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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended December 31, 2022

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

Commission File Number 1-13602

Veru Inc.

(Exact Name of Registrant as Specified in its Charter)

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

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

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

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

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

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

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

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

Large accelerated filer ☐	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 February 6, 2023, the registrant had 80,657,019 shares of $0.01 par value common stock outstanding.

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FORWARD LOOKING STATEMENTS

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

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

- government entities may take actions that directly or indirectly have the effect of limiting opportunities for sabizabulin as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments;
- government entities in the U.S. or elsewhere may declare the COVID-19 pandemic emergency over and, if sabizabulin is authorized in the U.S. or elsewhere for the treatment of certain COVID-19 patients under an Emergency Use Authorization or similar regime outside the U.S., such termination of the pandemic emergency may affect our ability to continue to market sabizabulin;
- product demand and market acceptance of our commercial products and our products in development, if approved;
- risks related to our ability to obtain insurance reimbursement from private payors or government payors, including Medicare and Medicaid, for our approved or authorized products, including, if authorized, sabizabulin for the treatment of certain COVID-19 patients, and similar risks relating to market or political acceptance of any potential or actual pricing for any such products;
- some of our products are in development and we may fail to successfully commercialize such products;
- risks related to any potential new telehealth platform developed or used by us in commercializing our current product or potential future products, including potential regulatory uncertainty around such platforms;
- risks related to intellectual property, including the uncertainty of obtaining intellectual property protections and in enforcing them, the possibility of infringing a third party's intellectual property, and licensing risks;
- competition from existing and new competitors including the potential for reduced sales, pressure on pricing and increased spending on marketing;
- risks related to compliance and regulatory matters, including costs and delays resulting from extensive government regulation and reimbursement and coverage under healthcare insurance and regulation as well as potential healthcare reform measures;
- the risk that we will be affected by regulatory and legal developments, including a reclassification of products or repeal or modification of part or all of the Patient Protection and Affordable Care Act (the "ACA");
- risks inherent in doing business on an international level, including currency risks, regulatory requirements, political risks, export restrictions and other trade barriers;
- the disruption of production at our manufacturing facilities or facilities of third parties on which we rely and/or of our ability to supply product due to raw material shortages, labor shortages, physical damage to our or third parties' facilities, COVID-19 (including the impact of COVID-19 on suppliers of key raw materials), product testing, transportation delays or regulatory or other governmental actions, and the duration and impact of any such disruptions;
- our reliance on major customers and risks related to delays in payment of accounts receivable by major customers;
- risks from rising costs of raw materials and our ability to pass along increased costs to our customers;
- risks related to our growth strategy;
- our continued ability to attract and retain highly skilled and qualified personnel;
- the costs and other effects of litigation, governmental investigations, legal and administrative cases and proceedings, settlements and investigations;
- government contracting risks, including the appropriations process and funding priorities, potential bureaucratic delays in awarding contracts, process errors, politics or other pressures, and the risk that government tenders and contracts may be subject to cancellation, delay, restructuring or substantial delayed payments;
- a governmental tender award indicates acceptance of the bidder's price rather than an order or guarantee of the purchase of any minimum number of units, and as a result government ministries or other public health sector customers may order and purchase fewer units than the full maximum tender amount;
- our ability to identify, successfully negotiate and complete suitable acquisitions, 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 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

	December 31, 2022	September 30, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 46,927,187	$ 80,190,675
Accounts receivable, net	3,864,310	3,550,895
Inventories, net	8,732,627	8,618,944
Prepaid research and development costs	10,416,934	10,444,587
Prepaid expenses and other current assets	3,067,587	1,964,373
Total current assets	73,008,645	104,769,474
Plant and equipment, net	1,425,970	1,185,766
Operating lease right-of-use assets	4,600,783	4,786,915
Deferred income taxes	13,052,163	12,965,985
Intangible assets, net	3,959,524	3,977,381
Goodwill	6,878,932	6,878,932
Other assets	856,435	1,561,564
Total assets	$ 103,782,452	$ 136,126,017
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,566,962	$ 22,003,394
Accrued research and development costs	12,678,176	9,071,503
Accrued compensation	7,135,943	5,986,557
Accrued expenses and other current liabilities	7,027,422	2,249,995
Residual royalty agreement liability, short-term portion	1,688,691	1,169,095
Operating lease liability, short-term portion	983,253	957,085
Total current liabilities	40,080,447	41,437,629
Residual royalty agreement liability, long-term portion	10,550,764	9,656,441
Operating lease liability, long-term portion	3,963,202	4,093,667
Deferred income taxes	63,426	81,067
Other liabilities	25,755	18,577
Total liabilities	54,683,594	55,287,381
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock; no shares issued and outstanding at December 31, 2022 and September 30, 2022	—	—
Common stock, par value $0.01 per share; 154,000,000 shares authorized, 82,806,832 and 82,692,598 shares issued and 80,623,128 and 80,508,894 shares outstanding at December 31, 2022 and September 30, 2022, respectively	828,068	826,926
Additional paid-in-capital	259,075,291	253,974,032
Accumulated other comprehensive loss	(581,519)	(581,519)
Accumulated deficit	(202,416,377)	(165,574,198)
Treasury stock, 2,183,704 shares, at cost	(7,806,605)	(7,806,605)
Total stockholders' equity	49,098,858	80,838,636
Total liabilities and stockholders' equity	$ 103,782,452	$ 136,126,017

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended December 31,	
	2022	2021
Net revenues	$ 2,507,794	$ 14,135,132
Cost of sales	1,805,739	2,293,050
Gross profit	702,055	11,842,082
Operating expenses:		
Research and development	18,744,349	10,081,161
Selling, general and administrative	17,545,865	6,723,206
Total operating expenses	36,290,214	16,804,367
Operating loss	(35,588,159)	(4,962,285)
Non-operating income (expenses):		
Interest expense	(873,230)	(1,158,682)
Change in fair value of derivative liabilities	(670,000)	(209,000)
Other income, net	220,932	64,616
Total non-operating expenses	(1,322,298)	(1,303,066)
Loss before income taxes	(36,910,457)	(6,265,351)
Income tax (benefit) expense	(68,278)	114,655
Net loss	$ (36,842,179)	$ (6,380,006)
Net loss per basic and diluted common shares outstanding	$ (0.46)	$ (0.08)
Basic and diluted weighted average common shares outstanding	80,558,670	80,023,168

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Treasury Stock, at Cost	Total
	Shares	Amount					
Balance at September 30, 2022	82,692,598	$ 826,926	$ 253,974,032	$ (581,519)	$ (165,574,198)	$ (7,806,605)	$ 80,838,636
Share-based compensation	—	—	4,845,269	—	—	—	4,845,269
Issuance of shares pursuant to share-based awards	114,234	1,142	255,990	—	—	—	257,132
Net loss	—	—	—	—	(36,842,179)	—	(36,842,179)
Balance at December 31, 2022	82,806,832	$ 828,068	$ 259,075,291	$ (581,519)	$ (202,416,377)	$ (7,806,605)	$ 49,098,858
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

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Three Months Ended December 31,	
	2022	2021
OPERATING ACTIVITIES		
Net loss	$ (36,842,179)	$ (6,380,006)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	63,218	43,228
Noncash change in right-of-use assets	186,132	100,822
Noncash interest expense, net of interest paid	743,919	376,358
Share-based compensation	4,845,269	1,880,428
Deferred income taxes	(103,819)	93,421
Change in fair value of derivative liabilities	670,000	209,000
Other	2,921	(52,776)
Changes in current assets and liabilities:		
Decrease in accounts receivable	400,585	724,683
(Increase) decrease in inventories	(116,604)	725,161
Increase in prepaid expenses and other assets	(1,084,432)	(4,105,738)
(Decrease) increase in accounts payable	(11,436,432)	677,937
Increase (decrease) in accrued expenses and other current liabilities	8,241,691	(2,831,116)
Decrease in operating lease liabilities	(104,297)	(119,194)
Net cash used in operating activities	(34,534,028)	(8,657,792)
INVESTING ACTIVITIES		
Cash proceeds from sale of PREBOOST® business	—	2,500,000
Capital expenditures	(285,565)	(302,209)
Net cash (used in) provided by investing activities	(285,565)	2,197,791
FINANCING ACTIVITIES		
Proceeds from stock option exercises	257,132	209,869
Proceeds from premium finance agreement	1,425,174	—
Installment payments on premium finance agreement	(126,201)	—
Cash paid for debt portion of finance lease	—	(5,442)
Net cash provided by financing activities	1,556,105	204,427
Net decrease in cash	(33,263,488)	(6,255,574)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	80,190,675	122,359,535
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 46,927,187	$ 116,103,961
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 129,311	$ 782,324

See notes to unaudited condensed consolidated financial statements.

VERU INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1 – Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements for Veru Inc. ("we," "our," "us," "Veru" or the "Company") have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) for reporting of interim financial information. Pursuant to these rules and regulations, certain information and footnote disclosures normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) have been condensed or omitted, although the Company believes that the disclosures made are adequate to make the information not misleading. Accordingly, these statements do not include all the disclosures normally required by U.S. GAAP for annual financial statements and should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations contained in this report and the audited financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended September 30, 2022. The accompanying condensed consolidated balance sheet as of September 30, 2022 has been derived from our audited financial statements. The unaudited condensed consolidated statements of operations and cash flows for the three months ended December 31, 2022 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 biopharmaceutical company focused on developing novel medicines for COVID-19 and other viral and acute respiratory distress syndrome (ARDS)-related diseases and for the management of breast and prostate cancers. The Company has multiple drug products under clinical development. The Company also has two approved products: the FC2 Female Condom/FC2 Internal Condom® (FC2), an FDA-approved product for the dual protection against unplanned pregnancy and the transmission of sexually transmitted infections, and ENTADFI™ (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia that was approved by the FDA in December 2021. Most of the Company's net revenues during the three months ended December 31, 2022 and 2021 were derived from sales of FC2.

Other comprehensive loss: Accounting principles generally require that recognized revenue, expenses, gains and losses be included in net loss. Although certain changes in assets and liabilities, such as foreign currency translation adjustments, are reported as a separate component of the equity section of the accompanying unaudited condensed consolidated balance sheets, these items, along with net loss, are components of other comprehensive loss. For the three months ended December 31, 2022 and 2021, comprehensive loss is equivalent to the reported net loss.

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

Note 2 – Liquidity

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

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

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 December 31, 2022 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 December 31, 2022 and 2021:

	Three Months Ended December 31,	
	2022	2021
Beginning balance	$ 4,294,000	$ 7,851,000
Change in fair value of derivative liabilities	670,000	209,000
Ending balance	$ 4,964,000	$ 8,060,000

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

The liabilities associated with embedded derivatives represent the fair value of the change of control provision in the Residual Royalty Agreement. See Note 8 for additional information. There is no current observable market for these types of derivatives. The Company estimates the fair value of the embedded derivative within the Residual Royalty Agreement by using a scenario-based method, whereby different scenarios are valued and probability weighted. The scenario-based valuation model incorporates transaction details such as the contractual terms of the instrument and assumptions including projected FC2 revenues, expected cash outflows, probability and estimated dates of a change of control, risk-free interest rates and applicable credit risk. A significant increase in projected FC2 revenues or a significant increase in the probability or acceleration of the timing of a change of control event, in isolation, would result in a significantly higher fair value measurement of the liability associated with the embedded derivative.

The following tables present quantitative information about the inputs and valuation methodologies used to determine the fair value of the embedded derivatives classified in Level 3 of the fair value hierarchy as of December 31, 2022 and September 30, 2022:

Valuation Methodology	Significant Unobservable Input	December 31, 2022	September 30, 2022
Scenario-Based	Estimated change of control dates	September 2023 to September 2025	September 2023 to September 2025
	Discount rate	10.2% to 10.7%	13.6% to 14.2%
	Probability of change of control	20% to 90%	20% to 90%

Note 4 – Revenue from Contracts with Customers

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

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

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

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

	Three Months Ended December 31,	
	2022	2021
FC2		
U.S. prescription channel	$ 163,004	$ 11,574,266
Global public health sector	2,336,997	2,560,866
Total FC2	2,500,001	14,135,132
ENTADFI	7,793	—
Net revenues	$ 2,507,794	$ 14,135,132

The following table presents net revenues by geographic area:

	Three Months Ended December 31,	
	2022	2021
United States	$ 809,377	$ 11,908,525
Uganda	257,469	*
Other	1,440,948	2,226,607
Net revenues	$ 2,507,794	$ 14,135,132

*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 $813,000 and $342,000 at December 31, 2022 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 December 31, 2022 and September 30, 2022:

	December 31, 2022	September 30, 2022
Trade receivables, gross	$ 3,888,248	$ 4,289,892
Less: allowance for doubtful accounts	(12,143)	(12,143)
Less: allowance for sales returns and payment term discounts	(11,795)	(12,854)
Less: long-term trade receivables*	—	(714,000)
Accounts receivable, net	$ 3,864,310	$ 3,550,895

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

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

At December 31, 2022, two customers had an accounts receivable balance greater than 10% of net accounts receivable, representing 76% of net accounts receivable and long-term trade receivables in the aggregate. At September 30, 2022, two customers had an accounts receivable balance greater than 10% of net accounts receivable and long-term trade receivables, representing 83% of net accounts receivable and long-term trade receivables in the aggregate.

For the three months ended December 31, 2022, there were three customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 64% of the Company's net revenues in the aggregate. For the three months ended December 31, 2021, there were two customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 80% of the Company's net revenues in the aggregate.

The Company maintains an allowance for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments on accounts receivable. Management determines the allowance for doubtful accounts by identifying troubled accounts and by using historical experience applied to an aging of accounts. Management also periodically evaluates individual customer receivables and considers a customer's financial condition, credit history, and the current economic conditions. Accounts receivable are charged-off when deemed uncollectible. There was no material change in the allowance for doubtful accounts for the three months ended December 31, 2022 and 2021.

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 December 31, 2022 and September 30, 2022:

	December 31, 2022	September 30, 2022
Raw material	$ 1,686,725	$ 1,662,712
Work in process	766,538	872,596
Finished goods	6,296,420	6,099,343
Inventories, gross	8,749,683	8,634,651
Less: inventory reserves	(17,056)	(15,707)
Inventories, net	$ 8,732,627	$ 8,618,944

Fixed Assets

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

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

	Estimated Useful Life	December 31, 2022	September 30, 2022
Plant and equipment:			
Manufacturing equipment	5 - 8 years	$ 3,153,918	$ 2,902,715
Office equipment, furniture and fixtures	3 - 10 years	1,474,837	1,440,475
Leasehold improvements	3 - 8 years	484,460	484,460
Total plant and equipment		5,113,215	4,827,650
Less: accumulated depreciation and amortization		(3,687,245)	(3,641,884)
Plant and equipment, net		$ 1,425,970	$ 1,185,766

Depreciation expense was approximately $45,000 and $25,000 for the three months ended December 31, 2022 and 2021, respectively. Plant and equipment included $561,000 and $276,000 at December 31, 2022 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 December 31, 2022:

	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Intangible asset with finite life:			
Covenants not-to-compete	$ 500,000	$ 440,476	$ 59,524
Indefinite-lived intangible assets:			
Acquired in-process research and development assets	3,900,000	—	3,900,000
Total intangible assets	$ 4,400,000	$ 440,476	$ 3,959,524

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 December 31, 2022 and 2021.

Goodwill

The carrying amount of goodwill at December 31, 2022 and September 30, 2022 was $6.9 million. There was no change in the balance during the three months ended December 31, 2022 and 2021. The Company's goodwill is assigned to the Research and Development reporting unit, which had a negative carrying amount as of December 31, 2022.

Note 8 – Debt

SWK Credit and 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.

For financial statement presentation, the embedded derivative liability has been included together with its host instrument as noted in the following table.

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

	December 31, 2022	September 30, 2022
Residual royalty agreement liability, fair value at inception	$ 346,000	$ 346,000
Add: accretion of liability using effective interest rate	10,824,138	9,950,908
Less: cumulative payments	(3,894,683)	(3,765,372)
Residual royalty agreement liability, excluding embedded derivative liability	7,275,455	6,531,536
Add: embedded derivative liability at fair value (see Note 3)	4,964,000	4,294,000
Total residual royalty agreement liability	12,239,455	10,825,536
Residual royalty agreement liability, short-term portion	(1,688,691)	(1,169,095)
Residual royalty agreement liability, long-term portion	$ 10,550,764	$ 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.

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 $1.3 million as of December 31, 2022 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 December 31, 2022 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 December 31, 2022 and September 30, 2022, and there was no activity during the three months ended December 31, 2022 and 2021.

Aspire Capital Purchase Agreement

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

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

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

Since inception of the 2020 Purchase Agreement, we have sold 1,644,737 shares of common stock to Aspire Capital resulting in proceeds to the Company of $5.0 million. The Company has not sold shares to Aspire Capital under the 2020 Purchase Agreement since June 2020. As of December 31, 2022, the amount remaining under the 2020 Purchase Agreement was $18.9 million, which is registered under the Company's shelf registration statement on Form S-3 (File No. 333-239493).

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

Note 10 – Share-based Compensation

We allocate share-based compensation expense to cost of sales, selling, general and administrative expense, and research and development expense based on the award holder's employment function. For the three months ended December 31, 2022 and 2021, we recorded share-based compensation expenses as follows:

	Three Months Ended December 31,	
	2022	**2021**
Cost of sales	$ 64,008	$ 21,076
Selling, general and administrative	3,612,099	1,395,558
Research and development	1,169,162	463,794
Share-based compensation	$ 4,845,269	$ 1,880,428

We have issued share-based awards to employees and non-executive directors under the Company's approved equity plans. Upon the exercise of share-based awards, new shares are issued from authorized common stock.

Equity Plans

In June 2022, the Company's board of directors adopted the Company's 2022 Employment Inducement Equity Incentive Plan (the "Inducement Plan"). The Inducement Plan is a non-shareholder approved stock plan adopted pursuant to the "inducement exception" provided under Nasdaq listing rules. The Inducement Plan is used exclusively for the issuance of equity awards to certain new hires who satisfied the requirements to be granted inducement grants under Nasdaq rules as an inducement material to the individual's entry into employment with the Company. The Company reserved 4,000,000 shares of common stock under the Inducement Plan and as of December 31, 2022, 3,587,950 shares remain available for issuance under the Inducement Plan.

In March 2018, the Company's stockholders approved the Company's 2018 Equity Incentive Plan (as amended, the "2018 Plan"). On March 29, 2022, the Company's stockholders approved an increase in the number of shares that may be issued under the 2018 Plan to 18.5 million. As of December 31, 2022, 3,900,900 shares remain available for issuance under the 2018 Plan.

In July 2017, the Company's stockholders approved the Company's 2017 Equity Incentive Plan (the "2017 Plan"). A total of 4.7 million shares are authorized for issuance under the 2017 Plan. As of December 31, 2022, 767 shares remain available for issuance under the 2017 Plan. The 2017 Plan replaced the Company's 2008 Stock Incentive Plan (the "2008 Plan"), and no further awards will be made under the 2008 Plan.

Stock Options

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

The following table outlines the weighted average assumptions for options granted during the three months ended December 31, 2022 and 2021:

	Three Months Ended December 31,	
	2022	**2021**
Weighted Average Assumptions:		
Expected volatility	98.43%	77.39%
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	4.25%	1.33%
Expected term (in years)	6.0	6.0
Fair value of options granted	$ 9.17	$ 5.60

During the three months ended December 31, 2022 and 2021, the Company used historical volatility of our common stock over a period equal to the expected life of the options to estimate their fair value. The dividend yield assumption is based on the Company's recent history and expectation of future dividend payouts on the common stock. The risk-free interest rate is based on the implied yield available on U.S. treasury zero-coupon issues with an equivalent remaining term.

The following table summarizes the stock options outstanding and exercisable at December 31, 2022:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2022	14,263,470	$ 5.00		
Granted	2,703,800	$ 11.47		
Exercised	(114,234)	$ 2.25		
Forfeited and expired	(4,566)	$ 9.78		
Outstanding at December 31, 2022	16,848,470	$ 6.06	7.54	$ 30,099,241
Exercisable at December 31, 2022	9,389,548	$ 2.69	6.19	$ 28,636,365

The aggregate intrinsic values in the table above are before income taxes and represent the number of in-the-money options outstanding or exercisable multiplied by the closing price per share of the Company's common stock on the last trading day of the quarter ended December 31, 2022 of $5.28, less the respective weighted average exercise price per share at period end.

The total intrinsic value of options exercised during the three months ended December 31, 2022 and 2021 was approximately $355,000 and $447,000, respectively. Cash received from options exercised during the three months ended December 31, 2022 and 2021 was approximately $257,000 and $210,000, respectively.

As of December 31, 2022, the Company had unrecognized compensation expense of approximately $49.6 million related to unvested stock options. This expense is expected to be recognized over a weighted average period of 2.2 years.

Stock Appreciation Rights

In connection with the closing of the APP Acquisition, the Company issued stock appreciation rights based on 50,000 and 140,000 shares of the Company's common stock to an employee and an outside director, respectively, that vested on October 31, 2018. The stock appreciation rights have a ten-year term and an exercise price per share of $0.95, which was the closing price per share of the Company's common stock as quoted on Nasdaq on the trading day immediately preceding the date of the completion of the APP Acquisition. Upon exercise, the stock appreciation rights will be settled in common stock issued under the 2017 Plan. As of December 31, 2022, 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 December 31, 2022.

The components of the Company's lease cost were as follows for the three months ended December 31, 2022 and 2021:

	Three Months Ended December 31,	
	2022	2021
Finance lease cost:		
Amortization of right-of-use assets	$ —	$ 2,178
Interest on lease liabilities	—	256
Operating lease cost	281,451	131,110
Short-term lease cost	10,101	12,771
Variable lease cost	50,091	46,019
Sublease income	(44,844)	(44,844)
Total lease cost	$ 296,799	$ 147,490

The Company paid cash of $228,000 and $153,000 for amounts included in the measurement of operating lease liabilities during the three months ended December 31, 2022 and 2021, respectively.

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

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

	December 31, 2022	September 30, 2022
Operating Leases		
Weighted-average remaining lease term	6.6	6.8
Weighted-average discount rate	7.6%	7.6%

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

Note 12 – Contingent Liabilities

The testing, manufacturing and marketing of consumer products by the Company and the clinical testing of our product candidates entail an inherent risk that product liability claims will be asserted against the Company. The Company maintains product liability insurance coverage for claims arising from the use of its products. The coverage amount is currently $30.0 million.

Legal Proceedings

On December 5, 2022, a putative class action complaint was filed in federal district court for the Southern District of Florida (Ewing v. Veru Inc., et al., Case No. 1:22-cv-23960) against the Company and certain of its current officers and directors (the "Ewing Complaint"). The Ewing Complaint alleges that certain public statements about sabizabulin as a treatment for COVID-19 between May 11, 2022 and November 9, 2022 violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. The Company believes that the allegations asserted in the Ewing Complaint are without merit, and the Company intends to vigorously defend the lawsuit. There can be no assurance that the Company will be successful. At this time, the Company is unable to estimate potential losses, if any, related to the lawsuit.

License and Purchase Agreements

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

Collaborative Arrangements

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

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

Note 13 – Income Taxes

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

As of September 30, 2022, the Company had U.S. federal and state NOL carryforwards of $112.5 million and $50.9 million, respectively, for income tax purposes with $29.7 million and $28.4 million, respectively, expiring in years 2023 to 2042 and $82.8 million and $22.5 million, respectively, which can be carried forward indefinitely. As of September 30, 2022, the Company also had U.S. federal research and development tax credit carryforwards of $8.5 million, expiring in years 2038 to 2042. The Company's U.K. subsidiary has U.K. NOL carryforwards of $63.1 million as of September 30, 2022, which can be carried forward indefinitely to be used to offset future U.K. taxable income.

The Tax Cuts and Jobs Act of 2017, which was signed into U.S. law in December 2017, eliminated the option to immediately deduct research and development expenditures in the year incurred under Section 174 of the Internal Revenue Code effective for the Company October 1, 2022. The amended provision under Section 174 of the Internal Revenue Code 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 December 31, 2022, we recorded a decrease to income tax benefit and an increase to deferred tax assets, before applying a valuation allowance, of approximately $3.7 million. 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 is zero.

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

	Three Months Ended December 31,	
	2022	2021
Income tax benefit at U.S. federal statutory rates	$ (7,751,197)	$ (1,315,724)
State income tax benefit, net of federal benefit	(600,164)	(101,875)
Non-deductible expenses	113,456	257,196
Effect of stock options exercised	83,736	(23,350)
U.S. research and development tax credit	(1,090,000)	(1,963,430)
Effect of foreign income tax rates	(80,110)	(29,761)
Effect of global intangible low taxed income	—	88,267
Change in valuation allowance	9,256,119	3,089,596
Other, net	(118)	113,736
Income tax (benefit) expense	$ (68,278)	$ 114,655

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

	December 31, 2022	September 30, 2022
Deferred tax assets:		
Federal net operating loss carryforwards	$ 26,379,703	$ 23,627,461
State net operating loss carryforwards	3,064,102	2,850,956
Foreign net operating loss carryforwards – U.K.	15,927,491	15,773,497
Foreign capital allowance – U.K.	128,490	128,490
U.S. research and development tax credit carryforwards	9,571,789	8,481,789
U.S. research and development expense	3,660,867	—
Accrued compensation	1,521,363	1,227,290
Share-based compensation	5,199,290	4,325,354
Interest expense	2,340,375	2,206,484
Change in fair value of derivative liabilities	372,203	220,607
Other, net – U.K.	265,631	265,631
Other, net – Malaysia	4,988	—
Other, net – U.S.	83,284	81,507
Gross deferred tax assets	68,519,576	59,189,066
Valuation allowance for deferred tax assets	(54,628,571)	(45,372,452)
Net deferred tax assets	13,891,005	13,816,614
Deferred tax liabilities:		
In-process research and development	(882,427)	(882,427)
Covenant not-to-compete	(13,468)	(17,508)
Other, net - Malaysia	—	(17,641)
Other, net – U.S.	(6,373)	(14,120)
Net deferred tax liabilities	(902,268)	(931,696)
Net deferred tax asset	$ 12,988,737	$ 12,884,918

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

	December 31, 2022	September 30, 2022
Deferred tax asset – U.K.	$ 13,047,175	$ 12,965,985
Deferred tax asset – Malaysia	4,988	—
Total deferred tax asset	$ 13,052,163	$ 12,965,985
Deferred tax liability – U.S.	$ (63,426)	$ (63,426)
Deferred tax liability – Malaysia	—	(17,641)
Total deferred tax liability	$ (63,426)	$ (81,067)

Note 14 – Net Loss Per Share

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

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

Overview

Veru is a biopharmaceutical company with a drug development program for the treatment of hospitalized COVID-19 patients at high risk for acute respiratory distress syndrome (ARDS) and other viral-related ARDS and for the management of advanced breast and prostate cancers, as well as a sexual health program which includes two FDA-approved products, the FC2 Female Condom® (Internal Condom) and ENTADFI™ (finasteride and tadalafil) capsules for oral use, for the treatment of benign prostatic hyperplasia (BPH).

Infectious Disease Program:

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

We discovered that sabizabulin, which is being developed for cancer indications for the treatment of COVID-19 viral infection, and the subsequent debilitating inflammatory effects that can lead 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 and death. 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. The outcome of this meeting was: (i) the FDA agreed that no additional efficacy studies were required to support an EUA application or a new drug application (NDA); and (ii) the FDA agreed that no additional safety data was required to support an EUA application and that collection of safety data under the EUA may satisfy the safety requirement for an NDA. The FDA agreed that the request for the EUA is supported by efficacy and safety from our positive Phase 3 study in hospitalized moderate to severe COVID-19 patients who are at high risk for ARDS and death and no additional clinical trials may be required to support an NDA submission. 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 clinical results from the Phase 3 COVID-19 study of oral sabizabulin in The New England Journal of Medicine Evidence. On November 9, 2022, the FDA's Pulmonary-Allergy Drugs Advisory Committee (PADAC) met to review sabizabulin for the EUA in hospitalized moderate to severe COVID-19 patients who are at high risk for ARDS. The advisory committee voted 8-5 that the known and potential benefits of sabizabulin when used for the treatment of adult patients hospitalized with COVID-19 at high risk of ARDS do not outweigh the known and potential risks of sabizabulin. However, there was additional discussion around the clinical trial design aspects of a potential confirmatory Phase 3 COVID-19 clinical trial as a requirement or condition for emergency use authorization. The FDA considers the input of the FDA advisory committee as part of their review of the EUA, but the advisory committee vote is not binding as the FDA makes the final decision on the request for EUA application.

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

The UK's Medicine and Healthcare Products Regulatory Agency (MHRA) informed the Company on July 25, 2022, that the sabizabulin marketing authorization application will receive expedited review. On July 27, 2022, sabizabulin triggered Article 18 in the European Union (EU) in which the European Medicines Agency (EMA) will evaluate sabizabulin to allow emergency use drug access to the EU Member States. On August 22, 2022, Australia's Therapeutic Goods Administration (TGA) determined that sabizabulin treatment in hospitalized COVID-19 patients at high risk for ARDS qualifies for an expedited, provisional registration regulatory pathway. Sabizabulin for COVID-19 is also currently under regulatory review for potential emergency or conditional authorization by Canada's Health Canada, South Korea's Ministry of Food and Drug Safety, and Switzerland's Swissmedic.

With the positive Phase 3 clinical results of sabizabulin in hospitalized moderate to severe COVID-19 patients at high risk for ARDS, we want to focus the clinical development of sabizabulin, a broad spectrum antiviral and anti-inflammatory agent, as a treatment for additional indications in COVID-19-related ARDS, Influenza related ARDS, and other viral-associated ARDS. The development program may include a confirmatory Phase 3 clinical study in hospitalized COVID-19 patients, if required, to support the full regulatory applications in multiple regions, including the U.S. and Europe.

Oncology Program:

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

Phase 3 clinical study – Enobosarm as a 3rd line treatment of AR+ER+HER2- metastatic breast cancer. We are enrolling the Phase 3 multicenter, international, open label, and randomized ARTEST registration clinical trial design to evaluate the efficacy and safety of enobosarm monotherapy versus physician's choice of either exemestane ⌖ everolimus or a SERM as the active comparator for the treatment of AR+ ER+ HER2- metastatic breast cancer in approximately 210 patients with sufficient AR nuclei staining in their breast cancer tissue who had tumor progression on a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor. We have identified that patients who have sufficient AR nuclei staining in their breast cancer tissue are most likely to respond to enobosarm.

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

Phase 3 clinical study – Enobosarm + abemaciclib combination as a 2nd line treatment of AR+ER+HER2- metastatic breast cancer. We are enrolling a Phase 3 multicenter, open label, randomized (1:1), active control clinical study, named ENABLAR-2 to evaluate the efficacy and safety of enobosarm plus abemaciclib combination therapy versus an alternative estrogen blocking agent (fulvestrant or an aromatase inhibitor) in subjects with AR+ ER+ HER2- metastatic breast cancer who have failed first line palbociclib (a CDK4/6 inhibitor) plus an estrogen blocking agent (non-steroidal aromatase inhibitor or fulvestrant) and have sufficient AR nuclei staining in their breast cancer tissue. We have completed Stage 1, which assessed and demonstrated the pharmacokinetics and tolerability of the enobosarm and abemaciclib combination. In Stage 2 of this Phase 3 study, we plan to enroll approximately 183 subjects. In January 2022, the Company entered into a clinical trial collaboration and supply agreement through which Eli Lilly and Company supplies abemaciclib for the ENABLAR-2 trial.

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

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

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

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

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

Phase 2 dose finding clinical study. We are currently enrolling a study to determine optimal dose of VERU-100 in men with advance hormone sensitive prostate cancer.

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

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

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

Sexual Health Program

The Company's sexual health program includes two FDA-approved products: FC2, for the dual protection against unplanned pregnancy and the transmission of sexually transmitted infections and ENTADFI™, for the treatment of BPH.

The Company sells FC2 in both the commercial sector and in the public health sector both in the U.S. and globally. In the U.S., FC2 is available by prescription through multiple telemedicine and internet pharmacy channels as well as retail pharmacies. The Company has launched its own dedicated direct to patient telemedicine and pharmacy services portal/platform to continue to drive sales growth. FC2 is also available to public health sector entities such as state departments of health and 501(c)(3) organizations. In the global public health sector, the Company markets FC2 to entities, including ministries of health, government health agencies, U.N. agencies, nonprofit organizations and commercial partners, that work to support and improve the lives, health and well-being of women around the world.

ENTADFI™ (finasteride and tadalafil) capsules for oral use was approved by the FDA as a new treatment for BPH, or an enlarged prostate gland. The co-administration of tadalafil and finasteride has been shown to provide faster and more effective treatment of BPH than finasteride alone without causing unwanted sexual side effects. ENTADFI treats BPH with low potential for adverse sexual side effects, and we believe that ENTADFI being one single pill will help increase drug compliance whereas poor compliance with a BPH medicine could lead to an increased chance of acute urinary retention, urosepsis, and death. We have now initiated the U.S. commercial launch of ENTADFI. The launch of ENTADFI has faced challenging market conditions in what has become a genericized market. As a result, the potential market size for ENTADFI is uncertain.

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

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 Company has received its first orders and is manufacturing units under this tender award.

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. The Company has also begun to recognize revenues from sales of ENTADFI. These sales are recognized upon shipment or delivery of the product to the customers depending on contract terms.

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

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

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

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

Conducting research and development is central to our infectious disease and oncology programs. The Company has multiple 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 $18.7 million and $10.1 million for the three months ended December 31 2022 and 2021, respectively, and we expect to continue this trend of increased expenses relating to research and development due to advancement of multiple drug candidates.

Results of Operations

THREE MONTHS ENDED DECEMBER 31, 2022 COMPARED TO THREE MONTHS ENDED DECEMBER 31, 2021

The Company generated net revenues of $2.5 million and net loss of $36.8 million, or $(0.46) per basic and diluted common share, for the three months ended December 31, 2022, compared to net revenues of $14.1 million and net loss of $6.4 million, or $(0.08) per basic and diluted common share, for the three months ended December 31, 2021. Net revenues decreased 82% compared to the prior period.

Most of the Company's net revenues for the three months ended December 31, 2022 and 2021 were derived from sales of FC2 in the U.S. prescription channel and global public health sector. There was a decrease in the FC2 average sales price per unit of 72%. The principal factor for the decrease in the FC2 average sales price per unit compared to prior period was the change in the sales mix with the global public health sector representing 93% of total FC2 net revenues in the current year period and the U.S. prescription channel representing 82% of total FC2 net revenues 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 99% in FC2 net revenues in the U.S. prescription channel and a decrease compared to the prior year period of 9% in FC2 net revenues in the global public health sector. The decrease in FC2 net revenues in the U.S. prescription channel is primarily due to lower volume from telemedicine customers as a result of business challenges they have been experiencing, which resulted in a slowdown in orders during recent quarters. We are working to restore ordering and utilization patterns in future periods based on growing awareness and demand through increased FC2 marketing efforts, as well as on-going discussions with new distribution partners in the telehealth sector. We are also working to generate additional revenues through our telehealth platform. We have begun to see an increase in U.S. public sector revenues through two new agreements recently executed.

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 $1.8 million in the three months ended December 31, 2022 from $2.3 million in the three months ended December 31, 2021 due to the decrease in unit sales.

Gross profit decreased to $0.7 million in the three months ended December 31, 2022 from $11.8 million in the three months ended December 31, 2021. Gross profit margin for the fiscal 2023 period was 28% of net revenues, compared to 84% 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 had higher profit margins, and reduced production as a result of lower sales volume, which results in a higher cost per unit.

Research and development expenses increased to $18.7 million in the three months ended December 31, 2022 from $10.1 million in the same period in fiscal 2022. The increase is primarily due to increased costs associated with the multiple in-process research and development projects, mainly for the Phase 3 COVID-19 registration trial and manufacturing costs of $8.0 million for pre-launch inventory, and increased personnel costs, resulting from increased headcount and an increase in the fair value of share-based compensation.

Selling, general and administrative expenses increased to $17.5 million in the three months ended December 31, 2022 from $6.7 million in the three months ended December 31, 2021. The increase is due primarily to commercialization costs of $8.4 million related to preparations for the potential launch of sabizabulin for COVID-19 incurred in the first quarter of fiscal 2023 and an increase in share-based compensation costs to $3.6 million from $1.4 million, resulting from increased headcount and an increase in the fair value of stock options granted, which was $9.17 per share weighted average in the first quarter of fiscal 2023 compared to $5.60 per share weighted average in the same period in fiscal 2022.

Interest expense, which is related to accretion of the liability for the Residual Royalty Agreement, was $0.9 million in the three months ended December 31, 2022, which is comparable with $1.2 million in the three months ended December 31, 2021. The decrease relates to a decrease in projected FC2 sales.

Expense associated with the change in fair value of the embedded derivatives related to the Residual Royalty Agreement was $0.7 million in the three months ended December 31, 2022, compared to expense of $0.2 million in the three months ended December 31, 2021. The liabilities associated with embedded derivatives represent the fair value of the change of control provisions in the Credit Agreement and Residual Royalty Agreement. See Note 3 and Note 8 to the financial statements included in this report for additional information.

Income tax benefit in the first quarter of fiscal 2023 was $68,000, compared to income tax expense of $0.1 million in the first quarter of fiscal 2022. The change is due to a tax benefit recorded in the current period due to a net loss recognized by our U.K. subsidiary compared to a tax expense in the prior year period due to net income recognized by our U.K. subsidiary. 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.

Liquidity and Sources of Capital

Liquidity

Our cash and cash equivalents on hand at December 31, 2022 was $46.9 million, compared to $80.2 million at September 30, 2022. At December 31, 2022, the Company had working capital of $32.9 million and stockholders' equity of $49.1 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.

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

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

Operating activities

Operating activities used cash of $34.5 million in the three months ended December 31, 2022. Cash used in operating activities included net loss of $36.8 million, adjustments to reconcile net loss to net cash used in operating activities totaling an increase of $6.4 million and changes in operating assets and liabilities resulting in a decrease of $4.1 million. Adjustments to net loss primarily consisted of $4.8 million of share-based compensation, interest expense in excess of interest paid of $0.7 million, and the change in fair value of derivative liabilities of $0.7 million. The decrease in cash from changes in operating assets and liabilities included a decrease in accounts payable of $11.4 million and an increase in prepaid expenses and other current assets of $1.1 million, partially offset by an increase in accrued expenses and other current liabilities of $8.2 million and a decrease in accounts receivable of $0.4 million.

Operating activities used cash of $8.7 million in the three months ended December 31, 2021. Cash used in operating activities included net loss of $6.4 million, adjustments to reconcile net loss to net cash used in operating activities totaling an increase of $2.7 million and changes in operating assets and liabilities resulting in a reduction of $4.9 million. Adjustments to net loss primarily consisted of $1.9 million of share-based compensation, interest expense in excess of interest paid of $0.4 million, and $0.2 million for the change in fair value of derivative liabilities. The decrease in cash from changes in operating assets and liabilities included an increase in prepaid expenses and other assets of $4.1 million and a decrease in accrued expenses and other current liabilities of $2.8 million, partially offset by a decrease in accounts receivable of $0.7 million, a decrease in inventories of $0.7 million, and an increase in accounts payable of $0.7 million.

Investing activities

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

Net cash from investing activities was $2.2 million in the three months ended December 31, 2021, primarily attributed to $2.5 million collected on notes receivable from the sale of the Company's PREBOOST® business, partially offset by $0.3 million associated with capital expenditures primarily at our U.S. location.

Financing activities

Net cash provided by financing activities in the three months ended December 31, 2022 was $1.6 million, and primarily consisted of proceeds from the Premium Finance Agreement of $1.4 million, which were used to finance the Company's directors and officers liability insurance premium and proceeds from stock option exercises of $0.3 million.

Net cash provided by financing activities in the three months ended December 31, 2021 was $0.2 million and primarily consisted of proceeds from stock option exercises of $0.2 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 $0.1 million and $0.8 million during the three months ended December 31, 2022 and 2021, respectively. The Company currently estimates the aggregate amount of quarterly revenue-based payments payable during the 12-month period subsequent to December 31, 2022 will be approximately $1.7 million under the Residual Royalty Agreement.

Aspire Capital Purchase Agreement

On June 26, 2020, the Company entered into a common stock purchase agreement (the "2020 Purchase Agreement") with Aspire Capital Fund, LLC (Aspire Capital) which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right, from time to time in its sole discretion during the 36-month term of the 2020 Purchase Agreement, to direct Aspire Capital to purchase up to $23.9 million of the Company's common stock in the aggregate. Upon execution of the 2020 Purchase Agreement, the Company issued and sold to Aspire Capital under the 2020 Purchase Agreement 1,644,737 shares of common stock at a price per share of $3.04, for an aggregate purchase price of $5,000,000. Other than the 212,130 shares of common stock issued to Aspire Capital in consideration for entering into the 2020 Purchase Agreement and the initial sale of 1,644,737 shares of common stock, the Company has no obligation to sell any shares of common stock pursuant to the 2020 Purchase Agreement and the timing and amount of any such sales are in the Company's sole discretion subject to the conditions and terms set forth in the 2020 Purchase Agreement. The Company has not sold shares to Aspire Capital under the 2020 Purchase Agreement since June 2020. As of December 31, 2022, the amount remaining under the 2020 Purchase Agreement was $18.9 million, which is registered under the Company's shelf registration statement on Form S-3 (File No. 333-239493).

Fair Value Measurements

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

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and the Company's Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Based on this evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective. It should be noted that in designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. The Company has designed its disclosure controls and procedures to reach a level of reasonable assurance of achieving desired control objectives and, based on the evaluation described above, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective at reaching that level of reasonable assurance.

Changes in Internal Control over Financial Reporting

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the risks and uncertainties relating to the Company's business disclosed in Part I, Item 1A, "Risk Factors," in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2022. There have been no material changes from the risk factors previously disclosed in Part I, Item 1A, "Risk Factors," in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2022.

Item 6. Exhibits

Exhibit Number	Description
3.1	Amended and Restated Articles of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Form SB-2 Registration Statement (File No. 333-89273) filed with the SEC on October 19, 1999).
3.2	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 27,000,000 shares (incorporated by reference to Exhibit 3.2 to the Company's Form SB-2 Registration Statement (File No. 333-46314) filed with the SEC on September 21, 2000).
3.3	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 35,500,000 shares (incorporated by reference to Exhibit 3.3 to the Company's Form SB-2 Registration Statement (File No. 333-99285) filed with the SEC on September 6, 2002).
3.4	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 38,500,000 shares (incorporated by reference to Exhibit 3.4 to the Company's Form 10-QSB (File No. 1-13602) filed with the SEC on May 15, 2003).
3.5	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company designating the terms and preferences for the Class A Preferred Stock – Series 3 (incorporated by reference to Exhibit 3.5 to the Company's Form 10-QSB (File No. 1-13602) filed with the SEC on May 17, 2004).
3.6	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company designating the terms and preferences for the Class A Preferred Stock – Series 4 (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on November 2, 2016).
3.7	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company changing the corporate name to Veru Inc. and increasing the number of authorized shares of common stock to 77,000,000 shares (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on August 1, 2017).
3.8	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 154,000,000 shares (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on March 29, 2019).
3.9	Amended and Restated By-Laws (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on May 4, 2018).
4.1	Amended and Restated Articles of Incorporation, as amended (same as Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7 and 3.8).
4.2	Articles II, VII and XI of the Amended and Restated By-Laws (included in Exhibit 3.9).
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002). *, **

101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended December 31, 2022, 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: February 9, 2023

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

DATE: February 9, 2023

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

Exhibit 31.1

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

I, Mitchell S. Steiner, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Veru Inc.;

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

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

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

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

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: February 9, 2023

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

Exhibit 31.2

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

I, Michele Greco, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Veru Inc.;

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

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

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

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

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: February 9, 2023

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

Exhibit 32.1

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

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned officers of Veru Inc. (the "Company") certifies that the Quarterly Report on Form 10-Q of the Company for the quarter ended December 31, 2022 fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934 and information contained in that Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 9, 2023

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

Date: February 9, 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.