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

# FORM 10-Q

**(Mark One)**

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended March 31, 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 May 9, 2022, the registrant had 80,073,683 shares of $0.01 par value common stock outstanding.

VERU INC.
INDEX

## 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 the anticipated or potential impact of COVID-19 and the global response thereto on our financial condition or business, our development and commercialization plans relating to our product candidates and products, 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, 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 due to COVID-19 or other reasons, 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"), including an emergency use authorization submission for sabizabulin for the treatment of certain COVID-19 patients, and potential delays in, or failure to obtain, regulatory approval of products under development or such an emergency use authorization, including the risk of a delay or failure in reaching agreement with the FDA on the design of a clinical trial or in obtaining authorization to commence a clinical trial or commercialize a product candidate in the U.S.;
- potential delays in the timing of FDA approval of the release of manufactured lots of approved products;
- 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;
- 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;

- product demand and market acceptance of our commercial product and our products in development, if approved;
- 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, in Part II, Item 1A, "Risk Factors" below in this report, and in Part I, Item 1A, "Risk Factors," in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2021. The Company undertakes no obligation to make any revisions to the forward-looking statements contained in this report or to update them to reflect events or circumstances occurring after the date of this report except as required by applicable law.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

| | March 31, 2022 | September 30, 2021 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 112,015,505 | $ 122,359,535 |
| Accounts receivable, net | 8,134,690 | 8,794,224 |
| Notes receivable | 2,500,000 | 5,000,000 |
| Inventory, net | 6,415,463 | 5,574,253 |
| Prepaid research and development costs | 9,738,551 | 9,174,586 |
| Prepaid expenses and other current assets | 1,657,144 | 850,889 |
| Total current assets | 140,461,353 | 151,753,487 |
| Plant and equipment, net | 1,025,463 | 592,603 |
| Operating lease right-of-use assets | 5,132,655 | 969,839 |
| Deferred income taxes | 13,019,385 | 13,024,550 |
| Intangible assets, net | 4,013,095 | 4,048,810 |
| Goodwill | 6,878,932 | 6,878,932 |
| Other assets | 2,294,366 | 878,502 |
| Total assets | $ 172,825,249 | $ 178,146,723 |
| | | |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 7,518,071 | $ 3,409,771 |
| Accrued research and development costs | 4,413,385 | 2,020,445 |
| Accrued compensation | 2,387,364 | 4,986,058 |
| Accrued expenses and other current liabilities | 2,191,136 | 1,615,922 |
| Residual royalty agreement liability, short-term portion | 3,833,162 | 3,237,211 |
| Operating lease liability, short-term portion | 838,340 | 497,903 |
| Total current liabilities | 21,181,458 | 15,767,310 |
| Residual royalty agreement liability, long-term portion | 11,121,490 | 9,397,136 |
| Operating lease liability, long-term portion | 4,445,432 | 609,921 |
| Deferred income taxes | 63,426 | 63,426 |
| Other liabilities | 15,000 | 14,986 |
| Total liabilities | 36,826,806 | 25,852,779 |
| | | |
| Commitments and contingencies (Note 12) | | |
| | | |
| Stockholders' equity: | | |
| Preferred stock; no shares issued and outstanding at March 31, 2022 and September 30, 2021 | — | — |
| Common stock, par value $0.01 per share; 154,000,000 shares authorized, 82,250,053 and 82,153,452 shares issued and 80,066,349 and 79,969,748 shares outstanding at March 31, 2022 and September 30, 2021, respectively | 822,501 | 821,535 |
| Additional paid-in-capital | 245,920,080 | 241,658,711 |
| Accumulated other comprehensive loss | (581,519) | (581,519) |
| Accumulated deficit | (102,356,014) | (81,798,178) |
| Treasury stock, 2,183,704 shares, at cost | (7,806,605) | (7,806,605) |
| Total stockholders' equity | 135,998,443 | 152,293,944 |
| Total liabilities and stockholders' equity | $ 172,825,249 | $ 178,146,723 |

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

| | Three Months Ended March 31, | | Six Months Ended March 31, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Net revenues | $ 13,028,394 | $ 13,340,487 | $ 27,163,526 | $ 27,957,476 |
| Cost of sales | 1,853,116 | 2,432,187 | 4,146,166 | 6,212,543 |
| Gross profit | 11,175,278 | 10,908,300 | 23,017,360 | 21,744,933 |
| Operating expenses: | | | | |
| Research and development | 15,541,104 | 7,572,813 | 25,622,265 | 13,250,567 |
| Selling, general and administrative | 7,399,138 | 4,806,897 | 14,122,344 | 9,188,777 |
| Total operating expenses | 22,940,242 | 12,379,710 | 39,744,609 | 22,439,344 |
| Gain on sale of PREBOOST® business | — | — | — | 18,410,158 |
| Operating (loss) income | (11,764,964) | (1,471,410) | (16,727,249) | 17,715,747 |
| Non-operating expenses: | | | | |
| Interest expense | (1,212,702) | (1,251,551) | (2,371,384) | (2,440,734) |
| Change in fair value of derivative liabilities | (1,229,000) | (53,000) | (1,438,000) | (657,000) |
| Other income (expense), net | 1,386 | (48,330) | 66,002 | (136,301) |
| Total non-operating expenses | (2,440,316) | (1,352,881) | (3,743,382) | (3,234,035) |
| (Loss) income before income taxes | (14,205,280) | (2,824,291) | (20,470,631) | 14,481,712 |
| Income tax (benefit) expense | (27,450) | 21,690 | 87,205 | 99,992 |
| Net (loss) income | $ (14,177,830) | $ (2,845,981) | $ (20,557,836) | $ 14,381,720 |
| Net (loss) income per basic common share outstanding | $ (0.18) | $ (0.04) | $ (0.26) | $ 0.20 |
| Basic weighted average common shares outstanding | 80,052,504 | 75,175,077 | 80,037,675 | 72,717,621 |
| Net (loss) income per diluted common share outstanding | $ (0.18) | $ (0.04) | $ (0.26) | $ 0.18 |
| Diluted weighted average common shares outstanding | 80,052,504 | 75,175,077 | 80,037,675 | 80,654,070 |

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, 2021 | 82,153,452 | $ 821,535 | $ 241,658,711 | $ (581,519) | $ (81,798,178) | $ (7,806,605) | $ 152,293,944 |
| Share-based compensation | — | — | 1,880,428 | — | — | — | 1,880,428 |
| Issuance of shares pursuant to share-based awards | 79,334 | 793 | 209,076 | — | — | — | 209,869 |
| Net loss | — | — | — | — | (6,380,006) | — | (6,380,006) |
| Balance at December 31, 2021 | 82,232,786 | 822,328 | 243,748,215 | (581,519) | (88,178,184) | (7,806,605) | 148,004,235 |
| Share-based compensation | — | — | 2,124,941 | — | — | — | 2,124,941 |
| Issuance of shares pursuant to share-based awards | 17,267 | 173 | 46,924 | — | — | — | 47,097 |
| Net loss | — | — | — | — | (14,177,830) | — | (14,177,830) |
| Balance at March 31, 2022 | 82,250,053 | $ 822,501 | $ 245,920,080 | $ (581,519) | $ (102,356,014) | $ (7,806,605) | $ 135,998,443 |
| Balance at September 30, 2020 | 72,047,385 | $ 720,474 | $ 126,971,518 | $ (581,519) | $ (89,192,552) | $ (7,806,605) | $ 30,111,316 |
| Share-based compensation | — | — | 785,297 | — | — | — | 785,297 |
| Issuance of shares pursuant to share-based awards | 468,611 | 4,686 | 619,133 | — | — | — | 623,819 |
| Issuance of shares pursuant to common stock purchase warrants | 1,574,611 | 15,746 | (15,746) | — | — | — | — |
| Net income | — | — | — | — | 17,227,701 | — | 17,227,701 |
| Balance at December 31, 2020 | 74,090,607 | 740,906 | 128,360,202 | (581,519) | (71,964,851) | (7,806,605) | 48,748,133 |
| Share-based compensation | — | — | 1,002,281 | — | — | — | 1,002,281 |
| Issuance of shares pursuant to share-based awards | 357,297 | 3,573 | 645,702 | — | — | — | 649,275 |
| Shares issued in connection with public offering of common stock, net of fees and costs | 7,419,354 | 74,194 | 107,868,104 | — | — | — | 107,942,298 |
| Net loss | — | — | — | — | (2,845,981) | — | (2,845,981) |
| Balance at March 31, 2021 | 81,867,258 | $ 818,673 | $ 237,876,289 | $ (581,519) | $ (74,810,832) | $ (7,806,605) | $ 155,496,006 |

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

| | Six Months Ended March 31, | |
|---|---|---|
| | 2022 | 2021 |
| OPERATING ACTIVITIES | | |
| Net (loss) income | $ (20,557,836) | $ 14,381,720 |
| Adjustments to reconcile net (loss) income to net cash used in operating activities: | | |
| Depreciation and amortization | 90,289 | 131,403 |
| Noncash change in right-of-use assets | 229,767 | 185,964 |
| Noncash interest expense, net of interest paid | 882,305 | (31,071) |
| Share-based compensation | 4,005,369 | 1,787,578 |
| Gain on sale of PREBOOST® business | — | (18,410,158) |
| Deferred income taxes | 5,165 | 30,923 |
| Change in fair value of derivative liabilities | 1,438,000 | 657,000 |
| Other | 8,552 | 41,513 |
| Changes in current assets and liabilities: | | |
| (Increase) decrease in accounts receivable | (764,466) | 79,083 |
| Increase in inventory | (853,762) | (1,132,902) |
| Increase in prepaid expenses and other assets | (1,358,084) | (2,434,908) |
| Increase in accounts payable | 4,108,300 | 2,815,773 |
| Increase in accrued expenses and other current liabilities | 378,567 | 191,734 |
| Decrease in operating lease liabilities | (216,635) | (223,917) |
| Net cash used in operating activities | (12,604,469) | (1,930,265) |
| | | |
| INVESTING ACTIVITIES | | |
| Cash proceeds from sale of PREBOOST® business | 2,500,000 | 15,000,000 |
| Capital expenditures | (487,434) | (12,118) |
| Net cash provided by investing activities | 2,012,566 | 14,987,882 |
| | | |
| FINANCING ACTIVITIES | | |
| Proceeds from stock option exercises | 256,966 | 1,273,094 |
| Proceeds from sale of shares in public offering, net of fees | — | 108,099,988 |
| Payment of costs related to public offering | — | (43,745) |
| Proceeds from premium finance agreement | — | 1,061,442 |
| Installment payments on premium finance agreement | — | (352,664) |
| Cash paid for debt portion of finance lease | (9,093) | (9,357) |
| Net cash provided by financing activities | 247,873 | 110,028,758 |
| | | |
| Net (decrease) increase in cash | (10,344,030) | 123,086,375 |
| CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD | 122,359,535 | 13,588,778 |
| CASH AND CASH EQUIVALENTS AT END OF PERIOD | $ 112,015,505 | $ 136,675,153 |
| | | |
| Supplemental disclosure of cash flow information: | | |
| Cash paid for interest | $ 1,489,079 | $ 2,471,805 |
| Schedule of non-cash investing and financing activities: | | |
| Right-of-use asset recorded in exchange for lease liabilities | $ 4,392,583 | $ — |
| Notes receivable for sale of PREBOOST® business | $ — | $ 5,000,000 |
| Costs related to public offering in accounts payable or accrued expenses and other current liabilities | $ — | $ 113,945 |

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, 2021. The accompanying condensed consolidated balance sheet as of September 30, 2021 has been derived from our audited financial statements. The unaudited condensed consolidated statements of operations and cash flows for the three and six months ended March 31, 2022 are not necessarily indicative of the results to be expected for any future period or for the fiscal year ending September 30, 2022.

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, Aspen Park Pharmaceuticals, Inc. (APP) and The Female Health Company Limited, and 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"), and The Female Health Company (UK) plc's wholly owned subsidiary, The Female Health Company (M) SDN.BHD (the "Malaysia subsidiary"). All significant intercompany transactions and accounts have been eliminated in consolidation. The Company is a biopharmaceutical company with a principal focus 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: ENTADFI™, a new treatment for benign prostatic hyperplasia that was approved by the FDA in December 2021, and 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. All of the Company's net revenues during the three and six months ended March 31, 2022 and the three months ended March 31, 2021 and most of the Company's net revenues during the six months ended March 31, 2021 were derived from sales of FC2.

Segments: We regularly review our operating segments and the approach used by management to evaluate performance and allocate resources. Prior to the commercialization of ENTADFI, we managed two distinct business segments: Pharmaceuticals, which engaged exclusively in research and development activities and FC2, which included the Company's single commercial product. Beginning in the second quarter of 2022, as a result of added commercialization efforts related to ENTADFI, the Company now operates as a single operating segment. Our determination that we operate as a single segment is consistent with the financial information regularly reviewed by the chief operating decision maker (CODM) for purposes of evaluating performance, allocating resources, setting incentive compensation targets, and planning and forecasting for future periods. Our CODM allocates resources and assesses financial performance on a consolidated basis.

Other comprehensive (loss) income: Accounting principles generally require that recognized revenue, expenses, gains and losses be included in net (loss) income. 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) income, are components of other comprehensive loss. For the three and six months ended March 31, 2022 and 2021, comprehensive (loss) income is equivalent to the reported net (loss) income.

Recently adopted accounting pronouncements: In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740), Simplifying the Accounting for Income Taxes. The new guidance eliminates certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period, and the recognition of deferred tax liabilities for outside basis differences. It also clarifies and simplifies other aspects of the accounting for income taxes. The Company adopted ASU 2019-12 on a prospective basis effective October 1, 2021. The adoption of ASU 2019-12 did not impact our consolidated financial statements and related disclosures.

**Note 2 – Sale of PREBOOST® Business**

On December 8, 2020, the Company entered into an Asset Purchase Agreement, pursuant to which the Company sold substantially all of the assets related to the Company's PREBOOST® business. PREBOOST® is a 4% benzocaine medicated individual wipe for the treatment of premature ejaculation. The transaction closed on December 8, 2020. The purchase price for the transaction was $20.0 million, consisting of $15.0 million paid at closing, a $2.5 million note receivable due 12 months after closing and a $2.5 million note receivable due 18 months after closing. The Company collected $2.5 million on the note receivable due 12 months after closing during the six months ended March 31, 2022 and $2.5 million remains outstanding as of March 31, 2022. Total assets sold, consisting of intangible assets, had a net book value of approximately $1.6 million, resulting in a pre-tax gain on sale of approximately $18.4 million. The Company had income before income taxes of $327,000 during the six months ended March 31, 2021 related to the PREBOOST® business before the sale.

**Note 3 – Fair Value Measurements**

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

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

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

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

Level 3 – Instruments with primarily unobservable value drivers.

As of March 31, 2022 and September 30, 2021, the Company’s financial liabilities measured at fair value on a recurring basis, which consisted of embedded derivatives, were classified within Level 3 of the fair value hierarchy.

The following table provides a reconciliation of the beginning and ending liability balance associated with embedded derivatives measured at fair value using significant unobservable inputs (Level 3) as of March 31, 2022 and 2021:

| | Six Months Ended March 31, | |
|---|---|---|
| | 2022 | 2021 |
| Beginning balance | $ 7,851,000 | $ 4,182,000 |
| Change in fair value of derivative liabilities | 1,438,000 | 657,000 |
| Ending balance | $ 9,289,000 | $ 4,839,000 |

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 provisions in the Credit Agreement and Residual Royalty Agreement. See Note 8 for additional information. There is no current observable market for these types of derivatives. The Company previously determined the fair value of the embedded derivatives using a Monte Carlo simulation model. Since the Credit Agreement has been satisfied as of September 30, 2021, the fair value of the embedded derivative within the Residual Royalty Agreement has been calculated by using a scenario-based method, whereby different scenarios are valued and probability weighted. The Company determined that with only the embedded derivative under the Residual Royalty Agreement remaining, there is no material difference between these two valuation models. The scenario-based valuation model incorporates transaction details such as the contractual terms of the instrument and assumptions including projected FC2 revenues, expected cash outflows, probability and estimated dates of a change of control, risk-free interest rates and applicable credit risk. A significant increase in projected FC2 revenues or a significant increase in the probability or acceleration of the timing of a change of control event, in isolation, would result in a significantly higher fair value measurement of the liability associated with the embedded derivative.

The following tables present quantitative information about the inputs and valuation methodologies used to determine the fair value of the embedded derivatives classified in Level 3 of the fair value hierarchy as of March 31, 2022 and September 30, 2021:

| Valuation Methodology | Significant Unobservable Input | March 31, 2022 |
|---|---|---|
| Scenario-Based | Estimated change of control dates | September 2023 to September 2025 |
| | Discount rate | 8.6% to 9.0% |
| | Probability of change of control | 20% to 90% |

| Valuation Methodology | Significant Unobservable Input | September 30, 2021 |
|---|---|---|
| Monte Carlo Simulation | Estimated change of control dates | September 2022 to September 2025 |
| | Discount rate | 6.6% to 7.9% |
| | Probability of change of control | 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 PREBOOST® medicated wipes for prevention of premature ejaculation before the sale of the PREBOOST® business. The following table presents net revenues from these three categories:

| | Three Months Ended March 31, | | Six Months Ended March 31, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| FC2 | | | | |
| U.S. prescription channel | $ 11,590,466 | $ 10,312,742 | $ 23,164,732 | $ 19,414,481 |
| Global public health sector | 1,437,928 | 3,027,745 | 3,998,794 | 7,680,164 |
| Total FC2 | 13,028,394 | 13,340,487 | 27,163,526 | 27,094,645 |
| PREBOOST® | — | — | — | 862,831 |
| Net revenues | $ 13,028,394 | $ 13,340,487 | $ 27,163,526 | $ 27,957,476 |

The following table presents net revenue by geographic area:

| | Three Months Ended March 31, | | Six Months Ended March 31, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| United States | $ 11,846,960 | $ 10,612,998 | $ 23,755,485 | $ 20,968,836 |
| Other | 1,181,434 | 2,727,489 | 3,408,041 | 6,988,640 |
| Net revenues | $ 13,028,394 | $ 13,340,487 | $ 27,163,526 | $ 27,957,476 |

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 $452,000 and $132,000 at March 31, 2022 and September 30, 2021, 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 $1.4 million of trade receivables with its distributor in Brazil as long-term as of March 31, 2022, because payment was expected in greater than one year. The long-term portion of trade receivables is included in other assets on the accompanying unaudited condensed consolidated balance sheet.

The components of accounts receivable consisted of the following at March 31, 2022 and September 30, 2021:

| | March 31, 2022 | September 30, 2021 |
|---|---|---|
| Trade receivables, gross | $ 9,790,124 | $ 8,938,849 |
| Less: allowance for doubtful accounts | (16,643) | (20,643) |
| Less: allowance for sales returns and payment term discounts | (210,791) | (123,982) |
| Less: long-term trade receivables* | (1,428,000) | — |
| Accounts receivable, net | $ 8,134,690 | $ 8,794,224 |

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

At March 31, 2022 and at September 30, 2021, no customers had a current accounts receivable balance that represented greater than 10% of current assets.

At March 31, 2022, three 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. At September 30, 2021, three customers had an accounts receivable balance greater than 10% of net accounts receivable, representing 90% of net accounts receivable in the aggregate.

For the three months ended March 31, 2022, there were two customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 83% of the Company's net revenues in the aggregate. For the three months ended March 31, 2021, there were two customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 77% of the Company's net revenues in the aggregate.

For the six months ended March 31, 2022, there were two customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 81% of the Company's net revenues in the aggregate. For the six months ended March 31, 2021, there were two customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 69% of the Company's net revenues in the aggregate.

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 six months ended March 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**

Inventory

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.

Inventory consisted of the following at March 31, 2022 and September 30, 2021:

| | March 31, 2022 | September 30, 2021 |
|---|---|---|
| FC2: | | |
| Raw material | $ 989,171 | $ 1,371,133 |
| Work in process | 44,106 | 112,915 |
| Finished goods | 4,805,101 | 4,547,690 |
| FC2, gross | 5,838,378 | 6,031,738 |
| Less: inventory reserves | (27,898) | (457,485) |
| FC2, net | 5,810,480 | 5,574,253 |
| ENTADFI: | | |
| Raw material | 60,124 | — |
| Work in process | 544,859 | — |
| Total ENTADFI | 604,983 | — |
| Inventory, net | $ 6,415,463 | $ 5,574,253 |

Fixed Assets

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

Plant and equipment consisted of the following at March 31, 2022 and September 30, 2021:

| | Estimated Useful Life | March 31, 2022 | September 30, 2021 |
|---|---|---|---|
| Plant and equipment: | | | |
| Manufacturing equipment | 5 - 8 years | $ 2,902,178 | $ 2,875,744 |
| Office equipment, furniture and fixtures | 3 - 10 years | 1,299,056 | 991,146 |
| Leasehold improvements | 3 - 8 years | 432,337 | 298,886 |
| Total plant and equipment | | 4,633,571 | 4,165,776 |
| Less: accumulated depreciation and amortization | | (3,608,108) | (3,573,173) |
| Plant and equipment, net | | $ 1,025,463 | $ 592,603 |

Depreciation expense was approximately $30,000 and $22,000 for the three months ended March 31, 2022 and 2021, respectively, and approximately $55,000 and $54,000 for the six months ended March 31, 2022 and 2021, respectively. Plant and equipment included $322,000 and $210,000 at March 31, 2022 and September 30, 2021, respectively, for deposits on equipment, furniture, and leasehold improvements, which have not been placed into service; therefore, the Company has not started to record depreciation expense.

**Note 7 – Intangible Assets and Goodwill**

Intangible Assets

The gross carrying amounts and net book value of intangible assets were as follows at March 31, 2022:

| | Gross Carrying Amount | Accumulated Amortization | Net Book Value |
|---|---|---|---|
| Intangible asset with finite life: | | | |
| Covenants not-to-compete | $ 500,000 | $ 386,905 | $ 113,095 |
| Indefinite-lived intangible assets: | | | |
| Acquired in-process research and development assets | 3,900,000 | — | 3,900,000 |
| Total intangible assets | $ 4,400,000 | $ 386,905 | $ 4,013,095 |

The gross carrying amounts and net book value of intangible assets were as follows at September 30, 2021:

| | Gross Carrying Amount | Accumulated Amortization | Net Book Value |
|---|---|---|---|
| Intangible asset with finite life: | | | |
| Covenants not-to-compete | $ 500,000 | $ 351,190 | $ 148,810 |
| Indefinite-lived intangible assets: | | | |
| Acquired in-process research and development assets | 3,900,000 | — | 3,900,000 |
| Total intangible assets | $ 4,400,000 | $ 351,190 | $ 4,048,810 |

Amortization expense was approximately $18,000 for the three months ended March 31, 2022 and 2021 and approximately $36,000 and $78,000 for the six months ended March 31, 2022 and 2021, respectively.

Goodwill

The carrying amount of goodwill at March 31, 2022 and September 30, 2021 was $6.9 million. There was no change in the balance during the six months ended March 31, 2022 and 2021.

**Note 8 – Debt**

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. After payment by the Company of certain fees and expenses of the Agent and the Lenders as required in the Credit Agreement, the Company received net proceeds of approximately $9.9 million from the $10.0 million loan under the Credit Agreement.

The Lenders were entitled to receive quarterly payments on the term loan based on the Company's product revenue from net sales of FC2 as provided in the Credit Agreement until the Company paid 176.5% of the aggregate amount advanced to the Company under 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, which commenced after the Company paid 175% of the aggregate amount advanced to the Company under the Credit Agreement based on a calculation of revenue-based payments 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. 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 Credit Agreement and a portion of the amount allocated to the Residual Royalty Agreement, in both cases equal to the fair value of the respective change of control provisions, was allocated to the embedded derivative liabilities. The derivative liabilities are adjusted to fair market value at each reporting period. For financial statement presentation, the embedded derivative liabilities have been included with their respective host instruments as noted in the following tables. The debt discounts were amortized to interest expense over the term of the Credit Agreement using the effective interest method. Additionally, the Company recorded deferred loan issuance costs of approximately $267,000 for legal fees incurred in connection with the Credit Agreement. The deferred loan issuance costs were presented as a reduction of the Credit Agreement obligation and were amortized to interest expense over the term of the Credit Agreement using the effective interest method.

At March 31, 2022 and September 30, 2021, the Residual Royalty Agreement liability consisted of the following:

| | March 31, 2022 | September 30, 2021 |
|---|---|---|
| Residual royalty agreement liability, fair value at inception | $ 346,000 | $ 346,000 |
| Add: accretion of liability using effective interest rate | 7,953,494 | 5,582,110 |
| Less: cumulative payments | (2,633,842) | (1,144,763) |
| Residual royalty agreement liability, excluding embedded derivative liability | 5,665,652 | 4,783,347 |
| Add: embedded derivative liability at fair value (see Note 3) | 9,289,000 | 7,851,000 |
| Total residual royalty agreement liability | 14,954,652 | 12,634,347 |
| Residual royalty agreement liability, short-term portion | (3,833,162) | (3,237,211) |
| Residual royalty agreement liability, long-term portion | $ 11,121,490 | $ 9,397,136 |

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

Interest expense related to the Credit Agreement and the Residual Royalty Agreement consisted of amortization of the discounts, accretion of the liability for the Residual Royalty Agreement and amortization of the deferred issuance costs. For the three and six months ended March 31, 2022 and 2021, interest expense related to the Credit Agreement and Residual Royalty Agreement was as follows:

| | Three Months Ended March 31, | | Six Months Ended March 31, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Amortization of discounts | $ — | $ 499,629 | $ — | $ 1,072,489 |
| Accretion of residual royalty agreement | 1,212,702 | 740,179 | 2,371,384 | 1,343,037 |
| Amortization of deferred issuance costs | — | 11,743 | — | 25,208 |
| Interest expense | $ 1,212,702 | $ 1,251,551 | $ 2,371,384 | $ 2,440,734 |

Premium Finance Agreement

On November 1, 2020, the Company entered into a Premium Finance Agreement to finance $1.1 million of its directors and officers liability insurance premium at an annual percentage rate of 3.94%. The financing was payable in three quarterly installments of principal and interest, beginning on January 1, 2021. The last payment was made in June 2021 and there was no balance outstanding as of March 31, 2022 or September 30, 2021.

**Note 9 – Stockholders' Equity**

Preferred Stock

The Company has 5,000,000 authorized shares designated as Class A Preferred Stock with a par value of $0.01 per share. There are 1,040,000 shares of Class A Preferred Stock – Series 1 authorized; 1,500,000 shares of Class A Preferred Stock – Series 2 authorized; 700,000 shares of Class A Preferred Stock – Series 3 authorized; and 548,000 shares of Class A Preferred Stock – Series 4 (the "Series 4 Preferred Stock") authorized. There were no shares of Class A Preferred Stock of any series issued and outstanding at March 31, 2022 and September 30, 2021. The Company has 15,000 authorized shares designated as Class B Preferred Stock with a par value of $0.50 per share. There were no shares of Class B Preferred Stock issued and outstanding at March 31, 2022 and September 30, 2021, and there was no activity during the six months then ended.

Common Stock Offering

On February 22, 2021, we completed an underwritten public offering of 7,419,354 shares of our common stock, which included the exercise in full of the underwriters' option to purchase additional shares, at a public offering price of $15.50 per share. Net proceeds to the Company from this offering were approximately $108.0 million after deducting underwriting discounts and commissions and costs paid by the Company. All of the shares sold in the offering were by the Company. The offering was made pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-239493).

Common Stock Purchase Warrants

In connection with the closing of the acquisition of APP (the "APP Acquisition") on October 31, 2016, the Company issued warrants to purchase up to 2,585,379 shares of the Company's common stock to Torreya Capital, the Company's then financial advisor (the "Financial Advisor Warrants"). The Financial Advisor Warrants had a five-year term expiring October 31, 2021, a cashless exercise feature and a strike price equal to $1.93 per share. The Financial Advisor Warrants vested upon issuance. During the first half of fiscal 2021, the remaining outstanding Financial Advisor Warrants to purchase 2,326,841 shares of the Company's common stock were exercised using the cashless exercise feature, resulting in the issuance of 1,574,611 shares of common stock. As of March 31, 2022, there were no outstanding common stock purchase warrants.

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 March 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 March 31, 2022 and September 30, 2021 is included in other assets on the accompanying unaudited condensed consolidated balance sheets.

**Note 10 – Share-based Compensation**

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

| | Three Months Ended March 31, | | Six Months Ended March 31, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Cost of sales | $ 24,572 | $ 18,415 | $ 45,648 | $ 34,627 |
| Selling, general and administrative | 1,588,043 | 713,603 | 2,983,601 | 1,275,087 |
| Research and development | 512,326 | 270,263 | 976,120 | 477,864 |
| Share-based compensation | $ 2,124,941 | $ 1,002,281 | $ 4,005,369 | $ 1,787,578 |

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 March 2018, the Company's stockholders approved the Company's 2018 Equity Incentive Plan (as amended, the "2018 Plan"). On March 29, 2022, the Company's stockholders approved an increase in the number of shares that may be issued under the 2018 Plan to 18.5 million. As of March 31, 2022, 7,944,769 shares remain available for issuance under the 2018 Plan.

In July 2017, the Company's stockholders approved the Company's 2017 Equity Incentive Plan (the "2017 Plan"). A total of 4.7 million shares are authorized for issuance under the 2017 Plan. As of March 31, 2022, 18,767 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 and six months ended March 31, 2022 and 2021:

| | Three Months Ended March 31, | | Six Months Ended March 31, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Weighted Average Assumptions: | | | | |
| Expected volatility | 76.12% | 77.71% | 77.27% | 68.32% |
| Expected dividend yield | 0.00% | 0.00% | 0.00% | 0.00% |
| Risk-free interest rate | 2.50% | 1.00% | 1.44% | 0.61% |
| Expected term (in years) | 6.0 | 6.0 | 6.0 | 5.9 |
| Fair value of options granted | $ 3.49 | $ 9.81 | $ 5.40 | $ 3.32 |

During the three and six months ended March 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 March 31, 2022:

| | Number of Shares | Weighted Average Exercise Price Per Share | Weighted Average Remaining Contractual Term (years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding at September 30, 2021 | 10,600,680 | $ 2.84 | | |
| Granted | 2,428,585 | $ 8.06 | | |
| Exercised | (96,601) | $ 2.66 | | |
| Forfeited and expired | (1,334) | $ 2.25 | | |
| Outstanding at March 31, 2022 | 12,931,330 | $ 3.82 | 7.68 | $ 27,990,898 |
| Exercisable at March 31, 2022 | 7,753,811 | $ 2.18 | 6.85 | $ 22,683,774 |

The aggregate intrinsic values in the table above are before income taxes and represent the number of in-the-money options outstanding or exercisable multiplied by the closing price per share of the Company's common stock on the last trading day of the quarter ended March 31, 2022 of $4.83, less the respective weighted average exercise price per share at period end.

The total intrinsic value of options exercised during the six months ended March 31, 2022 and 2021 was approximately $489,000 and $7.0 million, respectively. Cash received from options exercised during the six months ended March 31, 2022 and 2021 was approximately $257,000 and $1.3 million, respectively.

As of March 31, 2022, the Company had unrecognized compensation expense of approximately $18.3 million related to unvested stock options. This expense is expected to be recognized over a weighted average period of 1.9 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 March 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 has a finance lease for office equipment, furniture, and fixtures. The Company's leases have remaining lease terms of less than one year to five 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.

In June 2021, the Company executed a lease for its new corporate headquarters in Miami, Florida. The Company is leasing approximately 12,000 square feet of office space for an eight year term, which commenced on March 1, 2022. The space replaced the Company's previous corporate headquarters in Miami, Florida when the existing lease terminated at the end of February 2022. Annual base rent payments are $58.00 per square foot and are subject to a 3% annual escalation. Based on the terms of the lease agreement, the Company paid a security deposit of approximately $117,000, which is included in other assets on the accompanying unaudited condensed consolidated balance sheets as of March 31, 2022 and as of September 30, 2021. The Company does not have any leases that have not yet commenced as of March 31, 2022.

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

| | Three Months Ended March 31, | | Six Months Ended March 31, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Finance lease cost: | | | | |
| Amortization of right-of-use assets | $ 1,453 | $ 2,179 | $ 3,631 | $ 4,357 |
| Interest on lease liabilities | 147 | 777 | 403 | 1,716 |
| Operating lease cost | 182,845 | 136,613 | 313,955 | 271,939 |
| Short-term lease cost | 12,934 | 1,863 | 25,705 | 3,726 |
| Variable lease cost | 46,737 | 39,539 | 92,756 | 76,222 |
| Sublease income | (44,845) | (44,844) | (89,689) | (89,689) |
| Total lease cost | $ 199,271 | $ 136,127 | $ 346,761 | $ 268,271 |

The Company paid cash of $293,000 and $342,000 for amounts included in the measurement of operating lease liabilities during the six months ended March 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 March 31, 2022 and September 30, 2021.

Other information related to the Company's leases as of March 31, 2022 and September 30, 2021 was as follows:

| | March 31, 2022 | September 30, 2021 |
|---|---|---|
| **Operating Leases** | | |
| Weighted-average remaining lease term | 7.1 | 2.9 |
| Weighted-average discount rate | 7.8% | 11.5% |
| **Finance Leases** | | |
| Weighted-average remaining lease term | — | 0.4 |
| Weighted-average discount rate | — | 13.9% |

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

As of March 31, 2022, maturities of lease liabilities were as follows:

| | Operating Leases | Sublease Income |
|---|---|---|
| **Fiscal year ended September 30,** | | |
| 2022 | $ 391,230 | $ 101,997 |
| 2023 | 1,035,927 | 190,749 |
| 2024 | 933,828 | — |
| 2025 | 929,591 | — |
| 2026 | 783,843 | — |
| Thereafter | 2,856,734 | — |
| Total lease payments | 6,931,153 | $ 292,746 |
| Less imputed interest | (1,647,381) | |
| Total lease liabilities | $ 5,283,772 | |

**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 $20.0 million.

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, 2021, the Company had U.S. federal and state NOL carryforwards of $38.6 million and $24.9 million, respectively, for income tax purposes with $29.5 million and $22.5 million, respectively, expiring in years 2022 to 2040 and $9.1 million and $2.4 million, respectively, which can be carried forward indefinitely. As of September 30, 2021, the Company also had U.S. federal research and development tax credit carryforwards of $4.2 million, expiring in 2038 to 2041. The Company's U.K. subsidiary has U.K. NOL carryforwards of $63.5 million as of September 30, 2021, which can be carried forward indefinitely to be used to offset future U.K. taxable income.

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

| | Three Months Ended March 31, | | Six Months Ended March 31, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Income tax (benefit) expense at U.S. federal statutory rates | $ (2,983,109) | $ (593,101) | $ (4,298,833) | $ 3,041,159 |
| State income tax (benefit) expense, net of federal (benefit) expense | (230,978) | (45,923) | (332,853) | 235,473 |
| Non-deductible expenses | 102,733 | — | 359,929 | — |
| Effect of stock options exercised | — | 11,279 | (23,350) | (53,011) |
| Effect of common stock purchase warrants exercised | — | — | — | (2,038,919) |
| Effect of Paycheck Protection Program funds | — | (26,340) | — | (122,226) |
| U.S. research and development tax credit | (913,000) | — | (2,876,430) | — |
| Effect of foreign income tax rates | (9,677) | 4,993 | (39,438) | (27,577) |
| Effect of global intangible low taxed income | (75,278) | (55,388) | 12,989 | 69,757 |
| Change in valuation allowance | 4,043,065 | 727,034 | 7,132,661 | (1,005,752) |
| Other, net | 38,794 | (864) | 152,530 | 1,088 |
| Income tax (benefit) expense | $ (27,450) | $ 21,690 | $ 87,205 | $ 99,992 |

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

| | March 31, 2022 | September 30, 2021 |
|---|---|---|
| Deferred tax assets: | | |
| Federal net operating loss carryforwards | $ 10,575,927 | $ 8,209,224 |
| State net operating loss carryforwards | 1,837,652 | 1,646,827 |
| Foreign net operating loss carryforwards – U.K. | 15,871,243 | 15,875,889 |
| Foreign capital allowance – U.K. | 117,709 | 117,709 |
| U.S. research and development tax credit carryforwards | 5,637,845 | 2,761,415 |
| Share-based compensation | 2,874,945 | 2,071,838 |
| Interest expense | 1,904,690 | 1,368,042 |
| Change in fair value of derivative liabilities | 1,350,792 | 1,025,425 |
| Other, net – U.K. | 83,344 | 83,344 |
| Other, net – Malaysia | 100,133 | 100,654 |
| Other, net – U.S. | 228,738 | 203,237 |
| Gross deferred tax assets | 40,583,018 | 33,463,604 |
| Valuation allowance for deferred tax assets | (26,712,672) | (19,580,011) |
| Net deferred tax assets | 13,870,346 | 13,883,593 |
| Deferred tax liabilities: | | |
| In-process research and development | (882,427) | (882,427) |
| Covenant not-to-compete | (25,589) | (33,671) |
| Other, net – U.S. | (6,371) | (6,371) |
| Net deferred tax liabilities | (914,387) | (922,469) |
| Net deferred tax asset | $ 12,955,959 | $ 12,961,124 |

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

| | March 31, 2022 | September 30, 2021 |
|---|---|---|
| Deferred tax asset – U.K. | $ 12,919,252 | $ 12,923,896 |
| Deferred tax asset – Malaysia | 100,133 | 100,654 |
| Total deferred tax asset | $ 13,019,385 | $ 13,024,550 |
| | | |
| Deferred tax liability – U.S. | $ (63,426) | $ (63,426) |
| Total deferred tax liability | $ (63,426) | $ (63,426) |

**Note 14 – Net (Loss) Income Per Share**

Basic net (loss) income per common share is computed by dividing net (loss) income by the weighted average number of common shares outstanding for the period. Diluted net (loss) income per share is computed by dividing net (loss) 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, stock appreciation rights and common stock purchase warrants as determined under the treasury stock method.

The following table provides a reconciliation of the net (loss) income per basic and diluted common share outstanding:

| | Three Months Ended March 31, | | Six Months Ended March 31, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Net (loss) income | $ (14,177,830) | $ (2,845,981) | $ (20,557,836) | $ 14,381,720 |
| | | | | |
| Basic weighted average common shares outstanding | 80,052,504 | 75,175,077 | 80,037,675 | 72,717,621 |
| Net effect of dilutive instruments: | | | | |
| Stock options | — | — | — | 7,147,372 |
| Stock appreciation rights | — | — | — | 44,256 |
| Common stock purchase warrants | — | — | — | 744,821 |
| Total net effect of dilutive instruments | — | — | — | 7,936,449 |
| Diluted weighted average common shares outstanding | 80,052,504 | 75,175,077 | 80,037,675 | 80,654,070 |
| Net (loss) income per basic common share outstanding | $ (0.18) | $ (0.04) | $ (0.26) | $ 0.20 |
| Net (loss) income per diluted common share outstanding | $ (0.18) | $ (0.04) | $ (0.26) | $ 0.18 |

For the six months ended March 31, 2021, approximately 211,000 potentially dilutive instruments were excluded from the computation of net income per diluted weighted average common share outstanding because their effect would have been antidilutive. Due to our net loss for the three and six months ended March 31, 2022 and three months ended March 31, 2021, all potentially dilutive instruments were excluded because their inclusion would have been anti-dilutive. See Notes 9 and 10 for a discussion of our potentially dilutive instruments.

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

Overview

Veru 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 two FDA-approved products for sexual health.

**Biopharmaceuticals**

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

***Phase 3 COVID-19 registration trial – halted early by IDMC for clear efficacy benefit and no safety issues were identified: Sabizabulin 9mg for the treatment of hospitalized moderate to severe COVID-19 patients at high risk for ARDS and death.*** The Phase 3 COVID-19 study was a double-blind, randomized, placebo-controlled clinical trial conducted in approximately 210 hospitalized moderate to severe COVID-19 patients who were at high risk for ARDS and death. The primary endpoint was the proportion of deaths by Day 60. The FDA granted Fast Track designation to the Company's COVID-19 program in January 2022. In April 2022, a planned interim analysis of the first 150 patients randomized into the study was conducted and the Independent Data Monitoring Committee unanimously stopped the Phase 3 COVID-19 clinical study for positive efficacy and no safety issues were identified. Treatment with sabizabulin 9mg once daily, an oral, first-in-class, new chemical entity, cytoskeleton disruptor that has dual anti-inflammatory and antiviral properties, resulted in a clinically meaningful and statistically significant 55.2% relative reduction in deaths (p=0.0043).

On May 10, 2022, the Company had a pre-Emergency Use Authorization (EUA) meeting with the FDA to discuss next steps including the submission of an EUA application regarding sabizabulin for COVID-19. 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 will 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 COVID-19 study in hospitalized moderate to severe COVID-19 patients who are at high risk for ARDS and death and no additional clinical trials are required to support an NDA submission. We plan to submit the EUA application in the second quarter of calendar year 2022.

**The Company's breast cancer drug pipeline has three clinical development programs for two drugs: enobosarm, an oral selective androgen receptor targeting agonist, and sabizabulin, an oral cytoskeleton disruptor.**

***Phase 3 ARTEST clinical study – Enobosarm monotherapy as a 3rd line treatment of AR+ER+HER2- metastatic breast cancer (AR nuclei staining ≥40%).*** We are enrolling the Phase 3 multicenter, international, open label, and randomized (1:1) 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 AR nuclei staining ≥40% in their breast cancer tissue who have previously received a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor. We have identified that patients who have greater than 40% androgen receptor nuclei staining in their breast cancer tissue are most likely to respond to enobosarm. Based on the recommendation of the FDA to have a companion diagnostic test to determine the patient's AR status, we have partnered with Roche/Ventana Diagnostics, a global oncology diagnostics company, who is working to develop and, if approved, commercialize a companion diagnostic AR immunohistochemistry test. In January 2022, our enobosarm program received a Fast Track designation by the FDA.

***Phase 3 ENABLAR-2 clinical study – Enobosarm + abemaciclib combination as a 2nd line treatment of AR+ER+HER2- metastatic breast cancer (AR nuclei staining ≥40%).*** 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 previously received first line palbociclib (a CDK4/6 inhibitor) plus an estrogen blocking agent (non-steroidal aromatase inhibitor or fulvestrant) and have an AR nuclei staining ≥ 40% in their breast cancer tissue. We plan to enroll approximately 186 subjects in this Phase 3 clinical study.

***Planned Phase 2b clinical study – Sabizabulin monotherapy as a 3rd line treatment of AR+ER+HER2- metastatic breast cancer (AR nuclei staining <40%).*** 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 an AR nuclei staining <40%. 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 AR nuclei staining <40% in their breast cancer tissue who have previously received a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor.

**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 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.

***Planned Phase 3 registration clinical study.*** If the Phase 2 trial is successful, then, 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:

***Planned 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 Products**

ENTADFI™ (finasteride and tadalafil) was approved by the FDA in December 2021 as a new oral treatment for BPH, or an enlarged prostate gland. The co-administration of tadalafil and finasteride has been shown to provide quicker and more effective treatment of benign prostatic hyperplasia than finasteride alone without causing sexual adverse effects. We have been preparing to commercialize ENTADFI. Currently, the FDA is reviewing our product release criteria from our contract manufacturing facility, and we will need the FDA to approve such criteria in order for ENTADFI to be released for sale in the U.S. While we cannot be certain about the FDA's actions or timing, we currently expect clarity from FDA on our ability to release our product during the third quarter of calendar year 2022. Once we are able to release ENTADFI product, we plan to market ENTADFI to healthcare providers and patients via telemedicine and internet pharmacy services (including through a collaboration with GoodRx) and we expect that distribution will also be conducted through the traditional pharmaceutical distribution channels. We will plan to augment our marketing and sales efforts by seeking partners in the U.S. and outside the U.S. Commercialization preparations continue.

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 recently 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.

All 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. In October 2020, the Company was awarded up to 20 million units through its distributor in Brazil under the new Brazil female condom tender. The Company began shipping units under this tender award in the first quarter of fiscal 2021 and we have shipped approximately 9.7 million units through March 31, 2022. The Company does not anticipate any additional shipments under this tender in Brazil.

*FC2 Unit Sales.* Details of the quarterly unit sales of FC2 for the last five fiscal years were as follows:

| Period | 2022 | 2021 | 2020 | 2019 | 2018 |
|---|---|---|---|---|---|
| October 1 — December 31 | 6,260,484 | 12,318,988 | 10,070,700 | 7,382,524 | 4,399,932 |
| January 1 — March 31 | 4,164,852 | 8,189,552 | 6,884,472 | 9,792,584 | 4,125,032 |
| April 1 — June 30 | | 11,201,588 | 10,532,048 | 10,876,704 | 10,021,188 |
| July 1 — September 30 | | 6,095,332 | 5,289,908 | 9,842,020 | 6,755,124 |
| Total | 10,425,336 | 37,805,460 | 32,777,128 | 37,893,832 | 25,301,276 |

*Revenues*. Most of the Company's net revenues during the six months ended March 31, 2022 and 2021 were derived from sales of FC2 in the U.S. prescription channel and global public health sector. The Company also had revenues from sales of PREBOOST® (Roman Swipes) during the six months ended March 31, 2021 through the date the PREBOOST® business was sold on December 8, 2020. These sales are recognized upon shipment or delivery of the product to the customers depending on contract terms.

The Company's most significant customers have been 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.

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 seen an increase in the cost of the nitrile polymer used to produce FC2 and may experience increases in other raw material, logistic, and energy costs due to the impact of COVID-19 and increased inflation. Additionally, increases in Malaysian minimum wages will increase our production costs and those of our suppliers. 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 business model. The Company has multiple products under clinical 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 $15.5 million and $7.6 million for the three months ended March 31, 2022 and 2021, respectively, and $25.6 million and $13.3 million for the six months ended March 31, 2022 and 2021, respectively. We expect to continue this trend of increased expenses relating to research and development due to advancement of multiple drug candidates.

COVID-19 Environment

In December 2019, a novel strain of coronavirus was reported to have emerged in Wuhan, China. COVID-19, the disease caused by the coronavirus, has since spread to over 100 countries, including every state in the United States. On March 11, 2020, the World Health Organization declared COVID-19 a pandemic, and on March 13, 2020, the United States declared a national emergency with respect to the COVID-19 outbreak.

In an effort to contain and mitigate the spread of COVID-19, many countries, including the United States, the United Kingdom and Malaysia, have imposed unprecedented restrictions on travel, and there have been business closures and a substantial reduction in economic activity in countries that have had significant outbreaks of COVID-19. In addition, and in an attempt to slow the rapid growth of the COVID-19 infection rate, many governments around the world, including in the United States at the federal, state and local levels as well as in the United Kingdom and Malaysia, have from time to time imposed mandatory sheltering in place and social distancing restrictions that severely limit the ability of its citizens to travel freely and to conduct activities.

The COVID-19 pandemic has substantially impacted the global healthcare system, including the conduct of clinical trials. Many healthcare systems have restructured operations to prioritize caring for those suffering from COVID-19 and to limit or cease other activities. The severe burden on healthcare systems caused by this pandemic has also impaired the ability of many research sites to start new clinical trials or to enroll new patients in clinical trials. The imposed mandatory sheltering in place and social distancing restrictions may delay the recruitment of patients and impede their ability to effectively participate in such trials. Significant fees may also be owed to contract research organizations associated with starting and stopping clinical trials, typically more so than delaying the start of a clinical trial.

To date, COVID-19 has not impacted the Company's ability to supply product demand for FC2. Since the start of the pandemic, we have, from time to time, experienced some temporary disruptions to our manufacturing facility due to the implementation of government policies. Most recently, on June 1, 2021, the Malaysian government issued a nationwide lockdown order placing limitations on social and economic activity in the country. The Company was able to secure the required approvals, as a health product, to continue to partially operate by reducing the number of employees physically allowed in the facilities to 60% of the total workforce. On July 3, 2021, the lockdown was strengthened in the region in which the Company operates and the Company entered into a two-week period ceasing all operations, in common with similar manufacturing businesses. On July 19, 2021, after allowing some time for staff testing, operations resumed at the required levels of 60% of the total workforce. The Company has partially mitigated the disruption to production by changing staffing patterns. From time to time, we have temporarily paused operations as part of our contact tracing protocols and to allow for cleaning and disinfection of our production facility.

The Company has enrolled manufacturing staff in a vaccination program. More than 95% of the staff have received two doses of vaccination and more than 75% of staff have also received a booster. This has allowed shift patterns to return to normal and the facility is allowed to operate at 100% capacity under the current Malaysia control orders.

The Company has had and believes it continues to have a sufficient quantity of FC2 inventory both inside and outside of Malaysia to satisfy expected customer demand. The closure and reduced operating capacity did not have a material impact to the Company's consolidated operating results in fiscal 2021 or the first half of fiscal 2022 and we do not expect them to have a material impact on the Company's consolidated operating results in foreseeable future periods. The Company continues to operate enhanced health and safety protocols to protect the employees at its Malaysian facility, to respond in the event an employee at the facility is determined to have tested positive for COVID-19, and to mitigate the impact of COVID-19 on the Company's Malaysian manufacturing operations. However, no such measures can eliminate risks relating to the COVID-19 pandemic, and if the Company's Malaysian manufacturing facility is subject to future government mandates to counter COVID-19 or encounters labor or raw material shortages, transportation delays or other issues, our ability to supply product to our customers could be disrupted.

The sole supplier of the nitrile polymer sheath for FC2 also produces surgical gloves and has at times prioritized their production during the COVID-19 pandemic and may continue to do so, which could disrupt the Company's supply of a critical raw material. Malaysian ports are currently open for shipment but at reduced capacity, and the Company may also encounter issues shipping product into key markets or through freight or other carriers. To mitigate these factors, the Company continues to build strategic stock to ensure supply is available during a period of potential disruption. The COVID-19 pandemic and related economic disruption may also adversely affect customer demand for FC2. For example, sales of FC2 could be impacted in the U.S. prescription channel if insurance coverage is affected by job losses and in the global public health sector if governments delay future tenders or reduce spending on female condoms due to financial strains or changed spending priorities caused by the COVID-19 pandemic. The COVID-19 pandemic did not have a material net impact on our consolidated operating results during the three or six months ended March 31, 2022.

Significant uncertainty remains as to the potential impact of the COVID-19 pandemic on our operations, and on the global economy. It is currently not possible to predict how long the pandemic will last or the time that it will take for economic activity to return to prior levels as a result of uncertainties, including the extent and rate of the spread of the virus that continue to fluctuate, the potential for additional peaks in infection rates, and the timing and availability of vaccines, treatments or cures to slow and eventually stop the spread. We do not yet know the full extent of any impact on our business or our operations; however, we will continue to monitor the COVID-19 situation and its impact on our business closely and expect to reevaluate the timing of our anticipated clinical trials as the impact of COVID-19 on our industry becomes clearer.

Results of Operations

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

The Company generated net revenues of $13.0 million and net loss of $14.2 million, or $(0.18) per basic and diluted common share, for the three months ended March 31, 2022, compared to net revenues of $13.3 million and net loss of $2.8 million, or $(0.04) per basic and diluted common share, for the three months ended March 31, 2021. Net revenues decreased 2% over the prior period.

All of the Company's net revenues for the three months ended March 31, 2022 and 2021 were derived from sales of FC2 in the U.S. prescription channel and global public health sector. There was a 49% decrease in total FC2 unit sales and an increase in FC2 average sales price per unit of 92%. The principal factor for the increase in the FC2 average sales price per unit compared to prior period was the change in the sales mix with the U.S. prescription channel representing 89% of total FC2 net revenues in the current year period compared to 77% of total FC2 net revenues in the prior year period. The Company experienced an increase compared to the prior year period of 12% in FC2 net revenues in the U.S. prescription channel and a decrease compared to the prior year period of 53% in FC2 net revenues in the global public health sector. The increase in FC2 net revenues in the U.S. prescription channel is primarily due to an increase in price. The reduction in the global public health sector is primarily due to sales in the fiscal 2021 period related to the Brazil and South Africa tenders, which did not repeat in the fiscal 2022 period.

Cost of sales decreased to $1.9 million in the three months ended March 31, 2022 from $2.4 million in the three months ended March 31, 2021 due to the decrease in unit sales.

Gross profit increased to $11.2 million in the three months ended March 31, 2022 from $10.9 million in the three months ended March 31, 2021. Gross profit margin for the fiscal 2022 period was 86% of net revenues, compared to 82% of net revenues for the fiscal 2021 period. The increase in the gross profit and gross profit margin is primarily due to the increase in FC2 net revenues in the U.S. prescription channel with higher profit margins.

Significant quarter-to-quarter variances in the Company's results have historically resulted from the timing and shipment of large orders rather than from any fundamental changes in the business or the underlying demand for FC2. The Company is also currently seeing pressure on pricing for FC2 by large global agencies and donor governments in the developed world. As a result, the Company may continue to experience challenges for revenue from sales of FC2 in the global public health sector. The Company is experiencing increases in revenue from sales in the U.S. prescription channel, which is helping grow net revenues year to year.

Research and development expenses increased to $15.5 million in the three months ended March 31, 2022 from $7.6 million in the same period in fiscal 2021. The increase is primarily due to increased costs associated with the multiple in-process research and development projects and increased personnel costs. During the second quarter of fiscal 2022, the Company had four Phase 3 clinical trials and two Phase 2 clinical trial ongoing with additional clinical trial initiations planned. This clinical trial activity has resulted in increased costs.

Selling, general and administrative expenses increased to $7.4 million in the three months ended March 31, 2022 from $4.8 million in the three months ended March 31, 2021. The increase is due primarily to increased compensation costs, resulting from increased personnel, and increased share-based compensation costs, resulting from an increase in headcount and an increase in the fair value of stock options. Additionally, sales and marketing expenses have increased as a result of costs associated with the commercialization of ENTADFI™ and the launch of the Company's own dedicated direct to patient telemedicine and pharmacy services portal/platform for FC2.

Interest expense, which is related to the Credit Agreement and Residual Royalty Agreement, was $1.2 million in the three months ended March 31, 2022, which is comparable with $1.3 million in the three months ended March 31, 2021.

Expense associated with the change in fair value of the embedded derivatives related to the Credit Agreement and Residual Royalty Agreement was $1.2 million in the three months ended March 31, 2022, compared to expense of $53,000 in the three months ended March 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. The increase in the fair value of the embedded derivates is due to an increase in projected FC2 net revenues in future periods. See Note 3 and Note 8 to the financial statements included in this report for additional information.

Income tax benefit in the second quarter of fiscal 2022 was $27,000, compared to income tax expense of $22,000 in the second quarter of fiscal 2021. The change is due primarily to a decrease in taxable income in the U.K. and Malaysia. The U.S. continues to have a full valuation allowance on its deferred tax assets; therefore, activity in the U.S. has no effect on income tax expense.

SIX MONTHS ENDED MARCH 31, 2022 COMPARED TO SIX MONTHS ENDED MARCH 31, 2021

The Company generated net revenues of $27.2 million and net loss of $20.6 million, or $(0.26) per basic and diluted common share, for the six months ended March 31, 2022, compared to net revenues of $28.0 million and net income of $14.4 million, or $0.20 per basic common share and $0.18 per diluted common share, for the six months ended March 31, 2021. Net revenues decreased 3% over the prior period.

FC2 net revenues increased slightly year over year to $27.2 million from $27.1 million. There was a 49% decrease in total FC2 unit sales and an increase in FC2 average sales price per unit of 97%. The principal factor for the increase in the FC2 average sales price per unit compared to prior period was the change in the sales mix with the U.S. prescription channel representing 85% of total FC2 net revenues in the current year period compared to 72% of total FC2 net revenues in the prior year period. The Company experienced an increase compared to the prior year period of 19% in FC2 net revenues in the U.S. prescription channel and a decrease compared to the prior year period of 48% in FC2 net revenues in the global public health sector. The increase in FC2 net revenues in the U.S. prescription channel is due to increases in volume and price. The reduction in the global public health sector is primarily due to sales in the fiscal 2021 period related to the Brazil and South Africa tenders, which did not repeat in the fiscal 2022 period. Results for the six months ended March 31, 2021 included net revenues of $0.9 million related to the PREBOOST® business before the sale of such business in December 2020.

Cost of sales decreased to $4.1 million in the six months ended March 31, 2022 from $6.2 million in the six months ended March 31, 2021 due to the decrease in unit sales.

Gross profit increased to $23.0 million in the six months ended March 31, 2022 from $21.7 million in the six months ended March 31, 2021. Gross profit margin for the fiscal 2022 period was 85% of net revenues, compared to 78% of net revenues for the fiscal 2021 period. The increase in the gross profit and gross profit margin is primarily due to the increase in FC2 net revenues in the U.S. prescription channel with higher profit margins.

Significant quarter-to-quarter variances in the Company's results have historically resulted from the timing and shipment of large orders rather than from any fundamental changes in the business or the underlying demand for FC2. The Company is also currently seeing pressure on pricing for FC2 by large global agencies and donor governments in the developed world. As a result, the Company may continue to experience challenges for revenue from sales of FC2 in the global public health sector. The Company is experiencing increases in revenue from sales in the U.S. prescription channel, which is helping grow net revenues year to year.

Research and development expenses increased to $25.6 million in the six months ended March 31, 2022 from $13.3 million in the same period in fiscal 2021. The increase is primarily due to increased costs associated with the multiple in-process research and development projects and increased personnel costs. During the first half of fiscal 2022, the Company had four Phase 3 clinical trials and two Phase 2 clinical trial ongoing with additional clinical trial initiations planned. This clinical trial activity has resulted in increased costs.

Selling, general and administrative expenses increased to $14.1 million in the six months ended March 31, 2022 from $9.2 million in the six months ended March 31, 2021. The increase is due primarily to increased compensation costs, resulting from increased personnel, and increased share-based compensation costs, resulting from an increase in headcount and an increase in the fair value of stock options. Additionally, sales and marketing expenses have increased as a result of costs associated with the commercialization of ENTADFI™ and the launch of the Company's own dedicated direct to patient telemedicine and pharmacy services portal/platform for FC2.

During the first half of fiscal 2021, we recorded a pre-tax gain on sale of the Company's PREBOOST® business of $18.4 million. See Note 2 to the financial statements included in this report for additional information.

Interest expense, which is related to the Credit Agreement and Residual Royalty Agreement, was $2.4 million in the six months ended March 31, 2022, which is consistent with the six months ended March 31, 2021.

Expense associated with the change in fair value of the embedded derivatives related to the Credit Agreement and Residual Royalty Agreement was $1.4 million in the six months ended March 31, 2022, compared to expense of $0.7 million in the six months ended March 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. The increase in the fair value of the embedded derivates is due to an increase in projected FC2 net revenues in future periods. See Note 3 and Note 8 to the financial statements included in this report for additional information.

Income tax expense in the first half of fiscal 2022 was $87,000, compared to income tax expense of $100,000 in the first half of fiscal 2021. The slight decrease in the income tax expense is due primarily due to a decrease in taxable income in the U.K. and Malaysia. The U.S. continues to have a full valuation allowance on its deferred tax assets; therefore, activity in the U.S. has no effect on income tax expense.

Liquidity and Sources of Capital

***Liquidity***

Our cash and cash equivalents on hand at March 31, 2022 was $112.0 million, compared to $122.4 million at September 30, 2021. At March 31, 2022, the Company had working capital of $119.2 million and stockholders' equity of $136.0 million compared to working capital of $136.0 million and stockholders' equity of $152.3 million as of September 30, 2021. The decrease in working capital is primarily due to the decrease in cash on hand and an increase in accounts payable and accrued research and development costs.

We anticipate that we will continue to consume cash as we develop 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 II, Item 1A, "Risk Factors - We may need to seek and secure significant funding through financings or from other sources to effectively commercialize sabizabulin as a treatment for COVID-19" below in this Quarterly Report on Form 10-Q, and 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, 2021 for a description of certain risks that will affect our future capital requirements.

The Company believes its current cash position and cash expected to be generated from sales of the Company's approved products, FC2 and ENTADFI, are 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 $12.6 million in the six months ended March 31, 2022. Cash used in operating activities included net loss of $20.6 million, adjustments to reconcile net loss to net cash used in operating activities totaling an increase of $6.7 million and changes in operating assets and liabilities resulting in an increase of $1.3 million. Adjustments to net loss primarily consisted of $4.0 million of share-based compensation, interest expense in excess of interest paid of $0.9 million, and $1.4 million for the change in fair value of derivative liabilities. The increase in cash from changes in operating assets and liabilities included an increase in accounts payable of $4.1 million and an increase in accrued expenses and other current liabilities of $0.4 million, partially offset by an increase in accounts receivable of $0.8 million, an increase in inventory of $0.9 million, and an increase in prepaid expenses and other current assets of $1.4 million.

Operating activities used cash of $1.9 million in the six months ended March 31, 2021. Cash from operating activities included net income of $14.4 million, adjustments to reconcile net income to net cash provided by operating activities totaling a reduction of $15.6 million and changes in operating assets and liabilities of $0.7 million. Adjustments to net income primarily consisted of $18.4 million related to the gain on sale of the PREBOOST® business, $1.8 million of share-based compensation, and $0.7 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 $2.4 million and an increase in inventory of $1.1 million, partially offset by an increase in accounts payable of $2.8 million.

*Investing activities*

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

Net cash from investing activities was $15.0 million in the six months ended March 31, 2021, attributed to $15.0 million received from the sale of the Company's PREBOOST® business.

*Financing activities*

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

Net cash provided by financing activities in the six months ended March 31, 2021 was $110.0 million and primarily consisted of proceeds from the underwritten public offering of the Company's common stock, net of fees and costs paid through March 31, 2021 of $108.1 million (see discussion below) and proceeds from stock option exercises of $1.3 million.

***Sources of Capital***

*Common Stock Offering*

On February 22, 2021, we completed an underwritten public offering of 7,419,354 shares of our common stock, which included the exercise in full of the underwriters' option to purchase additional shares, at a public offering price of $15.50 per share. Net proceeds to the Company from this offering were $108.0 million after deducting underwriting discounts and commissions and costs incurred by the Company. All of the shares sold in the offering were by the Company. The offering was made pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-239493).

*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. Under the Credit Agreement, the Company is required to make quarterly payments on the term loan based on the Company's product revenue from net sales of FC2 until the earlier of receipt by the Lenders of a return premium specified in the Credit Agreement or a required payment upon termination of the Credit Agreement on March 5, 2025 or an earlier change of control of the Company or sale of the FC2 business. 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 $1.5 million during the six months ended March 31, 2022 and made total payments under the Credit Agreement of $2.5 million during the six months ended March 31, 2021. The Company currently estimates the aggregate amount of quarterly revenue-based payments payable during the 12-month period subsequent to March 31, 2022 will be approximately $3.8 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 March 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 March 31, 2022 and September 30, 2021, 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 provisions in the Credit Agreement and 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 previously determined the fair value of the embedded derivatives using a Monte Carlo simulation model. Since the Credit Agreement has been satisfied as of September 30, 2021, the fair value of the embedded derivative within the Residual Royalty Agreement has been calculated by using a scenario-based method, whereby different scenarios are valued and probability weighted. The Company determined that with only the embedded derivative under the Residual Royalty Agreement remaining, there is no material difference between these two valuation models. 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, 2021. There have been no material changes to such exposures since September 30, 2021.

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

Neither the Company nor any of its subsidiaries is a party to any material pending legal proceedings at the date of filing of this Quarterly Report on Form 10-Q.

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, 2021. 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, 2021, except for the following additional risk factors relating to our development of sabizabulin as a treatment for COVID-19 virus infection. Additional risks that we do not yet know of or that we currently think are immaterial may also impair our business operations, and there is significant uncertainty regarding the COVID-19 pandemic which could affect the risk factors set forth below.

***We may be unable to obtain an emergency use authorization from the FDA to market sabizabulin as a potential treatment for COVID-19 in the United States in a timely manner, if at all.***

In response to the global outbreak of COVID-19, we have been pursuing the development of sabizabulin as a treatment for COVID-19. Our ability to commercialize sabizabulin as a treatment for COVID-19 will depend on regulatory approval in the United States and other jurisdictions. In the United States, we initially plan to use the FDA's Emergency Use Authorization ("EUA") process. EUA is a form of temporary marketing authorization that the FDA may grant to an investigational drug at times when the Secretary of Health and Human Services has declared a public health emergency to exist. This declaration was made by the Secretary of Health and Human Services in March 2020 in relation to the COVID-19 pandemic. In order to grant an EUA, the FDA must determine that an investigational drug is safe and may be effective in treating the disease that is the subject of the public health emergency. Although the EUA process is designed to enable more expeditious marketing of a drug in response to a public health emergency, FDA review of an EUA application may take longer than expected and may result in the FDA requesting additional data or other information that may have the effect of delaying the EUA, and any agreements or positions taken by the FDA in a pre-EUA meeting does not bind the FDA or prevent it from later taking a different position, asking for more data, or delaying or denying the application. The FDA may decline to grant an EUA if it concludes that an investigational drug is not safe or effective. If any such issues arise in connection with our submission of an EUA for sabizabulin, our ability to market sabizabulin as a COVID-19 treatment may delayed or dependent on a more time-consuming regulatory approval process, which may have a material adverse effect on our business. If we are granted an EUA by the FDA for sabizabulin, we would be able to distribute sabizabulin under the conditions set forth in the EUA prior to FDA approval. Furthermore, the FDA may revoke (or refuse to grant) an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, and we cannot predict how long, if ever, an EUA would remain in place. Such revocation could adversely impact our business in a variety of ways, including if sabizabulin is not yet approved by the FDA and if we and our manufacturing partners have invested in the supply chain to provide sabizabulin under an EUA.

***We may be unable to obtain emergency authorizations or approvals from regulatory authorities in foreign countries to market sabizabulin as a potential treatment for COVID-19 in a timely manner, if at all.***

Similar to the regulatory challenges we face for an EUA or approval of sabizabulin for the treatment of COVID-19 in the United States, we will not be able to market sabizabulin for the treatment of COVID-19 in any foreign jurisdiction without an applicable authorization or approval in any such foreign jurisdiction. We have never received any such authorization or approval for any of our drug candidates from any foreign regulatory authority and, even if such an authorization or approval is granted, we have no experience marketing a drug outside the United States. Like any EUA or approval in the United States, any authorization or approval outside the United States may be subject to various conditions required by any such foreign regulatory authority. There can be no assurances of the timing of receipt of any such foreign authorization or approval or whether we will receive any such foreign authorization or approval at all and, if we do receive any such authorization or approval, whether we will be able to market sabizabulin on favorable economic terms.

***We lack experience in scaling-up and commercializing a drug product.***

We are working toward the large-scale technical development, manufacturing scale-up and larger scale deployment of sabizabulin as a COVID-19 treatment. To support the scale-up, we have expended and will need to continue to expend significant resources and capital. In connection with this process, we may seek to enter into a collaboration or other arrangement with a larger organization, although we may be unable to enter into such arrangements on favorable terms, or at all, or may decide to proceed with development and commercialization on our own. In that case, we will need to expend significant resources to commercialize sabizabulin, which may require additional financial resources. As part of our efforts, we intend to apply for an advanced purchase agreement from the U.S. government and governments outside the U.S. There can be no assurances that any such advanced purchase agreements will be provided. The government from which an advanced purchase agreement is obtained may also impose restrictions on or mandate input as to our conduct of manufacturing activities or distribution activities, which may cause delays in the event of disagreement.

In addition, since the path to licensure or emergency approval of any COVID-19 treatment remains uncertain, we may have a widely used drug in circulation in the United States or another country prior to our receipt of marketing approval. Unexpected safety issues, including any that we have not yet observed in our clinical trials for sabizabulin, could lead to significant reputational damage for us and our drug development program going forward and other issues, including delays in our other programs, the need for re-design of our clinical trials and the need for significant additional financial resources.

***If we are unable to manufacture sabizabulin as a COVID-19 treatment in sufficient quantities, at sufficient yields or are unable to obtain regulatory approvals for a manufacturing facility for sabizabulin, we may experience delays in product development, regulatory approval and commercial distribution.***

Commercialization of sabizabulin as a COVID-19 treatment will require access to facilities to manufacture sabizabulin at sufficient yields and at commercial-scale. We have no experience in manufacturing any of our drug candidates in the volumes that would be necessary to support commercial sales. Efforts to establish these capabilities may not meet initial expectations as to scheduling, scale-up, reproducibility, yield, purity, cost, potency or quality. In addition, other companies, many with substantial resources, may compete with us for access to materials needed to manufacture sabizabulin.

Manufacturing sabizabulin as a COVID-19 treatment will involve a complicated process with which we have limited experience. We are dependent on third-party organizations to conduct our manufacturing activities. If third-party manufacturing organizations are unable to manufacture sabizabulin in commercial quantities and at sufficient yields, then we will need to identify and reach supply arrangements with additional third parties. Third-party manufacturers must also be inspected by the FDA as part of the FDA's review of our marketing application. Sabizabulin may be in competition with other products for access to these facilities and may be subject to delays in manufacturing if third parties give other products higher priority. We may not be able to enter into any necessary additional third-party manufacturing arrangements on acceptable terms, or on a timely basis. In addition, we have to enter into technical transfer agreements and share our know-how with the third-party manufacturers, which can be time-consuming and may result in delays. Any delay in the manufacture or delivery of sabizabulin could adversely affect our ability to sell sabizabulin as a COVID-19 treatment, if approved.

Our reliance on third-party manufacturers may adversely affect our operations or result in unforeseen delays or other problems beyond our control. Because of contractual restraints and the limited number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture sabizabulin on a commercial scale, replacement of a manufacturer may be expensive and time-consuming and may cause interruptions in the production of sabizabulin. A third-party manufacturer may also encounter difficulties in production. These problems may include:

- difficulties with production costs, scale up and yields;
- availability of raw materials and supplies;
- quality control and assurance;
- shortages of qualified personnel;
- compliance with strictly enforced federal, state and foreign regulations that vary in each country where products might be sold; and
- lack of capital funding.

As a result, any delay or interruption could have a material adverse effect on our business, financial condition, or results of operations.

***We may face competition in connection with sabizabulin for a COVID-19 treatment.***

Another party may be successful in producing a more efficacious treatment for COVID-19 which may also lead to the diversion of governmental and quasi-governmental funding away from us and toward other companies. In particular, given the widespread media attention on the current COVID-19 pandemic, there are efforts by public and private entities to develop COVID-19 treatments. Those other entities may develop COVID-19 treatments that, as compared to sabizabulin, are more effective, become the standard of care, have broader market acceptance, are safer or have fewer or less severe side effects, are more convenient, are developed at a lower cost or earlier, or may be more successfully commercialized. Many of these other organizations are much larger than we are and have access to larger pools of capital and broader manufacturing infrastructure. Larger pharmaceutical and biotechnology companies have extensive experience in clinical testing and obtaining regulatory approval for their products, and may have the resources to heavily invest to accelerate discovery and development of their vaccine candidates. Our business could be materially and adversely affected if competitors develop and commercialize one or more COVID-19 treatments before we can complete development and seek approval for sabizabulin.

***Our ability to produce a treatment for the COVID-19 virus may be curtailed by government actions or interventions, which may be more likely during a global health crisis such as COVID-19.***

Given the significant global impact of the COVID-19 pandemic, it is possible that one or more government entities may take actions that directly or indirectly have the effect of diminishing some of our rights or opportunities with respect to sabizabulin and the economic value of a COVID-19 treatment to us could be limited. Governments and other health authorities may also focus on vaccines rather than treatment options such as sabizabulin in addressing the COVID-19 pandemic, which may reduce funding and other market opportunities for sabizabulin. We also intend to seek to enter into contracts with the U.S. government and other health authorities to supply sabizabulin, which will depend on spending and political priorities, the availability of alternative treatment options, and the continuation of the COVID-19 as a public health emergency. Government entities may also impose restrictions or limitations on our third-party service providers and may require us to obtain alternative sources for sabizabulin. If we are unable to timely enter into alternative arrangements, or if such alternative arrangements are not available on satisfactory terms, we will experience delays in the development or production of our sabizabulin, increased expenses, and delays in potential distribution or commercialization of our vaccine candidates, when and if approved.

***We may need to seek and secure significant funding through financings or from other sources to effectively commercialize sabizabulin as a treatment for COVID-19.***

We are currently advancing our pipeline of prostate and breast cancer drug candidates and are conducting multiple clinical studies. Discovering development candidates and developing investigational medicines is expensive, and we expect to continue to spend substantial amounts to (i) perform basic research, perform preclinical studies, and conduct clinical trials of our current and future programs, (ii) continue to develop and expand our platform and infrastructure and supply preclinical studies and clinical trials with appropriate grade materials (including cGMP materials), (iii) seek regulatory approvals for our investigational medicines, and (iv) launch and commercialize any products for which we receive regulatory approval, including building our own commercial sales, marketing, and distribution organization. Furthermore, our ongoing work on sabizabulin will require significant additional investment during 2022 and beyond.

As of March 31, 2022, we had approximately $112.0 million in cash and cash equivalents. We expect that our existing cash and cash equivalents will be sufficient to fund our current operations through at least the next twelve months. However, our operating plan may change as a result of many factors currently unknown to us, including with respect to our development, manufacturing and commercialization of sabizabulin for COVID-19 and availability and conditions of advanced purchase agreements, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, structured financings, government or other third-party funding, sales of assets, marketing and distribution arrangements, other collaborations and licensing arrangements, or a combination of these approaches. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Our spending will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with discovery of development candidates and development of our investigational medicines are highly uncertain, we are unable to estimate the actual funds we will require for development, marketing, and commercialization activities.

Item 6. Exhibits

| Exhibit Number | Description |
|---|---|
| 2.1 | Asset Purchase Agreement, dated as of December 8, 2020, between the Company and Roman Health Ventures Inc. (incorporated by reference to Exhibit 2.2 to the Company's Form 10-K (File No. 1-13602) filed with the SEC on December 10, 2020). |
| 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). |
| 10.1 | Veru Inc. 2018 Equity Incentive Plan (as amended and restated effective March 29, 2022) (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on March 31, 2022). * |

| | |
|---|---|
| 31.1 | Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. ** |
| 31.2 | Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. ** |
| 32.1 | Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002). **, *** |
| 101 | The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 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). |

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

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**VERU INC.**

DATE: May 12, 2022

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

DATE: May 12, 2022

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

**Exhibit 31.1**

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

I, Mitchell S. Steiner, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 12, 2022

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

**Exhibit 31.2**

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

I, Michele Greco, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 12, 2022

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

**Exhibit 32.1**

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

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned officers of Veru Inc. (the "Company") certifies that the Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 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: May 12, 2022

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

Date: May 12, 2022

/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.