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

FORM 10-Q/A

(Amendment No. 1)

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended June 30, 2023

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission File Number 1-13602

Veru Inc.

(Exact Name of Registrant as Specified in its Charter)

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

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value per share	VERU	Nasdaq Capital Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company☒
	Emerging growth company☐

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

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

As of August 8, 2023, the registrant had 90,280,439 shares of $0.01 par value common stock outstanding.

EXPLANATORY NOTE

Background of Restatement

Veru Inc. (“we,” “our,” “us,” “Veru” or the “Company”) is filing this Form 10-Q/A to amend and restate its Form 10-Q for the fiscal quarter ended June 30, 2023, which was originally filed with the U.S. Securities and Exchange Commission (the “SEC”) on August 10, 2023 (the “Original Form 10-Q”), to restate its previously issued unaudited condensed consolidated financial statements as of and for the three and nine months ended June 30, 2023 (the “Prior Financial Statements”), and to amend related disclosures, including regarding controls and procedures.

On November 15, 2023, we filed a Current Report on Form 8-K under Item 4.02(a) with the SEC relating to the Prior Financial Statements. As indicated in such Current Report on Form 8-K, on November 10, 2023, in connection with the preparation of the Company’s consolidated financial statements for the year ended September 30, 2023, we determined that a restatement of the Prior Financial Statements was necessary due to the identification of an error related to the accounting for the sale of ENTADFI assets on April 19, 2023, for which a gain on sale of $17.5 million was initially recorded. The Company determined that it was not probable, at the time of the transaction, that substantially all of the consideration promised under the asset purchase agreement would be collected. The consideration for the transaction should have only included the $6.0 million cash received by the Company at closing. The notes receivable in the aggregate principal amount of $14.0 million, and related imputed interest, issued pursuant to the asset purchase agreement, should not have been recorded in the financial statements due to the uncertainty involved in the collectability of these amounts. The corrected gain on the sale of ENTADFI assets should have been $4.7 million. As a result of the restatement there is:

- a $12.7 million decrease in the gain on the sale of the ENTADFI assets for the three and nine months ended June 30, 2023 versus the previously reported financial results;
- a $12.7 million increase in operating loss for the three and nine months ended June 30, 2023 versus the previously reported financial results, which resulted in a change from operating income of $4.9 million as previously reported for the three months ended June 30, 2023 to an operating loss of $7.9 million as restated for the three months ended June 30, 2023;
- a $13.0 million increase in net loss for the three and nine months ended June 30, 2023 versus the previously reported financial results, which resulted in a change from net income of $6.3 million as previously reported for the three months ended June 30, 2023 to a net loss of $6.7 million as restated for the three months ended June 30, 2023;
- elimination of notes receivable, short-term portion and notes receivable long-term portion from the Company’s unaudited condensed consolidated balance sheet as of June 30, 2023; and
- corresponding adjustments, and associated impacts of the adjustments, to:
    - accumulated deficit, total stockholders’ equity and total liabilities and stockholders’ equity in the Company’s unaudited condensed consolidated balance sheet as of June 30, 2023; and
    - net loss and adjustments to reconcile net loss to net cash used in operating activities in the Company's unaudited condensed consolidated statement of cash flows for the nine months ended June 30, 2023.

The restatement adjustments did not affect the net cash used in operating activities in the Company's unaudited condensed consolidated statement of cash flows for the nine months ended June 30, 2023.

See Note 1, Basis of Presentation and Restatement to the unaudited condensed consolidated financial statements included herein for additional information.

The Company also determined that there was an error in the going concern disclosures. Specifically, the Company considered if the Company's forecasted future cash flows will be sufficient to enable the Company to meet its contractual commitments and obligations as they come due in the ordinary course of business for a period of at least one year from the issuance of the Company's report on Form 10-Q for the quarterly period ended June 30, 2023 on August 10, 2023. As discussed in Note 2, Liquidity, Going Concern, and Management's Plans (Restated) to the unaudited condensed consolidated financial statements included herein, the collectability of the notes receivable and certain planned capital transactions were included in those cash flows but are not within the control of management and cannot be relied upon to provide future cash flows for the purpose of the going concern assessment. Therefore, the Company has concluded there is substantial doubt about the Company's ability to continue as a going concern, as described in Note 2.

Internal Control Considerations

As a result of the restatement of the Company's financial statements and the filing of this Form 10-Q/A, management has determined that a material weakness existed in the Company's internal control over financial reporting related to its controls over applying technical accounting guidance to nonrecurring events and transactions, specific to the evaluation of information that was known or knowable at the time of the transaction or event. The identified material weakness and the Company's remediation plan are further described in Item 4 within this Form 10-Q/A. In addition, as a result of the restatement of the Company's financial statements and the material weakness described above, management has reconsidered its assessment and now concludes that we did not maintain effective disclosure controls and procedures for the quarter ended June 30, 2023.

Items Amended in this Form 10-Q/A

For the convenience of the reader, this Form 10-Q/A presents the Original Form 10-Q, amended and restated in its entirety, with modifications as necessary to reflect the effects of the restatement of our previously issued unaudited condensed consolidated financial statements as of and for the three and nine months ended June 30, 2023. No attempt has been made in this Form 10-Q/A to update other disclosures presented in the Original Form 10-Q, except as required to reflect the effects of such restatement in the following amended items:

- Part I, Item 1. "Financial Statements";
- Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations";
- Part I, Item 4. "Controls and Procedures";
- Part II, Item 1A. "Risk Factors"; and
- Part II, Item 6. "Exhibits."

In addition, this Form 10-Q/A updates the signature page. In accordance with Rule 12b-15 under the Securities Exchange Act of 1934, the Company is also including with this Form 10-Q/A new certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act of 2022 from the Company's Chief Executive Officer (as principal executive officer) and Chief Financial Officer (as principal financial officer) dated as of the filing date of this Form 10-Q/A (included in Part II, Item 6. "Exhibits" and attached as Exhibits 31.1, 31.2, 32.1, and 32.2). Except as described above, this Form 10-Q/A is presented as of the date of the Original Form 10-Q and does not substantively amend, update or change any other items or disclosures contained in the Original Form 10-Q. Accordingly, this Form 10-Q/A does not reflect or purport to reflect any information or events occurring subsequent to August 10, 2023, the filing date of the Original Form 10-Q, unless specifically noted herein, or otherwise modify or update those disclosures affected by subsequent events, except to the extent they are otherwise required to be included and discussed herein. Among other things, forward-looking statements made in the Original Form 10-Q have not been revised to reflect events, results or developments that occurred or facts that became known to the Company after the date of the Original Form 10-Q, other than the restatement.

Accordingly, this Form 10-Q/A should be read in conjunction with the Company's filings with the SEC that were made after the filing of the Original Form 10-Q, including any amendments to those filings.

VERU INC.
INDEX

	PAGE
Forward Looking Statements	5
PART I. FINANCIAL INFORMATION	
Item 1. Financial Statements	8
Unaudited Condensed Consolidated Balance Sheets	8
Unaudited Condensed Consolidated Statements of Operations	9
Unaudited Condensed Consolidated Statements of Stockholders’ Equity	10
Unaudited Condensed Consolidated Statements of Cash Flows	12
Notes to Unaudited Condensed Consolidated Financial Statements	13
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	31
Item 3. Quantitative and Qualitative Disclosures About Market Risk	46
Item 4. Controls and Procedures	47
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	49
Item 1A. Risk Factors	50
Item 6. Exhibits	53

FORWARD LOOKING STATEMENTS

Certain statements included in this quarterly report on Form 10-Q which are not statements of historical fact are intended to be, and are hereby identified as, “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about our financial condition or business, our development and commercialization plans relating to our product candidates and products, including any potential development or commercialization of sabizabulin for certain COVID-19 patients and other acute respiratory distress syndrome (ARDS) indications and of enobosarm for certain breast cancer patients, 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 contingencies, financial condition, results of operations, liquidity, cost savings, future ordering patterns of our customers, objectives of management, business strategies, clinical trial timing, plans and results, the achievement of clinical and commercial milestones, the advancement of our technologies and our products and drug candidates, and other statements that are not historical facts. Forward-looking statements can be identified by the use of forward-looking words or phrases such as “anticipate,” “believe,” “could,” “expect,” “intend,” “may,” “opportunity,” “plan,” “predict,” “potential,” “estimate,” “should,” “will,” “would” or the negative of these terms or other words of similar meaning. These statements are based upon the Company’s current plans and strategies and reflect the Company’s current assessment of the risks and uncertainties related to its business and are made as of the date of this report. These statements are inherently subject to known and unknown risks and uncertainties. You should read these statements carefully because they discuss our future expectations or state other “forward-looking” information. There may be events in the future that we are not able to accurately predict or control and our actual results may differ materially from the expectations we describe in our forward-looking statements. Factors that could cause actual results to differ materially from those currently anticipated include the following:

- potential delays in the timing of and results from clinical trials and studies, including potential delays in the recruitment of patients and their ability to effectively participate in such trials and studies, and the risk that such results will not support marketing approval, emergency use authorization, or commercialization in the United States or in any foreign country;
- potential delays in the timing of any submission to the U.S. Food and Drug Administration (the “FDA”) or any other regulatory authority around the world and potential delays in, or failure to obtain, from any such regulatory authority approval of products under development or approval of any emergency use authorization applications the Company may submit for sabizabulin for certain COVID-19 patients, including the risk of a delay or failure in reaching agreement with the FDA on the design of any clinical trial, including any post-approval or post-authorization study, or in obtaining authorization to commence a clinical trial or commercialize a product candidate in the U.S. or elsewhere;
- potential delays in the timing of approval by the FDA or any other regulatory authority of the release of manufactured lots of approved products;
- clinical trial results supporting any potential regulatory approval or authorization of any of our products, including sabizabulin for the treatment of certain COVID-19 patients and other ARDS indications, may not be replicated in clinical practice;
- clinical results or early data from clinical trials may not be replicated or continue to occur in additional trials or may not otherwise support further development in the specified product candidate or at all;
- risks related to our ability to obtain sufficient financing on acceptable terms when needed to fund product development and our operations, including our ability to secure timely grant or other funding to develop, manufacture or distribute sabizabulin as a potential COVID-19 or other ARDS treatment;
- risks related to the development of our product portfolio, including clinical trials, regulatory approvals and time and cost to bring any of our product candidates to market, and risks related to efforts of our collaborators such as in the development of a companion diagnostic for enobosarm;
- our pursuit of a COVID-19 treatment candidate is still in development and we may be unable to develop a drug that successfully treats the virus in a timely manner, if at all;
- risks related to our commitment of financial resources and personnel to the development of a COVID-19 treatment which may cause delays in or otherwise negatively impact our other development programs or our working capital, despite uncertainties about the longevity and extent of COVID-19 as a global health concern and the possibility that as vaccines and other treatments become widely distributed the need for new COVID-19 treatment candidates may be reduced or eliminated;
- risks related to our ability to scale up and manufacture sabizabulin in sufficient quantities as a COVID-19 treatment if we receive an emergency use authorization in the U.S. or elsewhere;

- government entities may take actions that directly or indirectly have the effect of limiting opportunities for sabizabulin as a COVID-19 or other ARDS treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 or other ARDS treatments;
- government entities in the U.S. or elsewhere have and may continue to declare the COVID-19 pandemic emergency over and, if sabizabulin is authorized in the U.S. or elsewhere for the treatment of certain COVID-19 patients under an Emergency Use Authorization or similar regime outside the U.S., such termination of the pandemic emergency may affect our ability to continue to market sabizabulin;
- product demand and market acceptance of our commercial products and our products in development, if approved;
- risks related to our ability to obtain insurance reimbursement from private payors or government payors, including Medicare and Medicaid, for our approved or authorized products, including, if authorized, sabizabulin for the treatment of certain COVID-19 patients, and similar risks relating to market or political acceptance of any potential or actual pricing for any such products;
- some of our products are in development and we may fail to successfully commercialize such products;
- risks related to any potential new telehealth platform developed or used by us in commercializing our current product or potential future products, including potential regulatory uncertainty around such platforms 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 a large telehealth customer;
- risks related to intellectual property, including the uncertainty of obtaining intellectual property protections and in enforcing them, the possibility of infringing a third party's intellectual property, and licensing risks;
- competition from existing and new competitors including the potential for reduced sales, pressure on pricing and increased spending on marketing;
- risks related to compliance and regulatory matters, including costs and delays resulting from extensive government regulation and reimbursement and coverage under healthcare insurance and regulation as well as potential healthcare reform measures;
- the risk that we will be affected by regulatory and legal developments, including a reclassification of products or repeal or modification of part or all of the Patient Protection and Affordable Care Act;
- risks inherent in doing business on an international level, including currency risks, regulatory requirements, political risks, export restrictions and other trade barriers;
- the disruption of production at our manufacturing facilities or facilities of third parties on which we rely and/or of our ability to supply product due to raw material shortages, labor shortages, manufacturing partner business changes, physical damage to our or third parties' facilities, product testing, transportation delays or regulatory or other governmental actions, and the duration and impact of any such disruptions;
- our reliance on major customers and risks related to delays in, or failure to make, payment of accounts receivable by major customers;
- risks from rising costs of raw materials and our ability to pass along increased costs to our customers;
- risks related to our growth strategy;
- our continued ability to attract and retain highly skilled and qualified personnel;
- the costs and other effects of litigation, governmental investigations, legal and administrative cases and proceedings, settlements and investigations;
- government contracting risks, including the appropriations process and funding priorities, potential bureaucratic delays in awarding contracts, process errors, politics or other pressures, and the risk that government tenders and contracts may be subject to cancellation, delay, restructuring or substantial delayed payments;
- a governmental tender award indicates acceptance of the bidder's price rather than an order or guarantee of the purchase of any minimum number of units, and as a result government ministries or other public health sector customers may order and purchase fewer units than the full maximum tender amount;
- our ability to identify, successfully negotiate and complete suitable acquisitions, out-licensing transactions, in-licensing transactions or other strategic initiatives and to realize any potential benefits of such transactions or initiatives; 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, 2022. The Company undertakes no obligation to make any revisions to the forward-looking statements contained in this report or to update them to reflect events or circumstances occurring after the date of this report except as required by applicable law.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2023 (Restated)	September 30, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 16,213,136	$ 80,190,675
Accounts receivable, net	5,082,878	3,550,895
Inventories, net	6,489,968	8,618,944
Prepaid research and development costs	5,532,410	10,444,587
Prepaid expenses and other current assets	1,366,237	1,964,373
Total current assets	34,684,629	104,769,474
Plant and equipment, net	1,492,183	1,185,766
Operating lease right-of-use assets	4,495,336	4,786,915
Deferred income taxes	13,098,090	12,965,985
Intangible assets, net	23,810	3,977,381
Goodwill	6,878,932	6,878,932
Other assets	1,548,049	1,561,564
Total assets	$ 62,221,029	$ 136,126,017
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 18,118,594	$ 22,003,394
Accrued research and development costs	1,112,788	9,071,503
Accrued compensation	3,546,470	5,986,557
Accrued expenses and other current liabilities	2,789,733	2,249,995
Residual royalty agreement liability, short-term portion	1,061,893	1,169,095
Operating lease liability, short-term portion	1,056,702	957,085
Total current liabilities	27,686,180	41,437,629
Residual royalty agreement liability, long-term portion	9,276,735	9,656,441
Operating lease liability, long-term portion	3,805,137	4,093,667
Deferred income taxes	—	81,067
Other liabilities	40,111	18,577
Total liabilities	40,808,163	55,287,381
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock; no shares issued and outstanding at June 30, 2023 and September 30, 2022	—	—
Common stock, par value $0.01 per share; 154,000,000 shares authorized, 91,420,436 and 82,692,598 shares issued and 89,236,732 and 80,508,894 shares outstanding at June 30, 2023 and September 30, 2022, respectively	914,204	826,926
Additional paid-in-capital	276,756,250	253,974,032
Accumulated other comprehensive loss	(581,519)	(581,519)
Accumulated deficit	(247,869,464)	(165,574,198)
Treasury stock, 2,183,704 shares, at cost	(7,806,605)	(7,806,605)
Total stockholders' equity	21,412,866	80,838,636
Total liabilities and stockholders' equity	$ 62,221,029	$ 136,126,017

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2023 (Restated)	**2022**	**2023 (Restated)**	**2022**
Net revenues	$ 3,341,185	$ 9,602,195	$ 12,434,946	$ 36,765,721
Cost of sales	2,110,567	2,533,572	6,410,198	6,679,738
Gross profit	1,230,618	7,068,623	6,024,748	30,085,983
Operating expenses:				
Research and development	2,925,171	18,133,412	44,534,153	43,755,677
Selling, general and administrative	10,902,916	10,761,486	41,283,275	24,887,830
Provision for (recovery of) credit losses	—	(2,500)	3,911,714	(6,500)
Impairment of intangible assets	—	—	3,900,000	—
Total operating expenses	13,828,087	28,892,398	93,629,142	68,637,007
Gain on sale of ENTADFI® assets	4,723,623	—	4,723,623	—
Operating loss	(7,873,846)	(21,823,775)	(82,880,771)	(38,551,024)
Non-operating income (expenses):				
Interest expense	(648,917)	(1,185,093)	(2,219,840)	(3,556,477)
Change in fair value of derivative liabilities	1,789,000	881,000	2,319,000	(557,000)
Other income, net	131,133	69,895	409,059	135,897
Total non-operating income (expenses)	1,271,216	(234,198)	508,219	(3,977,580)
Loss before income taxes	(6,602,630)	(22,057,973)	(82,372,552)	(42,528,604)
Income tax expense (benefit)	57,551	137,603	(77,286)	224,808
Net loss	$ (6,660,181)	$ (22,195,576)	$ (82,295,266)	$ (42,753,412)
Net loss per basic and diluted common shares outstanding	$ (0.08)	$ (0.28)	$ (0.99)	$ (0.53)
Basic and diluted weighted average common shares outstanding	88,266,152	80,088,431	83,218,748	80,054,594

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, 2022	82,692,598	$ 826,926	$ 253,974,032	$ (581,519)	$ (165,574,198)	$ (7,806,605)	$ 80,838,636
Share-based compensation	—	—	4,845,269	—	—	—	4,845,269
Issuance of shares pursuant to share-based awards	114,234	1,142	255,990	—	—	—	257,132
Net loss	—	—	—	—	(36,842,179)	—	(36,842,179)
Balance at December 31, 2022	82,806,832	828,068	259,075,291	(581,519)	(202,416,377)	(7,806,605)	49,098,858
Share-based compensation	—	—	3,837,598	—	—	—	3,837,598
Issuance of shares pursuant to share-based awards	33,891	339	79,139	—	—	—	79,478
Sale of shares under common stock purchase agreement	1,920,013	19,200	2,552,351	—	—	—	2,571,551
Amortization of deferred costs	—	—	(78,677)	—	—	—	(78,677)
Net loss	—	—	—	—	(38,792,906)	—	(38,792,906)
Balance at March 31, 2023	84,760,736	847,607	265,465,702	(581,519)	(241,209,283)	(7,806,605)	16,715,902
Share-based compensation	—	—	4,550,832	—	—	—	4,550,832
Sale of shares under common stock purchase agreement	859,700	8,597	846,843	—	—	—	855,440
Amortization of deferred costs	—	—	(26,172)	—	—	—	(26,172)
Issuance of shares in a Private Investment in Public Equity, net of costs	5,000,000	50,000	4,919,045	—	—	—	4,969,045
Shares issued in connection with common stock purchase agreement	800,000	8,000	1,000,000	—	—	—	1,008,000
Net loss (restated)	—	—	—	—	(6,660,181)	—	(6,660,181)
Balance at June 30, 2023 (Restated)	91,420,436	$ 914,204	$ 276,756,250	$ (581,519)	$ (247,869,464)	$ (7,806,605)	$ 21,412,866

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (CONTINUED)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Treasury Stock, at Cost	Total
	Shares	Amount					
Balance at September 30, 2021	82,153,452	$ 821,535	$ 241,658,711	$ (581,519)	$ (81,798,178)	$ (7,806,605)	$ 152,293,944
Share-based compensation	—	—	1,880,428	—	—	—	1,880,428
Issuance of shares pursuant to share-based awards	79,334	793	209,076	—	—	—	209,869
Net loss	—	—	—	—	(6,380,006)	—	(6,380,006)
Balance at December 31, 2021	82,232,786	822,328	243,748,215	(581,519)	(88,178,184)	(7,806,605)	148,004,235
Share-based compensation	—	—	2,124,941	—	—	—	2,124,941
Issuance of shares pursuant to share-based awards	17,267	173	46,924	—	—	—	47,097
Net loss	—	—	—	—	(14,177,830)	—	(14,177,830)
Balance at March 31, 2022	82,250,053	822,501	245,920,080	(581,519)	(102,356,014)	(7,806,605)	135,998,443
Share-based compensation	—	—	2,910,976	—	—	—	2,910,976
Issuance of shares pursuant to share-based awards	61,636	616	153,337	—	—	—	153,953
Net loss	—	—	—	—	(22,195,576)	—	(22,195,576)
Balance at June 30, 2022	82,311,689	$ 823,117	$ 248,984,393	$ (581,519)	$ (124,551,590)	$ (7,806,605)	$ 116,867,796

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine Months Ended June 30,	
	2023 (Restated)	2022
OPERATING ACTIVITIES		
Net loss	$ (82,295,266)	$ (42,753,412)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	199,690	147,156
Impairment of intangible assets	3,900,000	—
Provision for credit losses	3,911,714	(6,500)
Gain on sale of ENTADFI® assets	(4,723,623)	—
Noncash change in right-of-use assets	556,475	411,002
Noncash interest expense, net of interest paid	1,832,092	1,415,978
Share-based compensation	13,233,699	6,916,345
Deferred income taxes	(213,172)	19,017
Change in fair value of derivative liabilities	(2,319,000)	557,000
Other	195,877	69,633
Changes in current assets and liabilities:		
Increase in accounts receivable	(4,729,697)	(930,021)
Decrease (increase) in inventories	845,688	(2,216,377)
Decrease (increase) in prepaid expenses and other assets	5,780,913	(1,737,701)
(Decrease) increase in accounts payable	(3,884,800)	3,526,541
(Decrease) increase in accrued expenses and other current liabilities	(10,358,135)	8,258,099
Decrease in operating lease liabilities	(453,809)	(303,266)
Net cash used in operating activities	(78,521,354)	(26,626,506)
INVESTING ACTIVITIES		
Cash proceeds from sale of ENTADFI® assets	6,000,000	—
Cash proceeds from sale of PREBOOST® business	—	5,000,000
Capital expenditures	(452,826)	(584,245)
Net cash provided by investing activities	5,547,174	4,415,755
FINANCING ACTIVITIES		
Proceeds from stock option exercises	336,610	410,919
Proceeds from sale of shares under common stock purchase agreement	3,426,991	—
Proceeds from sale of shares in a private investment in public equity, net of costs	4,969,045	—
Payment of deferred equity financing issuance costs	(263,757)	—
Proceeds from premium finance agreement	1,425,174	—
Installment payments on premium finance agreement	(897,422)	—
Cash paid for debt portion of finance lease	—	(9,093)
Net cash provided by financing activities	8,996,641	401,826
Net decrease in cash	(63,977,539)	(21,808,925)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	80,190,675	122,359,535
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 16,213,136	$ 100,550,610
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 387,748	$ 2,140,499
Schedule of non-cash investing and financing activities:		
Shares issued in connection with common stock purchase agreement	$ 1,008,000	
Right-of-use asset recorded in exchange for lease liabilities	$ 264,896	$ 4,411,474
Amortization of deferred costs related to common stock purchase agreement	$ 104,849	$ —

See notes to unaudited condensed consolidated financial statements.

VERU INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1 – Basis of Presentation and Restatement

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, 2022. The accompanying condensed consolidated balance sheet as of September 30, 2022 has been derived from our audited financial statements. The unaudited condensed consolidated statements of operations and cash flows for the three and nine months ended June 30, 2023 are not necessarily indicative of the results to be expected for any future period or for the fiscal year ending September 30, 2023.

The preparation of our unaudited interim condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates.

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

Principles of consolidation and nature of operations: Veru Inc. is referred to in these notes collectively with its subsidiaries as "we," "our," "us," "Veru" or the "Company." The consolidated financial statements include the accounts of Veru and its wholly owned subsidiaries, Veru International Holdco Inc., Aspen Park Pharmaceuticals, Inc. (APP) and The Female Health Company Limited; The Female Health Company Limited's wholly owned subsidiary, The Female Health Company (UK) plc (The Female Health Company Limited and The Female Health Company (UK) plc, collectively, the "U.K. subsidiary"); The Female Health Company (UK) plc's wholly owned subsidiary, The Female Health Company (M) SDN.BHD (the "Malaysia subsidiary"); and Veru International Holdco Inc.'s wholly owned subsidiaries, Veru Biopharma UK Limited, Veru Biopharma Europe Limited, and Veru Biopharma Netherlands B.V. All significant intercompany transactions and accounts have been eliminated in consolidation. The Company is a late clinical stage biopharmaceutical company focused on developing novel medicines for the treatment of breast cancer and for the treatment of viral induced acute respiratory distress syndrome (ARDS). Our drug development program includes enobosarm, a selective androgen receptor agonist, for the management of advanced breast cancer, and sabizabulin, a microtubule disruptor, for the treatment of hospitalized patients on oxygen support that are at high risk for 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 the transmission of sexually transmitted infections. The Company had ENTADFI® (finasteride and tadalafil) capsules for oral use (ENTADFI), a new treatment for benign prostatic hyperplasia that was approved by the FDA in December 2021. We sold substantially all of the assets related to ENTADFI on April 19, 2023. See Note 15 for additional information. Most of the Company's net revenues during the three and nine months ended June 30, 2023 and 2022 were derived from sales of FC2.

Restatement: The Company has restated its previously reported unaudited interim condensed consolidated financial statements as of and for the three and nine months ended June 30, 2023 to correct an error related to the accounting for the sale of ENTADFI assets on April 19, 2023. As discussed in Note 15, the Company entered into an asset purchase agreement with Blue Water Biotech Inc. formerly known as Blue Water Vaccines Inc. ("BWV"). Consideration per the asset purchase agreement included a payment of $6.0 million at closing and $14.0 million in notes receivable. The Company recorded a gain based on the total purchase price per the asset purchase agreement of $20.0 million and recorded notes receivable, net of imputed interest, for amounts to be received in the future.

In connection with the preparation of the Company's consolidated financial statements for the year ended September 30, 2023, the Company determined that it was not probable, at the time of the transaction, that substantially all of the consideration promised under the asset purchase agreement would be collected. The consideration for the transaction should have only included the $6.0 million cash received by the Company at closing, resulting in a misstatement of the gain on sale recorded as summarized below. The notes receivable in the aggregate principal amount of $14.0 million, and related imputed interest, issued pursuant to the asset purchase agreement, should not have been recorded in the financial statements due to the uncertainty involved in the collectability of the amounts.

As a result of the restatement, the Company has made adjustments to present the corrected amount of gain on the sale of ENTADFI assets as a reduction to the gain previously recognized in the accompanying condensed consolidated statements of operations and as a decrease in the notes receivable and related imputed interest previously recorded in the accompanying condensed consolidated balance sheet and statements of operations. The restatement adjustments did not affect the net cash used in operating activities in the Company's statement of cash flows.

The Company also determined that there was an error in the going concern disclosures. Specifically, the Company considered if the Company's forecasted future cash flows will be sufficient to enable the Company to meet its contractual commitments and obligations as they come due in the ordinary course of business for a period of at least one year from the issuance of the Company's report on Form 10-Q for the quarterly period ended June 30, 2023 on August 10, 2023. The collectability of the notes receivable and certain planned capital transactions were included in those cash flows but are not completely under the control of management and cannot be relied upon for the purposes of the going concern assessment. Therefore, the Company concluded there is substantial doubt about the Company's ability to continue as a going concern, as described in Note 2.

A summary of the impact of the error on the condensed consolidated balance sheet as of June 30, 2023 is as follows:

	As of June 30, 2023		
	As Reported	**Adjustment**	**As Restated**
Assets			
Notes receivable, short term portion	$ 8,536,535	$ (8,536,535)	$ —
Total current assets	$ 43,221,164	$ (8,536,535)	$ 34,684,629
Notes receivable, long-term portion	$ 4,437,850	$ (4,437,850)	$ —
Total assets	$ 75,195,414	$ (12,974,385)	$ 62,221,029
Liabilities and Stockholders' Equity			
Accumulated deficit	$ (234,895,079)	$ (12,974,385)	$ (247,869,464)
Total stockholders' equity	$ 34,387,251	$ (12,974,385)	$ 21,412,866
Total liabilities and stockholders' equity	$ 75,195,414	$ (12,974,385)	$ 62,221,029

A summary of the impact of the error on the condensed consolidated statement of operations for the three and nine months ended June 30, 2023 is as follows:

	Three Months Ended June 30, 2023		
	As Reported	**Adjustment**	**As Restated**
Gain on sale of ENTADFI® assets	$ 17,456,814	$ (12,733,191)	$ 4,723,623
Operating income (loss)	$ 4,859,345	$ (12,733,191)	$ (7,873,846)
Other income, net	$ 372,327	$ (241,194)	$ 131,133
Total non-operating income	$ 1,512,410	$ (241,194)	$ 1,271,216
Income (loss) before income taxes	$ 6,371,755	$ (12,974,385)	$ (6,602,630)
Net income (loss)	$ 6,314,204	$ (12,974,385)	$ (6,660,181)
Net income (loss) per basic common shares outstanding	$ 0.07	$ (0.15)	$ (0.08)
Net income (loss) per diluted common shares outstanding	$ 0.07	$ (0.15)	$ (0.08)
Diluted weighted average common shares outstanding	88,301,516	(35,364)	88,266,152

	Nine Months Ended June 30, 2023		
	As Reported	Adjustment	As Restated
Gain on sale of ENTADFI® assets	$ 17,456,814	$ (12,733,191)	$ 4,723,623
Operating loss	$ (70,147,580)	$ (12,733,191)	$ (82,880,771)
Other income, net	$ 650,253	$ (241,194)	$ 409,059
Total non-operating income	$ 749,413	$ (241,194)	$ 508,219
Loss before income taxes	$ (69,398,167)	$ (12,974,385)	$ (82,372,552)
Net loss	$ (69,320,881)	$ (12,974,385)	$ (82,295,266)
Net loss per basic common shares outstanding	$ (0.83)	$ (0.16)	$ (0.99)
Net loss per diluted common shares outstanding	$ (0.83)	$ (0.16)	$ (0.99)

A summary of the impact of the error on the condensed consolidated statement of cash flows for the nine months ended June 30, 2023 is as follows:

	Nine Months Ended June 30, 2023		
	As Reported	Adjustment	As Restated
OPERATING ACTIVITIES			
Net loss	$ (69,320,881)	$ (12,974,385)	$ (82,295,266)
Gain on sale of ENTADFI® assets	$ (17,456,814)	$ 12,733,191	$ (4,723,623)
Other	$ (45,317)	$ 241,194	$ 195,877

Other comprehensive loss: Accounting principles generally require that recognized revenue, expenses, gains and losses be included in net loss. Although certain changes in assets and liabilities, such as foreign currency translation adjustments, are reported as a separate component of the equity section of the accompanying unaudited condensed consolidated balance sheets, these items, along with net loss, are components of other comprehensive loss. For the three and nine months ended June 30, 2023 and 2022, comprehensive loss is equivalent to the reported net loss.

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

Note 2 – Liquidity, Going Concern, and Management's Plans (Restated)

We are not profitable and have had negative cash flow from operations. We will need substantial capital to support our drug development and any related commercialization efforts for our drug candidates. Because of the numerous risks and uncertainties associated with the development of pharmaceutical products, we are unable to estimate the exact amounts of expenditures necessary to fund development of our drug candidates and to obtain regulatory approvals thereon. To obtain the capital necessary to fund our operations, we expect to finance our cash needs through public or private equity offerings, debt financings and/or other capital sources, including, but not limited to, ongoing sales of FC2. Additional capital may not be available at such times and in such amounts as needed by us to fund our activities on a timely basis.

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

Note 3 – Fair Value Measurements

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

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

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

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

Level 3 – Instruments with primarily unobservable value drivers.

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

The following table provides a reconciliation of the beginning and ending liability balance associated with embedded derivatives measured at fair value using significant unobservable inputs (Level 3) as of June 30, 2023 and 2022:

	Nine Months Ended June 30,	
	2023	2022
Beginning balance	$ 4,294,000	$ 7,851,000
Change in fair value of derivative liabilities	(2,319,000)	557,000
Ending balance	$ 1,975,000	$ 8,408,000

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 June 30, 2023 and September 30, 2022:

Valuation Methodology	Significant Unobservable Input	June 30, 2023	September 30, 2022
Scenario-Based	Estimated change of control dates	September 2023 to June 2025	September 2023 to September 2025
	Discount rate	11.0% to 11.3%	13.6% to 14.2%
	Probability of change of control	50% to 90%	20% to 90%

Note 4 – Revenue from Contracts with Customers

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

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

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

The Company's revenue is from sales of FC2 in the U.S. prescription channel and direct sales of FC2 in the global public health sector, and also included sales of ENTADFI. The following table presents net revenues from these three categories:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2023	2022	2023	2022
FC2				
U.S. prescription channel	$ 863,379	$ 6,736,158	$ 5,172,543	$ 29,900,890
Global public health sector	2,478,031	2,866,037	7,249,315	6,864,831
Total FC2	3,341,410	9,602,195	12,421,858	36,765,721
ENTADFI	(225)	—	13,088	—
Net revenues	$ 3,341,185	$ 9,602,195	$ 12,434,946	$ 36,765,721

The following table presents net revenues by geographic area:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2023	2022	2023	2022
United States	$ 1,449,883	$ 7,024,786	$ 7,046,518	$ 30,780,271
South Africa	612,000	*	1,941,678	*
Other	1,279,302	2,577,409	3,446,750	5,985,450
Net revenues	$ 3,341,185	$ 9,602,195	$ 12,434,946	$ 36,765,721

*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 $6,000 and $342,000 at June 30, 2023 and September 30, 2022, respectively.

Note 5 – Accounts Receivable and Concentration of Credit Risk

The Company's standard credit terms vary from 30 to 120 days, depending on the class of trade and customary terms within a territory, so accounts receivable are affected by the mix of purchasers within the period. As is typical in the Company's business, extended credit terms may occasionally be offered as a sales promotion or for certain sales. For sales to the Company's distributor in Brazil, the Company has agreed to credit terms of up to 90 days subsequent to clearance of the product by the Ministry of Health in Brazil. The Company classified approximately $0.7 million of trade receivables with its distributor in Brazil as long-term as of September 30, 2022, because payment was expected in greater than one year. The long-term portion of trade receivables is included in other assets on the accompanying unaudited condensed consolidated balance sheet.

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

	June 30, 2023	September 30, 2022
Trade receivables, gross	$ 9,028,298	$ 4,289,892
Less: allowance for credit losses	(3,923,857)	(12,143)
Less: allowance for sales returns and payment term discounts	(21,563)	(12,854)
Less: long-term trade receivables*	—	(714,000)
Accounts receivable, net	$ 5,082,878	$ 3,550,895

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

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

At June 30, 2023, two customers had an accounts receivable balance greater than 10% of net accounts receivable, representing 58% of net accounts receivable in the aggregate. At September 30, 2022, two customers had an accounts receivable balance greater than 10% of net accounts receivable and long-term trade receivables, representing 83% of net accounts receivable and long-term trade receivables in the aggregate.

For the three months ended June 30, 2023, there were five customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 79% of the Company's net revenues in the aggregate. For the three months ended June 30, 2022, there were three customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 92% of the Company's net revenues in the aggregate, including The Pill Club that represented 69% of the Company's net revenue in the aggregate.

For the nine months ended June 30, 2023, there were two customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 56% of the Company's net revenues in the aggregate, including The Pill Club that represented 31% of the Company's net revenues in the aggregate. For the nine months ended June 30, 2022, there were two customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 78% of the Company's net revenues in the aggregate, including The Pill Club that represented 47% of the Company's net revenues in the aggregate.

The Company maintains an allowance for credit losses for estimated losses resulting from the inability of its customers to make required payments on accounts receivable. Management determines the allowance for credit losses by identifying troubled accounts and by using historical experience applied to an aging of accounts. Management also periodically evaluates individual customer receivables and considers a customer's financial condition, credit history, and the current economic conditions. In the case of a bankruptcy filing or other similar event indicating the collectability of specific customer accounts is no longer probable, a specific allowance for credit losses may be recorded to reduce the related receivable to the amount expected to be recovered. Accounts receivable are charged-off when deemed uncollectible. During the quarter ended March 31, 2023, the Company recorded a provision for credit losses of $3.9 million related to the total amount of receivables due from The Pill Club due to uncertainty related to their financial condition. On April 18, 2023, The Pill Club filed for Chapter 11 bankruptcy.

The table below summarizes the change in the allowance for credit losses for the nine months ended June 30, 2023 and 2022:

	Nine Months Ended June 30,	
	2023	2022
Beginning balance	$ 12,143	$ 20,643
Charges to expense, net of recoveries	3,911,714	(6,500)
Ending balance	$ 3,923,857	$ 14,143

Recoveries of accounts receivable previously charged off are recorded when received. In the global public health sector, the Company's customers are primarily large global agencies, non-government organizations, ministries of health and other governmental agencies, which purchase and distribute FC2 for use in HIV/AIDS prevention and family planning programs. In the U.S., the Company's customers include telemedicine providers who sell into the prescription channel.

Note 6 – Balance Sheet Information

Inventories

Inventories are valued at the lower of cost or net realizable value. The cost is determined using the first-in, first-out (FIFO) method. Inventories are also written down for management's estimates of product which will not sell prior to its expiration date. Write-downs of inventories establish a new cost basis which is not increased for future increases in the net realizable value of inventories or changes in estimated obsolescence.

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

	June 30, 2023	September 30, 2022
Raw material	$ 1,245,019	$ 1,662,712
Work in process	75,848	872,596
Finished goods	5,376,970	6,099,343
Inventories, gross	6,697,837	8,634,651
Less: inventory reserves	(207,869)	(15,707)
Inventories, net	$ 6,489,968	$ 8,618,944

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

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 June 30, 2023 and September 30, 2022:

	Estimated Useful Life	June 30, 2023	September 30, 2022
Plant and equipment:			
Manufacturing equipment	5 - 8 years	$ 3,295,743	$ 2,902,715
Office equipment, furniture and fixtures	3 - 10 years	1,498,968	1,440,475
Leasehold improvements	3 - 8 years	484,460	484,460
Total plant and equipment		5,279,171	4,827,650
Less: accumulated depreciation and amortization		(3,786,988)	(3,641,884)
Plant and equipment, net		$ 1,492,183	$ 1,185,766

Depreciation expense was approximately $53,000 and $39,000 for the three months ended June 30, 2023 and 2022, respectively, and approximately $146,000 and $94,000 for the nine months ended June 30, 2023 and 2022, respectively. Plant and equipment included $501,000 and $276,000 at June 30, 2023 and September 30, 2022, respectively, for deposits on equipment, furniture, and leasehold improvements, which have not been placed into service; therefore, the Company has not started to record depreciation expense.

Note 7 – Intangible Assets and Goodwill

Intangible Assets

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

	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Intangible asset with finite life:			
Covenants not-to-compete	$ 500,000	$ 476,190	$ 23,810
Indefinite-lived intangible assets:			
Acquired in-process research and development assets	—	—	—

Total intangible assets	$ 500,000	$ 476,190	$ 23,810

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

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

Amortization expense was approximately $18,000 for the three months ended June 30, 2023 and 2022 and approximately $54,000 for the nine months ended June 30, 2023 and 2022.

During the second quarter of fiscal 2023, the Company announced its strategic decision to refocus its drug development efforts on those drug candidates that it believes have the best opportunity to lead to long-term success and shareholder value creation. As part of this strategic decision, the Company has indefinitely ceased development of sabizabulin for prostate cancer and zuclomiphene. The Company has no current plans that would invest funds in the development of these two assets or that would lead to the Company deriving value from these two assets, which has met the criteria for abandonment under the accounting standards. This resulted in writing off the carrying amount of these two acquired in-process research and development assets and recording an impairment charge of $3.9 million during the quarter ended March 31, 2023.

Goodwill

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

Note 8 – Debt

SWK Residual Royalty Agreements

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

In connection with the Credit Agreement, the Company and the Agent also entered into a Residual Royalty Agreement, dated as of March 5, 2018 (as amended, the "Residual Royalty Agreement"), which provides for an ongoing royalty payment of 5% of product revenue from net sales of FC2. The Residual Royalty Agreement will terminate upon (i) a change of control or sale of the FC2 business and the payment by the Company of the amount due in connection therewith pursuant to the Residual Royalty Agreement, or (ii) mutual agreement of the parties. If a change of control or sale of the FC2 business occurs, the Agent will receive a payment that is the greater of (A) $2.0 million or (B) the product of (x) 5% of the product revenue from net sales of FC2 for the most recently completed 12-month period multiplied by (y) five.

For accounting purposes, the $10.0 million advance under the Credit Agreement was allocated between the Credit Agreement and the Residual Royalty Agreement on a relative fair value basis. A portion of the amount allocated to the Residual Royalty Agreement, equal to the fair value of the respective change of control provisions, was allocated to an embedded derivative liability. The derivative liability is adjusted to fair market value at each reporting period.

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

	June 30, 2023	September 30, 2022
Residual royalty agreement liability, fair value at inception	$ 346,000	$ 346,000
Add: accretion of liability using effective interest rate	12,170,748	9,950,908
Less: cumulative payments	(4,153,120)	(3,765,372)
Residual royalty agreement liability, excluding embedded derivative liability	8,363,628	6,531,536
Add: embedded derivative liability at fair value (see Note 3)	1,975,000	4,294,000
Total residual royalty agreement liability	10,338,628	10,825,536
Residual royalty agreement liability, short-term portion	(1,061,893)	(1,169,095)
Residual royalty agreement liability, long-term portion	$ 9,276,735	$ 9,656,441

As the Company has repaid the original principal of $10.0 million advanced in connection with the Credit Agreement and the Residual Royalty Agreement, payments under the Residual Royalty Agreement are classified as interest payments and included in operating activities on the accompanying unaudited condensed consolidated statements of cash flows. The short-term portion of the Residual Royalty Agreement liability represents the aggregate of the estimated quarterly payments on the Residual Royalty Agreement payable during the 12-month period subsequent to the balance sheet date.

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

Premium Finance Agreement

On November 1, 2022, the Company entered into a Premium Finance Agreement to finance $1.4 million of its directors and officers liability insurance premium at an annual percentage rate of 6.3%. The financing is payable in eleven monthly installments of principal and interest, beginning on December 1, 2022. The balance of the insurance premium liability is $0.5 million as of June 30, 2023 and is included in accrued expenses and other current liabilities on the accompanying unaudited condensed consolidated balance sheet.

Note 9 – Stockholders' Equity

Preferred Stock

The Company has 5,000,000 authorized shares designated as Class A Preferred Stock with a par value of $0.01 per share. There are 1,040,000 shares of Class A Preferred Stock – Series 1 authorized; 1,500,000 shares of Class A Preferred Stock – Series 2 authorized; 700,000 shares of Class A Preferred Stock – Series 3 authorized; and 548,000 shares of Class A Preferred Stock – Series 4 (the "Series 4 Preferred Stock") authorized. There were no shares of Class A Preferred Stock of any series issued and outstanding at June 30, 2023 and September 30, 2022. The Company has 15,000 authorized shares designated as Class B Preferred Stock with a par value of $0.50 per share. There were no shares of Class B Preferred Stock issued and outstanding at June 30, 2023 and September 30, 2022, and there was no activity during the nine months ended June 30, 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 June 30, 2023, $23.0 million remains available under that shelf registration statement. The Company's prior shelf registration statement on Form S-3 (File No. 333-239493) expired on July 1, 2023.

Aspire Capital Purchase Agreement

On June 26, 2020, the Company entered into a common stock purchase agreement (the “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.

During the nine months ended June 30, 2023, we sold 2,779,713 shares of common stock to Aspire Capital under the 2020 Purchase Agreement resulting in proceeds to the Company of $3.4 million. As a result of these sales, we recorded approximately $105,000 of deferred costs to additional paid-in capital.

During the 36-month term of the 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.

In consideration for entering into the 2020 Purchase Agreement and concurrently with the execution of the 2020 Purchase Agreement, the Company issued to Aspire Capital 212,130 shares of the Company’s common stock. The shares of common stock issued as consideration were valued at $681,000, based on the closing price per share of the Company’s common stock on the date the shares were issued. This amount and related expenses of $50,000, which total approximately $731,000, were recorded as deferred costs. The unamortized amount of deferred costs related to the 2020 Purchase Agreement remaining when the agreement terminated was $473,000 and was expensed at the time of termination. It is included in selling, general and administrative expenses on the accompanying unaudited condensed consolidated statements of operations for the three and nine month periods ended June 30, 2023. There were unamortized deferred costs related to the 2020 Purchase Agreement of $578,000 at September 30, 2022, which is included in other assets on the accompanying unaudited condensed consolidated balance sheet.

Private Investment in Public Equity

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

Lincoln Park Capital Fund LLC Purchase Agreement

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

Under the Lincoln Park Purchase Agreement, the Company has the right, but not the obligation, on any business day selected by the Company (the “Purchase Date”), provided that on such day the closing sale price per share of the Company’s common stock is above the Floor Price, as defined in the Lincoln Park Purchase Agreement, to require Lincoln Park to purchase up to 225,000 shares of the Company’s common stock (the “Regular Purchase Amount”) at the Purchase Price (as defined below) per purchase notice (each such purchase, a “Regular Purchase”) provided, however, that (1) the limit on the Regular Purchase Amount will be increased to 250,000 shares, if the closing sale price of the Company’s common stock on the applicable Purchase Date is not below $6.00 and to 275,000 shares, if

the closing sale price of the Company's common stock on the applicable Purchase Date is not below $8.00. Lincoln Park's committed obligation under each Regular Purchase shall not exceed $2,500,000 or 2,000,000 Purchase Shares per each Regular Purchase. The purchase price for Regular Purchases (the "Purchase Price") shall be equal to the lesser of: (i) the lowest sale price of the Company's common stock during the Purchase Date, or (ii) the average of the three lowest closing sale prices of the Company's common stock on the 10 consecutive business days ending on the business day immediately preceding such Purchase Date. The Company shall have the right to submit a Regular Purchase notice to Lincoln Park as often as every business day. A Regular Purchase notice is delivered to Lincoln Park after the market has closed (i.e., after 4:00 P.M. Eastern Time) so that the Purchase Price is always fixed and known at the time the Company elects to sell shares to Lincoln Park.

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

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

In consideration for entering into the Lincoln Park Purchase Agreement, concurrently with the execution of the Lincoln Park Purchase Agreement, the Company issued 800,000 shares of the Company's common stock to Lincoln Park. The shares of common stock issued as consideration were valued at $1.0 million, based on the closing price per share of the Company's common stock on the date the shares were issued. This amount and related expenses of $57,000, which total approximately $1.1 million, were recorded as deferred costs and are included in other assets on the accompanying unaudited condensed consolidated balance sheet as of June 30, 2023. We are obligated to issue $1.0 million of shares of the Company's common stock at the time Lincoln Park's purchases cumulatively reach an aggregate amount of $50.0 million of Purchase Shares.

Subsequent to June 30, 2023, we sold 1,000,000 shares of common stock to Lincoln Park under the Lincoln Park Purchase Agreement, resulting in proceeds to the Company of $1.2 million.

At-the-Market Sale Agreement

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

The Company is not obligated to sell any shares of common stock under the Jefferies Sales Agreement. Subject to the terms and conditions of the Jefferies Sales Agreement, Jefferies will use commercially reasonable efforts consistent with its normal trading and sales practices, to sell shares of common stock from time to time based upon the Company’s instructions, including any price, time or size limits specified by the Company. Upon delivery of a placement notice, and subject to our instructions in that notice, and the terms and conditions of the Jefferies Sales Agreement generally, Jefferies may sell the Company’s common stock by any method permitted by law deemed to be an “at the market offering” as defined by Rule 415(a)(4) promulgated under the Securities Act. Under the terms of the Sales Agreement, the Company cannot cause or request Jefferies to sell shares of common stock exceeding the number of shares of common stock authorized, unissued and available for issuance at any time. The Company will pay Jefferies a commission of 3% of the aggregate gross proceeds from each sale of common stock and has agreed to provide Jefferies with customary indemnification and contribution rights, including liabilities under the Securities Act and the Securities Exchange Act of 1934, as amended. The Company has also agreed to reimburse Jefferies for certain specified expenses. The Company incurred issuance costs of $207,000, which were deferred and are included in other assets on the accompanying unaudited condensed consolidated balance sheet as of June 30, 2023. The Company has not sold any shares of common stock under the Jefferies Sales Agreement.

Note 10 – Share-based Compensation

We allocate share-based compensation expense to cost of sales, selling, general and administrative expense, and research and development expense based on the award holder’s employment function. For the three and nine months ended June 30, 2023 and 2022, we recorded share-based compensation expenses as follows:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Cost of sales	$ 112,515	$ 25,275	$ 263,879	$ 70,923
Selling, general and administrative	3,667,599	2,052,755	10,183,510	5,036,356
Research and development	770,718	832,946	2,786,310	1,809,066
Share-based compensation	$ 4,550,832	$ 2,910,976	$ 13,233,699	$ 6,916,345

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 June 30, 2023, 3,895,250 shares remain available for issuance under the Inducement Plan.

In March 2018, the Company’s stockholders approved the Company's 2018 Equity Incentive Plan (as amended, the “2018 Plan”). On March 29, 2022, the Company’s stockholders approved an increase in the number of shares that may be issued under the 2018 Plan to 18.5 million. As of June 30, 2023, 2,431,616 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 June 30, 2023, 12,472 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 $317,000 and $1.8 million during the three and nine months ended June 30, 2023 for stock options forfeited during the period. The reduction in share-based compensation expense during the three and nine months ended June 30, 2022 for stock options forfeited was immaterial.

The following table outlines the weighted average assumptions for options granted during the three and nine months ended June 30, 2023 and 2022:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Weighted Average Assumptions:				
Expected volatility	104.96%	92.58%	101.37%	83.77%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%
Risk-free interest rate	3.51%	3.01%	3.92%	2.10%
Expected term (in years)	6.0	6.0	6.0	6.0
Fair value of options granted	$ 1.12	$ 8.97	$ 5.55	$ 6.92

During the three and nine months ended June 30, 2023 and 2022, the Company used historical volatility of our common stock over a period equal to the expected life of the options to estimate their fair value. The dividend yield assumption is based on the Company's recent history and expectation of future dividend payouts on the common stock. The risk-free interest rate is based on the implied yield available on U.S. treasury zero-coupon issues with an equivalent remaining term.

The following table summarizes the stock options outstanding and exercisable at June 30, 2023:

		Weighted Average		
	Number of Shares	**Exercise Price Per Share**	**Remaining Contractual Term (years)**	**Aggregate Intrinsic Value**
Outstanding at September 30, 2022	14,263,470	$ 5.00		
Granted	4,927,775	$ 6.93		
Exercised	(148,125)	$ 2.27		
Forfeited and expired	(1,078,262)	$ 11.00		
Outstanding at June 30, 2023	17,964,858	$ 5.19	7.19	$ 35,604
Exercisable at June 30, 2023	10,213,653	$ 3.43	5.77	$ 34,604

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 June 30, 2023 of $1.19, less the respective weighted average exercise price per share at period end.

The total intrinsic value of options exercised during the nine months ended June 30, 2023 and 2022 was approximately $486,000 and $1.3 million, respectively. Cash received from options exercised during the nine months ended June 30, 2023 and 2022 was approximately $337,000 and $411,000, respectively.

As of June 30, 2023, the Company had unrecognized compensation expense of approximately $34.8 million related to unvested stock options. This expense is expected to be recognized over a weighted average period of 2.1 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 June 30, 2023, vested stock appreciation rights based on 50,000 shares of common stock remain outstanding.

Note 11 – Leases

The Company has operating leases for its office, manufacturing and warehouse space, and office equipment. The Company's leases have remaining lease terms of less than one year to seven years, which include the option to extend a lease when the Company is reasonably certain to exercise that option. Certain of our lease agreements include variable lease payments for common area maintenance, real estate taxes, and insurance or based on usage for certain equipment leases. For one of our office space leases, the Company entered into a sublease, for which it receives sublease income. Sublease income is recognized as a reduction to operating lease costs as the sublease is outside of the Company's normal business operations. This is consistent with the Company's recognition of sublease income prior to the adoption of FASB ASC Topic 842. The Company does not have any leases that have not yet commenced as of June 30, 2023.

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

The components of the Company's lease cost were as follows for the three and nine months ended June 30, 2023 and 2022:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Finance lease cost:				
Amortization of right-of-use assets	$ —	$ —	$ —	$ 3,631
Interest on lease liabilities	—	—	—	403
Operating lease cost	277,211	285,010	838,112	598,965
Short-term lease cost	10,903	11,112	32,003	36,817
Variable lease cost	33,926	69,531	136,569	162,287
Sublease income	(44,844)	(44,844)	(134,533)	(134,533)
Total lease cost	$ 277,196	$ 320,809	$ 872,151	$ 667,570

The Company paid cash of $777,000 and $449,000 for amounts included in the measurement of operating lease liabilities during the nine months ended June 30, 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 June 30, 2023 and September 30, 2022.

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

	June 30, 2023	**September 30, 2022**
Operating Leases		
Weighted-average remaining lease term	6.1	6.8
Weighted-average discount rate	7.7%	7.6%

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

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

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, 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”). This 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 Complaint. The Maglia Lawsuit seeks to direct the Company to improve its corporate governance and internal procedures, and also seeks monetary damages, injunctive relief, restitution, and an award of reasonable fees and expenses. The Company believes that the allegations asserted in the Maglia Lawsuit are without merit, and the Company intends to vigorously defend the lawsuit. There can be no assurance that the Company will be successful. At this time, the Company is unable to estimate potential losses, if any, related to the Maglia Lawsuit.

License and Purchase Agreements

From time to time, we license or purchase rights to technology or intellectual property from third parties. These licenses and purchase agreements require us to pay upfront payments as well as development or other payments upon successful completion of preclinical, clinical, regulatory or revenue milestones. In addition, these agreements may require us to pay royalties on sales of products arising from the licensed or acquired technology or intellectual property. Because the achievement of future milestones is not reasonably estimable, we have not recorded a liability on the accompanying unaudited condensed consolidated financial statements for any of these contingencies.

Collaborative Arrangements

On January 31, 2022, the Company entered into a Clinical Trial Collaboration and Supply Agreement (the “Lilly Agreement”) with Eli Lilly and Company (“Lilly”). Under the Lilly Agreement, the Company is sponsoring a clinical trial in which both the Company’s enobosarm compound and Lilly’s compound are being dosed in combination. The Company is conducting the research at its own cost and Lilly is contributing its compound towards the study at no cost to the Company. The parties will continue to hold exclusive rights to all intellectual property relating solely to their own respective compounds. The Company will provide to Lilly copies of clinical data relating to the clinical trial and certain rights to use the clinical data. Veru maintains full exclusive, global commercialization rights to the enobosarm compound.

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

Note 13 – Income Taxes (Restated)

The Company accounts for income taxes using the liability method, which requires the recognition of deferred tax assets or liabilities for the tax-effected temporary differences between the financial reporting and tax bases of its assets and liabilities, and for net operating loss (NOL) and tax credit carryforwards.

As of September 30, 2022, the Company had U.S. federal and state NOL carryforwards of $112.7 million and $51.3 million, respectively, for income tax purposes with $29.7 million and $31.6 million, respectively, expiring in years 2023 to 2042 and $82.9 million and $19.6 million, respectively, which can be carried forward indefinitely. As of September 30, 2022, the Company also had U.S. federal research and development tax credit carryforwards of $5.9 million, expiring in years 2038 to 2042. The Company's U.K. subsidiary has U.K. NOL carryforwards of $63.1 million as of September 30, 2022, which can be carried forward indefinitely to be used to offset future U.K. taxable income.

The Tax Cuts and Jobs Act of 2017, which was signed into U.S. law in December 2017, eliminated the option to immediately deduct research and development expenditures in the year incurred under Section 174 of the Internal Revenue Code ("Section 174") effective for the Company October 1, 2022. The amended provision under Section 174 requires us to capitalize and amortize these expenditures over five years, for U.S.-based research, and over 15 years, for foreign-based research. As of June 30, 2023, we recorded a decrease to income tax benefit and an increase to deferred tax assets, before applying a valuation allowance, of approximately $8.7 million as a result of the amended provision under Section 174. Because the Company has a full valuation allowance recorded against U.S. deferred tax assets, the net impact to income tax benefit and deferred tax assets from the amended provision under Section 174 is zero.

A reconciliation of income tax expense (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 June 30,		Nine Months Ended June 30,	
	2023	2022	2023	2022
Income tax expense (benefit) at U.S. federal statutory rates	$ (1,386,552)	$ (4,632,174)	$ (17,298,236)	$ (8,931,007)
State income tax expense (benefit), net of federal benefit	(107,359)	(358,662)	(1,339,378)	(691,515)
Non-deductible expenses	(262,005)	(355,069)	185,564	4,860
Effect of stock options exercised	—	(147,570)	63,849	(170,920)
U.S. research and development tax credit	2,835,378	(1,283,944)	415,378	(4,160,374)
Effect of foreign income tax rates	406,324	366,493	307,188	327,055
Effect of global intangible low taxed income	(24,691)	(12,989)	(24,691)	—
Change in valuation allowance	(1,382,325)	6,504,878	17,640,877	13,637,539
Other, net	(21,219)	56,640	(27,837)	209,170
Income tax expense (benefit)	$ 57,551	$ 137,603	$ (77,286)	$ 224,808

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

	June 30, 2023	September 30, 2022
Deferred tax assets:		
Federal net operating loss carryforwards	$ 28,662,430	$ 23,627,461
State net operating loss carryforwards	3,253,511	2,850,956
Foreign net operating loss carryforwards – U.K.	16,083,790	15,773,497
Foreign capital allowance – U.K.	128,490	128,490
U.S. research and development tax credit carryforwards	8,066,411	8,481,789
U.S. research and development expense	8,722,825	—
Accrued compensation	764,724	1,227,290
Share-based compensation	6,926,088	4,325,354
Interest expense	2,575,342	2,206,484
Credit loss provision	885,562	—
Change in fair value of derivative liabilities	—	220,607
Other, net – U.K.	265,631	265,631
Other, net – Malaysia	4,712	—
Other, net – U.S.	81,387	81,507
Gross deferred tax assets	76,420,903	59,189,066
Valuation allowance for deferred tax assets	(63,013,329)	(45,372,452)
Net deferred tax assets	13,407,574	13,816,614
Deferred tax liabilities:		
In-process research and development	—	(882,427)
Change in fair value of derivative liabilities	(304,098)	—
Other, net - Malaysia	—	(17,641)
Other, net – U.S.	(5,386)	(31,628)
Net deferred tax liabilities	(309,484)	(931,696)
Net deferred tax asset	$ 13,098,090	$ 12,884,918

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

	June 30, 2023	September 30, 2022
Deferred tax asset – U.K.	$ 13,093,378	$ 12,965,985
Deferred tax asset – Malaysia	4,712	—
Total deferred tax asset	$ 13,098,090	$ 12,965,985
Deferred tax liability – U.S.	$ —	$ (63,426)
Deferred tax liability – Malaysia	—	(17,641)
Total deferred tax liability	$ —	$ (81,067)

Note 14 – Net Loss Per Share (Restated)

Basic net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period. Diluted net income (loss) per share is computed by dividing net income by the weighted average number of common shares outstanding during the period after giving effect to all dilutive potential common shares that were outstanding during the period. Dilutive potential common shares consist of the incremental common shares issuable upon the exercise of stock options and stock appreciation rights as determined under the treasury stock method. Due to our net loss for the periods presented, all potentially dilutive instruments were excluded because their inclusion would have been anti-dilutive. See Note 10 for a discussion of our potentially dilutive common shares.

Note 15 – Sale of ENTADFI Assets (Restated)

On April 19, 2023, the Company entered into an asset purchase agreement (the "BWV Asset Purchase Agreement") to sell substantially all of the assets related to ENTADFI® (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia that was approved by the FDA in December 2021, with Blue Water 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. The Company determined that it was not probable, at the time of the transaction, that substantially all of the consideration promised under the asset purchase agreement would be collected. Therefore, the Company recognizes the difference between the nonrefundable consideration received and the carrying amount of the assets as a gain. The gain is recorded considering only the nonrefundable consideration of $6.0 million received by the Company at closing. Total assets sold, consisting primarily of inventory, had a net book value of approximately $1.3 million. The Company recorded a gain of approximately $4.7 million on the transaction during the three months ended June 30, 2023. The gain calculation will be updated if additional consideration is received in future periods or when it is deemed probable that substantially all of the consideration promised will be collected. The Company will continue to evaluate the collectability of the notes receivable.

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

Note 16 – Subsequent Events

On July 24, 2023, the Company held a special meeting at which the Company's shareholders approved an increase in the number of authorized shares of common stock from 154,000,000 to 308,000,000.

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

RESTATEMENT

As discussed in the Explanatory Note to this Form 10-Q/A and in the section title "Restatement" in Note 1 to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q/A, we have restated the previously issued unaudited condensed consolidated financial statements as of and for the three and nine months ended June 30, 2023. The following discussion and analysis of our financial condition and results of operations incorporates the restated amounts.

Overview

Veru is a late clinical stage biopharmaceutical company focused on developing novel medicines for the treatment of advanced breast cancer and for the treatment of viral induced acute respiratory distress syndrome (ARDS). Our drug development program includes enobosarm, a selective androgen receptor agonist, for the second line treatment of metastatic breast cancer, and sabizabulin, a microtubule disruptor, for the treatment of hospitalized patients with viral lung infection on oxygen support who are at high risk for viral induced ARDS. The Company also has an FDA-approved commercial product, the FC2 Female Condom® (Internal Condom) (FC2), for the dual protection against unplanned pregnancy and sexually transmitted infections.

Oncology Program:

The Company's oncology drug pipeline is focused on the clinical development of enobosarm, an oral selective androgen receptor agonist, for the treatment of metastatic breast cancer.

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

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 90% of ER+ HER2- metastatic breast cancers have an androgen receptor, we are developing enobosarm, a selective androgen receptor targeted agent, 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 CDK 4/6 inhibitor alone. Interestingly, CDK 4/6 inhibitor treatment caused the metastatic breast cancer tissue to make higher amounts of AR which may explain the synergy of combining a CDK 4/6 inhibitor with enobosarm, a selective AR agonist. 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.

Phase 3 clinical ENABLAR-2 study – Enobosarm +/- abemaciclib (CDK 4/6 inhibitor) combination versus estrogen blocking agent (active control) as a second line treatment for AR+ ER+ HER2- metastatic breast cancer.

On March 30, 2023, the Company met with the FDA to gain further agreement on Phase 3 clinical trial design and program. The Phase 3 study has been amended to accommodate the FDA's latest recommendations to support registration as second line treatment for 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 Phase 3 ENABLAR-2 study has two distinct study stages. In Stage 1 of the Phase 3 study, the objectives are to optimize the dose of enobosarm in the abemaciclib combination and to assess the effects of enobosarm as a monotherapy. The clinical trial design of Stage 1 consists of five treatment arms of 32 patients each: estrogen blocking agent (active control); abemaciclib + enobosarm 9mg combination therapy; abemaciclib + enobosarm 3mg combination therapy; abemaciclib + enobosarm 1mg combination therapy; and enobosarm 9mg monotherapy. The primary endpoint for Stage 1 is objective tumor response rates (ORR). We are currently producing clinical supply of 1mg and 3mg enobosarm capsules for the additional dose optimization arms, which is expected to be available in the fourth quarter of calendar year 2023.

The Stage 1 initial run-in enrolled 3 patients to assess the safety and pharmacokinetics of the abemaciclib + enobosarm combination. In this run-in portion, there were no drug-to-drug interactions between abemaciclib and enobosarm, and there were no new safety findings. Further, the early preliminary clinical results showed 2 partial responses and 1 stable disease in the first 3 patients based on local assessments, and all patients are on study for over 9 months.

In Stage 2 of the Phase 3 study, we plan to enroll approximately 200 subjects in a multicenter, open label, randomized (1:1), active control clinical study, to evaluate the efficacy and safety of enobosarm with or without abemaciclib therapy (depending on the outcome of Stage 1) versus an alternative estrogen blocking agent (selective estrogen receptor degrader or an aromatase inhibitor) in subjects with AR+ ER+ HER2- metastatic breast cancer who have failed palbociclib (a CDK 4/6 inhibitor) plus an estrogen blocking agent (nonsteroidal aromatase inhibitor or selective estrogen receptor degrader). The primary endpoint for Stage 2 of the Phase 3 study is progression-free survival.

Our current plan is to have Phase 3 Stage 1 clinical results by late 2024 or 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 the Company plans to meet with the FDA to consider an accelerated approval regulatory pathway based on the clinical data from the Stage 1 portion of the Phase 3 study.

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

Infectious Disease Program:

Viral-Induced Acute Respiratory Distress Syndrome

The Company is developing sabizabulin 9mg, which has both host targeted antiviral and broad anti-inflammatory properties, as a two-pronged approach to the treatment of hospitalized patients with viral lung infection at high risk for ARDS and death. The Company has completed positive Phase 2 and positive Phase 3 COVID-19 clinical studies that 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. As viruses that cause viral lung infection and ARDS do so in a similar way, the Company believes sabizabulin has the potential to be a treatment for all types of viral, not only SARS-CoV-2, but also influenza A or B and Respiratory Syncytial Virus (RSV), lung infections in hospitalized patients on oxygen who are at high risk for ARDS and death. We plan to meet with FDA in September to expand the agreed upon Phase 3 confirmatory COVID-19 study into a Phase 3 study to treat hospitalized adult patients who have any kind of viral lung infection who are on oxygen support and at risk for ARDS.

COVID-19

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

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

On February 28, 2023, the FDA notified the Company that it has declined to grant at this time the Company's request for Emergency Use Authorization for sabizabulin to treat hospitalized moderate to severe COVID-19 patients who are at high risk for ARDS. In communicating its decision, the FDA stated that despite the FDA declining to issue an EUA for sabizabulin at this time, the FDA remains committed to working with the Company in the development of sabizabulin. Separately on February 16, 2023, the FDA also provided comments on a confirmatory Phase 3 study protocol submitted by the Company for hospitalized moderate to severe COVID-19 patients at risk for ARDS and death that could support a new EUA request to the FDA. At this time, the Company has been informed by all ex-US regulatory authorities, like the FDA, that they will require some level of additional data before granting emergency, conditional, and/or other authorization of sabizabulin for COVID-19.

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

Influenza

On April 4, 2023, the Company announced results from a preclinical study of sabizabulin demonstrating robust anti-inflammatory activity with improved outcomes in an H1N1 Influenza-Induced Pulmonary Inflammation Mouse ARDS Model conducted by a team of researchers at Labcorp Early Development Laboratories, Ltd, United Kingdom. Sabizabulin treatment resulted in a statistically significant decrease in the total number of inflammatory cells and the reduction in key cytokines and chemokines in lung fluid. Clinically, sabizabulin treatment resulted in a reduction in the severity of lung inflammation by histopathology and a dose-dependent improvement of lung function.

Viral lung infection and high risk for ARDS

In general, the COVID-19 virus and other types of viral infections trigger the immune system in a similar way to release an overwhelming amount of inflammatory proteins known as a cytokine storm. The cytokine storm causes tissue damage in the lungs leading to Acute Respiratory Distress Syndrome (ARDS). Common viral infections that cause ARDS include COVID-19, influenza A or B, and RSV. Patients who develop ARDS have a high mortality rate. As viral-induced ARDS results from the over-exaggerated immune inflammatory response by patients to the virus infection, rather than by viral mediated direct injury, an antiviral agent alone may not be effective. Sabizabulin, as a host targeted antiviral and broad-spectrum anti-inflammatory agent, has the potential to address the virus infection and the inflammation caused by the cytokine storm that causes ARDS, multi-organ failure, and death.

In the current endemic phase, COVID-19 infection is estimated to be the 4th leading cause of death in the United States. ARDS remains a frequent serious complication of severe COVID-19 infection. It has been reported that up to 33% of hospitalized patients with COVID-19 have ARDS, and 75% to 92% of patients admitted to the intensive care unit with COVID-19 have ARDS. The mortality rate of COVID-19 associated ARDS is 45%, and among patients who died from COVID-19, there is a 90% incidence of ARDS. As the COVID-19 endemic continues, there also is a need to remain vigilant and focused on preparedness for the next wave of infections involving new viral strains. COVID-19 will be a problem for the foreseeable future, and there is a need for effective therapies, especially for those hospitalized patients with moderate-to-severe COVID-19 infection at high risk for ARDS. Further, the influenza burden estimates according to the Centers for Disease Control and Prevention in the United States were up to 630,000 hospitalizations and up to 55,000 deaths in the past 6 months. RSV was responsible for 177,000 hospitalizations and 14,000 deaths among adults 65 years and older in the United States. Pathogenesis and mortality rates for hospitalized influenza and RSV adult patients who have viral lung infection and who develop ARDS are similar to COVID-19-associated ARDS. Patients with viral lung infection who are on oxygen support and who are at risk for ARDS represent a high unmet need and a potentially large market opportunity, with very limited treatment options.

Although we have reached agreement with the FDA for the design of Phase 3 confirmatory COVID-19 clinical trial (discussed above), the Company now plans to meet with the FDA again to reach agreement on the design of a proposed expanded Phase 3 confirmatory study evaluating sabizabulin 9mg for the treatment of hospitalized adult patients who have viral lung infection and are on oxygen support who are at high risk for ARDS and death regardless of the type of virus. The FDA has granted a meeting with Veru for September 2023. We will provide an update on the viral lung infection ARDS program after we meet with the FDA. If we reach agreement with the FDA on the proposed ARDS sabizabulin study, we would not expect to pursue the Phase 3 confirmatory COVID-only study or the influenza A or B-only study.

The Influenza & Emerging Infectious Diseases Division of the Biomedical Advanced Research and Development Authority (BARDA) is planning a large multicenter clinical trial in hospitalized adult patients with ARDS. This clinical trial will evaluate the safety and efficacy of novel threat-agnostic and host-directed therapeutics that could address ARDS caused by known and unknown health security threats such as pandemic influenza, COVID-19, other emerging infectious diseases, and chemical, biological, radiological, and nuclear incidents. Veru was selected as one of the finalists and presented sabizabulin as a broad antiviral and anti-inflammatory agent in hospitalized adult patients at high risk for ARDS. The ARDS Therapeutics Pitch event “Just Breathe” was conducted at the end of July 2023. We expect to be notified of the decision early in the fourth quarter of calendar year 2023. BARDA plans to select up to three Phase 2 therapeutic candidates representing different mechanisms of action for participation in the planned BARDA-sponsored ARDS clinical study which would have 200 subjects per arm.

Smallpox and Ebola Viruses

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

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

Sabizabulin, as a host targeted antiviral and broad anti-inflammatory agent, may be useful as a novel treatment not only against smallpox and other poxviruses, but also may reduce the hyperactive immune response triggered by poxviruses that is responsible for severe pneumonia, ARDS, multi-organ failure, and death. Based on the preclinical data, the Company plans to expand the sabizabulin program to include other serious virus infections that pose a global public health threat to society. The Company plans to have pre-IND meetings with the FDA to discuss Animal Rule regulatory requirements for assessing the efficacy of sabizabulin for smallpox virus as well as Ebola virus. The smallpox virus pre-IND meeting has been granted and will take place in August 2023. Clinical human efficacy trials of drugs for preventing or treating smallpox and Ebola viruses are not feasible and challenge studies in healthy subjects are unethical. Therefore, drugs for these indications are generally developed and approved under a regulatory pathway commonly referred to as the *Animal Rule* (21 CFR part 314, subpart I, for drugs and 21 CFR part 601, subpart H, for biologics). The FDA may grant marketing approval based on adequate and well-controlled animal efficacy studies when the results of those studies establish that the drug is reasonably likely to produce clinical benefit in humans.

Sexual Health Program

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

The Company sells FC2 in both the U.S. commercial sector and in the public health sector both in the U.S. and globally.

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

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

Having taken the time to refine our marketing, drive operational improvements, and enhance the patient experience during the initial launch phase over the last nine months, there are increasing new prescriptions being written and filled through our FC2 telehealth portal. During the third quarter of fiscal 2023, we saw our acquisition costs remain stable with new prescriptions growing over 115%, providing prescriptions to approximately 4,400 patients in total. We believe these results support our strategy and demonstrate high demand for FC2. We plan to continue to grow and deepen our investment in a profitable way by further expanding our presence both in social media channels and online search.

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

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

Sale of ENTADFI

The Company had another FDA-approved product, ENTADFI® (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia that was approved by the FDA in December 2021. This product was part of the Company's sexual health program. On April 19, 2023, the Company entered into an Asset Purchase Agreement with Blue Water Vaccines Inc. (BWV) to sell substantially all of the assets related to ENTADFI. The transaction closed on April 19, 2023. The purchase price for the transaction was $20.0 million, consisting of $6.0 million paid at closing, $4.0 million payable by September 30, 2023, $5.0 million payable 12 months after closing, and $5.0 million payable by September 30, 2024, plus up to $80.0 million based on BWV's net revenues from ENTADFI after closing.

Consolidated Operations:

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

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

The Pill Club had historically been our largest telehealth customer for FC2, accounting for 44% of our net revenues (including 58% of our U.S. prescription channel revenue) in fiscal 2022 and 43% of our net revenues (including 57% of our U.S. prescription channel revenue) in fiscal 2021. We sold FC2 to The Pill Club at a wholesale price pursuant to purchase orders received from The Pill Club from time to time. The Pill Club took title to FC2 and then acted as a distributor of FC2. The Pill Club was solely responsible for its interactions with health care providers and patients (including, without limitation, the conduct of the telehealth physician-patient interactions), pricing of the FC2 products that it distributed, and legal and regulatory compliance. We had no oversight of The Pill Club's operations.

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

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

We also have a concentration of accounts receivable with The Pill Club, which totaled $3.9 million as of June 30, 2023. During the quarter ended March 31, 2023, the Company recorded a provision for credit losses for the entire amount of these receivables, due to the uncertainty as to whether or when The Pill Club would pay these amounts. The Pill Club filed for Chapter 11 bankruptcy on April 18, 2023 and its assets were sold in June 2023 to satisfy a secured creditor. Our claims against The Pill Club for these receivables have been filed with The Pill Club bankruptcy estate and we will continue to pursue payment for as much of the receivables as possible. It is uncertain at this time what assets will be available to satisfy unsecured creditors, such as Veru.

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

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

The Company manufactures FC2 in a leased facility located in Selangor D.E., Malaysia, resulting in a portion of the Company's operating costs being denominated in foreign currencies. While a significant portion of the Company's future unit sales are likely to be in foreign markets, all sales are denominated in the U.S. dollar. Effective October 1, 2009, the Company's U.K. and Malaysia subsidiaries adopted the U.S. dollar as their functional currency, further reducing the Company's foreign currency risk.

The Company relies on supply for its principal raw material for FC2 from one supplier who is a technical market leader in synthetic polymers. The supplier has indicated that it intends to close the facility where our specialty grade of nitrile is currently manufactured at the end of our current fiscal year. We intend to move to an alternative grade of nitrile, which will require us to incur costs to formulate and test the alternative grade and seek FDA approval of the alternative grade. The supplier has stated that it will assist in providing continuity of supply while we transfer to the standardized grade of nitrile. We have sufficient inventory in the U.S. to cover all the expected demand from the U.S. prescription channel while this transfer occurs. Additionally, we plan to build sufficient inventory to cover any gap of supply resulting from such a transfer or change in raw material grade. However, if this transfer or change of raw material grade results in an interruption of supply of FC2, we may not have sufficient supply to fulfill orders in the global public health sector.

Operating Expenses. The Company manufactures FC2 at its Malaysian facility. The Company's cost of sales consists primarily of direct material costs, direct labor costs and indirect production and distribution costs. Direct material costs include raw materials used to make FC2, principally a nitrile polymer. Indirect production costs include logistics, quality control and maintenance expenses, as well as costs for electricity and other utilities. All the key components for the manufacture of FC2 are essentially available from either multiple sources or multiple locations within a source.

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

Conducting research and development is central to our oncology 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 $2.9 million and $18.1 million for the three months ended June 30, 2023 and 2022, respectively, and $44.5 million and $43.8 million for the nine months ended June 30, 2023 and 2022, respectively. We expect to continue this trend of investing significant resources in research and development due to advancement of our drug candidates, enobosarm and sabizabulin, at the same time.

Results of Operations (Restated)

THREE MONTHS ENDED JUNE 30, 2023 COMPARED TO THREE MONTHS ENDED JUNE 30, 2022

The Company generated net revenues of $3.3 million and net loss of $6.7 million, or $(0.08) per basic and diluted common share, for the three months ended June 30, 2023, compared to net revenues of $9.6 million and net loss of $22.2 million, or $(0.28) per basic and diluted common share, for the three months ended June 30, 2022. Net revenues decreased 65% compared to the prior period.

All of the Company's net revenues for the three months ended June 30, 2023 and 2022 were derived from sales of FC2 in the U.S. prescription channel and global public health sector. There was a change in the sales mix with the U.S. prescription channel representing 26% of total FC2 net revenues in the current year period compared to 70% in the prior year period and the global public health sector representing 74% of total FC2 net revenues in the current year period compared to 30% in the prior year period. Sales to the global public health sector are at a lower sales price per unit. The Company experienced a decrease compared to the prior year period of 87% in FC2 net revenues in the U.S. prescription channel and a decrease compared to the prior year period of 14% in FC2 net revenues in the global public health sector.

The decrease in FC2 net revenues in the U.S. prescription channel is primarily due to net revenues from The Pill Club of $6.6 million in the prior year period. We did not have any net revenues from The Pill Club in the current year period due to The Pill Club's Chapter 11 bankruptcy filing. We are working to increase net revenues in future periods based on growing awareness and demand through increased FC2 marketing efforts, through our telehealth platform, and through discussions with potential new distribution partners in the telehealth sector.

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 $2.1 million in the three months ended June 30, 2023 from $2.5 million in the three months ended June 30, 2022 due to a decrease in unit sales, partially offset by a higher cost per unit sold, due to reduced production volume as a result of lower sales volume.

Gross profit decreased to $1.2 million in the three months ended June 30, 2023 from $7.1 million in the three months ended June 30, 2022. Gross profit margin for the fiscal 2023 period was 37% of net revenues, compared to 74% of net revenues for the fiscal 2022 period. The decrease in the gross profit and gross profit margin is primarily due to the decrease in FC2 net revenues in the U.S. prescription channel, which have higher profit margins and reduced production as a result of lower sales volume, which results in a higher cost per unit.

Research and development expenses decreased to $2.9 million in the three months ended June 30, 2023 from $18.1 million in the same period in fiscal 2022. The decrease is primarily 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. Increased costs in the prior year period were mainly related to sabizabulin for COVID-19 and the Company's related emergency use authorization application.

Selling, general and administrative expenses were $10.9 million in the three months ended June 30, 2023, which is comparable with $10.8 million in the three months ended June 30, 2022.

During the quarter ended June 30, 2023, the Company recorded a pre-tax gain of $4.7 million on the sale of the Company's ENTADFI ® assets. See 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 $0.6 million in the three months ended June 30, 2023, compared with $1.2 million in the three months ended June 30, 2022. The decrease relates to a decrease in actual and projected FC2 sales.

The gain associated with the change in fair value of the embedded derivative related to the Residual Royalty Agreement was $1.8 million in the three months ended June 30, 2023, compared to a gain of $0.9 million in the three months ended June 30, 2022. The liability associated with embedded derivative represents the fair value of the change of control provisions in the Residual Royalty Agreement. The decrease in the fair value of the embedded derivative in the current year period is due to a change in the estimated change of control dates related to the FC2 business. See Note 3 and Note 8 to the financial statements included in this report for additional information.

Income tax expense in the second quarter of fiscal 2023 was $58,000, compared to income tax expense of $137,000 in the second quarter of fiscal 2022. Income tax expense is primarily due to the Company's subsidiary in Malaysia. 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.

NINE MONTHS ENDED JUNE 30, 2023 COMPARED TO NINE MONTHS ENDED JUNE 30, 2022

The Company generated net revenues of $12.4 million and net loss of $82.3 million, or $(0.99) per basic and diluted common share, for the nine months ended June 30, 2023, compared to net revenues of $36.8 million and net loss of $42.8 million, or $(0.53) per basic and diluted common share, for the nine months ended June 30, 2022. Net revenues decreased 66% compared to the prior period.

Most of the Company's net revenues for the nine months ended June 30, 2023 and 2022 were derived from sales of FC2 in the U.S. prescription channel and global public health sector. There was a change in the sales mix with the U.S. prescription channel representing 42% of total FC2 net revenues in the current year period compared to 81% in the prior year period and the global public health sector representing 58% of total FC2 net revenues in the current year period compared to 19% in the prior year period.

The decrease in FC2 net revenues in the U.S. prescription channel is primarily due to lower volume from telemedicine customers as a result of on-going business challenges, which based on discussions with such customers, we understand included changes in strategy, the impact of rebranding, and reductions in marketing spending and which resulted in a slowdown in orders during recent quarters, which resulted in those customers discontinuing operations. Specifically, net revenues from The Pill Club were $3.9 million in the current year period compared to $17.4 million in the prior year period. We have recorded a provision for credit losses for the net revenues during the current year period, which were included in the gross accounts receivable balance at June 30, 2023, due to The Pill Club's Chapter 11 bankruptcy filing in April 2023. Net revenues from another prescription channel customer were $11.3 million in the prior year period and zero in the current year period, which based on customer discussions, we understand to be due to inventory management after a reduction in orders from its most significant customer, due to discontinued operations, which resulted in our customer ceasing orders. We are working to increase net revenues in future periods based on growing awareness and demand through increased FC2 marketing efforts, through our telehealth platform, and through discussions with potential new distribution partners in the telehealth sector.

The increase in FC2 net revenues in the global public health sector is because the Company began shipping units under the 2022 South Africa Tender in the current year period as well as increases in the U.S. public sector. Significant quarter-to-quarter variances in sales in the global public health sector have historically resulted from the timing and shipment of large orders rather than from any fundamental changes in the business or the underlying demand for FC2. The Company is also currently seeing pressure on pricing for FC2 by large global agencies and donor governments in the developed world. As a result, the Company may continue to experience challenges for revenue from sales of FC2 in the global public health sector.

Cost of sales decreased to $6.4 million in the nine months ended June 30, 2023 from $6.7 million in the nine months ended June 30, 2022. The decrease is due to a decrease in units sold, partially offset by a higher cost per unit sold, due to reduced production volume as a result of lower sales volume.

Gross profit decreased to $6.0 million in the nine months ended June 30, 2023 from $30.1 million in the nine months ended June 30, 2022. Gross profit margin for the fiscal 2023 period was 48% of net revenues, compared to 82% of net revenues for the fiscal 2022 period. The decrease in the gross profit and gross profit margin is primarily due to the decrease in FC2 net revenues in the U.S. prescription channel, which have higher profit margins, and reduced production as a result of lower sales volume, which results in a higher cost per unit.

Research and development expenses was $44.5 million in the nine months ended June 30, 2023 compared with $43.8 million in the same period in fiscal 2022. Increased research and development expenses in the second half of fiscal 2022 and the first half of fiscal 2023 were mainly related to sabizabulin for COVID-19 and the Company's emergency use authorization application. In the third quarter of fiscal 2023, research and development expense has decreased due to the Company's updated strategy to refocus development efforts on those drug candidates which it believes have the best opportunity to lead to long-term success and shareholder value creation.

Selling, general and administrative expenses increased to $41.3 million in the nine months ended June 30, 2023 from $24.9 million in the nine months ended June 30, 2022. The increase is due primarily to commercialization costs of $12.9 million related to preparations for the potential launch of sabizabulin for COVID-19 incurred in the fiscal 2023 period prior to the FDA's declination decision on the Company's EUA application, and an increase in share-based compensation costs to $10.2 million from $5.0 million, resulting from increased number of unvested stock options, for which the Company recognizes expense over a three year period.

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

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

During the quarter ended June 30, 2023, the Company recorded a pre-tax gain of $4.7 million on the sale of the Company's ENTADFI ® assets. See 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 $2.2 million in the nine months ended June 30, 2023, decreased from $3.6 million in the nine months ended June 30, 2022. The decrease relates to a decrease in actual and projected FC2 sales.

The gain associated with the change in fair value of the embedded derivatives related to the Residual Royalty Agreement was $2.3 million in the nine months ended June 30, 2023, compared to a loss of $0.6 million in the nine months ended June 30, 2022. The liability associated with embedded derivative represents the fair value of the change of control provisions in the Residual Royalty Agreement. The decrease in the fair value of the embedded derivative in the current year period is due to a decrease in projected FC2 net revenues in future periods and a change in the estimated change of control dates. See Note 3 and Note 8 to the financial statements included in this report for additional information.

Income tax benefit in the fiscal 2023 period was $77,000, compared to income tax expense of $0.2 million in the fiscal 2022 period. The change is due to a tax benefit recorded in the current period due to a net loss recognized by our U.K. subsidiary and a benefit recorded for the elimination of deferred tax liabilities upon the impairment of the IPR&D assets, compared to a tax expense in the prior year period due to net income recognized by our U.K. and Malaysia subsidiaries. The U.S. continues to have a full valuation allowance on its deferred tax assets; therefore, activity in the U.S. has no effect on income tax expense or benefit.

Liquidity and Sources of Capital

Liquidity

Our cash and cash equivalents on hand at June 30, 2023 was $16.2 million, compared to $80.2 million at September 30, 2022. At June 30, 2023, the Company had working capital of $7.0 million and stockholders' equity of $21.4 million compared to working capital of $63.3 million and stockholders' equity of $80.8 million as of September 30, 2022. The decrease in working capital is primarily due to the decrease in cash on hand, related to our increased spend on research and development and drug commercialization costs, partially offset by a decrease in accounts payable and accrued expenses.

We are not profitable and have had negative cash flow from operations. We will need substantial capital to support our drug development and any related commercialization efforts for our drug candidates. Because of the numerous risks and uncertainties associated with the development of pharmaceutical products, we are unable to estimate the exact amounts of expenditures necessary to fund development of our drug candidates and to obtain regulatory approvals thereon. To obtain the capital necessary to fund our operations, we expect to finance our cash needs through public or private equity offerings, debt financings and/or other capital sources, including, but not limited to, ongoing sales of FC2. Additional capital may not be available at such times and in such amounts as needed by us to fund our activities on a timely basis.

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

Operating activities

Operating activities used cash of $78.5 million in the nine months ended June 30, 2023. Cash used in operating activities included net loss of $82.3 million, adjustments to reconcile net loss to net cash used in operating activities totaling an increase of $16.6 million and changes in operating assets and liabilities resulting in a decrease of $12.8 million. Adjustments to net loss primarily consisted of $13.2 million of share-based compensation, $3.9 million for impairment of intangible assets, $3.9 million provision for credit losses, and interest expense in excess of interest paid of $1.8 million, partially offset by the gain on sale of ENTADFI assets of $4.7 million and the change in fair value of the derivate liabilities of $2.3 million. The decrease in cash from changes in operating assets and liabilities included a decrease in accrued expenses and other current liabilities of $10.4 million, a decrease in accounts payable of $3.9 million and an increase in accounts receivable of $4.7 million, partially offset by a decrease in prepaid expenses and other current assets of $5.8 million.

Operating activities used cash of $26.6 million in the nine months ended June 30, 2022. Cash used in operating activities included net loss of $42.8 million, adjustments to reconcile net loss to net cash used in operating activities totaling an increase of $9.5 million and changes in operating assets and liabilities resulting in an increase of $6.6 million. Adjustments to net loss primarily consisted of $6.9 million of share-based compensation and interest expense in excess of interest paid of $1.4 million. The increase in cash from changes in operating assets and liabilities included an increase in accounts payable of $3.5 million and an increase in accrued expenses and other current liabilities of $8.3 million, partially offset by an increase in accounts receivable of $0.9 million, an increase in inventory of $2.2 million, and an increase in prepaid expenses and other current assets of $1.7 million.

Investing activities

Net cash from investing activities was $5.5 million in the nine months ended June 30, 2023, and consisted of $6.0 million received from the sale of the Company's ENTADFI assets, partially offset by $0.5 million of capital expenditures primarily at our Malaysia location.

Net cash from investing activities was $4.4 million in the nine months ended June 30, 2022, and consisted of $5.0 million collected on notes receivable from the sale of the Company's PREBOOST® business, partially offset by $0.6 million associated with capital expenditures primarily at our U.S. location.

Financing activities

Net cash provided by financing activities in the nine months ended June 30, 2023 was $9.0 million, and primarily consisted of proceeds from the sale of shares to Frost Gamma Investments Trust ("FGI") in a private investment in public equity of $5.0 million, proceeds from sale of shares under the common stock purchase agreement with Aspire Capital (see discussion below) of $3.4 million, and proceeds from stock option exercises of $0.3 million.

Net cash provided by financing activities in the nine months ended June 30, 2022 was $0.4 million, attributed to proceeds from stock option exercises of $0.4 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 $0.4 million and $2.1 million during the nine months ended June 30, 2023 and 2022, respectively. The Company currently estimates the aggregate amount of quarterly revenue-based payments payable during the 12-month period subsequent to June 30, 2023 will be approximately $1.1 million under the Residual Royalty Agreement.

Aspire Capital Purchase Agreement

On June 26, 2020, the Company entered into a common stock purchase agreement (the "2020 Purchase Agreement") with Aspire Capital Fund, LLC (Aspire Capital) which 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 nine months ended June 30, 2023, we sold 2,779,713 shares of common stock to Aspire Capital under the 2020 Purchase Agreement, resulting in proceeds to the Company of $3.4 million. 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 FGI, pursuant to which, on the date thereof, the Company issued and sold 5,000,000 shares of the Company's common stock to FGI at a price of $1.00 per share, for a total investment of $5,000,000, through a private investment in public equity financing. The shares of common stock issued to FGI pursuant to the Stock Purchase Agreement were not registered under the Securities Act. The Company filed a registration statement under the Securities Act to register the resale of the shares of common stock issued to FGI, which was declared effective on May 24, 2023.

Lincoln Park Capital Fund, LLC Purchase Agreement

On May 2, 2023, the Company entered into a common stock purchase agreement (the "Lincoln Park Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right, but not the obligation, to sell to Lincoln Park up to $100.0 million of shares (the "Purchase Shares") of the Company's common stock over the 36-month term of the Lincoln Park Purchase Agreement. On the date the Company executed the Lincoln Park Purchase Agreement, we also issued 800,000 shares of the Company's common stock to Lincoln Park as an initial fee for Lincoln Park's commitment to purchase shares of the Company's common stock under the Lincoln Park Purchase Agreement, and we are obligated to issue $1.0 million of shares of the Company's common stock at the time Lincoln Park's purchases cumulatively reach an aggregate amount of $50.0 million (such shares, collectively, the "Commitment Shares"). The Purchase Shares and Commitment Shares under the Lincoln Park Purchase Agreement have been registered pursuant to the Company's effective shelf registration statement on Form S-3 (File No. 333-270606), and a related prospectus supplement that was filed with the SEC on May 3, 2023. No shares of common stock have been sold under the Lincoln Park Purchase Agreement as of June 30, 2023. Subsequent to June 30, 2023, we sold 1,000,000 shares of common stock to Lincoln Park under the Lincoln Park Purchase Agreement, resulting in proceeds to the Company of $1.2 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. The Company has not sold any shares of common stock under the Jefferies Sales Agreement.

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.

Fair Value Measurements

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

The fair values of these liabilities were estimated based on unobservable inputs (Level 3 measurement), which requires highly subjective judgment and assumptions. The Company estimates the fair value of the embedded derivative within the Residual Royalty Agreement using a scenario-based method, whereby different scenarios are valued and probability weighted. The scenario-based valuation model incorporates transaction details such as the contractual terms of the instrument and assumptions including projected FC2 revenues, expected cash outflows, probability and estimated dates of a change of control, risk-free interest rates and applicable credit risk. As a result, the use of different estimates or assumptions would result in a higher or lower fair value and different amounts being recorded in the Company's financial statements. Material changes in any of these inputs could result in a significantly higher or lower fair value measurement at future reporting dates, which could have a material effect on our results of operations. See Note 3 to the financial statements included in this report for additional information.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

Limitations on Effectiveness of Controls and Procedures

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

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Quarter Report on Form 10-Q/A, 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 June 30, 2023, due to the material weakness in internal control over financial reporting described below.

As further described below, our management is in the process of developing plans to remediate the material weakness identified, but it has not been remediated as of the date of the filing of this Form 10-Q/A.

Material Weakness in Internal Control Over Financial Reporting

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

Subsequent to the filing of the Original Form 10-Q, in connection with the restatement, management identified a material weakness in the Company's internal control over financial reporting related to its controls over applying technical accounting guidance to nonrecurring events and transactions, specific to the evaluation of information that was known or knowable at the time of the transaction or event. Refer to the section titled "Restatement" in Note 1 to the unaudited interim condensed consolidated financial statements as of and for the three and nine months ended June 30, 2023 included in this Form 10-Q/A.

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.

This matter has been reviewed with our Audit Committee and the material weakness resulted in the restatement described in Note 1 to the unaudited interim condensed consolidated financial statements as of and for the three and nine months ended June 30, 2023 included in this Form 10-Q/A.

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

Remediation Plan

We are evaluating the material weakness and are developing a plan of remediation to strengthen the effectiveness of the design and operation of our internal control environment. The remediation plan will include the following actions:

- enhance our review procedures with respect to 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 developing a review checklist, and apply that information to the applicable accounting guidance.

The actions that we are taking are subject to ongoing senior management review as well as Audit Committee oversight. We are committed to maintaining a strong internal control environment and believe that these remediation efforts, encapsulated in a nonrecurring transactions review checklist, will represent significant improvements to the internal controls around complex nonrecurring transactions. We have started to implement these steps; however, some of these steps will take time to be fully integrated and assessed as being designed and operating effectively. Until the remediation steps set forth above are fully implemented and tested, the material weakness described above will continue to exist.

Changes in Internal Control over Financial Reporting

As discussed above, we identified a material weakness in our control over financial reporting for the period covered by the Form 10-Q/A and are developing 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 period covered by this Quarterly Report on Form 10-Q/A that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

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

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

We will need large amounts of capital to support our development and commercialization efforts for our drug candidates, including the Phase 3 COVID-19 confirmatory study for certain COVID-19 patients. If we are unable to secure sufficient capital to fund our operations, we will not be able to continue these efforts and we might have to enter into strategic collaborations that could require us to share commercial rights to one or more of our drug candidates with third parties in ways that we currently do not intend or on terms that may not be favorable to us. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms and not enter into strategic collaborations, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

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

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

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

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

We are subject to risks relating to the concentration of accounts receivable with The Pill Club.

The Pill Club was one of our largest customers, accounting for 44% of our net revenues in fiscal 2022 and 43% of our net revenues in fiscal 2021. We have a concentration of accounts receivable at The Pill Club, with $3.9 million of accounts receivable as of June 30, 2023. On April 18, 2023, The Pill Club filed for Chapter 11 bankruptcy and its assets were sold in June 2023 to satisfy a secured creditor. Our claims against The Pill Club for these receivables have been filed with The Pill Club bankruptcy estate and we will continue to pursue payment for as much of the receivables as possible but we may not recover all or any of these receivables. It is uncertain at this time what assets will be available to satisfy unsecured creditors, such as Veru.

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

We have relied on a sole supplier for the principal raw material for FC2. The supplier has indicated that it intends to close the facility where our specialty grade of nitrile is currently manufactured at the end of our current fiscal year. We intend to move to an alternative grade of nitrile, which will require us to incur costs to formulate and test the alternative grade and seek FDA approval of the alternative grade. We are not certain of the amount of time or costs involved in this transition. In addition, while the supplier has stated that it will assist in providing continuity of supply while we transfer to the alternative grade of nitrile and we have sufficient inventory in the U.S. to cover all the expected demand from the U.S. prescription channel while this transfer occurs, if this transfer or change in raw material grade results in an interruption of supply of FC2, we may not have sufficient supply to fulfill orders in the global public health sector.

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

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

Subsequent to the filing of the Original Form 10-Q, in connection with the restatement, management identified a material weakness in the Company’s internal control over financial reporting related to its controls over applying technical accounting guidance to nonrecurring events and transactions, specific to the evaluation of information that was known or knowable at the time of the transaction or event. Refer to the section titled "Restatement” in Note 1 to the unaudited interim condensed consolidated financial statements as of and for the three and nine months ended June 30, 2023 included in this Form 10-Q/A. Management determined that such material weakness resulted in the Company’s internal control over financial reporting and disclosure controls and procedures not being effective as of June 30, 2023.

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

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

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

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

Subsequent to the filing of the Original Form 10-Q, in connection with the restatement, management identified a material weakness in the Company’s internal control over financial reporting related to its controls over applying technical accounting guidance to nonrecurring events and transactions, specific to the evaluation of information that was known or knowable at the time of the transaction or event. Refer to the section titled "Restatement” in Note 1 to the unaudited interim condensed consolidated financial statements as of and for the three and nine months ended June 30, 2023 included in this Form 10-Q/A.

As a result of the restatement described above, we have incurred, and may continue to incur, unanticipated costs for accounting and legal fees in connection with, or related to, such restatement. In addition, such restatement could subject us to a number of additional risks and uncertainties, including the increased possibility of legal proceedings and inquiries, sanctions or investigations by the SEC or other regulatory authorities. Any of the foregoing may adversely affect our reputation, the accuracy and timing of our financial reporting, or our business, results of operations, liquidity and financial condition, or cause stockholders, investors, members and customers to lose confidence in the accuracy and completeness of our financial reports or cause the market price of our common stock to decline.

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	Stock Purchase Agreement, dated as of April 12, 2023, between the Company and Frost Gamma Investments Trust (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on April 13, 2023).
10.2	Purchase Agreement, dated May 2, 2023, between the Company and Lincoln Park Capital Fund LLC (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on May 3, 2023).
10.3	Registration Rights Agreement, dated May 2, 2023, between the Company and Lincoln Park Capital Fund LLC (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on May 3, 2023).
10.4	Open Market Sale Agreement, dated May 12, 2023, between the Company and Jefferies LLC (incorporated by reference to Exhibit 1.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on May 12, 2023).
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 June 30, 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: November 15, 2023

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

DATE: November 15, 2023

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

Exhibit 31.1

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

I, Mitchell S. Steiner, certify that:

1. I have reviewed this quarterly report on Amendment No. 1 on Form 10-Q/A 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: November 15, 2023

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

Exhibit 31.2

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

I, Michele Greco, certify that:

1. I have reviewed this quarterly report on Amendment No. 1 on Form 10-Q/A 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: November 15, 2023

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

Exhibit 32.1

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

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned officers of Veru Inc. (the "Company") certifies that the Quarterly Report on Amendment No. 1 on Form 10-Q/A of the Company for the quarter ended June 30, 2023 fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934 and information contained in that Amendment No. 1 on Form 10-Q/A fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 15, 2023

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

Date: November 15, 2023

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

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