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

FORM 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended December 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 x 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 x No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer x	Smaller reporting companyx
	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 x

As of March 29, 2024, the registrant had 146,381,186 shares of $0.01 par value common stock outstanding.

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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 enobosarm initially as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a glucagon-like peptide-1 receptor agonist (“GLP-1 RA”) who are at-risk for developing muscle atrophy and muscle weakness, enobosarm for certain breast cancer patients, and sabizabulin for viral-induced acute respiratory distress syndrome (“ARDS”) indications, the outlook for growth in our FC2 business through telehealth customers, our portal and the global public health sector, future financial and operating results, plans, objectives, expectations and intentions, costs and expenses, royalty payments, outcome of litigation and other contingencies, financial condition, results of operations, liquidity, cost savings, our ability to continue as a going concern, future ordering patterns of our customers, objectives of management, business strategies, clinical trial timing, plans and results, the achievement of clinical and commercial milestones, the advancement of our technologies and our products and drug candidates, and other statements that are not historical facts. 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 (“EUA”), or commercialization in the United States or in any foreign country;
- potential delays in the timing of any submission to the U.S. Food and Drug Administration (the “FDA”) or any other regulatory authority around the world and potential delays in, or failure to obtain, from any such regulatory authority approval of products under development, including the risk of a delay or failure in reaching agreement with the FDA on the design of any clinical trial, including any post-approval or post-authorization study, or in obtaining authorization to commence a clinical trial or commercialize a product candidate in the U.S. or elsewhere;
- potential delays in the timing of approval by the FDA or any other regulatory authority of the release of manufactured lots of approved products;
- clinical trial results supporting any potential regulatory approval or authorization of any of our products, including enobosarm initially as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness, enobosarm for breast cancer, and sabizabulin for the treatment of viral-induced ARDS, may not be replicated in clinical practice;
- clinical results or early data from clinical trials may not be replicated or continue to occur in additional trials or may not otherwise support further development in the specified product candidate or at all;
- risks related to our ability to obtain sufficient financing on acceptable terms when needed to fund product development and our operations and to enable us to continue as a going concern;
- we are currently not eligible to use the Form S-3 registration statement, which could impair our capital-raising activities;
- we need to secure significant funding to advance our drug candidates, including government grants, pharmaceutical company partnerships, or similar external sources to advance the development of sabizabulin as a treatment for viral-induced ARDS;
- we may not receive any additional payments from Onconetix, Inc. formerly known as Blue Water Vaccines Inc. (“BWV”) in connection with the sale of our ENTADFI assets and may not receive any value for the shares of Series A Convertible Preferred Stock of BWV we hold;

- risks related to the development of our product portfolio, including clinical trials, regulatory approvals and time and cost to bring any of our product candidates to market, and risks related to efforts of our collaborators;
- product demand and market acceptance of our commercial products and our products in development, if approved;
- risks related to our ability to obtain insurance reimbursement from private payors or government payors, including Medicare and Medicaid, and similar risks relating to market or political acceptance of any potential or actual pricing for any of our product candidates that, if approved, we attempt to commercialize;
- some of our products are in development and we may fail to successfully commercialize such products;
- risks related to any potential new telehealth platform developed or used by us in commercializing our current product or potential future products, including potential regulatory uncertainty around such platforms and market awareness and acceptance of any telehealth platform we develop or use;
- risks related to our ability to increase sales of FC2 after significant declines in recent periods due to telehealth industry consolidation and the bankruptcy of large telehealth customers;
- risks related to intellectual property, including the uncertainty of obtaining intellectual property protections and in enforcing them, the possibility of infringing a third party's intellectual property, and licensing risks;
- competition from existing and new competitors including the potential for reduced sales, pressure on pricing and increased spending on marketing;
- risks related to compliance and regulatory matters, including costs and delays resulting from extensive government regulation and reimbursement and coverage under healthcare insurance and regulation as well as potential healthcare reform measures;
- the risk that we will be affected by regulatory and legal developments, including a reclassification of products or repeal or modification of part or all of the Patient Protection and Affordable Care Act;
- risks inherent in doing business on an international level, including currency risks, regulatory requirements, political risks, export restrictions and other trade barriers;
- the disruption of production at our manufacturing facilities or facilities of third parties on which we rely and/or of our ability to supply product due to raw material shortages, labor shortages, manufacturing partner business changes, physical damage to our or third parties' facilities, product testing, transportation delays or regulatory or other governmental actions, and the duration and impact of any such disruptions;
- our reliance on major customers and risks related to delays in, or failure to make, payment of accounts receivable by major customers;
- risks from rising costs of raw materials and our ability to pass along increased costs to our customers;
- risks related to our growth strategy;
- our continued ability to attract and retain highly skilled and qualified personnel;
- risks relating to the restatement of our unaudited condensed consolidated financial statements as of and for the three and nine months ended June 30, 2023 and the restatement of our audited consolidated financial statements as of and for the years ended September 30, 2023 and 2022;
- the costs and other effects of litigation, governmental investigations, legal and administrative cases and proceedings, settlements and investigations;
- our ability to remediate the material weaknesses in our internal control over financial reporting that we have identified and the risk that we identify additional deficiencies in our internal control over financial reporting or otherwise fail to maintain an effective system of internal controls;
- government contracting risks, including the appropriations process and funding priorities, potential bureaucratic delays in awarding contracts, process errors, politics or other pressures, and the risk that government tenders and contracts may be subject to cancellation, delay, restructuring or substantial delayed payments;
- a governmental tender award indicates acceptance of the bidder's price rather than an order or guarantee of the purchase of any minimum number of units, and as a result government ministries or other public health sector customers may order and purchase fewer units than the full maximum tender amount;
- our ability to identify, successfully negotiate and complete suitable acquisitions, out-licensing transactions, in-licensing transactions or other strategic initiatives and to realize any potential benefits of such transactions or initiatives; and
- our ability to successfully integrate acquired businesses, technologies or products.

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, 2023, as amended by Amendment No. 1 to the Company’s Annual Report on Form 10-K/A as filed with the Securities and Exchange Commission on April 1, 2024 (references in this report to the Company’s Annual Report on Form 10-K for the fiscal year ended September 30, 2023 include such Amendment No. 1). 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

	December 31, 2023	September 30, 2023 (Restated)
Assets		
Current assets:		
Cash and cash equivalents	$ 40,579,059	$ 9,625,494
Accounts receivable, net	2,382,937	4,506,508
Inventories, net	6,912,203	6,697,117
Prepaid research and development costs	1,228,509	1,006,252
Prepaid expenses and other current assets	2,241,959	1,097,851
Total current assets	53,344,667	22,933,222
Plant and equipment, net	1,560,325	1,652,732
Operating lease right-of-use assets	4,133,726	4,332,473
Investments in equity securities	538,474	—
Deferred income taxes	12,788,705	12,707,419
Goodwill	6,878,932	6,878,932
Other assets	1,322,056	1,518,313
Total assets	$ 80,566,885	$ 50,023,091
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,518,382	$ 12,931,172
Accrued compensation	2,153,893	990,609
Accrued expenses and other current liabilities	2,083,956	1,987,738
Residual royalty agreement liability, short-term portion	825,180	864,623
Operating lease liability, short-term portion	1,043,342	1,036,590
Total current liabilities	16,624,753	17,810,732
Residual royalty agreement liability, long-term portion	8,883,432	8,870,136
Operating lease liability, long-term portion	3,456,428	3,634,114
Other liabilities	—	29,948
Total liabilities	28,964,613	30,344,930
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock; no shares issued and outstanding at December 31, 2023 and September 30, 2023	—	—
Common stock, par value $0.01 per share; 308,000,000 shares authorized, 148,564,890 and 93,966,402 shares issued and 146,381,186 and 91,782,698 shares outstanding at December 31, 2023 and September 30, 2023, respectively	1,485,649	939,664
Additional paid-in-capital	323,548,937	283,894,830
Accumulated other comprehensive loss	(581,519)	(581,519)
Accumulated deficit	(265,044,190)	(256,768,209)
Treasury stock, 2,183,704 shares, at cost	(7,806,605)	(7,806,605)
Total stockholders' equity	51,602,272	19,678,161
Total liabilities and stockholders' equity	$ 80,566,885	$ 50,023,091

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended December 31,	
	2023	2022 (Restated)
Net revenues	$ 2,140,726	$ 2,507,794
Cost of sales	990,274	1,805,739
Gross profit	1,150,452	702,055
Operating expenses:		
Research and development	1,650,050	20,611,127
Selling, general and administrative	8,301,431	17,545,865
Total operating expenses	9,951,481	38,156,992
Gain on sale of ENTADFI® assets	918,372	—
Operating loss	(7,882,657)	(37,454,937)
Non-operating income (expenses):		
Interest expense	(164,957)	(873,230)
Change in fair value of derivative liabilities	(2,000)	(670,000)
Change in fair value of equity securities	(379,898)	—
Other income, net	81,092	220,932
Total non-operating expenses	(465,763)	(1,322,298)
Loss before income taxes	(8,348,420)	(38,777,235)
Income tax benefit	(72,439)	(68,278)
Net loss	$ (8,275,981)	$ (38,708,957)
Net loss per basic and diluted common shares outstanding	$ (0.08)	$ (0.48)
Basic and diluted weighted average common shares outstanding	100,601,946	80,558,670

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 (Restated)	Treasury Stock, at Cost	Total (Restated)
	Shares	Amount					
Balance at September 30, 2023 (Restated)	93,966,402	$ 939,664	$283,894,830	$ (581,519)	$(256,768,209)	$ (7,806,605)	$ 19,678,161
Share-based compensation	—	—	3,406,949	—	—	—	3,406,949
Issuance of shares pursuant to Jefferies Sales Agreement, net of commissions and costs	90,156	902	65,649				66,551
Shares issued in connection with common stock purchase agreement	1,800,000	18,000	1,643,490				1,661,490
Amortization of deferred costs			(164,313)				(164,313)
Shares issued in connection with public offering of common stock, net of fees and costs	52,708,332	527,083	34,702,332				35,229,415
Net loss	—	—	—	—	(8,275,981)	—	(8,275,981)
Balance at December 31, 2023	148,564,890	$ 1,485,649	$323,548,937	$ (581,519)	$(265,044,190)	$ (7,806,605)	$ 51,602,272
Balance at September 30, 2022 (Restated)	82,692,598	$ 826,926	$253,974,032	$ (581,519)	$(163,615,517)	$ (7,806,605)	$ 82,797,317
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 (Restated)	—	—	—	—	(38,708,957)	—	(38,708,957)
Balance at December 31, 2022 (Restated)	82,806,832	$ 828,068	$259,075,291	$ (581,519)	$(202,324,474)	$ (7,806,605)	$ 49,190,761

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Three Months Ended December 31,	
	2023	2022 (Restated)
OPERATING ACTIVITIES		
Net loss	$ (8,275,981)	$ (38,708,957)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	72,129	63,218
Noncash change in right-of-use assets	198,747	186,132
Noncash interest expense, net of interest paid	(28,147)	743,919
Gain on sale of ENTADFI® assets	(918,372)	—
Share-based compensation	3,406,949	4,845,269
Deferred income taxes	(81,286)	(103,819)
Change in fair value of derivative liabilities	2,000	670,000
Change in fair value of equity securities	379,898	—
Other	12,958	2,921
Changes in current assets and liabilities:		
Decrease in accounts receivable	2,123,571	400,585
Increase in inventories	(201,814)	(116,604)
(Increase) decrease in prepaid expenses and other assets	(1,340,373)	656,817
Decrease in accounts payable	(2,495,250)	(11,436,432)
Increase in accrued expenses and other current liabilities	1,295,516	8,367,220
Decrease in operating lease liabilities	(170,934)	(104,297)
Net cash used in operating activities	(6,020,389)	(34,534,028)
INVESTING ACTIVITIES		
Capital expenditures	—	(285,565)
Net cash used in investing activities	—	(285,565)
FINANCING ACTIVITIES		
Proceeds from stock option exercises	—	257,132
Proceeds from sale of shares under common stock purchase agreement	1,661,490	—
Proceeds from sale of shares in public offering, net of commissions and costs	35,378,888	—
Proceeds from sale of shares pursuant to Jefferies Sales Agreement, net of commissions	66,551	—
Proceeds from premium finance agreement	—	1,425,174
Installment payments on premium finance agreement	(132,975)	(126,201)
Net cash provided by financing activities	36,973,954	1,556,105
Net increase (decrease) in cash	30,953,565	(33,263,488)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	9,625,494	80,190,675
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 40,579,059	$ 46,927,187
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 193,104	$ 129,311
Schedule of non-cash investing and financing activities:		
Equity securities received for sale of ENTADFI® assets	$ 918,372	$ —
Costs related to public offering in accounts payable or accrued expenses and other current liabilities	$ 149,473	$ —
Amortization of deferred costs related to common stock purchase agreement	$ 164,313	$ —

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 (the "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, 2023. The accompanying condensed consolidated balance sheet as of September 30, 2023 has been derived from our audited financial statements. The unaudited condensed consolidated statements of operations and cash flows for the three months ended December 31, 2023 are not necessarily indicative of the results to be expected for any future period or for the fiscal year ending September 30, 2024.

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 metabolic diseases (obesity), oncology, and acute respiratory distress syndrome (ARDS). Our drug development program includes enobosarm, a selective androgen receptor modulator, for preferential loss of fat while preventing the loss of muscle and bone, in combination with weight loss drugs, and for the management of advanced breast cancer and sabizabulin, a microtubule disruptor, for the treatment of hospitalized patients with viral induced ARDS. The Company also has the FC2 Female Condom/FC2 Internal Condom® (FC2), an FDA-approved commercial product for the dual protection against unplanned pregnancy and sexually transmitted infections. The Company had ENTADFI® (finasteride and tadalafil) capsules for oral use (ENTADFI), a new treatment for benign prostatic hyperplasia that was approved by the FDA in December 2021. We sold substantially all of the assets related to ENTADFI on April 19, 2023. See Note 15 for additional information. Most of the Company's net revenues during the three months ended December 31, 2023 and 2022 were derived from sales of FC2.

Restatement: In connection with the preparation of its unaudited condensed consolidated financial statements for the three months ended December 31, 2023, the Company identified errors related to the accounting for research and development expenses associated with the Company's projects with third-party service providers. The Company inaccurately estimated the work completed by the third-party service providers. Refer to Amendment No. 1 to the Company's Annual Report on Form 10-K/A for the fiscal year ended December 31, 2023, filed with the SEC on April 1, 2024 for more information regarding the restatement of the consolidated financial statements for the fiscal years ended September 30, 2023 and 2022. Due to the inaccurate estimation of the work completed by third-party service providers, the Company understated its operating expenses for research and development for the three months ended December 31, 2022. As a result, this report reflects a restatement of the Company's interim financial statements for the three months ended December 31, 2022.

A summary of the impact of the error on the unaudited condensed consolidated balance sheet as of December 31, 2022 is as follows:

	As of December 31, 2022		
	As Reported	Adjustment	As Restated
Assets			
Prepaid research and development costs	$ 10,416,934	$ (2,508,816)	$ 7,908,118
Total current assets	$ 73,008,645	$ (2,508,816)	$ 70,499,829
Total assets	$ 103,782,452	$ (2,508,816)	$ 101,273,636
Liabilities and Stockholders' Equity			
Accrued research and development costs	$ 12,678,176	$ (2,600,719)	$ 10,077,457
Total current liabilities	$ 40,080,447	$ (2,600,719)	$ 37,479,728
Total liabilities	$ 54,683,594	$ (2,600,719)	$ 52,082,875
Accumulated deficit	$ (202,416,377)	$ 91,903	$ (202,324,474)
Total stockholders' equity	$ 49,098,858	$ 91,903	$ 49,190,761
Total liabilities and stockholders' equity	$ 103,782,452	$ (2,508,816)	$ 101,273,636

A summary of the error of the impact of the error on the unaudited condensed consolidated statement of operations for the three months ended December 31, 2022 is as follows:

	Three Months Ended December 31, 2022		
	As Reported	Adjustment	As Restated
Research and development	$ 18,744,349	$ 1,866,778	$ 20,611,127
Total operating expenses	$ 36,290,214	$ 1,866,778	$ 38,156,992
Operating loss	$ (35,588,159)	$ (1,866,778)	$ (37,454,937)
Loss before income taxes	$ (36,910,457)	$ (1,866,778)	$ (38,777,235)
Net loss	$ (36,842,179)	$ (1,866,778)	$ (38,708,957)
Net loss per basic and diluted common shares outstanding	$ (0.46)	$ (0.02)	$ (0.48)

With respect to the unaudited condensed consolidated statement of cash flows, all adjustments are to line items within operating cash flows and there was no impact to the subtotal of operating, investing, or financing cash flows for each period. A summary of the impact of the error on the unaudited condensed consolidated statement of cash flows for the three months ended December 31, 2022 is as follows:

	Three Months Ended December 31, 2022		
	As Reported	Adjustment	As Restated
OPERATING ACTIVITIES			
Net loss	$ (36,842,179)	$ (1,866,778)	$ (38,708,957)
(Increase) decrease in prepaid expenses and other assets	$ (1,084,432)	$ 1,741,249	$ 656,817
Increase in accrued expenses and other current liabilities	$ 8,241,691	$ 125,529	$ 8,367,220

Investments in equity securities: Investments in equity securities consist of 3,000 shares of Series A Convertible Preferred Stock (the "BWV Preferred Stock") of Onconetix, Inc., formerly known as Blue Water Vaccines Inc. ("BWV"). The Company has elected to measure the BWV Preferred Stock using the fair value option, as provided for by FASB Accounting Standards Codification (ASC) 825, *Financial Instruments*, which allows entities to make an irrevocable election of fair value as the initial and subsequent measurement attribute for certain eligible financial assets and liabilities. Under the fair value option, related gains and losses on the financial instrument will be reflected in non-operating income (expenses) in the Company's statements of operations. The decision to elect the fair value option is determined on an instrument-by-instrument basis and must be applied to an entire instrument and is irrevocable once elected. Pursuant to this guidance, the carrying value will be adjusted to estimated fair value at the end of each quarter.

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 months ended December 31, 2023 and 2022, comprehensive loss is equivalent to the reported net loss.

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

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which includes amendments that further enhance income tax disclosures, primarily through standardization and disaggregation of rate reconciliation categories and income taxes paid by jurisdiction. The amendments are effective for the Company's annual periods beginning fiscal year ended September 30, 2026, with early adoption permitted, and should be applied either prospectively or retrospectively. The Company is currently evaluating the impact of adopting this ASU on its disclosures.

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 and cash expected to be generated from sales of FC2 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 statement on Form S-3 (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 Lincoln Park Capital Fund, LLC (see Note 9) or its open market sale agreement with Jefferies LLC (see Note 9) to the extent sales may be made pursuant to such agreement. The Company's failure to timely file this Quarterly Report on Form 10-Q for the quarter ended December 31, 2023 and a Current Report on Form 8-K that was due on February 27, 2024 may impair its ability to raise capital under the Company's current effective shelf registration statement on Form S-3 (File No. 333-270606) or under a new registration statement. See Part II, Item 1A, "Risk Factors."

Note 3 – Fair Value Measurements

ASC 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 December 31, 2023 and September 30, 2023, 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 December 31, 2023 and 2022:

	Three Months Ended December 31,	
	2023	2022
Beginning balance	$ 1,331,000	$ 4,294,000
Change in fair value of derivative liabilities	2,000	670,000
Ending balance	$ 1,333,000	$ 4,964,000

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 December 31, 2023 and September 30, 2023:

Valuation Methodology	Significant Unobservable Input	December 31, 2023	September 30, 2023
Scenario-Based	Estimated change of control dates	December 2024 to December 2026	December 2024 to December 2026
	Discount rate	12.9% to 13.7%	14.1% to 15.1%
	Probability of change of control	20% to 90%	20% to 90%

The Company also has an investment in equity securities consisting of the BWV Preferred Stock. The BWV Preferred Stock was received on October 3, 2023 as a settlement of the receivable due on September 30, 2023 related to the sale of ENTADFI. See Note 15 for additional information. The Company has elected to measure the BWV Preferred Stock at fair value in accordance with ASC 825. The investment in the BWV Preferred Stock is classified within Level 3 of the fair value hierarchy because there is no market for the BWV Preferred Stock and the fair value is determined using significant unobservable inputs. The fair value of the BWV Preferred Stock has been determined using a probability-weighted bond plus call option model, which incorporates the stock price of BWV on the valuation date, expected volatility, expected term, and an applicable discount rate. The Company has also applied a discount for lack of marketability due to the fact that there is no market for the preferred stock and a probability of dissolution. The following table summarizes the significant unobservable inputs used in the bond plus call model as of October 3, 2023 (the date the shares of BWV Preferred Stock were received and initially recognized) and as of December 31, 2023:

Significant Unobservable Input	October 3, 2023	December 31, 2023
Expected volatility	79%	69%
Expected term	3.0 years	2.76 years
Discount rate	35%	35%
Probability of dissolution	60%	60%
Discount for lack of marketability	15%	13%

Estimating the fair value of the shares of BWV Preferred Stock requires the use of estimates and judgments. Changes in estimates and judgments could result in a significant change in estimate of the fair value and future adjustments. Based on discussions with representatives of BWV after December 31, 2023, the Company believes that BWV is insolvent. An increase in the probability of dissolution from the percentages set forth in the table above, in isolation, would result in a lower fair value measurement of the shares of BWV Preferred Stock.

The following table provides a reconciliation of the beginning and ending balance associated with the BWV Preferred Stock measured at fair value for the three months ended December 31, 2023, which is presented as investments in equity securities on the accompanying unaudited condensed consolidated balance sheet:

	Three Months Ended December 31,	
	2023	2022
Beginning balance	$ —	$ —
Additions	918,372	—
Change in fair value of equity securities	(379,898)	—
Ending balance	$ 538,474	$ —

Note 4 – Revenue from Contracts with Customers

The Company generates 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 for the three months ended December 31, 2022. The following table presents net revenues from these three categories:

	Three Months Ended December 31,	
	2023	2022
FC2		
Global public health sector	$ 1,507,007	$ 2,336,997
U.S. prescription channel	633,719	163,004
Total FC2	2,140,726	2,500,001
ENTADFI	—	7,793
Net revenues	$ 2,140,726	$ 2,507,794

The following table presents net revenues by geographic area:

	Three Months Ended December 31,	
	2023	2022
United States	$ 1,356,089	$ 809,377
Uganda	*	257,469
Other	784,637	1,440,948
Net revenues	$ 2,140,726	$ 2,507,794

*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 $392,000 and $105,000 at December 31, 2023 and September 30, 2023, 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 has $1.4 million of trade receivables as of December 31, 2023 due from its distributor in Brazil for sales recognized in fiscal 2021, which the Company expects to be paid within one year.

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

	December 31, 2023	September 30, 2023
Trade receivables, gross	$ 6,323,066	$ 8,445,370
Less: allowance for credit losses	(3,923,857)	(3,923,857)
Less: allowance for sales returns and payment term discounts	(16,272)	(15,005)
Accounts receivable, net	$ 2,382,937	$ 4,506,508

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

At December 31, 2023, two customers had an accounts receivable balance greater than 10% of net accounts receivable, representing 67% of net accounts receivable in the aggregate. At September 30, 2023, three customers had an accounts receivable balance greater than 10% of net accounts receivable, representing 71% of net accounts receivable in the aggregate.

For the three months ended December 31, 2023, there were three customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 66% of the Company's net revenues in the aggregate. For the three months ended December 31, 2022, there were three customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 64% of the Company's net revenues in the aggregate.

The Company maintains an allowance for 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. The Company has an allowance for credit losses of $3.9 million related to the total amount of receivables due from The Pill Club due to The Pill Club's Chapter 11 bankruptcy, filed on April 18, 2023. The Company has an open claim with The Pill Club bankruptcy estate for these receivables but it is unlikely that any amounts will be recovered.

There were no material changes in the allowance for credit losses for the three months ended December 31, 2023 and 2022. 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. prescription channel, the Company's customers include primarily telehealth providers.

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 December 31, 2023 and September 30, 2023:

	December 31, 2023	September 30, 2023
Raw material	$ 1,442,876	$ 1,854,810
Work in process	38,252	112,799
Finished goods	5,586,068	4,913,295
Inventories, gross	7,067,196	6,880,904
Less: inventory reserves	(154,993)	(183,787)
Inventories, net	$ 6,912,203	$ 6,697,117

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 December 31, 2023 and September 30, 2023:

	Estimated Useful Life	December 31, 2023	September 30, 2023
Plant and equipment:			
Manufacturing equipment	5 - 8 years	$ 2,981,891	$ 3,008,122
Office equipment, furniture and fixtures	3 - 10 years	1,471,379	1,471,870
Leasehold improvements	3 - 8 years	960,694	960,694
Total plant and equipment		5,413,964	5,440,686
Less: accumulated depreciation and amortization		(3,853,639)	(3,787,954)
Plant and equipment, net		$ 1,560,325	$ 1,652,732

Depreciation expense was approximately $66,000 and $45,000 for the three months ended December 31, 2023 and 2022, respectively. Plant and equipment included $187,000 and $214,000 at December 31, 2023 and September 30, 2023, 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 – Goodwill

The carrying amount of goodwill at December 31, 2023 and September 30, 2023 was $6.9 million. There was no change in the balance during the three months ended December 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 December 31, 2023.

Note 8 – Debt

SWK Residual Royalty Agreement

On March 5, 2018, the Company entered into a Credit Agreement (as amended, the "Credit Agreement") with the financial institutions party thereto from time to time (the "Lenders") and SWK Funding LLC, as agent for the Lenders (the "Agent"), for a synthetic royalty financing transaction. On and subject to the terms of the Credit Agreement, the Lenders provided the Company with a term loan of $10.0 million, which was advanced to the Company on the date of the Credit Agreement. The Company repaid the loan and return premium specified in the Credit Agreement in August 2021, and as a result has no further obligations under the Credit Agreement. The Agent has released its security interest in Company collateral previously pledged to secure its obligations under the Credit Agreement.

In connection with the Credit Agreement, 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 December 31, 2023 and September 30, 2023, the Residual Royalty Agreement liability consisted of the following:

	December 31, 2023	September 30, 2023
Residual royalty agreement liability, fair value at inception	$ 346,000	$ 346,000
Add: accretion of liability using effective interest rate	12,542,906	12,377,949
Less: cumulative payments	(4,513,294)	(4,320,190)
Residual royalty agreement liability, excluding embedded derivative liability	8,375,612	8,403,759
Add: embedded derivative liability at fair value (see Note 3)	1,333,000	1,331,000
Total residual royalty agreement liability	9,708,612	9,734,759
Residual royalty agreement liability, short-term portion	(825,180)	(864,623)
Residual royalty agreement liability, long-term portion	$ 8,883,432	$ 8,870,136

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.

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 was $0.1 million as of September 30, 2023 and was included in accrued expenses and other current liabilities on the accompanying unaudited condensed consolidated balance sheet. The last payment was made in October 2023 and there is no balance outstanding as of December 31, 2023.

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 December 31, 2023 and September 30, 2023. 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 December 31, 2023 and September 30, 2023, and there was no activity during the three months ended December 31, 2023 and 2022.

Shelf Registration Statement

In March 2023, the Company filed a shelf registration statement on Form S-3 (File No. 333-270606) with a capacity of $200 million, which was declared effective by the SEC on April 14, 2023. As of December 31, 2023, $35.1 million remains available under that shelf registration statement. The Company's failure to timely file this Quarterly Report on Form 10-Q for the quarter ended December 31, 2023 and a Current Report on Form 8-K that was due on February 27, 2024 may impair its ability to raise capital under the Company's current effective shelf registration statement on Form S-3 (File No. 333-270606). See Part II, Item 1A, "Risk Factors."

Common Stock Offering

On December 18, 2023, we completed an underwritten public offering of 52,708,332 shares of our common stock, which included the exercise in full of the underwriters' option to purchase additional shares, at a public offering price of $0.72 per share. Net proceeds to the Company from this offering were approximately $35.2 million after deducting underwriting discounts and commissions and costs incurred by the Company. All of the shares sold in the offering were by the Company. The offering was made pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-270606).

Lincoln Park Capital Fund LLC Purchase Agreement

On May 2, 2023, the Company entered into a purchase agreement (as amended, the "Lincoln Park Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company may sell to Lincoln Park up to $100.0 million of shares (the "Purchase Shares") of the Company's common stock over the 36 month term of the Lincoln Park Purchase Agreement. The Lincoln Park Purchase Agreement may be terminated by the Company at any time, at its sole discretion, without any cost or penalty, by giving one business day notice to Lincoln Park. Lincoln Park has covenanted not to in any manner whatsoever enter into or effect, directly or indirectly, any short selling or hedging of the Company's common stock. On December 13, 2023, the Company entered into an amendment (the "Lincoln Park Amendment") with Lincoln Park to reduce the amount of shares of common stock subject to the registration from $100.0 million to $50.0 million until the Company has sold at least $50.0 million of shares of common stock under the Lincoln Park Purchase Agreement. The issuance of shares of common stock pursuant to the Lincoln Park Purchase Agreement up to $50.0 million have been registered pursuant to the Company's effective shelf registration statement on Form S-3 (File No. 333-270606), and a related prospectus supplement that was filed with the SEC on May 3, 2023, as further supplemented on December 13, 2023 to reflect the Lincoln Park Amendment.

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 not below $0.25 per share (subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as provided 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).

During the three months ended December 31, 2023, we sold 1,800,000 shares of common stock to Lincoln Park resulting in proceeds to the Company of $1.7 million. As a result of these sales, we recorded approximately $164,000 of deferred costs to additional paid-in capital. Since inception of the Lincoln Park Purchase Agreement through December 31, 2023, we have sold 3,025,000 shares of common stock to Lincoln Park resulting in proceeds to the Company of $3.1 million.

In consideration for entering into the Lincoln Park Purchase Agreement, concurrently with the execution of the Lincoln Park Purchase Agreement, the Company issued 800,000 shares of the Company's common stock to Lincoln Park. The shares of common stock issued as consideration were valued at $1.0 million, based on the closing price per share of the Company's common stock on the date the shares were issued. This amount and related expenses of $57,000, which total approximately $1.1 million, were recorded as deferred costs. The unamortized deferred costs related to the Lincoln Park Purchase Agreement of $870,000 and $1.0 million as of December 31, 2023 and September 30, 2023, respectively, are included in other assets on the accompanying unaudited condensed consolidated balance sheets.

At-the-Market Sale Agreement

On May 12, 2023, the Company entered into an Open Market Sale Agreement℠ (the "Jefferies Sales Agreement") with Jefferies LLC ("Jefferies"), as sales agent, pursuant to which the Company may issue and sell, from time to time, through Jefferies, shares of the Company's common stock, with an aggregate value of up to $75 million (not to exceed the lesser of 39,609,072 shares of common stock or the number of authorized, unissued and available shares of common stock at any time). Shares of common stock offered and sold pursuant to the Jefferies Sale Agreement have been registered pursuant to the Company's effective shelf registration statement on Form S-3 (File No. 333-270606), and a related prospectus supplement that was filed with the SEC on May 12, 2023. The Company will pay Jefferies a commission of 3% of the aggregate gross proceeds from each sale of common stock. The Company incurred issuance costs of $207,000, which were recorded as deferred costs.

During the three months ended December 31, 2023, we sold 90,156 shares of common stock under the Jefferies Sales Agreement resulting in net proceeds to the Company of $67,000. Since inception of the Jefferies Sales Agreement through December 31, 2023, we have sold 1,367,415 shares of common stock resulting in net proceeds to the Company of $1.1 million. The unamortized deferred costs related to the Jefferies Sales Agreement of $204,000 as of December 31, 2023 and September 30, 2023 are included in other assets on the accompanying unaudited condensed consolidated balance sheets.

As a result of the Company's failure to timely file this Quarterly Report on Form 10-Q for the quarter ended December 31, 2023 and a Current Report on Form 8-K that was due on February 27, 2024, the Company is not in compliance with a provision of the Jefferies Sales Agreement, which would prevent it from making additional sales under the Jefferies Sales Agreement unless such non-compliance is waived.

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 months ended December 31, 2023 and 2022, we recorded share-based compensation expenses as follows:

	Three Months Ended December 31,	
	2023	2022
Cost of sales	$ 96,705	$ 64,008
Selling, general and administrative	2,826,865	3,612,099
Research and development	483,379	1,169,162
Share-based compensation	$ 3,406,949	$ 4,845,269

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 December 31, 2023, 3,967,083 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 December 31, 2023, 2,739,330 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 December 31, 2023, 398,105 shares remain available for issuance under the 2017 Plan. The 2017 Plan replaced the Company's 2008 Stock Incentive Plan (the "2008 Plan"), and no further awards will be made under the 2008 Plan.

Stock Options

Each option grants the holder the right to purchase from us one share of our common stock at a specified price, which is generally the closing price per share of our common stock on the date the option is issued. Options generally vest on a pro-rata basis on each anniversary of the issuance date within three years of the date the option is issued. Options may be exercised after they have vested and prior to the specified expiry date provided applicable exercise conditions are met, if any. The expiry date can be for periods of up to ten years from the date the option is issued. The fair value of each option is estimated on the date of grant using the Black-Scholes option pricing model based on the assumptions established at that time. The Company accounts for forfeitures as they occur and does not estimate forfeitures as of the option grant date. The Company recognized a reduction in share-based compensation expense of $1.1 million during the three months ended December 31, 2023 for stock options forfeited during the period. The reduction in share-based compensation expense during the three months ended December 31, 2022 for stock options forfeited was immaterial.

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

	Three Months Ended December 31,	
	2023	2022
Weighted Average Assumptions:		
Expected volatility	103.99%	98.43%
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	4.73%	4.25%
Expected term (in years)	6.0	6.0
Fair value of options granted	$ 0.60	$ 9.17

During the three months ended December 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 December 31, 2023:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2023	17,367,643	$ 5.28		
Granted	300,000	$ 0.73		
Exercised	—	$ —		
Forfeited and expired	(511,672)	$ 8.96		
Outstanding at December 31, 2023	17,155,971	$ 5.09	6.72	$ —
Exercisable at December 31, 2023	11,707,344	$ 4.25	5.78	$ —

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 December 31, 2023 of $0.72, less the respective weighted average exercise price per share at period end.

There were no stock options exercised during the three months ended December 31, 2023. The total intrinsic value of options exercised during the three months ended December 31, 2022 was approximately $355,000. Cash received from options exercised during the three months ended December 31, 2022 was approximately $257,000.

As of December 31, 2023, the Company had unrecognized compensation expense of approximately $21.9 million related to unvested stock options. This expense is expected to be recognized over a weighted average period of 1.8 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 December 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 two years to six years. 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. This lease, and the related sublease, terminated on October 31, 2023 and will not be renewed. The Company does not have any leases that have not yet commenced as of December 31, 2023.

The components of the Company's lease cost were as follows for the three months ended December 31, 2023 and 2022:

	Three Months Ended December 31,	
	2023	2022
Operating lease cost	$ 264,389	$ 281,451
Short-term lease cost	10,214	10,101
Variable lease cost	28,502	50,091
Sublease income	(15,148)	(44,844)
Total lease cost	$ 287,957	$ 296,799

The Company paid cash of $256,000 and $228,000 for amounts included in the measurement of operating lease liabilities during the three months ended December 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 December 31, 2023 and September 30, 2023.

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

	December 31, 2023	September 30, 2023
Operating Leases		
Weighted-average remaining lease term (years)	5.7	6.1
Weighted-average discount rate	7.6%	7.7%

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 $10.0 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 Mitchell Steiner, its Chairman, CEO and President, and Michele Greco, its CFO (the "Ewing Lawsuit"). The First Amended Class Action Complaint, filed on September 15, 2023 by purported stockholders Dr. Myo Thant and Karen Brounstein, alleges that certain public statements about sabizabulin as a treatment for COVID-19 between March 1, 2021 and March 2, 2023 violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, and seeks monetary damages.

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

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

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

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

The Ewing Lawsuit, Maglia Lawsuit, Franchi Lawsuit, Renbarger Lawsuit, and Alshourbagy Lawsuit are collectively referred to as the "Shareholder Litigation." At this time, the Company is unable to estimate potential losses, if any, related to the Shareholder Litigation.

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"). The Company was sponsoring a clinical trial in which both the Company's enobosarm compound and Lilly's compound were being dosed in combination. The ENABLAR-2 clinical trial is currently suspended. Under the Lilly agreement, the Company conducts the research at its own cost and Lilly contributes its compound towards the study at no cost to the Company. The parties continue to hold exclusive rights to all intellectual property relating solely to their own respective compounds. The Company would 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 would be 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.

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

	Three Months Ended December 31,	
	2023	2022 (Restated)
Income tax benefit at U.S. federal statutory rates	$ (1,753,168)	$ (8,143,219)
State income tax benefit, net of federal benefit	(135,745)	(630,518)
Non-deductible expenses	89,410	113,456
Effect of stock options exercised	—	83,736
U.S. research and development tax credit	(170,000)	(1,090,000)
Effect of foreign income tax rates	(91,591)	(80,110)
Change in valuation allowance	1,988,678	9,678,495
Other, net	(23)	(118)
Income tax benefit	$ (72,439)	$ (68,278)

Note 14 – Net Income (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 – Sale of ENTADFI Assets

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

On September 29, 2023, the Company entered into an Amendment to the BWV Asset Purchase Agreement (the "Amendment") providing that the promissory note for the $4.0 million installment of the purchase price due September 30, 2023 would be deemed paid and fully satisfied upon (1) the payment to the Company of the sum of $1.0 million in immediately available funds on September 29, 2023 and (2) the issuance to the Company by October 3, 2023 of 3,000 shares of BWV Preferred Stock. The Company received payment of $1.0 million on September 29, 2023 and the BWV Preferred Stock on October 3, 2023, which the Company determined had a fair value as of October 3, 2023 of $0.9 million. The BWV Preferred Stock is convertible by the Company at any time and from time to time from and after one year from the date of issuance of the BWV Preferred Stock into that number of shares of the Purchaser's common stock determined by dividing the stated value of $1,000 per share by the Conversion Price of $0.5254 per share. The BWV Preferred Stock issued to the Company is initially convertible into an aggregate of approximately 5,709,935 shares of BWV's common stock, subject to certain shareholder approval limitations. BWV agreed in the Amendment to use commercially reasonable efforts to obtain such shareholder approval by December 31, 2023. Such shareholder approval has not been obtained as of December 31, 2023. BWV also agreed to include the shares of common stock issuable upon conversion of the BWV Preferred Stock in the next resale registration statement filed with the Securities and Exchange Commission. Such registration statement has not been filed as of December 31, 2023.

The Company determined that it was not probable, at the time of the transaction and at December 31, 2023, that substantially all of the consideration promised under the BWV Asset Purchase Agreement would be collected. Therefore, the Company recognized the difference between the nonrefundable consideration received and the carrying amount of the assets as a gain. The Company recorded a gain of approximately $5.7 million on the transaction during fiscal 2023. The Company recognized a gain on sale of $0.9 million during the quarter ended December 31, 2023 based on the determination of the fair market value of the BWV Preferred Stock. Additional gain could be recognized in future periods if additional consideration is received or when it is deemed probable that substantially all of the consideration promised will be collected. The Company will continue to evaluate the collectability of the notes receivable for future installments of the purchase price. The Company does not expect that BWV will be able to pay the notes receivable unless BWV raises additional capital. Based on discussions with representatives of BWV after December 31, 2023, the Company believes that BWV is insolvent and that there is substantial risk that BWV will not make any payment on the outstanding notes receivable when due.

Note 16 – Subsequent Events

A supplier claimed that we owed approximately $10 million for products and services relating to our efforts to commercialize sabizabulin under an EUA. We disputed the amount owed and on February 29, 2024, we entered into an agreement with the supplier, which resolves the dispute by modifying the payment terms under the original agreement. The Company agreed to pay $8.3 million, with $2.3 million payable upon execution of the agreement, $3.5 million payable in equal monthly installments over 48 months, and $2.5 million payable (the "Balance") on or prior to December 31, 2025 out of the proceeds of certain payments that may be received by the Company from BWV on notes receivable due in April 2024 and September 2024. If all or any portion of the Balance remains unpaid as of December 31, 2025, the Company shall pay the amount of the unpaid Balance in equal monthly installments over 24 months, commencing in January 2026. The agreement resulted in a reduction of the liability recorded as of December 31, 2023, included in accounts payable on the accompanying unaudited condensed consolidated balance sheet, of $0.6 million, which will be recorded as a reduction in research and development expense for the three and six months ended March 31, 2024.

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

As discussed in the section titled "Restatement" in Note 1 to the unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, the financial information as of September 30, 2023 and for the three months ended December 31, 2022 included herein has been restated. The following discussion and analysis of our financial condition and results of operations incorporates the restated amounts.

Overview

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

Obesity and Overweight Program

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

Overweight and obese patients treated with GLP-1 RA drugs have significant weight loss composed of reductions in both fat mass and lean body mass (muscle). Up to 20-50% of the total weight loss caused by GLP-1 RA treatment is attributable to muscle loss. According to the CDC, 41.5% of older adults have obesity and could benefit from weight loss medication. Up to 34.4% of obese patients in the United States over the age of 60 have sarcopenic obesity. Sarcopenic obese patients are patients who have both obesity and age-related low muscle mass at the same time and are potentially at the greatest risk for developing critically low muscle mass when taking a currently approved GLP-1 RA drug. Patients with critically low muscle mass may experience muscle weakness leading to poor balance, decreased gait speed, mobility disability, falls, bone fractures, and increased mortality.

We believe there is an urgent unmet medical need for a drug when given in combination with a GLP-1 RA that could prevent the loss of muscle, while preferentially reducing fat in not only overweight or obese patients, but especially for sarcopenic obese or overweight elderly patients who are at-risk for developing muscle atrophy and muscle weakness leading to frailty. We believe that enobosarm, our novel small molecule, oral SARM, may potentially address this unmet medical need.

Enobosarm has been studied in five separate third-party clinical studies involving 968 older men and postmenopausal women as well as older patients who have muscle wasting because of advanced cancer. Advanced cancer simulates a “starvation state” where there is significant loss or wasting of both muscle and fat mass like what is observed with GLP-1 RA treatment. These third-party clinical trials include two Phase 2 clinical trials in 168 healthy older or sarcopenic subjects and one Phase 2b clinical trial and two Phase 3 clinical trials in 800 subjects who have muscle loss caused by cancer. We believe the totality of the clinical data we own from these five clinical trials provide strong clinical rationale for the co-administration of enobosarm and a GLP-1 RA in at-risk sarcopenic obese or overweight elderly patients as the combination has the potential to ameliorate the muscle wasting effects of currently approved GLP-1 RA therapies and also allow for preferential loss of fat mass. In addition, we believe there is also clinical rationale for the administration of enobosarm to “rescue” at-risk sarcopenic obese or overweight elderly patients who may be forced to discontinue treatment with a GLP-1 RA due to the muscle loss depleting their muscle mass to critically low amounts resulting in muscle weakness and physical function limitations. In one of the Phase 2 clinical trials, enobosarm was evaluated in 120 elderly men over 60 years old and postmenopausal women treated for 12 weeks, patients receiving 3mg dose of enobosarm (n=24) demonstrated a statistically significant (i) increase in total lean body mass (average increase of 1.25 kg ($p = < 0.001$)) and (ii) decrease in total fat mass (average decrease of 0.32 kg ($p=0.049$)). When measuring physical function by stair climb test, patients receiving 3mg dose of enobosarm in this trial also demonstrated statistically significant improvements compared to placebo ($p=0.049$).

Although these five third-party clinical trials were not specifically conducted in an obese population, an ad hoc subset analysis was performed on obese patients, who had a BMI of 30 or greater, who were enrolled in the Phase 3 placebo-controlled 504 clinical study which evaluated enobosarm 3mg treatment in metastatic lung cancer patients on chemotherapy. Even though a small sample size of 29 subjects, notable differences consistent with an obesity drug that preserves muscle and decreases fat were observed. At 12 weeks, enobosarm 3mg treated subjects had 4.96% increase in total lean body mass (muscle) compared to placebo and a 5.77 % reduction in fat mass compared to placebo. By 21 weeks, enobosarm 3mg treatment resulted in a 14.4% loss in total fat mass and a 4.51% loss of total DEXA body weight compared to placebo while maintaining total lean mass. It should be noted that these results were from the short-term treatment of enobosarm alone.

Enobosarm has a large safety database, which includes 27 clinical trials involving 1581 men and women dosed with duration of treatment in some patients for up to 3 years. In this large safety database, enobosarm was generally well tolerated with no increase in gastrointestinal side effects. This is important as there are already significant and frequent gastrointestinal side effects with a GLP-1 RA treatment alone.

Although these five clinical trials were previously conducted by third parties, Veru owns all this clinical data as part of our enobosarm exclusive global in-license agreement.

Although no preclinical studies or clinical trials evaluating the combination of enobosarm and a GLP-1 RA have been completed to date, we believe that the patient efficacy and safety data that were generated from these five enobosarm clinical trials in both elderly patients and in patients with a cancer induced starvation-like state provide strong clinical rationale that enobosarm may address this unmet medical need.

We submitted an Investigational New Drug Application (IND) for enobosarm for a Phase 2b clinical study in January 2024. In February 2024, the Company received FDA clearance to initiate the Phase 2b, multicenter, double-blind, placebo-controlled, randomized, dose-finding clinical trial designed to evaluate the safety and efficacy of enobosarm 3mg, enobosarm 6mg, or placebo as a treatment to augment fat loss and to prevent muscle loss in 90 sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness. The primary endpoint is lean body mass (muscle), and the key secondary endpoint is total body fat mass at 16 weeks. The clinical study is expected to begin in April 2024 with the topline clinical results from the trial expected in the end of the fourth calendar quarter of 2024. The purpose of the Phase 2b clinical trial is to select the optimal dose of enobosarm in combination with a GLP-1 RA that best preserves muscle and reduces fat after 16 weeks of treatment to advance into a Phase 3 obesity or overweight clinical trial.

After completing the efficacy dose-finding portion of the Phase 2b clinical trial, it is expected that participants will then continue into a Phase 2b extension trial where all patients will stop treatment with the GLP-1 RA drug, but continue taking placebo, 3mg enobosarm, or 6 mg of enobosarm for 12 weeks to determine the ability of enobosarm to maintain muscle and prevent fat and weight rebound after stopping a GLP-1 RA. The results of the separate Phase 2b open label extension clinical study are expected in the second quarter of calendar year 2025.

There can be no assurances that we will be able to cost- effectively continue development of enobosarm, or that enobosarm will receive FDA approval or be commercialized, for this application.

Oncology Program

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

Enobosarm is a new class of endocrine therapy for advanced breast cancer. Enobosarm is an oral, new chemical entity, selective androgen receptor modulator designed to activate the AR in AR+ ER+ HER2- metastatic breast cancer and thereby suppress tumor growth without the unwanted masculinizing side effects. Enobosarm has extensive nonclinical and clinical experience having been evaluated in 27 separate clinical studies in approximately 1,580 subjects dosed, including three Phase 2 clinical trials in advanced breast cancer involving more than 191 patients. In one of the Phase 2 clinical trials conducted in women with AR+ ER+ HER2- metastatic breast cancer, enobosarm demonstrated significant antitumor efficacy in heavily pretreated cohorts that failed estrogen blocking agents, chemotherapy and/or CDK 4/6 inhibitors and was well tolerated with a favorable safety profile.

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

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

The primary endpoint for the Stage 1 portion of the Phase 3 clinical trial is objective tumor response rates (“ORR”). We are currently producing clinical supply of 3mg and 6mg enobosarm capsules for the additional dose optimization arms.

We began patient enrollment in April 2022. As of August 2023, we had completed the target enrollment of three patients in the Stage 1a portion of the Phase 3 ENABLAR-2 clinical trial to assess the safety and pharmacokinetics of the combination of abemaciclib and enobosarm. There were no reported drug-to-drug interactions between abemaciclib and enobosarm or new safety findings in the three patients as of the data cutoff date. Further, the early preliminary clinical results showed two partial responses and one stable disease in the first three patients based on local assessments, and as of the cutoff date the patients were on study for 9, 11 and 12 months from first day of dosing to disease progression by blinded central assessment.

Subject to the availability of sufficient funding, we expect to have topline data from Stage 1b of our Phase 3 ENABLAR-2 clinical trial by early 2025. If enobosarm monotherapy or abemaciclib + enobosarm combination therapy compared to estrogen blocking agent (active control) demonstrates significant improvement in ORR, which is considered a surrogate endpoint for clinical benefit, then we may meet with the FDA to consider an accelerated approval regulatory pathway based on the clinical data from the Stage 1b portion of the Phase 3 clinical trial. Granting accelerated approval for investigational products is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for this approval pathway, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies for these designations, the FDA may, among other things, later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. There can be no assurances that the FDA will accept our proposed trial design, that we will be able to cost-effectively continue development of enobosarm, or that enobosarm will receive FDA approval or be commercialized, for this application.

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

Infectious Disease Program

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

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

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

Sexual Health Program

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

We sell FC2 in the U.S. in both the prescription channel and in the public health sector and globally we sell in the public sector.

In the U.S. prescription channel, FC2 is available through multiple telehealth and telepharmacy channels as well as retail pharmacies. While there has been recent consolidation in the telehealth industry, we continue to believe that telehealth will be an important commercial strategy in the U.S. for access to birth control products, including FC2, given both healthcare industry dynamics and our product's profile. In order to maximize its reach and to have more direct control of the promotion, distribution, and sales of FC2, we launched our own telehealth portal in April 2022.

Having taken the time to refine our marketing, drive operational improvements, and enhance the patient experience during the portal launch phase over the last year, there are increasing new prescriptions being written and filled through our FC2 telehealth portal. During the quarter ended December 31, 2023, even though our portal faced challenges, we had some of the highest fulfillment and refill rates since our initial launch and also had increases in the average number of units being dispensed for new prescriptions.

We expect revenue from the U.S. prescription channel to demonstrate growth both from our dedicated FC2 telehealth portal and from the addition of new commercial distribution strategies. We intend to continue leveraging relationships with entities in the U.S. public health sector such as state departments of health and 501(c)(3) organizations.

In the global public health sector outside the U.S., we market FC2 to entities, including ministries of health, government health agencies, U.N. agencies, nonprofit organizations and commercial partners, that work to support and improve the lives, health and well-being of women around the world. After the COVID-19 pandemic, there has been an increase in interest to resume distribution of FC2 in the global public sector. We are currently supplying a large multi-year South African tender for female condoms, which is expected to continue until 2025 and have seen sales grow in the current year as the current tender launched. A formal Brazil tender process is expected to commence in calendar year 2024.

Sale of ENTADFI

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

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

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.

We have developed our own telehealth portal to grow revenues from the U.S. prescription channel to compensate for lost revenues from our former telehealth customers that are no longer in business. The Company is exploring additional commercial distribution strategies and expects to continue generating revenue from global public health sector agencies who purchase and distribute FC2 for HIV/AIDS prevention and family planning. The Company has experienced revenue growth from the U.S. public sector through its relationship with distributors and will continue to work with these distributors to identify future growth opportunities.

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. 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.

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 seen increases in the cost of the nitrile polymer used to produce FC2, as well as transportation costs, and may also experience increases in other material costs due to the impact of inflation. Also, the Company's decision to launch a telehealth portal my result in increases in expenses associated with acquiring new FC2 users. As a result, there may be an unfavorable impact on the Company's selling expenses and income from operations if it cannot pass through these increases to its customers.

Conducting research and development is central to our obesity and overweight, 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 $1.7 million and $20.6 million for the three months ended December 31, 2023 and 2022, respectively. The decrease in expenses in the three months ended December 31, 2023 is due to the termination of various trials that had been ongoing during the three months ended December 31, 2022 as a result of the Company’s updated strategy to refocus development efforts on those drug candidates which it believes have the best opportunity to lead to long-term success and shareholder value creation. We expect to continue investing significant resources in research and development in the future due to advancement of our drug candidates.

Results of Operations

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

The Company generated net revenues of $2.1 million and net loss of $8.3 million, or $(0.08) per basic and diluted common share, for the three months ended December 31, 2023, compared to net revenues of $2.5 million and net loss of $38.7 million, or $(0.48) per basic and diluted common share, for the three months ended December 31, 2022. Net revenues decreased 15% compared to the prior period.

Substantially all of the Company's net revenues for the three months ended December 31, 2023 and 2022 were derived from sales of FC2 in the U.S. prescription channel and global public health sector. In the U.S. prescription channel, the Company's customers include primarily telehealth providers. In the global public health sector, the Company's customers are primarily health care distributors, large global agencies, non-government organizations, ministries of health and other governmental agencies that purchase and distribute FC2 for use in HIV/AIDS prevention and family planning programs.

For the three months ended December 31, 2023 and 2022, the Company had net revenues from the U.S. prescription channel of $0.6 million and $0.2 million, respectively, and net revenues from the global public health sector of $1.5 million and $2.3 million, respectively. There was a change in the sales mix with the U.S. prescription channel representing 30% of total FC2 net revenues in the current year period compared to 7% in the prior year period and the global public health sector representing 70% of total FC2 net revenues in the current year period compared to 93% in the prior year period. Global public health sector sales are at a lower sales price per unit. The Company experienced an increase compared to the prior year period of 289% in FC2 net revenues in the U.S. prescription channel and a decrease compared to the prior year period of 36% in FC2 net revenues in the global public health sector. The increase in FC2 net revenues in the U.S. prescription channel is primarily due to sales through our telehealth portal. The decrease in sales in the global public health sector is due to timing and shipment of orders.

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. The decrease in FC2 net revenues in the global public health sector outside of the U.S. was partially offset by an increase in FC2 net revenues in the U.S. public health sector.

Cost of sales decreased to $1.0 million in the three months ended December 31, 2023 from $1.8 million in the three months ended December 31, 2022 primarily due to the decrease in unit sales.

Gross profit increased to $1.2 million in the three months ended December 31, 2023 from $0.7 million in the three months ended December 31, 2022. Gross profit margin for the fiscal 2023 period was 54% of net revenues, compared to 28% of net revenues for the fiscal 2022 period. The increase in the gross profit and gross profit margin is primarily due to the change in our sales mix, which included an increase in FC2 net revenues in the U.S. prescription channel, which have higher profit margins.

Research and development expenses decreased to $1.7 million in the three months ended December 31, 2023 from $20.6 million in the same period in fiscal 2022. The decrease is due to the Company's updated strategy to refocus development efforts on those drug candidates which it believes have the best opportunity to lead to long-term success and shareholder value creation. The Company did not have significant research and development activity during the three months ended December 31, 2023 as it was preparing to submit an IND for enobosarm for a Phase 2b clinical study and the development of its other programs has been paused. The Company incurred a significant amount of expenses in the prior year period related to sabizabulin for COVID-19 and the Company's related emergency use authorization application. Additionally, personnel costs included in research and development expenses decreased by $1.5 million due to a reduction in headcount.

Selling, general and administrative expenses were $8.3 million in the three months ended December 31, 2023, which is decreased from $17.5 million in the three months ended December 31, 2022. The decrease is due primarily to commercialization costs incurred in the prior year of $8.4 million related to the preparation for the potential launch of sabizabulin for COVID, which did not occur.

The Company recorded a gain on sale of ENTADFI assets of $0.9 million in the three months ended December 31, 2023, related to the receipt of the shares of BWV Preferred Stock. Refer to Note 15 to the financial statements included in this report for additional information.

Interest expense, which is related to accretion of the liability for the Residual Royalty Agreement, was $0.2 million in the three months ended December 31, 2023, compared with $0.9 million in the three months ended December 31, 2022. The decrease relates to a decrease in actual and projected FC2 sales.

The loss associated with the change in fair value of the embedded derivative related to the Residual Royalty Agreement was $2,000 in the three months ended December 31, 2023, compared to $0.7 million in the three months ended December 31, 2022. The liability associated with embedded derivative represents the fair value of the change of control provisions in the Residual Royalty Agreement. See Note 3 and Note 8 to the financial statements included in this report for additional information.

The loss associated with the change in fair value of equity securities for the three months ended December 31, 2023 was $0.4 million. This is due to the change in fair value of the shares of BWV Preferred Stock, primarily driven by a decrease in the stock price of BWV. See Note 3 to the financial statements included in this report for additional information.

Income tax benefit in the three months ended December 31, 2023 was $72,000, compared to $68,000 in the three months ended December 31, 2022. The income tax benefits are primarily due to a taxable loss during the period for the Company's subsidiary in the U.K. 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 December 31, 2023 was $40.6 million, compared to $9.6 million at September 30, 2023. At December 31, 2023, the Company had working capital of $36.7 million and stockholders' equity of $51.6 million compared to working capital of $5.1 million and stockholders' equity of $19.7 million as of September 30, 2023. The increase in working capital is primarily due to the increase in cash on hand, related to the public offering of our common stock, which resulted in net proceeds to the Company of approximately $35.2 million.

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. 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, 2023 for a description of certain risks that will affect our future capital requirements.

The Company believes its current cash position and cash expected to be generated from sales of FC2 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 statement on Form S-3 (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 Lincoln Park Capital Fund, LLC (see Note 9) or its open market sale agreement with Jefferies LLC (see Note 9) to the extent sales may be made pursuant to such agreement.

The Company's failure to timely file this Quarterly Report on Form 10-Q for the quarter ended December 31, 2023 and a Current Report on Form 8-K that was due on February 27, 2024 may impair its ability to raise capital under the Company's current effective shelf registration statement on Form S-3 (File No. 333-270606) or under a new registration statement. See Part II, Item 1A, "Risk Factors."

A supplier claimed that we owed approximately $10 million for products and services relating to our efforts to commercialize sabizabulin under an EUA. We disputed the amount owed and on February 29, 2024, we entered into an agreement with the supplier, which resolves the dispute by modifying the payment terms under the original agreement. The Company agreed to pay $8.3 million, with $2.3 million payable upon execution of the agreement, $3.5 million payable in equal monthly installments over 48 months, and $2.5 million payable (the "Balance") on or prior to December 31, 2025 out of the proceeds of certain payments that may be received by the Company from BWV on notes receivable due in April 2024 and September 2024. If all or any portion of the Balance remains unpaid as of December 31, 2025, the Company shall pay the amount of the unpaid Balance in equal monthly installments over 24 months, commencing in January 2026.

Operating activities

Operating activities used cash of $6.0 million in the three months ended December 31, 2023. Cash used in operating activities included net loss of $8.3 million, adjustments to reconcile net loss to net cash used in operating activities totaling an increase of $3.0 million and changes in operating assets and liabilities resulting in a decrease of $0.8 million. Adjustments to net loss primarily consisted of $3.4 million of share-based compensation and $0.4 million for the change in fair value of equity securities, partially offset by the gain on sale of ENTADFI assets of $0.9 million. The decrease in cash from changes in operating assets and liabilities included a decrease in accounts payable of $2.5 million and an increase in prepaid expenses and other assets of $1.3 million, partially offset by a decrease in accounts receivable of $2.1 million and an increase in accrued expenses and other current liabilities of $1.3 million.

Operating activities used cash of $34.5 million in the three months ended December 31, 2022. Cash used in operating activities included net loss of $38.7 million, adjustments to reconcile net loss to net cash used in operating activities totaling an increase of $6.4 million and changes in operating assets and liabilities resulting in a decrease of $2.2 million. Adjustments to net loss primarily consisted of $4.8 million of share-based compensation, interest expense in excess of interest paid of $0.7 million, and the change in fair value of derivative liabilities of $0.7 million. The decrease in cash from changes in operating assets and liabilities included a decrease in accounts payable of $11.4 million, partially offset by an increase in accrued expenses and other current liabilities of $8.4 million, a decrease in prepaid expenses and other current assets of $0.7 million, and a decrease in accounts receivable of $0.4 million.

Investing activities

The Company did not have cash flows from investing activities during the three months ended December 31, 2023.

Net cash used in investing activities was $0.3 million in the three months ended December 31, 2022, and consisted of capital expenditures primarily at our Malaysia location.

Financing activities

Net cash provided by financing activities in the three months ended December 31, 2023 was $37.0 million, and primarily consisted of proceeds from the sale of shares in a public offering, net of commissions and costs, of $35.4 million and proceeds from sale of shares under the common stock purchase agreement with Lincoln Park Capital (see discussion below) of $1.7 million.

Net cash provided by financing activities in the three months ended December 31, 2022 was $1.6 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 and 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 $0.2 million and $0.1 million during the three months ended December 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 December 31, 2023 will be approximately $0.8 million under the Residual Royalty Agreement.

Common Stock Offering

On December 18, 2023, we completed an underwritten public offering of 52,708,332 shares of our common stock, which included the exercise in full of the underwriters' option to purchase additional shares, at a public offering price of $0.72 per share. Net proceeds to the Company from this offering were approximately $35.2 million after deducting underwriting discounts and commissions and costs paid by the Company. All of the shares sold in the offering were by the Company. The offering was made pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-270606).

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 provided that, upon the terms and subject to the conditions and limitations set forth therein, the Company had the right, from time to time in its sole discretion during the 36-month term of the 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 had 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 36-month term of the 2020 Purchase Agreement, we sold 4,424,450 shares of common stock to Aspire Capital resulting in proceeds to the Company of $8.4 million. On June 26, 2023, the term of the 2020 Purchase Agreement expired and no additional shares of common stock will be sold under the agreement.

Private Investment in Public Equity

On April 12, 2023, the Company entered into a stock purchase agreement (the "Stock Purchase Agreement") with Frost Gamma Investments Trust ("FGI"), pursuant to which, on the date thereof, the Company issued and sold 5,000,000 shares of the Company's common stock to FGI at a price of $1.00 per share, for a total investment of $5,000,000, through a private investment in public equity financing. The shares of common stock issued to FGI pursuant to the Stock Purchase Agreement were not registered under the Securities Act of 1933, as amended (the "Securities Act"). The Company filed a registration statement under the Securities Act to register the resale of the shares of common stock issued to FGI, which was declared effective on May 24, 2023.

Lincoln Park Capital Fund, LLC Purchase Agreement

On May 2, 2023, the Company entered into a common stock purchase agreement (as amended, the "Lincoln Park Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right, but not the obligation, to sell to Lincoln Park up to $100.0 million of shares (the "Purchase Shares") of the Company's common stock over the 36-month term of the Lincoln Park Purchase Agreement. On the date the Company executed the Lincoln Park Purchase Agreement, we also issued 800,000 shares of the Company's common stock to Lincoln Park as an initial fee for Lincoln Park's commitment to purchase shares of the Company's common stock under the Lincoln Park Purchase Agreement, and we are obligated to issue $1.0 million of shares of the Company's common stock at the time Lincoln Park's purchases cumulatively reach an aggregate amount of $50.0 million (such shares, collectively, the "Commitment Shares"). On December 13, 2023, the Company entered into an amendment (the "Lincoln Park Amendment") with Lincoln Park to reduce the amount of shares of common stock subject to the registration from $100.0 million to $50.0 million until the Company has sold at least $50.0 million of shares of common stock under the Lincoln Park Purchase Agreement. The Purchase Shares up to $50.0 million and Commitment Shares under the Lincoln Park Purchase Agreement have been registered pursuant to the Company's effective shelf registration statement on Form S-3 (File No. 333-270606), and a related prospectus supplement that was filed with the SEC on May 3, 2023, as further supplemented on December 13, 2023 to reflect the Lincoln Park Amendment.

During the three months ended December 31, 2023, we sold 1,800,000 shares of common stock to Lincoln Park resulting in proceeds to the Company of $1.7 million. Since inception of the Lincoln Park Purchase Agreement through December 31, 2023, we have sold 3,025,000 shares of common stock to Lincoln Park resulting in proceeds to the Company of $3.1 million.

Open Market Sale Agreement with Jefferies LLC

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

The Company is not obligated to sell any shares of common stock under the Jefferies Sales Agreement. Subject to the terms and conditions of the Jefferies Sales Agreement, Jefferies will use commercially reasonable efforts consistent with its normal trading and sales practices, to sell shares of common stock from time to time based upon the Company's instructions, including any price, time or size limits specified by the Company. Upon delivery of a placement notice, and subject to our instructions in that notice, and the terms and conditions of the Jefferies Sales Agreement generally, Jefferies may sell the Company's common stock by any method permitted by law deemed to be an "at the market offering" as defined by Rule 415(a)(4) promulgated under the Securities Act. Under the terms of the Sales Agreement, the Company cannot cause or request Jefferies to sell shares of common stock exceeding the number of shares of common stock authorized, unissued and available for issuance at any time. The Company will pay Jefferies a commission of 3% of the aggregate gross proceeds from each sale of common stock and has agreed to provide Jefferies with customary indemnification and contribution rights, including liabilities under the Securities Act and the Securities Exchange Act of 1934, as amended. The Company has also agreed to reimburse Jefferies for certain specified expenses. Shares of common stock will be offered and sold pursuant to the Jefferies Sale Agreement, the Company's effective shelf registration statement on Form S-3 (File No. 333-270606), and a related prospectus supplement that was filed with the SEC on May 12, 2023.

During the three months ended December 31, 2023, we sold 90,156 shares of common stock under the Jefferies Sales Agreement resulting in net proceeds to the Company of $67,000. Since inception of the Jefferies Sales Agreement through December 31, 2023, we have sold 1,367,415 shares of common stock resulting in net proceeds to the Company of $1.1 million.

As a result of the Company's failure to timely file this Quarterly Report on Form 10-Q for the quarter ended December 31, 2023 and a Current Report on Form 8-K that was due on February 27, 2024, the Company is not in compliance with a provision of the Jefferies Sales Agreement which would prevent it from making additional sales under the Jefferies Sales Agreement unless such non-compliance is waived.

Fair Value Measurements

As of December 31, 2023 and September 30, 2023, 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.

The Company also has an investment in the BWV Preferred Stock. The BWV Preferred Stock was received on October 3, 2023 as a settlement of the receivable due related to the sale of ENTADFI. See Note 15 to the financial statements included in this report for additional information. The investment in the BWV Preferred Stock is classified within Level 3 of the fair value hierarchy because there is no market for the BWV Preferred Stock. The fair value of the BWV Preferred Stock has been determined using a probability-weighted bond plus call option model, which incorporates the stock price of BWV on the valuation date, expected volatility, expected term, and an applicable discount rate. The Company has also applied a discount for lack of marketability due to the fact that there is no market for the preferred stock. 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, 2023. There have been no material changes to such exposures since September 30, 2023.

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 not effective as of December 31, 2023, due to the material weaknesses in our internal control over financial reporting described below.

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.

Material Weaknesses in Internal Control Over Financial Reporting

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

Management identified material weaknesses in the Company's internal control over financial reporting as of September 30, 2023 related to: (1) its controls over applying technical accounting guidance to nonrecurring events and transactions, specific to the evaluation of information that was known or knowable at the time of the transaction or event, and (2) its management review control over its estimate of research and development expenses associated with activities conducted by third-party service providers.

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

With respect to the estimate of research and development expenses associated with activities conducted by third-party service providers, our internal controls did not define the precision at which the control activity operated such that the control was not properly designed to detect or prevent material errors in the inputs used in the calculation. This resulted in a restatement of our financial statements as of and for the years ended September 30, 2023 and 2022.

As a result of the identified material weaknesses, management directed a comprehensive review of complex, nonrecurring transactions and of the estimated research and development expenses associated with activities conducted by third-party service providers to assess the possibility of further material misstatements that may remain unidentified. As a result of such review, and notwithstanding the material weaknesses described above, our management, including our Chief Executive Officer and Chief Financial Officer, believe that the unaudited condensed consolidated financial statements included in this Form 10-Q as of and for the three-month period ended December 31, 2023 fairly present, in all material respects, our financial condition, results of operations, and cash flows for the period presented in conformity with U.S. GAAP.

Remediation Activities

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

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

We are evaluating the material weakness related to the Company's estimate of research and development expenses associated with activities conducted by third-party service providers and are developing a plan of remediation, which will include the following:

- enhance our review procedures with respect to the calculation of the estimated research and development expenses associated with activities conducted by third-party service providers and
- implement additional procedures to obtain information that is known or knowable to the Company at the time of developing estimates related to third-party transactions, including obtaining confirmation of the work completed by third parties or performing alternative procedures if confirmations are not available.

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

Changes in Internal Control over Financial Reporting

As discussed above, we identified material weaknesses in our control over financial reporting for the period covered by this Form 10-Q and are implementing a plan of remediation to strengthen the design and operation of our control environment. Other than that described above, there were no changes in the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended) during the 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, 2023. 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, 2023, except for the following additional risk factor. Additional risks that we do not yet know of or that we currently think are immaterial may also impair our business operations.

As a result of our failure to timely file two reports with the SEC, we are currently ineligible to file a registration statement on Form S-3, which may impair our ability to raise capital on terms favorable to us, in a timely manner or at all.

Form S-3 permits eligible issuers to conduct registered offerings using a short form registration statement that allows the issuer to incorporate by reference its past and future filings and reports made under the Exchange Act. In addition, Form S-3 enables eligible issuers to conduct primary offerings under Rule 415 of the Securities Act. The shelf registration process, combined with the ability to forward incorporate information, allows issuers to avoid delays and interruptions in the offering process and to access the capital markets in a more expeditions and efficient manner than raising capital in a standard registered offering pursuant to a registration statement on Form S-1. The ability to newly register securities for resale may also be limited as a result of the loss of Form S-3 eligibility with respect to such registrations.

As a result of our failure to timely file this Quarterly Report on Form 10-Q for the quarter ended December 31, 2023 and a Current Report on Form 8-K that was due on February 27, 2024, we are ineligible to file new registration statements on Form S-3 until no earlier than March 1, 2025. Our Form S-3 ineligibility may significantly impair our ability to raise necessary capital needed for our business. If we seek to access the capital markets through a registered offering pursuant to a new registration statement on Form S-1, we would be required to disclose the proposed offering and the material terms thereof before the offering commences. As a result of such disclosure and potential for SEC review of such registration statement on Form S-1, we may experience delays in the offering process and we may incur increased offering and transaction costs and other impediments to such an offering. If we are unable to raise capital through a registered offering, we would be required to raise capital on a private placement basis, which may be subject to pricing, size and other limitations imposed under NASDAQ rules, or seek other sources of capital. While we believe we will be able to continue to use our current effective shelf registration statement on Form S-3 (File No. 333-270606) (the “Current Shelf Registration Statement”) until we file our Annual Report on Form 10-K for the year ending September 30, 2024, our failure to timely file this report and the Form 8-K may impair our ability to conduct an underwritten or other offering under the Current Shelf Registration Statement, and as a result of this filing delinquency we are not in compliance with a provision of the Jefferies Sales Agreement which would prevent us from making additional sales under the Jefferies Sales Agreement unless such non-compliance is waived. Between the time we file our Annual Report on Form 10-K for the year ending September 30, 2024 and at least March 1, 2025, we will not be able to sell any securities pursuant to the Current Shelf Registration Statement, including under the Lincoln Park Purchase Agreement.

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

In April 2023, we sold our ENTADFI assets to BWV and on September 29, 2023, we entered into an amendment to the BWV Asset Purchase Agreement which provided that the promissory note for the $4 million installment of the purchase price due September 30, 2023 was deemed paid and fully satisfied upon (1) the payment to us of the sum of $1.0 million in immediately available funds on September 29, 2023, and (2) the issuance to us by October 3, 2023 of 3,000 shares of BWV Series A Preferred Stock. The BWV Series A Preferred Stock may not be converted into shares of BWV common stock until one year after issuance. Although BWV’s common stock is currently traded on the Nasdaq Capital Market, there is limited trading volume and we do not have any registration rights with respect to the shares of BWV common stock issuable upon conversion of the BWV Series A Preferred Stock, which means that any sales by us of those shares may be subject to volume and other limitations pursuant to Rule 144 under the Securities Act of 1933, as amended. Under the BWV Asset Purchase Agreement, BWV is obligated to pay an additional $10 million in installments in our fiscal year 2024 pursuant to unsecured promissory notes, plus up to an additional $80 million in milestone payments based on BWV’s net sales from ENTADFI business after closing.

There is uncertainty as to whether and when we will receive any future installment payments of purchase price or sales milestone payments under the BWV Asset Purchase Agreement, and there is a risk of a future default by BWV in performing its payment obligations, and we do not have a security interest in any of BWV's assets and accordingly would be an unsecured creditor in the event that BWV defaults. We received payment of $1.0 million on September 29, 2023. There can be no assurance as to (1) whether and when we will receive the future installment payments of purchase price or sales milestone payments under the BWV Asset Purchase Agreement, (2) the ability of BWV to obtain the requisite approval of its shareholders for the conversion of all the shares of BWV Series A Preferred Stock, and (3) whether and when we will be able to receive any cash proceeds from the BWV Series A Preferred Stock. Based on discussions with representatives of BWV after December 31, 2023, the Company believes that BWV is insolvent and that there is a substantial risk that BWV will not make any payment on the outstanding notes receivable when due. If BWV fails to pay the outstanding notes receivable when due or an event of default under the notes receivable otherwise occurs, we may, among other things, declare the full amount outstanding to be due and sue to collect the notes receivable, which actions may force BWV into bankruptcy. There can be no assurance as to whether we would be able to collect any amounts due under the notes receivable if BWV files for bankruptcy and, in such event, the BWV Series A Preferred Stock would likely have no value.

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	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 308,000,000 shares (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on July 28, 2023).
3.10	Amended and Restated By-Laws (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on May 4, 2018).
4.1	Amended and Restated Articles of Incorporation, as amended (same as Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, and 3.9).

4.2	Articles II, VII and XI of the Amended and Restated By-Laws (included in Exhibit 3.10).
10.1	Letter Agreement, dated December 13, 2023, between the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on December 13, 2023).
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 December 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: April 1, 2024

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

DATE: April 1, 2024

/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: April 1, 2024

/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: April 1, 2024

/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 December 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: April 1, 2024

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

Date: April 1, 2024

/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.