% of the Company's net revenues in the aggregate. For the three months ended March 31, 2022, there were two customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 83% of the Company's net revenues in the aggregate, including The Pill Club that represented 41% of the Company's net revenue in the aggregate.

For the six months ended March 31, 2023, there were three customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 69% of the Company's net revenues in the aggregate, including The Pill Club that represented 43% of the Company's net revenues in the aggregate. For the six months ended March 31, 2022, there were two customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 81% of the Company's net revenues in the aggregate, including The Pill Club that represented 40% of the Company's net revenues in the aggregate.

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. In the case of a bankruptcy filing or other similar event indicating the collectability of specific customer accounts is no longer probable, a specific allowance for credit losses may be recorded to reduce the related receivable to the amount expected to be recovered. Accounts receivable are charged-off when deemed uncollectible. During the quarter ended March 31, 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 uncertainty related to their financial condition. On April 18, 2023, The Pill Club filed for Chapter 11 bankruptcy.

The table below summarizes the change in the allowance for credit losses for the six months ended March 31, 2023 and 2022:

	Six Months Ended March 31,	
	2023	2022
Beginning balance	$ 12,143	$ 20,643
Charges to expense, net of recoveries	3,911,714	(4,000)
Ending balance	$ 3,923,857	$ 16,643

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

Note 6 – Balance Sheet Information

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.

Inventories consisted of the following at March 31, 2023 and September 30, 2022:

	March 31, 2023	September 30, 2022
Raw material	$ 1,438,804	$ 1,662,712
Work in process	715,480	872,596
Finished goods	5,716,317	6,099,343
Inventories, gross	7,870,601	8,634,651
Less: inventory reserves	(205,407)	(15,707)
Inventories, net	$ 7,665,194	$ 8,618,944

Fixed Assets

We record equipment, furniture and fixtures, and leasehold improvements at historical cost. Expenditures for maintenance and repairs are recorded to expense. Depreciation and amortization are primarily computed using the straight-line method. Depreciation and amortization are computed over the estimated useful lives of the respective assets. Leasehold improvements are depreciated on a straight-line basis over the lesser of the remaining lease term or the estimated useful lives of the improvements.

Plant and equipment consisted of the following at March 31, 2023 and September 30, 2022:

	Estimated Useful Life	March 31, 2023	September 30, 2022
Plant and equipment:			
Manufacturing equipment	5 - 8 years	$ 3,281,354	$ 2,902,715
Office equipment, furniture and fixtures	3 - 10 years	1,488,987	1,440,475
Leasehold improvements	3 - 8 years	484,460	484,460
Total plant and equipment		5,254,801	4,827,650
Less: accumulated depreciation and amortization		(3,735,012)	(3,641,884)
Plant and equipment, net		$ 1,519,789	$ 1,185,766

Depreciation expense was approximately $48,000 and $30,000 for the three months ended March 31, 2023 and 2022, respectively, and approximately $93,000 and $55,000 for the six months ended March 31, 2023 and 2022, respectively. Plant and equipment included $525,000 and $276,000 at March 31, 2023 and September 30, 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 7 – Intangible Assets and Goodwill

Intangible Assets

The gross carrying amounts and net book value of intangible assets were as follows at March 31, 2023:

	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Intangible asset with finite life:			
Covenants not-to-compete	$ 500,000	$ 458,333	$ 41,667
Indefinite-lived intangible assets:			
Acquired in-process research and development assets	—	—	—
Total intangible assets	$ 500,000	$ 458,333	$ 41,667

The gross carrying amounts and net book value of intangible assets were 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 expense was approximately $18,000 for the three months ended March 31, 2023 and 2022 and approximately $36,000 for the six months ended March 31, 2023 and 2022.

During the second quarter of fiscal 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. As of March 31, 2023, 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 during the quarter ended March 31, 2023.

Goodwill

The carrying amount of goodwill at March 31, 2023 and September 30, 2022 was $6.9 million. There was no change in the balance during the six months ended March 31, 2023 and 2022. The Company's goodwill is assigned to the Research and Development reporting unit, which had a negative carrying amount as of March 31, 2023.

Note 8 – Debt

SWK Residual Royalty Agreements

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, 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 respective change of control provisions, was allocated to an embedded derivative liability. The derivative liability is adjusted to fair market value at each reporting period.

At March 31, 2023 and September 30, 2022, the Residual Royalty Agreement liability consisted of the following:

	March 31, 2023	September 30, 2022
Residual royalty agreement liability, fair value at inception	$ 346,000	$ 346,000
Add: accretion of liability using effective interest rate	11,521,831	9,950,908
Less: cumulative payments	(4,019,683)	(3,765,372)
Residual royalty agreement liability, excluding embedded derivative liability	7,848,148	6,531,536
Add: embedded derivative liability at fair value (see Note 3)	3,764,000	4,294,000
Total residual royalty agreement liability	11,612,148	10,825,536
Residual royalty agreement liability, short-term portion	(1,354,823)	(1,169,095)
Residual royalty agreement liability, long-term portion	$ 10,257,325	$ 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 unaudited condensed consolidated statements of cash flows. The short-term portion of the Residual Royalty Agreement liability represents the aggregate of the estimated quarterly payments on the Residual Royalty Agreement payable during the 12-month period subsequent to the balance sheet date.

Interest expense on the accompanying unaudited condensed 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. Subsequent to March 31, 2023, the Company learned of The Pill Club's bankruptcy filing, which results in uncertainty whether sales to The Pill Club will continue in the future. A decrease in our projected FC2 revenues may result in a decreased Residual Royalty Agreement liability in future periods.

Premium Finance Agreement

On November 1, 2022, the Company entered into a Premium Finance Agreement to finance $1.4 million of its directors and officers liability insurance premium at an annual percentage rate of 6.3%. The financing is payable in eleven monthly installments of principal and interest, beginning on December 1, 2022. The balance of the insurance premium liability is $0.9 million as of March 31, 2023 and is included in accrued expenses and other current liabilities on the accompanying unaudited condensed consolidated balance sheet.

Note 9 – Stockholders' Equity

Preferred Stock

The Company has 5,000,000 authorized 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 (the "Series 4 Preferred Stock") authorized. There were no shares of Class A Preferred Stock of any series issued and outstanding at March 31, 2023 and September 30, 2022. The Company has 15,000 authorized 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 March 31, 2023 and September 30, 2022, and there was no activity during the six months ended March 31, 2023 and 2022.

Shelf Registration Statements

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 SEC on April 14, 2023. As of March 31, 2023, $16.1 million remained available under the Company's 2020 shelf registration statement on Form S-3 (File No. 333-239493).

Aspire Capital Purchase Agreement

On June 26, 2020, the Company entered into a common stock purchase agreement (the "2020 Purchase Agreement") with Aspire Capital Fund, LLC (Aspire Capital) which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right, from time to time in its sole discretion during the 36-month term of the 2020 Purchase Agreement, to direct Aspire Capital to purchase up to $23.9 million of the Company's common stock in the aggregate. Concurrently with entering into the 2020 Purchase Agreement, the Company also entered into a registration rights agreement with Aspire Capital (the "Registration Rights Agreement"), in which the Company agreed to prepare and file under the Securities Act of 1933 (the "Securities Act") one or more prospectus supplement for the sale or potential sale of the shares of the Company's common stock that have been and may be issued to Aspire Capital under the 2020 Purchase Agreement.

Under the 2020 Purchase Agreement, on any trading day selected by the Company, the Company has the right, in its sole discretion, to present Aspire Capital with a purchase notice (each, a "Purchase Notice"), directing Aspire Capital (as principal) to purchase up to 200,000 shares of the Company's common stock per business day at a per share price (the "Purchase Price") equal to the lesser of the lowest sale price of the Company's common stock on the purchase date or the average of the three lowest closing sale prices for the Company's common stock during the ten consecutive trading days ending on the trading day immediately preceding the purchase date.

In addition, on any date on which the Company submits a Purchase Notice to Aspire Capital in an amount equal to 200,000 shares and the closing sale price of our common stock is equal to or greater than $0.50 per share, the Company also has the right, in its sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice (each, a "VWAP Purchase Notice") directing Aspire Capital to purchase an amount of common stock equal to up to 30% of the aggregate shares of the common stock traded on its principal market on the next trading day (the "VWAP Purchase Date"), subject to a maximum number of shares the Company may determine. The purchase price per share pursuant to such VWAP Purchase Notice is generally 97% of the volume-weighted average price for the Company's common stock traded on its principal market on the VWAP Purchase Date.

During the six months ended March 31, 2023, we sold 1,920,013 shares of common stock to Aspire Capital under the 2020 Purchase Agreement resulting in proceeds to the Company of $2.6 million. As a result of these sales, we recorded approximately $79,000 of deferred costs to additional paid-in capital.

Since inception of the 2020 Purchase Agreement through March 31, 2023, we have sold 3,564,750 shares of common stock to Aspire Capital resulting in proceeds to the Company of $7.6 million. As of March 31, 2023, the amount remaining under the 2020 Purchase Agreement was $16.3 million, which is registered under the Company's shelf registration statement on Form S-3 (File No. 333-239493). Subsequent to March 31, 2023, we sold 859,700 shares of common stock to Aspire Capital under the 2020 Purchase Agreement resulting in proceeds to the Company of $0.8 million.

In consideration for entering into the 2020 Purchase Agreement and concurrently with the execution of the 2020 Purchase Agreement, the Company issued to Aspire Capital 212,130 shares of the Company's common stock. The shares of common stock issued as consideration were valued at $681,000, based on the closing price per share of the Company's common stock on the date the shares were issued. This amount and related expenses of $50,000, which total approximately $731,000, were recorded as deferred costs. The unamortized amount of deferred costs related to the 2020 Purchase Agreement of $500,000 and $578,000 at March 31, 2023 and September 30, 2022, respectively, is included in other assets on the accompanying unaudited condensed consolidated balance sheets.

Note 10 – 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. For the three and six months ended March 31, 2023 and 2022, we recorded share-based compensation expenses as follows:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2023	2022	2023	2022
Cost of sales	$ 87,356	$ 24,572	$ 151,364	$ 45,648
Selling, general and administrative	2,903,812	1,588,043	6,515,911	2,983,601
Research and development	846,430	512,326	2,015,592	976,120
Share-based compensation	$ 3,837,598	$ 2,124,941	$ 8,682,867	$ 4,005,369

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 certain new hires who satisfied the requirements to be granted inducement grants under Nasdaq rules as an inducement material to the individual's entry into employment with the Company. The Company reserved 4,000,000 shares of common stock under the Inducement Plan and as of March 31, 2023, 3,895,250 shares remain available for issuance under the Inducement Plan.

In March 2018, the Company's stockholders approved the Company's 2018 Equity Incentive Plan (as amended, 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 March 31, 2023, 4,349,265 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 March 31, 2023, 6,792 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 $1.4 million during the three and six months ended March 31, 2023 for stock options forfeited during the period. The reduction in share-based compensation expense during the three and six months ended March 31, 2022 for stock options forfeited was immaterial.

The following table outlines the weighted average assumptions for options granted during the three and six months ended March 31, 2023 and 2022:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2023	2022	2023	2022
Weighted Average Assumptions:				
Expected volatility	102.90%	76.12%	98.49%	77.27%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%
Risk-free interest rate	3.84%	2.50%	4.24%	1.44%
Expected term (in years)	5.6	6.0	6.0	6.0
Fair value of options granted	$ 3.63	$ 3.49	$ 9.10	$ 5.40

During the three and six months ended March 31, 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 March 31, 2023:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2022	14,263,470	$ 5.00		
Granted	2,736,775	$ 11.38		
Exercised	(148,125)	$ 2.27		
Forfeited and expired	(799,231)	$ 11.73		
Outstanding at March 31, 2023	16,052,889	$ 5.78	7.05	$ 28,260
Exercisable at March 31, 2023	9,652,972	$ 2.96	5.89	$ 28,260

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 quarter ended March 31, 2023 of $1.16, less the respective weighted average exercise price per share at period end.

The total intrinsic value of options exercised during the six months ended March 31, 2023 and 2022 was approximately $486,000 and $489,000, respectively. Cash received from options exercised during the six months ended March 31, 2023 and 2022 was approximately $337,000 and $257,000, respectively.

As of March 31, 2023, the Company had unrecognized compensation expense of approximately $38.7 million related to unvested stock options. This expense is expected to be recognized over a weighted average period of 2.0 years.

Stock Appreciation Rights

In connection with the closing of our acquisition of Aspen Park Pharmaceuticals, Inc. on October 31, 2016 (the "APP Acquisition"), the Company issued stock appreciation rights based on 50,000 and 140,000 shares of the Company's common stock to an employee and an outside director, respectively, that vested on October 31, 2018. The stock appreciation rights have a ten-year term and an exercise price per share of $0.95, which was the closing price per share of the Company's common stock as quoted on Nasdaq on the trading day immediately preceding the date of the completion of the APP Acquisition. Upon exercise, the stock appreciation rights will be settled in common stock issued under the 2017 Plan. As of March 31, 2023, vested stock appreciation rights based on 50,000 shares of common stock remain outstanding.

Note 11 – Leases

The Company has operating leases for its office, manufacturing and warehouse space, and office equipment. The Company's leases have remaining lease terms of less than one year to seven years, which include the option to extend a lease when the Company is reasonably certain to exercise that option. Certain of our lease agreements include variable lease payments for common area maintenance, real estate taxes, and insurance or based on usage for certain equipment leases. For one of our office space leases, the Company entered into a sublease, for which it receives sublease income. Sublease income is recognized as a reduction to operating lease costs as the sublease is outside of the Company's normal business operations. This is consistent with the Company's recognition of sublease income prior to the adoption of FASB ASC Topic 842. The Company does not have any leases that have not yet commenced as of March 31, 2023.

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 commenced, it was reasonably certain that the Company would exercise that option. The option to exercise required 6 months of 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 components of the Company's lease cost were as follows for the three and six months ended March 31, 2023 and 2022:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2023	2022	2023	2022
Finance lease cost:				
Amortization of right-of-use assets	$ —	$ 1,453	$ —	$ 3,631
Interest on lease liabilities	—	147	—	403
Operating lease cost	279,450	182,845	560,901	313,955
Short-term lease cost	10,999	12,934	21,100	25,705
Variable lease cost	52,552	46,737	102,643	92,756
Sublease income	(44,845)	(44,845)	(89,689)	(89,689)
Total lease cost	$ 298,156	$ 199,271	$ 594,955	$ 346,761

The Company paid cash of $482,000 and $293,000 for amounts included in the measurement of operating lease liabilities during the six months ended March 31, 2023 and 2022, respectively.

The Company's operating lease right-of-use assets and the related lease liabilities are presented as separate line items on the accompanying unaudited condensed consolidated balance sheets as of March 31, 2023 and September 30, 2022.

Other information related to the Company's leases as of March 31, 2023 and September 30, 2022 was as follows:

	March 31, 2023	September 30, 2022
Operating Leases		
Weighted-average remaining lease term	6.2	6.8
Weighted-average discount rate	7.8%	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.

Note 12 – Contingent Liabilities

The testing, manufacturing and marketing of consumer products by the Company and the clinical testing of our product candidates 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 $30.0 million.

Legal Proceedings

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 certain of its current officers and directors (the "Ewing Complaint"). The Ewing Complaint alleges that certain public statements about sabizabulin as a treatment for COVID-19 between May 11, 2022 and November 9, 2022 violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. The Company believes that the allegations asserted in the Ewing Complaint are without merit, and the Company intends to vigorously defend the lawsuit. There can be no assurance that the Company will be successful. At this time, the Company is unable to estimate potential losses, if any, related to the 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 on the accompanying unaudited condensed 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 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 13 – 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.

As of September 30, 2022, the Company had U.S. federal and state NOL carryforwards of $112.5 million and $50.9 million, respectively, for income tax purposes with $29.7 million and $28.4 million, respectively, expiring in years 2023 to 2042 and $82.8 million and $22.5 million, respectively, which can be carried forward indefinitely. As of September 30, 2022, the Company also had U.S. federal research and development tax credit carryforwards of $8.5 million, expiring in years 2038 to 2042. The Company's U.K. subsidiary has U.K. NOL carryforwards of $63.1 million as of September 30, 2022, 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 March 31, 2023, we recorded a decrease to income tax benefit and an increase to deferred tax assets, before applying a valuation allowance, of approximately $8.2 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.

A reconciliation of income tax (benefit) expense and the amount computed by applying the U.S. statutory rate of 21% to loss before income taxes is as follows:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2023	2022	2023	2022
Income tax benefit at U.S. federal statutory rates	$ (8,160,487)	$ (2,983,109)	$ (15,911,684)	$ (4,298,833)
State income tax benefit, net of federal benefit	(631,855)	(230,978)	(1,232,019)	(332,853)
Non-deductible expenses	334,113	102,733	447,569	359,929
Effect of stock options exercised	(19,887)	—	63,849	(23,350)
U.S. research and development tax credit	(1,330,000)	(913,000)	(2,420,000)	(2,876,430)
Effect of foreign income tax rates	(19,026)	(9,677)	(99,136)	(39,438)
Effect of global intangible low taxed income	—	(75,278)	—	12,989
Change in valuation allowance	9,767,083	4,043,065	19,023,202	7,132,661
Other, net	(6,500)	38,794	(6,618)	152,530
Income tax (benefit) expense	$ (66,559)	$ (27,450)	$ (134,837)	$ 87,205

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

	March 31, 2023	September 30, 2022
Deferred tax assets:		
Federal net operating loss carryforwards	$ 28,569,803	$ 23,627,461
State net operating loss carryforwards	3,233,713	2,850,956
Foreign net operating loss carryforwards – U.K.	16,003,790	15,773,497
Foreign capital allowance – U.K.	128,490	128,490
U.S. research and development tax credit carryforwards	10,901,789	8,481,789
U.S. research and development expense	8,228,433	—
Accrued compensation	622,992	1,227,290
Share-based compensation	5,981,261	4,325,354
Interest expense	2,463,631	2,206,484
Change in fair value of derivative liabilities	100,687	220,607
Other, net – U.K.	265,631	265,631
Other, net – Malaysia	4,979	—
Other, net – U.S.	970,352	81,507
Gross deferred tax assets	77,475,551	59,189,066
Valuation allowance for deferred tax assets	(64,395,654)	(45,372,452)
Net deferred tax assets	13,079,897	13,816,614
Deferred tax liabilities:		
In-process research and development	—	(882,427)
Covenant not-to-compete	(9,428)	(17,508)
Other, net - Malaysia	—	(17,641)
Other, net – U.S.	—	(14,120)
Net deferred tax liabilities	(9,428)	(931,696)
Net deferred tax asset	$ 13,070,469	$ 12,884,918

The deferred tax amounts have been classified on the accompanying unaudited condensed consolidated balance sheets as follows:

	March 31, 2023	September 30, 2022
Deferred tax asset – U.K.	$ 13,065,490	$ 12,965,985
Deferred tax asset – Malaysia	4,979	—
Total deferred tax asset	$ 13,070,469	$ 12,965,985
Deferred tax liability – U.S.	$ —	$ (63,426)
Deferred tax liability – Malaysia	—	(17,641)
Total deferred tax liability	$ —	$ (81,067)

Note 14 – Net Loss Per Share

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing net 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. 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 10 for a discussion of our potentially dilutive common shares.

Note 15 – Subsequent Events

Frost Gamma Investments Trust Stock Purchase Agreement

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. The shares of common stock issued to FGI pursuant to the Stock Purchase Agreement were not registered under the Securities Act. The Company is obligated to file a registration statement under the Securities Act within 45 days after the date of the Stock Purchase Agreement to register the resale of the shares of common stock issued to FGI.

Sale of ENTADFI

On April 19, 2023, the Company entered into an 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 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 believes that the probability of receiving any Milestone Payments is remote. The Company will determine the gain on sale of ENTADFI based on the purchase price of $20.0 million. The Company expects to record a gain of approximately $17.7 million on the transaction.

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 the Company may sell to Lincoln Park up to $100,000,000 of shares (the "Purchase Shares") of the Company's common stock over the 36 month term of the Lincoln Park Purchase Agreement.

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).

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 to terminate the Lincoln Park Purchase Agreement. Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of the Company's common stock. 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 its commitment to purchase shares of the Company's common stock under the Lincoln Park Purchase Agreement, and we are obligated to issue $1,000,000 of shares of the Company's common stock at the time Lincoln Park's purchases cumulatively reach an aggregate amount of $50,000,000 of Purchase Shares (together the "Commitment Shares").

The issuance of the Purchase Shares and Commitment Shares have been registered pursuant to the Company's effective shelf registration statement on Form S-3 (File No. 333-270606).

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

Veru is a late clinical stage biopharmaceutical company focused on developing novel medicines for the treatment of breast cancer and for SARS-Cov-2 and other viral acute respiratory distress syndrome (ARDS)-related diseases. Our drug development program includes enobosarm, a selective androgen receptor agonist, for the management of advanced breast cancer, and sabizabulin, a microtubule disruptor, for the treatment of hospitalized COVID-19 patients at high risk for ARDS and other viral-related ARDS. The Company also has an FDA-approved commercial product, the FC2 Female Condom® (Internal Condom) (FC2), for the dual protection against unplanned pregnancy and sexually transmitted infections.

On March 14, 2023, at the Oppenheimer 33rd Annual Healthcare Conference, the Company presented its updated strategy as part of the Company's ongoing effort to (i) refocus its drug development efforts on those drug candidates which it believes have the best opportunity to lead to long-term success and shareholder value creation and (ii) conserve cash, including a reduction in personnel and certain other measures to reduce costs. The presentation included a description of the Company's refocused research and development strategy which includes the following: (i) plans for an amended ongoing Phase 2b/3 study of enobosarm and abemaciclib combination in the second line metastatic setting for AR+ ER+ HER2- metastatic breast cancer patients, with the Company's clinical trial collaboration partner, Eli Lilly & Company, supplying abemaciclib, (ii) a planned Phase 3 study of enobosarm in bone-only non-measurable metastatic ER+ HER2- breast cancer, and (iii) plans for continued development of sabizabulin in a Phase 3 COVID-19 confirmatory study in hospitalized moderate to severe COVID-19 patients at high risk for ARDS, with future planned development of sabizabulin in a Phase 3 clinical study in hospitalized influenza patients at high risk for ARDS. In addition, the Company announced that Veru is reserving sabizabulin for clinical development only in infectious disease indications, and accordingly, has terminated the Phase 3 VERACITY trial of sabizabulin in certain prostate cancer patients. Further, Phase 2 development of the VERU-100 asset will be paused with efforts to find a potential suitable development partner for VERU-100 to share the costs of such future development. The zuclomiphene development program has been stopped.

Oncology Program:

The Company's oncology drug pipeline has two clinical development programs for enobosarm, oral selective androgen receptor agonist, for the treatment of metastatic breast cancer.

Enobosarm is the first new class of endocrine therapy in advanced breast cancer in decades. Enobosarm is an oral, first-in-class, new chemical entity, selective androgen receptor agonist that activates the androgen receptor (AR) in AR+ ER+ HER2- metastatic breast cancer, which results in tumor suppressor activity without the unwanted masculinizing side effects and changes in hematocrit. Enobosarm has extensive nonclinical and clinical experience having been evaluated in 25 separate clinical studies in approximately 1,450 subjects dosed, including three Phase 2 clinical studies in advanced breast cancer involving more than 250 patients. In the two Phase 2 clinical studies conducted in women with AR+ ER+ HER2- metastatic breast cancer, enobosarm demonstrated significant antitumor efficacy in heavily pretreated cohorts that failed estrogen blocking agents, chemotherapy, and/or CDK 4/6 inhibitors and was well tolerated with a favorable safety profile.

In preclinical studies, metastatic breast cancer tissue samples taken from patients who have metastatic breast cancer that had become resistant to CDK4/6 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 either drug alone. Interestingly, CDK 4/6 inhibitor treatment caused the metastatic breast cancer tissue to make higher amounts of AR which may explain the synergy of combining a CDK 4/6 inhibitor with enobosarm, a selective AR agonist.

Phase 2b/3 clinical ENABLAR-2 study – Enobosarm + abemaciclib combination as a 2nd line treatment in AR+ ER+ HER2- metastatic breast cancer. On March 30, 2023, the Company met with the FDA to gain further agreement on Phase 2b/3 clinical trial design and program. The Phase 2b/3 study has been amended to accommodate the FDA's latest recommendations to support registration. In the first stage, the dose of enobosarm in the abemaciclib combination is being optimized and safety of the combination therapy is being assessed in 3 arms of 40 patients each: abemaciclib + enobosarm 9mg combination therapy, abemaciclib + enobosarm 1mg combination therapy, and an estrogen blocking agent (control arm). In Stage 2 of the Phase 2b/3 study, we plan to enroll approximately 210 subjects in a multicenter, open label, randomized (1:1), active control clinical study, to evaluate the efficacy and safety of enobosarm plus abemaciclib combination therapy versus an alternative estrogen blocking agent (fulvestrant or an aromatase inhibitor) in subjects with AR+ ER+ HER2- metastatic breast cancer who have failed palbociclib (a CDK4/6 inhibitor) plus an estrogen blocking agent (non-steroidal aromatase inhibitor or fulvestrant). In January 2022, Veru entered into a clinical trial collaboration and supply agreement through which Eli Lilly and Company supplies abemaciclib for the ENABLAR-2 trial.

Planned Phase 2b/3 clinical study evaluating enobosarm monotherapy for the treatment of bone-only non-measurable ER+HER2- metastatic breast cancer. Bone is the most frequent site of breast cancer metastasis, with bone metastases noted in 60–80% of metastatic breast cancer patients. Patients with bone-only metastasis are a unique subpopulation of metastatic breast cancer representing up to 51% of patients with metastatic breast cancer. Although a significant number of patients, bone-only metastatic breast cancer patients have very limited therapeutic options. Enobosarm inhibits breast cancer growth and builds and heals bone by increasing both cortical and trabecular bone. Further, enobosarm increases muscle mass and improves physical function which may reduce skeletal related events. Accordingly, enobosarm could be a potential therapeutic option for women with bone-only non-measurable metastatic breast cancer. The Company is planning a clinical development program to evaluate enobosarm monotherapy in bone-only non-measurable metastatic breast cancer.

Infectious Disease Program:

Viral infections can trigger the immune system to release an overwhelming amount of inflammatory proteins known as a cytokine storm. The cytokine storm causes tissue damage in the lungs leading to Acute Respiratory Distress Syndrome (ARDS). Patients who develop ARDS have a high mortality rate. Viral induced ARDS remains a significant unmet medical need with limited treatment options. Common viral infections that cause ARDS include COVID-19, influenza, and respiratory syncytial virus (RSV). Other virus infections that may also lead to ARDS and death posing a global public health threat to society include smallpox and Ebola viruses. A single outbreak involving any one of these viruses would be an immediate global emergency with limited existing options available for treatment. Sabizabulin, as a host targeted antiviral and broad-spectrum anti-inflammatory agent, has the potential to address the virus infection and the inflammation caused by the cytokine storm that causes ARDS, multi-organ failure, and death.

COVID-19 virus: The Company is developing sabizabulin 9mg, which has both host targeted antiviral and broad anti-inflammatory properties, as a two-pronged approach to the treatment of hospitalized moderate to severe hospitalized COVID-19 patients at high risk for ARDS and death.

In the current endemic phase, COVID-19 infection is estimated to be the 4th leading cause of death in the United States. ARDS remains a frequent serious complication of severe COVID-19 infection. It has been reported that up to 33% of hospitalized patients with COVID-19 have ARDS, and 75% to 92% of patients admitted to the intensive care unit with COVID-19 have ARDS. The mortality rate of COVID-19 associated ARDS is 45%, and among patients who died from COVID-19, there is a 90% incidence of ARDS. As the COVID-19 endemic continues, there also is a need to remain vigilant and focused on preparedness for the next wave of infections involving new viral strains. COVID-19 will be a problem for the foreseeable future, and there is a need for effective therapies, especially for those hospitalized patients with moderate-to-severe COVID-19 infection at high risk for ARDS.

The Company has completed positive Phase 2 and positive Phase 3 COVID-19 clinical trials evaluating sabizabulin in hospitalized moderate to severe COVID-19 patients at high risk for ARDS and death. The Phase 3 clinical study was a double-blind, randomized, placebo-controlled study in 204 hospitalized moderate to severe COVID-19 patients at high risk for ARDS. The primary endpoint was the proportion of patients that died by Day 60. Based on a planned interim analysis of the first 150 patients randomized, the Independent Data Monitoring Committee unanimously recommended that the study be stopped for clear evidence of clinical efficacy and identified no safety concerns. In the interim analysis, treatment with sabizabulin 9 mg once daily resulted in a clinically meaningful and statistically significant 55.2% relative reduction in deaths compared to placebo.

On May 10, 2022, the Company had a pre-emergency use authorization (EUA) meeting with the FDA to discuss the submission of an EUA application for sabizabulin COVID-19 treatment. On June 7, 2022, the Company submitted a request for FDA emergency use authorization for sabizabulin in adult hospitalized moderate to severe COVID-19 patients at high risk for ARDS and death. On July 6, 2022, the Company announced the publication of the interim efficacy and full safety clinical results from the Phase 3 COVID-19 study of sabizabulin in The New England Journal of Medicine Evidence.

On February 28, 2023, the FDA notified the Company that it has declined to grant at this time the Company's request for Emergency Use Authorization for sabizabulin to treat hospitalized moderate to severe COVID-19 patients who are at high risk for ARDS. In communicating its decision, the FDA stated that despite the FDA declining to issue an EUA for sabizabulin at this time, the FDA remains committed to working with the Company in the development of sabizabulin. Separately on February 16, 2023, the FDA also provided comments on a confirmatory Phase 3 study protocol submitted by the Company for hospitalized moderate to severe COVID-19 patients at risk for ARDS and death that could support a new EUA request to the FDA. In regard to study design, the FDA stated that strong consideration should be given to appropriate time frames for interim analyses so that, should a strong efficacy signal again be observed, the trial could be stopped in an efficient time frame.

On April 27, 2023, the Company met with the FDA and reached agreement on the design of the Phase 3 confirmatory COVID-19 clinical trial to evaluate sabizabulin treatment of hospitalized moderate to severe COVID-19 patients who are at high risk for ARDS and the path forward to submit a new EUA application and/or NDA. The FDA agreed to a confirmatory Phase 3, randomized (1:1), multicenter, global, efficacy and safety study of sabizabulin 9mg oral daily dose plus standard of care treatment versus placebo plus standard of care treatment in 408 hospitalized adult patients with moderate to severe SARS-CoV-2 infection who are at high risk for ARDS. The indication (patient population) for sabizabulin will be expanded to include all hospitalized moderate to severe COVID-19 patients: WHO-4 (passive, low flow oxygen), WHO-5 (forced, high flow oxygen), or WHO-6 (mechanical ventilation) without a requirement to have a comorbidity. The primary efficacy endpoint will be all-cause mortality at Day 60, secondary endpoints include days in the hospital, days in the ICU, days on mechanical ventilation, and proportion of patients alive without respiratory failure, and an exploratory endpoint will be the presence of long COVID-19 symptoms at Day 180. In order to get a potentially efficacious drug to patients in an efficient time frame, two planned interim efficacy analyses will be conducted: first planned interim analysis is expected to occur when 204 patients (50%) have completed the Day 60 primary efficacy endpoint, and the second planned interim analysis is expected to occur when 290 patients (71%) have completed the Day 60 primary efficacy endpoint. If either of the interim efficacy analyses meets the statistical significance criteria, the trial could be stopped for efficacy. Should the pre-specified primary efficacy endpoint analysis demonstrate a statistically significant effect on all-cause mortality favoring sabizabulin, the Company may consider a new request for an EUA or a submission of an NDA, as the Company would potentially have two adequate and well controlled trials for review. As the program has Fast Track designation, a rolling NDA submission is a possibility for sabizabulin. The Phase 3 confirmatory COVID-19 clinical trial is expected to begin enrollment in second half of 2023, and the first planned interim efficacy analysis is anticipated to be conducted in 2024.

On January 30, 2023, the White House Office of Management and Budget announced that the Biden administration plans to terminate the COVID-19 national and public health emergencies on May 11, 2023 (the "May 11 Termination"). The FDA's authority to issue emergency use authorizations stems from a separate emergency declaration by the Secretary of the Department of Health and Human Services regarding medical countermeasures in the fight against COVID-19. This separate HHS emergency currently remains in effect. The FDA announced on January 31, 2023 that the May 11 Termination would not impact the FDA's ability to authorize new treatments for emergency use, that existing EUAs would remain in effect and that it may continue to issue new EUAs when criteria for issuance are met.

The UK's Medicine and Healthcare Products Regulatory Agency (MHRA) informed the Company on July 25, 2022, that the sabizabulin marketing authorization application will receive expedited review. On July 27, 2022, sabizabulin triggered Article 18 in the European Union (EU) in which the European Medicines Agency (EMA) will evaluate sabizabulin to allow emergency use drug access to the EU Member States. On August 22, 2022, Australia's Therapeutic Goods Administration (TGA) determined that sabizabulin treatment in hospitalized COVID-19 patients at high risk for ARDS qualifies for an expedited, provisional registration regulatory pathway. Sabizabulin for COVID-19 has also been under regulatory review by the ACCESS Consortium made up of MHRA, TGA, and Swissmedic. At this time, the Company believes that it is most likely that all ex-US regulatory authorities, like the FDA, will require some level of additional data, including from the confirmatory Phase 3 study before granting emergency, conditional, and/or other authorization of sabizabulin for COVID-19.

Influenza virus: The Company plans to expand the clinical development of sabizabulin 9mg in a Phase 3 clinical study for the treatment of hospitalized influenza patients at high risk for ARDS and death.

On April 4, 2023, the Company announced results from a preclinical study of sabizabulin demonstrating robust anti-inflammatory activity with improved outcomes in an H1N1 Influenza-Induced Pulmonary Inflammation Mouse ARDS Model conducted by a team of researchers at Labcorp Early Development Laboratories, Ltd, United Kingdom. Sabizabulin treatment resulted in a statistically significant decrease in the total number of inflammatory cells and the reduction in key cytokines and chemokines in lung fluid. Clinically, sabizabulin treatment resulted in a reduction in the severity of lung inflammation by histopathology and a dose-dependent improvement of lung function. Oral administration of 2 mg/kg sabizabulin resulted in the reduction of the clinical signs and body weight loss associated with H1N1 infection. The Company expects to submit the full data set for presentation in future scientific meetings and peer-reviewed publications.

These preclinical data suggest that sabizabulin has the potential to be a treatment for hospitalized influenza patients at high risk for ARDS and death. Pathogenesis and mortality rates for hospitalized influenza patients who develop ARDS are similar to COVID-19-associated ARDS, representing a high unmet need with very limited treatment options. According to CDC, the influenza burden estimates in the United States were up to 630,000 hospitalizations and up to 55,000 deaths in the past 6 months. Accordingly, Veru is planning a double-blind randomized placebo-controlled Phase 3 clinical trial evaluating sabizabulin in hospitalized adult influenza patients at high risk for ARDS.

Smallpox and Ebola viruses: The Company is planning pre-IND meetings with FDA to discuss the development of sabizabulin for smallpox and Ebola viruses under the Animal Rules FDA regulatory approval pathway.

On April 11, 2023, Veru announced positive results from a preclinical in vitro study evaluating the effects of sabizabulin against prototypical poxvirus, vaccinia virus, which demonstrated that sabizabulin prevented both the release of poxvirus from infected cells and the spread of poxvirus to healthy cells conducted by a team of researchers led by Brian M. Ward, Ph.D., Associate Professor of Microbiology and Immunology, University of Rochester School of Medicine and Dentistry, Rochester, New York. The Company expects to submit the full data set for presentation in future scientific meetings and peer-reviewed publications.

Sabizabulin, as a host targeted antiviral and broad anti-inflammatory agent, may be useful as a novel treatment not only against smallpox and other poxviruses, but also may reduce the hyperactive immune response triggered by poxviruses that is responsible for severe pneumonia, ARDS, multi-organ failure, and death. Based on the preclinical data, the Company plans to expand the sabizabulin program to include other serious virus infections that pose a global public health threat to society. The Company plans to have pre-IND meetings with the FDA to discuss Animal Rule regulatory requirements for assessing the efficacy of sabizabulin for smallpox virus as well as Ebola virus. Clinical human efficacy trials of drugs for preventing or treating smallpox and Ebola viruses are not feasible and challenge studies in healthy subjects are unethical. Therefore, drugs for these indications are generally developed and approved under a regulatory pathway commonly referred to as the *Animal Rule* (21 CFR part 314, subpart I, for drugs and 21 CFR part 601, subpart H, for biologics). FDA may grant marketing approval based on adequate and well-controlled animal efficacy studies when the results of those studies establish that the drug is reasonably likely to produce clinical benefit in humans.

Sexual Health Program

The Company's sexual health program consists of FC2, an FDA-approved commercial product for the dual protection against unplanned pregnancy and sexually transmitted infections.

The Company sells FC2 in both the commercial sector and in the public health sector both in the U.S. and globally. In the U.S., FC2 is available by prescription through multiple telemedicine and internet pharmacy channels as well as retail pharmacies. The Company 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. In the global public health sector, the Company markets FC2 to entities, including ministries of health, government health agencies, U.N. agencies, nonprofit organizations and commercial partners, that work to support and improve the lives, health and well-being of women around the world.

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 with 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.

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's most significant customer base is telemedicine providers in the U.S. who sell into the prescription channel and global public health sector agencies who purchase and/or distribute FC2 for use in preventing the transmission of HIV/AIDS and/or family planning. We are seeing an increase in U.S. public sector revenues.

The Pill Club has historically been our largest telehealth customer for FC2, accounting for 44% of our net revenues (including 58% of our U.S. prescription channel revenue) in fiscal 2022 and 43% of our net revenues (including 57% of our U.S. prescription channel revenue) in fiscal 2021. We sell 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 takes title to FC2 and then acts as a distributor of FC2. The Pill Club is 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 distributes, and legal and regulatory compliance. We have 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. However, to the extent that the settlement adversely affects The Pill Club's FC2 sales, our business may be adversely affected.

As a result of the settlement, The Pill Club has informed us that it expects to modify some of its business practices regarding its sales of FC2 to patients, notwithstanding that The Pill Club did not agree that it had violated any laws in the Settlement Agreement. It is not clear to Veru at this time when such new business model will be in operation in California or in any other states. The Pill Club filed for Chapter 11 bankruptcy on April 18, 2023, which increases the uncertainty regarding The Pill Club's future operations and its financial resources to continue large purchases of FC2. Such changes may make it difficult to restore The Pill Club's ordering patterns in future periods, and as a result net revenues from sales of FC2 may not return to past levels.

We also have a concentration of accounts receivable with The Pill Club, which totals $3.9 million as of March 31, 2023. During the quarter ended March 31, 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. Veru had been making significant efforts to obtain clarity from The Pill Club on when this payment would be made. On March 29, 2023, The Pill Club refused delivery of a shipment of FC2 for which it had previously submitted a binding purchase order and which it was contractually bound to accept. On March 30, 2023, the Company provided written notice to The Pill Club that the Company believed The Pill Club was in default for the past due payment and the refused shipment. These breaches remained uncured 10 calendar days after the default notice and accordingly, the Company's contract with The Pill Club for the sale of FC2 automatically terminated by its terms. The Pill Club's Chapter 11 bankruptcy filing was on April 18, 2023, after the termination of the Company's contract with The Pill Club.

Due to The Pill Club's recent Chapter 11 bankruptcy and the termination of our contract with The Pill Club, we expect that our revenue from The Pill Club will be substantially reduced or possibly eliminated. It is possible that individual purchases of FC2 could be made by The Pill Club from time to time but any such potential purchases would be outside of the existing contract if that contract terminates.

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 recently indicated that it intends to close the facility where our specialty grade of nitrile is currently manufactured at the end of our current fiscal 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. We have sufficient inventory in the U.S. to cover all the expected demand from the U.S. prescription channel while this transfer occurs. Additionally, we plan to build sufficient inventory to cover any gap of supply resulting from such a transfer or change in raw material grade. However, if this transfer or change of raw material grade results in an interruption of supply of FC2, we may not have sufficient supply to fulfill orders in the global public health sector.

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, and may experience increases in other material costs due to the impact of COVID-19 and increased inflation. Our costs of sales and gross margins may be adversely impacted if we are unable to pass along cost increases to our customers.

Conducting research and development is central to our oncology 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 $22.9 million and $15.5 million for the three months ended March 31 2023 and 2022, respectively, and $41.6 million and $25.6 million for the six months ended March 31, 2023 and 2022, respectively. We expect to continue this trend of investing significant resources in research and development due to advancement of several drug candidates at the same time.

Results of Operations

THREE MONTHS ENDED MARCH 31, 2023 COMPARED TO THREE MONTHS ENDED MARCH 31, 2022

The Company generated net revenues of $6.6 million and net loss of $38.8 million, or $(0.48) per basic and diluted common share, for the three months ended March 31, 2023, compared to net revenues of $13.0 million and net loss of $14.2 million, or $(0.18) per basic and diluted common share, for the three months ended March 31, 2022. Net revenues decreased 49% compared to the prior period.

Most of the Company's net revenues for the three months ended March 31, 2023 and 2022 were derived from sales of FC2 in the U.S. prescription channel and global public health sector. There was a decrease in the FC2 average sales price per unit of 61%. The principal factor for the decrease in the FC2 average sales price per unit compared to prior period was the change in the sales mix with the U.S. prescription channel representing 63% of total FC2 net revenues in the current year period compared to 89% in the prior year period and the global public health sector representing 37% of total FC2 net revenues in the current year period compared to 11% in the prior year period. Sales to the global public health sector are at a lower sales price per unit. The Company experienced a decrease compared to the prior year period of 64% in FC2 net revenues in the U.S. prescription channel and an increase compared to the prior year period of 69% in FC2 net revenues in the global public health sector.

The decrease in FC2 net revenues in the U.S. prescription channel is primarily due to lower volume from telemedicine customers as a result of on-going business challenges, which based on discussion with such customers, we understand to include changes in strategy, the impact of rebranding, and reductions in marketing spending, which resulted in a slowdown in orders during recent quarters. Specifically, net revenues from The Pill Club were $3.9 million in the current year period compared to $5.4 million in the prior year period. The Company is uncertain whether sales to The Pill Club will continue in the future, due to The Pill Club's Chapter 11 bankruptcy filing. We have recorded a provision for credit losses for the net revenues during the current year quarter, which were included in the gross accounts receivable balance at March 31, 2023. Net revenues from another prescription channel customer were $5.5 million in the prior year period and zero in the current year period, which based on customer discussions, we understand to be due to inventory management after a reduction in orders from its most significant customer, which resulted in it ceasing orders. We are working to increase net revenues in future periods based on growing awareness and demand through increased FC2 marketing efforts, through our telehealth platform, and through discussions with potential new distribution partners in the telehealth sector. We have also begun to see an increase in U.S. public sector revenues through two new agreements recently executed.

The increase in FC2 net revenues in the global public health sector is because the Company began shipping units under the 2022 South Africa Tender in the current year period. Significant quarter-to-quarter variances in sales in the global public health sector 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 donor governments in the developed world. As a result, the Company may continue to experience challenges for revenue from sales of FC2 in the global public health sector.

Cost of sales increased to $2.5 million in the three months ended March 31, 2023 from $1.9 million in the three months ended March 31, 2022 due to an increase in unit sales.

Gross profit decreased to $4.1 million in the three months ended March 31, 2023 from $11.2 million in the three months ended March 31, 2022. Gross profit margin for the fiscal 2023 period was 62% of net revenues, compared to 86% of net revenues for the fiscal 2022 period. The decrease in the 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.

Research and development expenses increased to $22.8 million in the three months ended March 31, 2023 from $15.5 million in the same period in fiscal 2022. The increase is primarily due to increased costs associated with the multiple in-process research and development projects, mainly for preparations for the Phase 3 COVID-19 confirmatory study and costs related to the ongoing and planned enobosarm studies, and increased personnel costs, resulting from increased headcount and an increase in the fair value of share-based compensation.

Selling, general and administrative expenses increased to $12.8 million in the three months ended March 31, 2023 from $7.4 million in the three months ended March 31, 2022. The increase is due primarily to commercialization costs of $3.7 million related to the Company's preparations for the potential launch of sabizabulin for COVID-19 incurred in the fiscal 2023 period prior to the FDA's decision on the Company's EUA application and an increase in share-based compensation costs to $2.9 million from $1.6 million, resulting from increased headcount and an increase in the fair value of stock options granted, which was $9.10 per share weighted average for options granted in the six months ended March 31, 2023 compared to $5.40 per share weighted average for options granted in the six months ended March 31, 2022.

The Company recorded a provision for credit losses of $3.9 million during the quarter ended March 31, 2023 related to the total amount of receivables due from The Pill Club due to uncertainty related to their financial condition. There was no provision for credit losses recorded in fiscal 2022.

During the quarter ended March 31, 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.

Interest expense, which is related to accretion of the liability for the Residual Royalty Agreement, was $0.7 million in the three months ended March 31, 2023, compared with $1.2 million in the three months ended March 31, 2022. The decrease relates to a decrease in actual and projected FC2 sales.

A gain associated with the change in fair value of the embedded derivative related to the Residual Royalty Agreement was $1.2 million in the three months ended March 31, 2023, compared to a loss of $1.3 million in the three months ended March 31, 2022. The liability associated with embedded derivative represents the fair value of the change of control provisions in the Residual Royalty Agreement. The decrease in the fair value of the embedded derivative in the current year period is due to a decrease in projected FC2 net revenues in future periods and a change in the estimated change of control dates. See Note 3 and Note 8 to the financial statements included in this report for additional information.

Income tax benefit in the second quarter of fiscal 2023 was $67,000, compared to income tax benefit of $27,000 in the second quarter of fiscal 2022. The U.S. continues to have a full valuation allowance on its deferred tax assets; therefore, activity in the U.S. has no effect on income tax expense or benefit.

SIX MONTHS ENDED MARCH 31, 2023 COMPARED TO SIX MONTHS ENDED MARCH 31, 2022

The Company generated net revenues of $9.1 million and net loss of $75.6 million, or $(0.94) per basic and diluted common share, for the six months ended March 31, 2023, compared to net revenues of $27.2 million and net loss of $20.6 million, or $(0.26) per basic and diluted common share, for the six months ended March 31, 2022. Net revenues decreased 67% compared to the prior period.

Most of the Company's net revenues for the six months ended March 31, 2023 and 2022 were derived from sales of FC2 in the U.S. prescription channel and global public health sector. There was a decrease in the FC2 average sales price per unit of 62%. The principal factor for the decrease in the FC2 average sales price per unit compared to prior period was the change in the sales mix with the U.S. prescription channel representing 47% of total FC2 net revenues in the current year period compared to 85% in the prior year period and the global public health sector representing 53% of total FC2 net revenues in the current year period compared to 15% in the prior year period.

The decrease in FC2 net revenues in the U.S. prescription channel is primarily due to lower volume from telemedicine customers as a result of on-going business challenges, which based on discussions with such customers, we understand included changes in strategy, the impact of rebranding, and reductions in marketing spending and which resulted in a slowdown in orders during recent quarters. Specifically, net revenues from The Pill Club were $3.9 million in the current year period compared to $10.8 million in the prior year period. The Company is uncertain whether sales to The Pill Club will continue in the future, due to The Pill Club's Chapter 11 bankruptcy filing. We have recorded a provision for credit losses for the net revenues during the current year period, which were included in the gross accounts receivable balance at March 31, 2023. Net revenues from another prescription channel customer were $11.3 million in the prior year period and zero in the current year period, which based on customer discussions, we understand to be due to inventory management after a reduction in orders from its most significant customer, which resulted in it ceasing orders. We are working to increase net revenues in future periods based on growing awareness and demand through increased FC2 marketing efforts, through our telehealth platform, and through discussions with potential new distribution partners in the telehealth sector. We have also begun to see an increase in U.S. public sector revenues through two new agreements recently executed.

The increase in FC2 net revenues in the global public health sector is because the Company began shipping units under the 2022 South Africa Tender in the current year period. Significant quarter-to-quarter variances in sales in the global public health sector 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 donor governments in the developed world. As a result, the Company may continue to experience challenges for revenue from sales of FC2 in the global public health sector.

Cost of sales increased to $4.3 million in the six months ended March 31, 2023 from $4.1 million in the six months ended March 31, 2022 due to reduced production volume as a result of lower sales volume, which results in a higher cost per unit sold.

Gross profit decreased to $4.8 million in the six months ended March 31, 2023 from $23.1 million in the six months ended March 31, 2022. Gross profit margin for the fiscal 2023 period was 53% of net revenues, compared to 85% of net revenues for the fiscal 2022 period. The decrease in the 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 as a result of lower sales volume, which results in a higher cost per unit.

Research and development expenses increased to $41.6 million in the six months ended March 31, 2023 from $25.6 million in the same period in fiscal 2022. The increase is primarily due to increased costs associated with the multiple in-process research and development projects, mainly for preparations for the Phase 3 COVID-19 confirmatory study, pre-launch inventory costs of $12.4 million prior to the FDA's decision on the Company's EUA application, and costs related to the ongoing and planned enobosarm studies, and increased personnel costs, resulting from increased headcount and an increase in the fair value of share-based compensation.

Selling, general and administrative expenses increased to $30.4 million in the six months ended March 31, 2023 from $14.1 million in the six months ended March 31, 2022. The increase is due primarily to commercialization costs of $12.1 million related to preparations for the potential launch of sabizabulin for COVID-19 incurred in the fiscal 2023 period prior to the FDA's decision on the Company's EUA application, and an increase in share-based compensation costs to $6.5 million from $3.0 million, resulting from increased headcount and an increase in the fair value of stock options granted, which was $9.10 per share weighted average for options granted in the six months ended March 31, 2023 compared to $5.40 per share weighted average for options granted in the six months ended March 31, 2022.

The Company recorded a provision for credit losses of $3.9 million during the quarter ended March 31, 2023 related to the total amount of receivables due from The Pill Club due to uncertainty related to their financial condition. There was no provision for credit losses recorded in fiscal 2022.

During the quarter ended March 31, 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.

Interest expense, which is related to accretion of the liability for the Residual Royalty Agreement, was $1.6 million in the six months ended March 31, 2023, compared with $2.4 million in the six months ended March 31, 2022. The decrease relates to a decrease in actual and projected FC2 sales.

A gain associated with the change in fair value of the embedded derivatives related to the Residual Royalty Agreement was $0.5 million in the six months ended March 31, 2023, compared to a loss of $1.4 million in the six months ended March 31, 2022. The liability associated with embedded derivative represents the fair value of the change of control provisions in the Residual Royalty Agreement. The decrease in the fair value of the embedded derivative in the current year period is due to a decrease in projected FC2 net revenues in future periods and a change in the estimated change of control dates. See Note 3 and Note 8 to the financial statements included in this report for additional information.

Income tax benefit in the first half of fiscal 2023 was $0.1 million, compared to income tax expense of $87,000 in the first half of fiscal 2022. The change is due to a tax benefit recorded in the current period due to a net loss recognized by our U.K. subsidiary and a benefit recorded for the elimination of deferred tax liabilities upon the impairment of the IPR&D assets, compared to a tax expense in the prior year period due to net income recognized by our U.K. and Malaysia subsidiaries. The U.S. continues to have a full valuation allowance on its deferred tax assets; therefore, activity in the U.S. has no effect on income tax expense or benefit.

Liquidity and Sources of Capital

Liquidity

Our cash and cash equivalents on hand at March 31, 2023 was $23.5 million, compared to $80.2 million at September 30, 2022. At March 31, 2023, the Company had working capital of $4.0 million and stockholders' equity of $16.7 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, and a decrease in prepaid research and development costs.

We anticipate that we will continue to consume cash as we develop and commercialize our drug candidates. Because of the numerous risks and uncertainties associated with the development of pharmaceutical products, we are unable to estimate the exact amounts of capital outlays and operating expenditures necessary to fund development of our drug candidates and obtain regulatory approvals. Our future capital requirements will depend on many factors. See Part I, Item 1A, "Risk Factors - Risks Related to Our Financial Position and Need for Capital" in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2022 for a description of certain risks that will affect our future capital requirements.

The Company believes its current cash position, cash expected to be generated from sales of FC2, cash to be received from the sale of ENTADFI (see note 15 to the financial statements included in this report) and its ability to secure equity financing or other financing alternatives will be adequate to fund planned operations of the Company for the next 12 months. To the extent the Company may need additional capital for its operations or the conditions for raising capital are favorable, the Company may access financing alternatives that may include debt financing, common stock offerings, or financing involving convertible debt or other equity-linked securities and may include financings under the Company's current effective shelf registration statements on Form S-3 (File No. 333-239493 and File No. 333-270606) or under a new registration statement.

Operating activities

Operating activities used cash of $60.1 million in the six months ended March 31, 2023. Cash used in operating activities included net loss of $75.6 million, adjustments to reconcile net loss to net cash used in operating activities totaling an increase of $17.8 million and changes in operating assets and liabilities resulting in a decrease of $2.2 million. Adjustments to net loss primarily consisted of $8.7 million of share-based compensation, $3.9 million for impairment of intangible assets, $3.9 million provision for credit losses, and interest expense in excess of interest paid of $1.3 million. The decrease in cash from changes in operating assets and liabilities included an increase in accounts payable of $3.9 million and a decrease in accounts payable of $4.8 million, partially offset by a decrease in prepaid expenses and other current assets of $4.5 million and an increase in accrued expenses and other current liabilities of $1.4 million.

Operating activities used cash of $12.6 million in the six months ended March 31, 2022. Cash used in operating activities included net loss of $20.6 million, adjustments to reconcile net loss to net cash used in operating activities totaling an increase of $6.7 million and changes in operating assets and liabilities resulting in an increase of $1.3 million. Adjustments to net loss primarily consisted of $4.0 million of share-based compensation, interest expense in excess of interest paid of $0.9 million, and $1.4 million for the change in fair value of derivative liabilities. The increase in cash from changes in operating assets and liabilities included an increase in accounts payable of $4.1 million and an increase in accrued expenses and other current liabilities of $0.4 million, partially offset by an increase in accounts receivable of $0.8 million, an increase in inventory of $0.9 million, and an increase in prepaid expenses and other current assets of $1.4 million.

Investing activities

Net cash used in investing activities was $0.4 million in the six months ended March 31, 2023, and consisted of capital expenditures primarily at our Malaysia location.

Net cash provided by investing activities was $2.0 million in the six months ended March 31, 2022, and consisted of $2.5 million collected on notes receivable from the sale of the Company's PREBOOST® business, partially offset by $0.5 million associated with capital expenditures primarily at our U.S. location.

Financing activities

Net cash provided by financing activities in the six months ended March 31, 2023 was $3.8 million, and primarily consisted of proceeds from the Premium Finance Agreement of $1.4 million, which were used to finance the Company's directors and officers liability insurance premium, offset by payments on such agreement of $0.5 million, proceeds from sale of shares under the common stock purchase agreement with Aspire Capital (see discussion below) and proceeds from stock option exercises of $0.3 million.

Net cash provided by financing activities in the six months ended March 31, 2022 was $0.2 million and primarily consisted of proceeds from stock option exercises of $0.3 million.

Sources of Capital

SWK Credit Agreement

On March 5, 2018, the Company entered into a Credit Agreement (as amended, the "Credit Agreement") with the financial institutions party thereto from time to time (the "Lenders") and SWK Funding LLC, as agent for the Lenders (the "Agent"), for a synthetic royalty financing transaction. On and subject to the terms of the Credit Agreement, the Lenders provided the Company with a term loan of $10.0 million, which was advanced to the Company on the date of the Credit Agreement. 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 $0.3 million and $1.5 million during the six months ended March 31, 2023 and 2022, respectively. The Company currently estimates the aggregate amount of quarterly revenue-based payments payable during the 12-month period subsequent to March 31, 2023 will be approximately $1.4 million under the Residual Royalty Agreement.

Aspire Capital Purchase Agreement

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

During the six months ended March 31, 2023, we sold 1,920,013 shares of common stock to Aspire Capital under the 2020 Purchase Agreement, resulting in proceeds to the Company of $2.6 million. Since inception of the 2020 Purchase Agreement through March 31, 2023, we sold 3,564,750 shares of common stock to Aspire Capital resulting in proceeds to the Company of $7.6 million. Subsequent to March 31, 2023, we sold 859,700 shares of common stock to Aspire Capital under the 2020 Purchase Agreement, resulting in proceeds to the Company of $0.8 million. As of May 9, 2023, the amount remaining under the 2020 Purchase Agreement was $15.5 million, which is registered under the Company's shelf registration statement on Form S-3 (File No. 333-239493).

Stock Purchase Agreement

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. The shares of common stock issued to FGI pursuant to the Stock Purchase Agreement were not registered under the Securities Act. The Company is obligated to file a registration statement under the Securities Act within 45 days after the date of the Stock Purchase Agreement to register the resale of the shares of common stock issued to FGI.

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 the Company has the right, but not the obligation, to sell to Lincoln Park up to $100.0 million of 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. The capacity 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).

Fair Value Measurements

As of March 31, 2023 and September 30, 2022, the Company's financial liabilities measured at fair value on a recurring basis, which consisted of embedded derivatives, represent the fair value of the change of control provision in the Residual Royalty Agreement. See Note 8 to the financial statements included in this report for additional information.

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 for additional information.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The Company's exposure to market risk was discussed in the “Quantitative and Qualitative Disclosures About Market Risk” section contained in the Company’s Annual Report on Form 10-K for the fiscal year ended September 30, 2022. There have been no material changes to such exposures since September 30, 2022.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, 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 effective. It should be noted that in designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. The Company has designed its disclosure controls and procedures to reach a level of reasonable assurance of achieving desired control objectives and, based on the evaluation described above, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective at reaching that level of reasonable assurance.

Changes in Internal Control over Financial Reporting

There were no changes in the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended) during the Company's most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

For a description of our material pending legal proceedings, see Legal Proceedings in Note 12, Contingent Liabilities, to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q and incorporated herein by reference.

Item 1A. Risk Factors

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the risks and uncertainties relating to the Company's business disclosed in Part I, Item 1A, "Risk Factors," in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2022. There have been no material changes from the risk factors previously disclosed in Part I, Item 1A, "Risk Factors," in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2022, except for the following additional risk factors relating to the Company's refocused research and development strategy and other business matters. Additional risks that we do not yet know of or that we currently think are immaterial may also impair our business operations.

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

We will need large amounts of capital to support our development and commercialization efforts for our drug candidates, including the Phase 3 COVID-19 confirmatory study for certain COVID-19 patients. If we are unable to secure sufficient capital to fund our operations, we will not be able to continue these efforts and we might have to enter into strategic collaborations that could require us to share commercial rights to one or more of our drug candidates with third parties in ways that we currently do not intend or on terms that may not be favorable to us. Our ability to raise capital through equity financing may be limited by the number of authorized shares of our common stock, which is currently 154 million shares, and as of May 9, 2023, we had 39.6 million authorized but unissued shares of common stock (after deducting the number of shares issuable upon exercise, conversion or exchange of our outstanding securities or otherwise reserved for future issuance). In order to raise significant additional amounts from equity financing, we may need to seek stockholder approval to amend our Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock, and any such amendment would require the approval of the holders of at least two-thirds of the outstanding shares of our common stock. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms and not enter into strategic collaborations, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

Our ability to obtain an EUA from the FDA to market sabizabulin as a potential treatment for certain COVID-19 patients will depend on the federal government continuing to issue EUAs for treatments relating to COVID-19 in the United States.

We may submit a new EUA application sabizabulin as a potential treatment for certain COVID-19 patients based on the results of the Phase 3 COVID-19 confirmatory study for certain COVID-19 patients we plan to conduct. In addition to the risks relating to the EUA process disclosed in the risk factors in our annual report on Form 10-K for the year ended September 30, 2022, we are subject to risks relating to whether COVID-19 continues to be treated as a public health emergency supporting the issuance of EUAs for COVID-19 treatments in the United States. On January 30, 2023, the White House Office of Management and Budget announced that the Biden administration plans to terminate the COVID-19 national and public health emergencies on May 11, 2023 (the "May 11 Termination"). The FDA announced on January 31, 2023, that the May 11 Termination would not impact the FDA's ability to authorize new treatments for emergency use, that existing EUAs would remain in effect and that it may continue to issue new EUAs when criteria for issuance are met. However, if the FDA were to determine to cease issuing EUAs for COVID-19 treatments, whether as a result of the May 11 Termination or otherwise, we may not be able to obtain an EUA for sabizabulin as a potential treatment for certain COVID-19 patients and in that case we would not be able to market sabizabulin as a potential treatment for certain COVID-19 patients in the United Statues unless it was approved by the FDA following the submission of a new drug application.

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, may not return to past levels due to risks that include potential operational challenges of The Pill Club stemming from its settlement with the California Attorney General, potential issues with The Pill Club's business and financial condition as a result of the effects of such settlement, The Pill Club's recent Chapter 11 bankruptcy filing, or other reasons, and the termination of our contract with The Pill Club due to recent payment and shipment acceptance breaches by 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 dedicated direct to patient telemedicine and pharmacy services portal/platform. 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 are subject to risks relating to the concentration of accounts receivable with The Pill Club.

The Pill Club is one of our largest customers, accounting for 44% of our net revenues in fiscal 2022 and 43% of our net revenues in fiscal 2021. We have a concentration of accounts receivable at The Pill Club, with $3.9 million of accounts receivable as of March 31, 2023, including $1.3 million of accounts receivable that are past due. Veru had been making significant efforts to obtain clarity from The Pill Club on when this payment would be made. On March 29, 2023, The Pill Club refused delivery of a shipment of FC2 for which it had previously submitted a binding purchase order and which it was contractually bound to accept. On March 30, 2023, Veru provided written notice to The Pill Club that Veru believed The Pill Club was in default for the past due payment and the refused shipment. These breaches remained uncured 10 calendar days after the default notice and accordingly, Veru's contract with The Pill Club for the sale of FC2 automatically terminated by its terms. On April 18, 2023, The Pill Club filed for Chapter 11 bankruptcy.

These adverse changes in our relationship with The Pill Club, including a termination of our contract with The Pill Club, and in The Pill Club's business and financial condition following its settlement with the California Attorney General and its Chapter 11 bankruptcy filing, could result in a delay in payment of, or an inability to pay, its outstanding accounts receivable balance or an inability or unwillingness to place new orders for FC2, any of which could have a material adverse effect on our cash flows and liquidity.

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 recently indicated that it intends to close the facility where our specialty grade of nitrile is currently manufactured at the end of our current fiscal 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, while the supplier has stated that it will assist in providing continuity of supply while we transfer to the alternative grade of nitrile and we have sufficient inventory in the U.S. to cover all the expected demand from the U.S. prescription channel while this transfer occurs, if this transfer or change in raw material grade results in an interruption of supply of FC2, we may not have sufficient supply to fulfill orders in the global public health sector.

Item 6. Exhibits

Exhibit Number	Description
2.1	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).
3.1	Amended and Restated Articles of Incorporation (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 the Amended and Restated Articles of Incorporation of the Company changing the corporate name to Veru Inc. and increasing the number of authorized shares of common stock to 77,000,000 shares (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on August 1, 2017).
3.8	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 154,000,000 shares (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on March 29, 2019).
3.9	Amended and Restated By-Laws (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on May 4, 2018).
4.1	Amended and Restated Articles of Incorporation, as amended (same as Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7 and 3.8).
4.2	Articles II, VII and XI of the Amended and Restated By-Laws (included in Exhibit 3.9).
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *

32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002). *, **
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, formatted in iXBRL (Inline Extensible Business Reporting Language): (1) the Unaudited Condensed Consolidated Balance Sheets, (2) the Unaudited Condensed Consolidated Statements of Operations, (3) the Unaudited Condensed Consolidated Statements of Stockholders' Equity, (4) the Unaudited Condensed Consolidated Statements of Cash Flows and (5) the Notes to the Unaudited Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as iXBRL and contained in Exhibit 101).

* 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.

SIGNATURES

Pursuant to the requirements 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.

VERU INC.

DATE: May 11, 2023

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

DATE: May 11, 2023

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

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 quarterly report on Form 10-Q 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: May 11, 2023

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

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 quarterly report on Form 10-Q 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: May 11, 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 Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2023 fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934 and information contained in that Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 11, 2023

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

Date: May 11, 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.