**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 June 30, 2021

☐ **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.) |
| **48 NW 25th Street, Suite 102, 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 August 9, 2021, the registrant had 79,853,748 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, future financial and operating results, plans, objectives, expectations and intentions, costs and expenses, debt repayments, 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;
- potential delays in the timing of any submission to the U.S. Food and Drug Administration (the “FDA”) and potential delays in, or failure to obtain, regulatory approval of products under development, 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.;
- 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 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 to market;
- 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 become widely distributed the need for new COVID-19 treatment candidates may be reduced or eliminated;
- 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 any of our products, if approved;
- some of our products are in development and we may fail to successfully commercialize such products;
- 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 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 or other strategic initiatives; and
- our ability to successfully integrate acquired businesses, technologies or products.

All forward-looking statements in this report should be considered in the context of the risks and other factors described above and in Part I, Item 1A, "Risk Factors," in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2020. The Company undertakes no obligation to make any revisions to the forward-looking statements contained in this report or to update them to reflect events or circumstances occurring after the date of this report except as required by applicable law.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

| | June 30, 2021 | September 30, 2020 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 123,155,968 | $ 13,588,778 |
| Accounts receivable, net | 8,313,543 | 5,227,237 |
| Notes receivable | 5,000,000 | — |
| Inventory, net | 6,945,916 | 6,704,134 |
| Prepaid research and development costs | 9,546,026 | 613,274 |
| Prepaid expenses and other current assets | 1,444,081 | 881,267 |
| Total current assets | 154,405,534 | 27,014,690 |
| Plant and equipment, net | 392,012 | 312,691 |
| Operating lease right-of-use assets | 1,069,472 | 1,352,315 |
| Deferred income taxes | 12,379,578 | 9,466,800 |
| Intangible assets, net | 4,066,667 | 5,752,127 |
| Goodwill | 6,878,932 | 6,878,932 |
| Other assets | 880,888 | 766,120 |
| Total assets | $ 180,073,083 | $ 51,543,675 |
| | | |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 4,927,680 | $ 2,812,673 |
| Accrued research and development costs | 2,327,323 | 934,110 |
| Accrued compensation | 2,760,029 | 2,274,396 |
| Accrued expenses and other current liabilities | 2,095,688 | 1,177,126 |
| Credit agreement liability | 884,917 | 5,841,874 |
| Residual royalty agreement liability, short-term portion | 3,679,871 | 1,100,193 |
| Operating lease liability, short-term portion | 536,449 | 586,769 |
| Total current liabilities | 17,211,957 | 14,727,141 |
| Residual royalty agreement liability, long-term portion | 7,100,145 | 5,617,494 |
| Operating lease liability, long-term portion | 702,993 | 990,020 |
| Deferred income taxes | 74,724 | 74,724 |
| Other liabilities | 14,986 | 22,980 |
| Total liabilities | 25,104,805 | 21,432,359 |
| | | |
| Commitments and contingencies (Note 12) | | |
| | | |
| Stockholders' equity: | | |
| Preferred stock; no shares issued and outstanding at June 30, 2021 and September 30, 2020 | — | — |
| Common stock, par value $0.01 per share; 154,000,000 shares authorized, 82,037,452 and 72,047,385 shares issued and 79,853,748 and 69,863,681 shares outstanding at June 30, 2021 and September 30, 2020, respectively | 820,375 | 720,474 |
| Additional paid-in-capital | 240,039,725 | 126,971,518 |
| Accumulated other comprehensive loss | (581,519) | (581,519) |
| Accumulated deficit | (77,503,698) | (89,192,552) |
| Treasury stock, 2,183,704 shares, at cost | (7,806,605) | (7,806,605) |
| Total stockholders' equity | 154,968,278 | 30,111,316 |
| Total liabilities and stockholders' equity | $ 180,073,083 | $ 51,543,675 |

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

| | Three Months Ended June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Net revenues | $ 17,655,592 | $ 10,321,754 | $ 45,613,068 | $ 30,842,874 |
| Cost of sales | 3,782,480 | 3,802,636 | 9,995,023 | 9,618,163 |
| Gross profit | 13,873,112 | 6,519,118 | 35,618,045 | 21,224,711 |
| Operating expenses: | | | | |
| Research and development | 11,188,246 | 4,436,496 | 24,438,813 | 13,666,730 |
| Selling, general and administrative | 5,556,730 | 3,475,474 | 14,745,507 | 11,034,904 |
| Total operating expenses | 16,744,976 | 7,911,970 | 39,184,320 | 24,701,634 |
| Gain on sale of PREBOOST® business | — | — | 18,410,158 | — |
| Operating (loss) income | (2,871,864) | (1,392,852) | 14,843,883 | (3,476,923) |
| Non-operating expenses: | | | | |
| Interest expense | (1,287,525) | (1,169,692) | (3,728,259) | (3,476,079) |
| Change in fair value of derivative liabilities | (1,372,000) | (169,000) | (2,029,000) | (94,000) |
| Other expense, net | (34,540) | (53,334) | (170,841) | (63,369) |
| Total non-operating expenses | (2,694,065) | (1,392,026) | (5,928,100) | (3,633,448) |
| (Loss) income before income taxes | (5,565,929) | (2,784,878) | 8,915,783 | (7,110,371) |
| Income tax (benefit) expense | (2,873,063) | 240,502 | (2,773,071) | 30,619 |
| Net (loss) income | $ (2,692,866) | $ (3,025,380) | $ 11,688,854 | $ (7,140,990) |
| Net (loss) income per basic common share outstanding | $ (0.03) | $ (0.05) | $ 0.16 | $ (0.11) |
| Basic weighted average common shares outstanding | 79,729,370 | 66,728,782 | 75,054,871 | 65,709,139 |
| Net (loss) income per diluted common share outstanding | $ (0.03) | $ (0.05) | $ 0.14 | $ (0.11) |
| Diluted weighted average common shares outstanding | 79,729,370 | 66,728,782 | 82,807,156 | 65,709,139 |

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, 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 |
| Share-based compensation | — | — | 1,900,085 | — | — | — | 1,900,085 |
| Issuance of shares pursuant to share-based awards | 170,194 | 1,702 | 263,351 | — | — | — | 265,053 |
| Net loss | — | — | — | — | (2,692,866) | — | (2,692,866) |
| Balance at June 30, 2021 | 82,037,452 | $ 820,375 | $ 240,039,725 | $ (581,519) | $ (77,503,698) | $ (7,806,605) | $ 154,968,278 |

See notes to unaudited condensed consolidated financial statements.

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

| | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Loss | Accumulated Deficit | Treasury Stock, at Cost | Total |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | | | | | |
| Balance at September 30, 2019 | 67,221,951 | $ 672,220 | $ 110,268,057 | $ (581,519) | $ (70,219,017) | $ (7,806,605) | $ 32,333,136 |
| Share-based compensation | — | — | 614,498 | — | — | — | 614,498 |
| Issuance of shares pursuant to share-based awards | 867 | 8 | (8) | — | — | — | — |
| Net loss | — | — | — | — | (3,305,101) | — | (3,305,101) |
| Balance at December 31, 2019 | 67,222,818 | 672,228 | 110,882,547 | (581,519) | (73,524,118) | (7,806,605) | 29,642,533 |
| Share-based compensation | — | — | 681,680 | — | — | — | 681,680 |
| Issuance of shares pursuant to share-based awards | 356,424 | 3,564 | 405,068 | — | — | — | 408,632 |
| Sale of shares under common stock purchase agreement | 300,000 | 3,000 | 1,224,000 | — | — | — | 1,227,000 |
| Amortization of deferred costs | — | — | (34,759) | — | — | — | (34,759) |
| Net loss | — | — | — | — | (810,509) | — | (810,509) |
| Balance at March 31, 2020 | 67,879,242 | 678,792 | 113,158,536 | (581,519) | (74,334,627) | (7,806,605) | 31,114,577 |
| Share-based compensation | — | — | 685,314 | — | — | — | 685,314 |
| Shares issued in connection with common stock purchase agreement | 212,130 | 2,121 | 678,816 | — | — | — | 680,937 |
| Sale of shares under common stock purchase agreement | 3,842,070 | 38,421 | 12,134,578 | — | — | — | 12,172,999 |
| Amortization of deferred costs | — | — | (356,172) | — | — | — | (356,172) |
| Issuance of shares pursuant to common stock purchase warrants | 109,143 | 1,092 | (1,092) | — | — | — | — |
| Issuance of shares pursuant to share-based awards | 4,800 | 48 | 6,784 | — | — | — | 6,832 |
| Net loss | — | — | — | — | (3,025,380) | — | (3,025,380) |
| Balance at June 30, 2020 | 72,047,385 | $ 720,474 | $ 126,306,764 | $ (581,519) | $ (77,360,007) | $ (7,806,605) | $ 41,279,107 |

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

| | Nine Months Ended June 30, | |
|---|---|---|
| | 2021 | 2020 |
| OPERATING ACTIVITIES | | |
| Net income (loss) | $ 11,688,854 | $ (7,140,990) |
| Adjustments to reconcile net income (loss) to net cash used in operating activities: | | |
| Depreciation and amortization | 170,713 | 347,159 |
| Noncash change in right-of-use assets | 282,843 | 240,282 |
| Noncash interest expense, net of interest paid | (2,923,628) | 3,476,079 |
| Share-based compensation | 3,687,663 | 1,981,492 |
| Gain on sale of PREBOOST® business | (18,410,158) | — |
| Deferred income taxes | (2,912,778) | (198,202) |
| Provision for obsolete inventory | 175,085 | 227,982 |
| Change in fair value of derivative liabilities | 2,029,000 | 94,000 |
| Other | (3,000) | 7,500 |
| Changes in current assets and liabilities: | | |
| (Increase) decrease in accounts receivable | (3,083,306) | 194,471 |
| Increase in inventory | (416,867) | (1,775,018) |
| Increase in prepaid expenses and other assets | (9,610,334) | (4,794) |
| Increase in accounts payable | 2,115,007 | 648,239 |
| Increase in accrued expenses and other current liabilities | 2,783,696 | 556,330 |
| Decrease in operating lease liabilities | (337,346) | (243,514) |
| Net cash used in operating activities | (14,764,556) | (1,588,984) |
| | | |
| INVESTING ACTIVITIES | | |
| Cash proceeds from sale of PREBOOST® business | 15,000,000 | — |
| Capital expenditures | (154,416) | (73,444) |
| Net cash provided by (used in) investing activities | 14,845,584 | (73,444) |
| | | |
| FINANCING ACTIVITIES | | |
| | | — |
| Proceeds from sale of shares in public offering, net of fees | 108,099,988 | |
| Payment of costs related to public offering | (137,690) | — |
| Installment payments on SWK credit agreement | — | (3,325,180) |
| Proceeds from stock option exercises | 1,538,147 | 415,464 |
| Proceeds from premium finance agreement | 1,061,442 | 836,780 |
| Installment payments on premium finance agreement | (1,061,442) | (555,920) |
| Proceeds from sale of shares under common stock purchase agreement | — | 13,399,999 |
| Cash paid for debt portion of finance lease | (14,283) | (9,444) |
| Net cash provided by financing activities | 109,486,162 | 10,761,699 |
| | | |
| Net increase in cash | 109,567,190 | 9,099,271 |
| CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD | 13,588,778 | 6,295,152 |
| CASH AND CASH EQUIVALENTS AT END OF PERIOD | $ 123,155,968 | $ 15,394,423 |
| | | |
| Supplemental disclosure of cash flow information: | | |
| Cash paid for interest | $ 6,651,887 | $ — |
| Schedule of non-cash investing and financing activities: | | |
| Right-of-use assets recorded in exchange for lease liabilities | $ — | $ 1,253,233 |
| Notes receivable for sale of PREBOOST® business | $ 5,000,000 | $ — |
| Amortization of deferred costs related to common stock purchase agreement | $ — | $ 390,931 |
| Shares issued in connection with common stock purchase agreement | $ — | $ 680,937 |
| Increase in other assets from accrued expenses | $ — | $ 50,284 |
| Costs related to public offering in accrued expenses and other current liabilities | $ 20,000 | $ — |

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, 2020. The accompanying condensed consolidated balance sheet as of September 30, 2020 has been derived from our audited financial statements. The unaudited condensed consolidated statements of operations for the three and nine months ended June 30, 2021 and cash flows for the nine months ended June 30, 2021 are not necessarily indicative of the results to be expected for any future period or for the fiscal year ending September 30, 2021.

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 an oncology biopharmaceutical company with a focus on developing novel medicines for the management of prostate and breast cancers. The Company has multiple drug products under clinical development. During fiscal 2020, the Sexual Health Business segment also included PREBOOST® 4% benzocaine medicated individual wipe for the treatment of premature ejaculation. The PREBOOST® business was sold on December 8, 2020. See Note 2 for additional information. Most of the Company's net revenues during the three and nine months ended June 30, 2021 and 2020 were derived from sales of 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.

Reclassifications: Certain prior period amounts on the accompanying unaudited interim condensed consolidated financial statements have been reclassified to conform with the current period presentation. These reclassifications had no effect on the results of operations or financial position for any period presented.

Other comprehensive income (loss): Accounting principles generally require that recognized revenue, expenses, gains and losses be included in net income (loss). Although certain changes in assets and liabilities, such as foreign currency translation adjustments, are reported as a separate component of the equity section of the accompanying unaudited condensed consolidated balance sheets, these items, along with net income (loss), are components of other comprehensive loss. For the three and nine months ended June 30, 2021 and 2020, comprehensive income (loss) is equivalent to the reported net income (loss).

Recently adopted accounting pronouncements: In June 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-13, Financial Instruments—Credit Losses (Topic 326). This ASU introduces a new accounting model, the Current Expected Credit Losses model (CECL), which could result in earlier recognition of credit losses and additional disclosures related to credit risk. The CECL model requires the Company to use a forward-looking expected credit loss impairment methodology for the recognition of credit losses for financial instruments at the time the financial asset is originated or acquired. The expected credit losses are adjusted each period for changes in expected lifetime credit losses. This model replaces the multiple existing impairment models in current U.S. GAAP, which generally require that a loss be incurred before it is recognized. The new standard also applies to receivables arising from revenue transactions such as accounts receivable. The Company adopted ASU 2016-13 on a modified-retrospective basis effective October 1, 2020. The adoption of ASU 2016-13 did not impact our consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU 2017-04, Intangibles - Goodwill and Other Topics (Topic 350): Simplifying the Test for Goodwill Impairment. The purpose of ASU 2017-04 is to reduce the cost and complexity of evaluating goodwill for impairment. It eliminates the need for entities to calculate the implied fair value of goodwill by assigning the fair value of a reporting unit to all of its assets and liabilities as if that reporting unit had been acquired in a business combination. Under this amendment, an entity will perform its goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An impairment charge is recognized for the amount by which the carrying value exceeds the reporting unit's fair value. The Company adopted ASU 2017-04 on a prospective basis effective October 1, 2020. The adoption of ASU 2017-04 did not impact our consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework – Change to the Disclosure Requirements for Fair Value Measurement. ASU 2018-13 modifies the disclosure requirements by adding, removing, and modifying certain required disclosures for fair value measurements for assets and liabilities disclosed within the fair value hierarchy. The Company adopted ASU 2018-13 on a retrospective basis effective October 1, 2020. The adoption of ASU 2018-13 did not impact our financial position, results of operations, or cash flows as it modified disclosure requirements only.

**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 and was a commercial product in the Company's Sexual Health Division until the date of the sale. 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. 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 nine months ended June 30, 2021 related to the PREBOOST® business before the sale. The Company had income before income taxes of $450,000 and $729,000 during the three and nine months ended June 30, 2020, respectively, related to the PREBOOST® business.

**Note 3 – Fair Value Measurements**

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

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

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

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

Level 3 – Instruments with primarily unobservable value drivers.

As of June 30, 2021 and September 30, 2020, the Company's financial liabilities measured at fair value on a recurring basis, which consisted of embedded derivatives, were classified within Level 3 of the fair value hierarchy.

The following table provides a reconciliation of the beginning and ending liability balance associated with embedded derivatives measured at fair value using significant unobservable inputs (Level 3) as of June 30, 2021 and 2020:

| | Nine Months Ended June 30, | |
|---|---|---|
| | 2021 | 2020 |
| Beginning balance | $ 4,182,000 | $ 3,625,000 |
| Change in fair value of derivative liabilities | 2,029,000 | 94,000 |
| Ending balance | $ 6,211,000 | $ 3,719,000 |

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 determined the fair value of the embedded derivatives using a Monte Carlo simulation model to value the financial liabilities at inception and on subsequent valuation dates. This valuation model incorporates the contractual terms of the instruments and assumptions including projected FC2 revenues, expected cash outflows, expected repayment dates, probability and estimated dates of a change of control, expected volatility, and 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 liabilities associated with the embedded derivatives.

The following table presents quantitative information about the inputs and valuation methodologies used to determine the fair value of the embedded derivatives classified in Level 3 of the fair value hierarchy as of June 30, 2021 and September 30, 2020:

| | | Weighted Average (range, if applicable) | |
|---|---|---|---|
| Valuation Methodology | Significant Unobservable Input | June 30, 2021 | September 30, 2020 |
| Monte Carlo Simulation | Estimated change of control dates | September 2022 to September 2025 | December 2021 to June 2022 |
| | Discount rate | 4.6% to 7.9% | 14.1% to 16.0% |
| | Probability of change of control | 20% to 90% | 20% to 90% |

**Note 4 – Revenue from Contracts with Customers**

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

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

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

The Company's revenue is from sales of FC2 in the U.S. prescription channel and direct sales of FC2 in the global public health sector, and also included sales of 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 June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| FC2 | | | | |
| U.S. prescription channel | $ 13,501,862 | $ 5,391,523 | $ 32,916,343 | $ 18,395,280 |
| Global public health sector | 4,153,730 | 4,254,197 | 11,833,894 | 11,197,635 |
| Total FC2 | 17,655,592 | 9,645,720 | 44,750,237 | 29,592,915 |
| PREBOOST® | - | 676,034 | 862,831 | 1,249,959 |
| Net revenues | $ 17,655,592 | $ 10,321,754 | $ 45,613,068 | $ 30,842,874 |

The following table presents net revenue by geographic area:

| | Three Months Ended June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| United States | $ 14,080,810 | $ 6,396,762 | $ 35,049,646 | $ 20,575,515 |
| South Africa | * | 1,182,225 | * | * |
| Other | 3,574,782 | 2,742,767 | 10,563,422 | 10,267,359 |
| Net revenues | $ 17,655,592 | $ 10,321,754 | $ 45,613,068 | $ 30,842,874 |

*Less than 10% of total net revenues and included in Other

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 $699,000 and $6,000 at June 30, 2021 and September 30, 2020, 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 components of accounts receivable consist of the following at June 30, 2021 and September 30, 2020:

| | June 30, 2021 | September 30, 2020 |
|---|---|---|
| Trade receivables, gross | $ 8,441,224 | $ 5,332,786 |
| Less: allowance for doubtful accounts | (22,643) | (25,643) |
| Less: allowance for sales returns and payment term discounts | (105,038) | (79,906) |
| Accounts receivable, net | $ 8,313,543 | $ 5,227,237 |

At June 30, 2021 and at September 30, 2020, no customers had a current accounts receivable balance that represented greater than 10% of current assets.

At June 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. At September 30, 2020, three customers had an accounts receivable balance greater than 10% of net accounts receivable, representing 89% of net accounts receivable in the aggregate.

For the three months ended June 30, 2021, there were two customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 75% of the Company's net revenues in the aggregate. For the three months ended June 30, 2020, there were three customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 72% of the Company's net revenues in the aggregate.

For the nine months ended June 30, 2021, there were two customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 71% of the Company's net revenues in the aggregate. For the nine months ended June 30, 2020, there were three customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 74% 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 nine months ended June 30, 2021 and 2020.

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 June 30, 2021 and September 30, 2020:

| | June 30, 2021 | September 30, 2020 |
|---|---|---|
| FC2: | | |
| Raw material | $ 1,317,901 | $ 962,860 |
| Work in process | 90,583 | 106,272 |
| Finished goods | 5,679,518 | 5,634,612 |
| FC2, gross | 7,088,002 | 6,703,744 |
| Less: inventory reserves | (142,086) | (29,331) |
| FC2, net | 6,945,916 | 6,674,413 |
| PREBOOST® | | |
| Finished goods | — | 29,721 |
| Inventory, net | $ 6,945,916 | $ 6,704,134 |

Fixed Assets

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

Plant and equipment consisted of the following at June 30, 2021 and September 30, 2020:

| | Estimated Useful Life | June 30, 2021 | September 30, 2020 |
|---|---|---|---|
| Plant and equipment: | | | |
| Manufacturing equipment | 5 - 8 years | $ 2,770,149 | $ 2,752,854 |
| Office equipment, furniture and fixtures | 3 - 10 years | 903,400 | 803,484 |
| Leasehold improvements | 3 - 8 years | 298,886 | 298,886 |
| Total plant and equipment | | 3,972,435 | 3,855,224 |
| Less: accumulated depreciation and amortization | | (3,580,423) | (3,542,533) |
| Plant and equipment, net | | $ 392,012 | $ 312,691 |

**Note 7 – Intangible Assets and Goodwill**

Intangible Assets

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

| | Gross Carrying Amount | Accumulated Amortization | Net Book Value |
|---|---|---|---|
| Intangible asset with finite life: | | | |
| Covenants not-to-compete | $ 500,000 | $ 333,333 | $ 166,667 |
| Indefinite-lived intangible assets: | | | |
| Acquired in-process research and development assets | 3,900,000 | — | 3,900,000 |
| Total intangible assets | $ 4,400,000 | $ 333,333 | $ 4,066,667 |

The gross carrying amounts and net book value of intangible assets were as follows at September 30, 2020:

| | Gross Carrying Amount | Accumulated Amortization | Net Book Value |
|---|---|---|---|
| Intangible assets with finite lives: | | | |
| Developed technology - PREBOOST® | $ 2,400,000 | $ 768,111 | $ 1,631,889 |
| Covenants not-to-compete | 500,000 | 279,762 | 220,238 |
| Total intangible assets with finite lives | 2,900,000 | 1,047,873 | 1,852,127 |
| Acquired in-process research and development assets | 3,900,000 | — | 3,900,000 |
| Total intangible assets | $ 6,800,000 | $ 1,047,873 | $ 5,752,127 |

As discussed in Note 2, the Company sold its intangible assets related to PREBOOST® as part of the sale of the PREBOOST® business on December 8, 2020. The remaining net book value of the PREBOOST® developed technology, acquired in the acquisition of APP, was $1.6 million on the date of the sale. Amortization expense was approximately $18,000 and $79,000 for the three months ended June 30, 2021 and 2020, respectively, and approximately $96,000 and $237,000 for the nine months ended June 30, 2021 and 2020, respectively.

Goodwill

The carrying amount of goodwill at June 30, 2021 and September 30, 2020 was $6.9 million. There was no change in the balance during the nine months ended June 30, 2021 and 2020.

**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 are 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 has paid 176.5% of the aggregate amount advanced to the Company under the Credit Agreement. If product revenue from net sales of FC2 for the 12-month period ended as of the last day of the respective quarterly payment period is less than $10.0 million, the quarterly payments will be 32.5% of product revenue from net sales of FC2 during the quarterly period. If product revenue from net sales of FC2 for the 12-month period ended as of the last day of the respective quarterly payment period is equal to or greater than $10.0 million, the quarterly payments are calculated as follows: (i) as it relates to each quarter during the 2019 calendar year, the sum of 12.5% of product revenue from net sales of FC2 up to and including $12.5 million in the Elapsed Period (as defined in the Credit Agreement), plus 5% of product revenue from net sales of FC2 greater than $12.5 million in the Elapsed Period, (ii) as it relates to each quarter during the 2020 calendar year, the sum of 25% of product revenue from net sales of FC2 up to and including $12.5 million in the Elapsed Period, plus 10% of product revenue from net sales of FC2 greater than $12.5 million in the Elapsed Period, and (iii) as it relates to each quarter during the 2021 calendar year and thereafter, the sum of 30% of product revenue from net sales of FC2 up to and including $12.5 million in the Elapsed Period, plus 20% of product revenue from net sales of FC2 greater than $12.5 million in the Elapsed Period. Upon the Credit Agreement's termination date of March 5, 2025, the Company must pay 176.5% of the aggregate amount advanced to the Company under the Credit Agreement less the amounts previously paid by the Company from product revenue. The payment requirements described above reflect an amendment to the Credit Agreement dated May 13, 2019 (the "Second Amendment") which included a reduction to the percentages to be used to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar year 2019, a return to the original percentages to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar year 2020 and an increase to the percentages to be used to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar year 2021 and thereafter until the loan has been repaid.

Upon a change of control of the Company or sale of the FC2 business, the Company must pay off the loan by making a payment to the Lenders equal to (i) 176.5% of the aggregate amount advanced to the Company under the Credit Agreement less the amounts previously paid by the Company from product revenue from net sales of FC2, plus (ii) 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. A "change of control" under the Credit Agreement includes (i) an acquisition by any person of direct or indirect ownership of more than 50% of the Company's issued and outstanding voting equity, (ii) a change of control or similar event in the Company's articles of incorporation or bylaws, (iii) certain Key Persons as defined in the Credit Agreement cease to serve in their current executive capacities unless replaced within 90 days by a person reasonably acceptable to the Agent, which acceptance not to be unreasonably withheld, or (iv) the sale of all or substantially all of the Company's assets.

The Credit Agreement contains customary representations and warranties in favor of the Agent and the Lenders and certain covenants, including financial covenants addressing minimum quarterly marketing and distribution expenses for FC2 and a requirement to maintain minimum unencumbered liquid assets of $1.0 million. The Credit Agreement also restricts the payment of dividends and share repurchases. The recourse of the Lenders and the Agent for obligations under the Credit Agreement is limited to assets relating to FC2.

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 commencing after the Company would have 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 without taking into account the amendments to the payment requirements under the Credit Agreement effected by the Second Amendment. 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 Credit Agreement, or (ii) mutual agreement of the parties. If a change of control or sale of the FC2 business occurs prior to payment in full of the Credit Agreement, there will be no further payment due with respect to the Residual Royalty Agreement. If a change of control or sale of the FC2 business occurs after payment in full of the Credit Agreement, 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.

Pursuant to a Guarantee and Collateral Agreement dated as of March 5, 2018 (the "Collateral Agreement") and an Intellectual Property Security Agreement dated as of March 5, 2018 (the "IP Security Agreement"), the Company's obligations under the Credit Agreement are secured by a lien against substantially all of the assets of the Company that relate to or arise from FC2. In addition, pursuant to a Pledge Agreement dated as of March 5, 2018 (the "Pledge Agreement"), the Company's obligations under the Credit Agreement are secured by a pledge of up to 65% of the outstanding shares of The Female Health Company Limited, a wholly owned U.K. subsidiary.

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 are being amortized to interest expense over the expected term of the loan 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 are presented as a reduction of the Credit Agreement obligation and are being amortized to interest expense over the expected term of the loan using the effective interest method. The Second Amendment was accounted for as a debt modification, which resulted in prospective adjustment to the effective interest rate.

At June 30, 2021 and September 30, 2020, the Credit Agreement liability consisted of the following:

| | June 30, 2021 | September 30, 2020 |
|---|---|---|
| Aggregate repayment obligation | $ 17,650,000 | $ 17,650,000 |
| Less: cumulative payments | (16,704,398) | (10,314,495) |
| Remaining repayment obligation | 945,602 | 7,335,505 |
| Less: unamortized discounts | (59,291) | (1,459,330) |
| Less: unamortized deferred issuance costs | (1,394) | (34,301) |
| Credit agreement liability | $ 884,917 | $ 5,841,874 |

The Company made its final payment to repay the original principal of $10.0 million during the quarter ended September 30, 2020. Remaining quarterly payments under the Credit Agreement will be classified as interest payments, consistent with the terms of the Credit Agreement. The Company currently estimates the remaining repayment obligation under the Credit Agreement will be paid during the 12-month period subsequent to June 30, 2021.

At June 30, 2021 and September 30, 2020, the Residual Royalty Agreement liability consisted of the following:

| | June 30, 2021 | September 30, 2020 |
|---|---|---|
| Residual royalty agreement liability, fair value at inception | $ 346,000 | $ 346,000 |
| Add: accretion of liability using effective interest rate | 4,485,000 | 2,189,687 |
| Less: cumulative payments | (261,984) | — |
| Residual royalty agreement liability, excluding embedded derivative liability | 4,569,016 | 2,535,687 |
| Add: embedded derivative liability at fair value (see Note 3) | 6,211,000 | 4,182,000 |
| Total residual royalty agreement liability | 10,780,016 | 6,717,687 |
| Residual royalty agreement liability, short-term portion | (3,679,871) | (1,100,193) |
| Residual royalty agreement liability, long-term portion | $ 7,100,145 | $ 5,617,494 |

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 nine months ended June 30, 2021 and 2020, interest expense related to the Credit Agreement and Residual Royalty Agreement was as follows:

| | Three Months Ended June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Amortization of discounts | $ 327,550 | $ 782,169 | $ 1,400,039 | $ 2,488,747 |
| Accretion of residual royalty agreement | 952,276 | 369,138 | 2,295,313 | 928,835 |
| Amortization of deferred issuance costs | 7,699 | 18,385 | 32,907 | 58,497 |
| Interest expense | $ 1,287,525 | $ 1,169,692 | $ 3,728,259 | $ 3,476,079 |

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 June 30, 2021.

On November 1, 2019, the Company entered into a Premium Finance Agreement to finance $837,000 of its directors and officers liability insurance premium at an annual percentage rate of 4.18%. The financing was payable in three quarterly installments of principal and interest, which began on January 1, 2020. The last payment was made on July 1, 2020 and there was no balance outstanding as of September 30, 2020.

**Note 9 – Stockholders' Equity**

Preferred Stock

The Company has 5,000,000 authorized shares designated as Class A Preferred Stock with a par value of $0.01 per share. There are 1,040,000 shares of Class A Preferred Stock – Series 1 authorized; 1,500,000 shares of Class A Preferred Stock – Series 2 authorized; 700,000 shares of Class A Preferred Stock – Series 3 authorized; and 548,000 shares of Class A Preferred Stock – Series 4 (the "Series 4 Preferred Stock") authorized. There were no shares of Class A Preferred Stock of any series issued and outstanding at June 30, 2021 and September 30, 2020. The Company has 15,000 authorized shares designated as Class B Preferred Stock with a par value of $0.50 per share. There were no shares of Class B Preferred Stock issued and outstanding at June 30, 2021 and September 30, 2020, and there was no activity during the nine-month periods 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 $107.9 million after deducting underwriting discounts and commissions and costs incurred by the Company through June 30, 2021. 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. As of September 30, 2020, an aggregate of 2,326,841 shares of common stock remained available for purchase under the Financial Advisor Warrants. During the first quarter of fiscal 2021, the remaining 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 June 30, 2021, 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. As of June 30, 2021, 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 June 30, 2021 and September 30, 2020 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 nine months ended June 30, 2021 and 2020, we recorded share-based compensation expenses as follows:

| | Three Months Ended June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Cost of sales | $ 15,921 | $ 7,743 | $ 50,548 | $ 38,713 |
| Selling, general and administrative | 1,444,145 | 490,647 | 2,719,232 | 1,442,970 |
| Research and development | 440,019 | 186,924 | 917,883 | 499,809 |
| Share-based compensation | $ 1,900,085 | $ 685,314 | $ 3,687,663 | $ 1,981,492 |

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"). A total of 11.0 million shares are authorized for issuance under the 2018 Plan. As of June 30, 2021, 2,848,780 shares remain available for issuance under the 2018 Plan.

In July 2017, the Company's stockholders approved the Company's 2017 Equity Incentive Plan (the "2017 Plan"). A total of 4.7 million shares are authorized for issuance under the 2017 Plan. As of June 30, 2021, 18,433 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 nine months ended June 30, 2021 and 2020:

| | Three Months Ended June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Weighted Average Assumptions: | | | | |
| Expected volatility | 78.53% | — | 68.88% | 63.13% |
| Expected dividend yield | 0.00% | — | 0.00% | 0.00% |
| Risk-free interest rate | 1.10% | — | 0.64% | 1.63% |
| Expected term (in years) | 6.0 | — | 5.9 | 5.9 |
| Fair value of options granted | $ 5.98 | $ — | $ 3.46 | $ 1.14 |

During the three and nine months ended June 30, 2021 and 2020, the Company used historical volatility of our common stock over a period equal to the expected life of the options to estimate their fair value. The dividend yield assumption is based on the Company's recent history and expectation of future dividend payouts on the common stock. The risk-free interest rate is based on the implied yield available on U.S. treasury zero-coupon issues with an equivalent remaining term.

The following table summarizes the stock options outstanding and exercisable at June 30, 2021:

| | Number of Shares | Weighted Average Exercise Price Per Share | Weighted Average Remaining Contractual Term (years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding at September 30, 2020 | 8,599,000 | $ 1.67 | | |
| Granted | 3,228,625 | $ 5.47 | | |
| Exercised | (996,102) | $ 1.54 | | |
| Forfeited and expired | (91,269) | $ 1.74 | | |
| Outstanding at June 30, 2021 | 10,740,254 | $ 2.83 | 7.91 | $ 60,768,816 |
| Exercisable at June 30, 2021 | 5,933,601 | $ 1.66 | 7.01 | $ 38,057,411 |

The aggregate intrinsic values in the table above are before income taxes and represent the number of in-the-money options outstanding or exercisable multiplied by the closing price per share of the Company's common stock on the last trading day of the quarter ended June 30, 2021 of $8.07, less the respective weighted average exercise price per share at period end.

The total intrinsic value of options exercised during the nine months ended June 30, 2021 and 2020 was approximately $8.3 million and $1.1 million, respectively. Cash received from options exercised during the nine months ended June 30, 2021 and 2020 was approximately $1.5 million and $415,000, respectively. During the nine months ended June 30, 2020, 223,415 options were exercised using the cashless exercise feature available under the 2017 Plan and 2018 Plan, which resulted in the issuance of 143,958 shares of common stock. There were no options exercised using the cashless exercise feature during the nine months ended June 30, 2021.

As of June 30, 2021, the Company had unrecognized compensation expense of approximately $10.6 million related to unvested stock options. This expense is expected to be recognized over a weighted average period of 1.8 years.

During the quarter ended June 30, 2021, the Company modified stock options held by an optionee upon resignation from the board of directors. As permitted under the 2018 Plan and with the approval of the Compensation Committee of the Board of Directors, the stock options were modified to accelerate vesting to the date of resignation. The aggregate amount of expense recognized in connection with the modification of stock options for the three and nine months ended June 30, 2021 was approximately $536,000 and is included in selling, general and administrative expenses on the accompanying unaudited condensed consolidated statements of operations.

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 June 30, 2021, 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 will be leasing approximately 12,000 square feet of office space for an eight year term commencing on the later of March 1, 2022 or the date the landlord substantially completes tenant improvements. The space will replace the Company's current corporate headquarters in Miami, Florida when the existing lease terminates at the end of February 2022. Annual base rent payments will be $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 sheet as of June 30, 2021. The Company does not have any other leases that have not yet commenced as of June 30, 2021.

The components of the Company's lease cost were as follows for the three and nine months ended June 30, 2021 and 2020:

| | Three Months Ended June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Finance lease cost: | | | | |
| Amortization of right-of-use assets | $ 2,178 | $ 2,178 | $ 6,535 | $ 6,535 |
| Interest on lease liabilities | 611 | 1,238 | 2,327 | 4,097 |
| Operating lease cost | 136,140 | 124,326 | 408,079 | 378,006 |
| Short-term lease cost | 1,863 | 1,863 | 5,589 | 5,589 |
| Variable lease cost | 48,061 | 24,213 | 124,283 | 91,349 |
| Sublease income | (44,844) | (45,382) | (134,533) | (135,071) |
| Total lease cost | $ 144,009 | $ 108,436 | $ 412,280 | $ 350,505 |

The Company paid cash of $497,000 and $350,000 for amounts included in the measurement of operating lease liabilities during the nine months ended June 30, 2021 and 2020, respectively.

The Company's operating lease right-of-use assets and the related lease liabilities are presented as separate line items on the accompanying unaudited condensed consolidated balance sheets as of June 30, 2021 and September 30, 2020.

Other information related to the Company's leases as of June 30, 2021 and September 30, 2020 was as follows:

| | June 30, 2021 | September 30, 2020 |
|---|---|---|
| **Operating Leases** | | |
| Weighted-average remaining lease term | 3.1 | 3.6 |
| Weighted-average discount rate | 11.5% | 11.5% |
| **Finance Leases** | | |
| Weighted-average remaining lease term | 0.7 | 1.4 |
| Weighted-average discount rate | 13.9% | 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.

**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.

Litigation

From time to time we may be involved in litigation or other contingencies arising in the ordinary course of business. Based on the information presently available, management believes there are no contingencies, claims or actions, pending or threatened, the ultimate resolution of which will have a material adverse effect on our financial position, liquidity or results of operations.

In accordance with FASB ASC 450, Contingencies, we accrue loss contingencies including costs of settlement, damages and defense related to litigation to the extent they are probable and reasonably estimable. Otherwise, we expense these costs as incurred. If the estimate of a probable loss is a range and no amount within the range is more likely, we accrue the minimum amount of the range.

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.

**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, 2020, the Company had U.S. federal and state NOL carryforwards of $42.0 million and $25.6 million, respectively, for income tax purposes with $13.8 million and $19.8 million, respectively, expiring in years 2022 to 2040 and $28.2 million and $5.8 million, respectively, which can be carried forward indefinitely. As of September 30, 2020, the Company also had U.S. federal research and development tax credit carryforwards of $0.9 million, expiring in 2040. The Company's U.K. subsidiary has U.K. NOL carryforwards of $61.3 million as of September 30, 2020, which can be carried forward indefinitely to be used to offset future U.K. taxable income.

On June 10, 2021 the U.K. Finance Act 2021 was enacted increasing the U.K. tax rate from 19% to 25% effective April 1, 2023. The increase in the tax rate increased the value of the deferred tax assets in the U.K. by $3.7 million with a corresponding valuation allowance of $0.8 million, which resulted in a net income tax benefit of $3.0 million for the three and nine months ended June 30, 2021.

A reconciliation of income tax (benefit) 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 June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Income tax (benefit) expense at U.S. federal statutory rates | $ (1,168,845) | $ (584,825) | $ 1,872,314 | $ (1,493,179) |
| State income tax (benefit) expense, net of federal (benefit) expense | (90,502) | (45,268) | 144,971 | (115,615) |
| Non-deductible expenses | (2,807) | 332,230 | (2,807) | 335,869 |
| Effect of stock options exercised | 53,011 | — | — | — |
| Effect of common stock purchase warrants exercised | — | — | (2,038,919) | — |
| Effect of Paycheck Protection Program funds | 8,784 | — | (113,442) | — |
| U.S. research and development tax credit | (919,415) | — | (919,415) | — |
| Effect of foreign income tax rates | (3,716,935) | (16,478) | (3,744,512) | 49,908 |
| Effect of global intangible low taxed income | 78,626 | 85,522 | 148,383 | 101,642 |
| Change in valuation allowance | 2,834,482 | 415,449 | 1,828,730 | 1,097,900 |
| Other, net | 50,538 | 53,872 | 51,626 | 54,094 |
| Income tax (benefit) expense | $ (2,873,063) | $ 240,502 | $ (2,773,071) | $ 30,619 |

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

| | June 30, 2021 | September 30, 2020 |
|---|---|---|
| Deferred tax assets: | | |
| Federal net operating loss carryforwards | $ 8,269,223 | $ 8,759,589 |
| State net operating loss carryforwards | 1,647,082 | 1,682,104 |
| Foreign net operating loss carryforwards – U.K. | 15,259,909 | 11,655,853 |
| Foreign capital allowance – U.K. | 149,371 | 113,522 |
| U.S. research and development tax credit carryforwards | 919,415 | — |
| Share-based compensation | 770,598 | 1,255,983 |
| Interest expense | 1,165,193 | 850,248 |
| Change in fair value of derivative liabilities | 654,354 | 195,265 |
| Other, net – U.K. | 123,341 | 93,739 |
| Other, net – U.S. | 187,644 | 179,677 |
| Gross deferred tax assets | 29,146,130 | 24,785,980 |
| Valuation allowance for deferred tax assets | (15,903,470) | (14,074,740) |
| Net deferred tax assets | 13,242,660 | 10,711,240 |
| Deferred tax liabilities: | | |
| In-process research and development | (882,427) | (882,427) |
| Developed technology | — | (369,237) |
| Covenant not-to-compete | (37,711) | (49,832) |
| Other, net – Malaysia | (11,297) | (11,297) |
| Other, net – U.S. | (6,371) | (6,371) |
| Net deferred tax liabilities | (937,806) | (1,319,164) |
| Net deferred tax asset | $ 12,304,854 | $ 9,392,076 |

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

| | June 30, 2021 | September 30, 2020 |
|---|---|---|
| Deferred tax asset – U.K. | $ 12,379,578 | $ 9,466,800 |
| Total deferred tax asset | $ 12,379,578 | $ 9,466,800 |
| | | |
| Deferred tax liability – U.S. | $ (63,427) | $ (63,427) |
| Deferred tax liability – Malaysia | (11,297) | (11,297) |
| Total deferred tax liability | $ (74,724) | $ (74,724) |

**Note 14 – Paycheck Protection Program**

The CARES Act established the Paycheck Protection Program (PPP) administered by the U.S. Small Business Administration (SBA), which authorized forgivable loans to small businesses. Pursuant to the CARES Act, PPP loans will be fully forgiven if the funds are used for payroll costs, rent and utilities, subject to certain conditions, including maintaining employees and maintaining salary levels. In April 2020, the Company applied for a PPP loan and received funding of approximately $540,000. The Company expended the funds received under the PPP in full on qualifying expenses, and maintained the conditions set forth by the PPP. The Company submitted its application for forgiveness in September 2020 and the SBA approved the forgiveness of the full amount of the loan and the related interest on November 10, 2020. For accounting purposes, the Company treated the PPP loan as a government grant. As a result, the Company recorded a reduction to selling, general and administrative expenses of approximately $420,000 and a reduction to payroll-related research and development expenses of approximately $120,000 related to these funds within the unaudited condensed consolidated statements of operations for the three and nine months ended June 30, 2020.

**Note 15 – 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 June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Net (loss) income | $ (2,692,866) | $ (3,025,380) | $ 11,688,854 | $ (7,140,990) |
| | | | | |
| Basic weighted average common shares outstanding | 79,729,370 | 66,728,782 | 75,054,871 | 65,709,139 |
| Net effect of dilutive instruments: | | | | |
| Stock options | — | — | 7,208,123 | — |
| Stock appreciation rights | — | — | 44,379 | — |
| Common stock purchase warrants | — | — | 499,783 | — |
| Total net effect of dilutive instruments | — | — | 7,752,285 | — |
| Diluted weighted average common shares outstanding | 79,729,370 | 66,728,782 | 82,807,156 | 65,709,139 |
| Net (loss) income per basic common share outstanding | $ (0.03) | $ (0.05) | $ 0.16 | $ (0.11) |
| Net (loss) income per diluted common share outstanding | $ (0.03) | $ (0.05) | $ 0.14 | $ (0.11) |

For the nine months ended June 30, 2021, approximately 819,000 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 months ended June 30, 2021 and three and nine months ended June 30, 2020, 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.

**Note 16 – Industry Segments**

The Company currently operates in two reporting segments: Sexual Health Business and Research and Development. The Sexual Health Business segment consists of the Company's commercial product, FC2. The Sexual Health Business also included PREBOOST® before the sale of the business in December 2020. The Research and Development segment consists of multiple drug products under clinical development. The Company's Sexual Health Business segment will include any future revenues, cost of sales and selling expenses for TADFIN™, if approved. Costs associated with the development of TADFIN™ are currently included in the Research and Development segment. There are no significant inter-segment sales. We evaluate the performance of each segment based on operating profit or loss. There is no inter-segment allocation of non-operating expenses and income taxes. Our chief operating decision-maker (CODM) is Mitchell S. Steiner, M.D., our Chairman, President and Chief Executive Officer.

The Company's operating (loss) income by segment was as follows:

| | Three Months Ended June 30, | | Nine Months Ended June 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Sexual health business | $ 12,960,770 | $ 5,749,513 | $ 32,804,711 | $ 18,052,461 |
| Research and development | (11,362,155) | (4,432,497) | (24,962,340) | (13,606,628) |
| Corporate | (4,470,479) | (2,709,868) | 7,001,512 | (7,922,756) |
| Operating (loss) income | $ (2,871,864) | $ (1,392,852) | $ 14,843,883 | $ (3,476,923) |

All of our net revenues, which are primarily derived from the sale of FC2, are attributed to the Sexual Health Business reporting segment. See Note 4 for additional information regarding our net revenues. Costs related to the office located in London, England are fully dedicated to FC2 and are presented as a component of the Sexual Health Business segment. Drug commercialization costs are included in the Research and Development segment. Certain expenses in the three and nine months ended June 30, 2020 have been reclassified to conform to the current period presentation. The gain on sale of the PREBOOST® business and depreciation and amortization related to long-lived assets that are not utilized in the production of FC2 are not reported as part of the reporting segments or reviewed by the CODM. These amounts are included in Corporate in the reconciliations above. Total assets are not presented by reporting segment as they are not reviewed by the CODM when evaluating the reporting segments' performance.

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

Overview

Veru is an oncology biopharmaceutical company with a focus on developing novel medicines for the management of prostate and breast cancers.

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

*Sabizabulin (VERU-111) for the treatment of men with metastatic castration resistant prostate cancer who have also become resistant to at least one androgen receptor targeting agent*

Sabizabulin (VERU-111) is an oral, first-in-class, new chemical entity that targets and inhibits microtubules to disrupt transport of the androgen receptor into the nucleus (androgen receptor transport disruptor). Open label Phase 1b and Phase 2 clinical studies with sabizabulin in men with metastatic castration and androgen receptor targeting agent resistant prostate cancer are ongoing. The Phase 1b clinical study completed enrollment of 39 men. The Phase 1b study has yielded promising efficacy and safety clinical data. Daily chronic drug administration appears feasible and safe. The Phase 2 clinical study has completed enrollment of 41 men with metastatic castration resistant prostate cancer who have also become resistant to at least one androgen receptor targeting agent, such as abiraterone or enzalutamide, but prior to proceeding to IV chemotherapy. Evidence of tumor efficacy including PSA declines and objective tumor responses (partial and complete responses) were observed, and sabizabulin was well tolerated with no clinically relevant neutropenia or neurotoxicity. The safety profile is similar to what has been reported in the FDA package inserts for an androgen receptor targeting agent, enzalutamide or abiraterone. In July 2020, the Company had a meeting with the FDA and received positive input from the FDA on the pivotal Phase 3 trial design for sabizabulin. The indication is for the treatment in men with metastatic castration resistant prostate cancer who have failed one androgen receptor targeting agent, but prior to IV chemotherapy. The Phase 3 VERACITY clinical study is an open label, randomized, multicenter, registration study evaluating sabizabulin daily dosing versus an alternative androgen receptor targeting agent as the active control. The primary endpoint is radiographic progression-free survival. The Phase 3 study is expected to enroll approximately 245 men with a 2:1 randomization of sabizabulin versus the active control. The Company is currently enrolling patients in its pivotal Phase 3 VERACITY study, which is expected to be conducted in approximately 45 clinical sites across the U.S.

*VERU-100 for androgen deprivation therapy (ADT) of advanced prostate cancer*

VERU-100 is a novel, proprietary long-acting gonadotropin-releasing hormone (GnRH) antagonist peptide three-month subcutaneous depot formulation designed to address the current limitations of commercially available ADT. Androgen deprivation therapy is currently the mainstay of advanced prostate cancer treatment and is used as a foundation of treatment throughout the course of the disease even as other endocrine, chemotherapy, or radiation treatments are added or stopped. Specifically, VERU-100 is a chronic, long-acting GnRH antagonist peptide administered as a small volume, three-month depot subcutaneous injection without a loading dose. VERU-100 immediately suppresses testosterone with no testosterone surge upon initial or repeated administration, a problem that occurs with currently approved luteinizing hormone-releasing hormone (LHRH) agonists used for ADT. There are no GnRH antagonist depot injectable formulations commercially approved beyond a one-month injection. The Company is currently enrolling patients in its VERU-100 Phase 2 study. The Phase 2 clinical trial is an open label, multicenter, dose finding study evaluating the efficacy and safety of subcutaneous injected doses of VERU-100 in men with hormone sensitive advanced prostate cancer. The VERU-100 Phase 2 study is expected to enroll approximately 35 patients. The primary efficacy endpoint is percent of men that reach castrate levels of total testosterone (<50 ng/dL) by Day 28 and maintain castrate testosterone levels for 90 days. If the Phase 2 trial is successful, the Phase 3 clinical trial of approximately 100 men is planned to initiate in the fourth quarter of calendar year 2021.

*Zuclomiphene citrate for the treatment of men who have hot flashes caused by androgen deprivation therapy for advanced prostate cancer*

Zuclomiphene citrate is an oral nonsteroidal estrogen receptor agonist being developed to treat hot flashes, a common side effect caused by ADT in men with advanced prostate cancer. Following an End of Phase 2 meeting with the FDA, the Company plans to advance zuclomiphene citrate to a Phase 3 clinical trial in men with advanced prostate cancer who experience moderate to severe hot flashes.

**The Company's breast cancer drug pipeline includes enobosarm and sabizabulin.**

*Enobosarm, selective androgen receptor targeted agonist, for the treatment of androgen receptor positive (AR+), estrogen receptor positive (ER+) and human epidermal growth factor receptor 2 negative (HER2-) metastatic breast cancer (3rd line metastatic setting)*

Enobosarm is the first new class of targeting endocrine therapy in advanced breast cancer in decades. Enobosarm is an oral, first-in-class, new chemical entity, selective androgen receptor agonist that activates the androgen receptor (AR) in AR+ ER+ HER2- metastatic breast cancer, which results in tumor suppressor activity without the unwanted masculinizing side effects. Enobosarm has extensive nonclinical and clinical experience having been evaluated in 25 separate clinical studies in approximately 1,450 subjects dosed, including three Phase 2 clinical studies in advanced breast cancer involving more than 250 patients. In the two Phase 2 clinical studies conducted in women with AR+ ER+ HER2- metastatic breast cancer, enobosarm demonstrated significant antitumor efficacy in heavily pretreated cohorts that failed estrogen receptor targeting agents, chemotherapy, and/or CDK 4/6 inhibitors and was well tolerated with a favorable safety profile. In the fourth quarter of calendar 2020, the FDA agreed to 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 metastatic AR+ ER+ HER2- breast cancer in approximately 210 patients with ≥ 40% AR staining in breast cancer tissue who have failed a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor. The primary endpoint is radiographic progression-free survival. The pivotal Phase 3 ARTEST study is anticipated to commence in the second half of calendar year 2021.

In June 2021 at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting, the Company announced additional clinical results from the enobosarm Phase 2 study demonstrating that the anticancer benefits of enobosarm were related to the presence and amount of AR expression in breast cancer tissue in subjects with AR+ ER+ HER2- metastatic breast cancer. In the Phase 2 study, the presence and the amount of AR receptor expression in breast cancer tissue correlated with the antitumor response. The best overall target lesion reduction of >30% occurred only in subjects who were AR+ (>10% AR nuclei staining). In a post-hoc analysis of 84 women (9mg and 18 mg cohorts combined) who had AR+ ER+ HER2- metastatic breast cancer, measurable disease, and centrally confirmed AR status at study entry, an AR positivity threshold of ≥40% staining in breast cancer tissue distinguished patients that were most likely to respond to enobosarm. AR positivity ≥40% was common as 52% of subjects in study met this threshold.

Focusing on the post-hoc analysis in the 9mg cohort, the dose selected for the Phase 3 ARTEST study, the objective response rate (percent of patients with a best overall response of complete response or partial response) was 48% for ≥40% AR positivity versus 0% for <40% AR positivity ($p<0.0001$). Similarly, the clinical benefit rate (percentage of patients with a best overall response of complete response, partial response, or stable disease) was 79% for ≥40% AR positivity versus 18% for <40% AR positivity ($p<0.0001$). The median radiographic progression free survival was 5.5 month for ≥40% AR positivity versus 2.75 months for <40% AR positivity ($p<0.001$). Enobosarm was very well tolerated without masculinizing side effects, increases in hematocrit, or liver toxicity.

Conclusions from Phase 2 study presented at ASCO 2021:

- Enobosarm, a selective AR agonist, targets AR, a tumor suppressor, in AR+ ER+ HER2- metastatic breast cancer
- Objective tumor responses (efficacy) to enobosarm monotherapy require the presence and a threshold level of AR expression (≥40% AR cutoff) in heavily pretreated AR+ ER+ HER2- metastatic breast cancer
- AR may be used as a biomarker to identify patients with AR+ ER+ HER2- metastatic breast cancer that are most likely to respond to enobosarm
- Enobosarm treatment was well tolerated as an endocrine therapy without masculinizing side effects, increases in hematocrit, or liver toxicity
- Targeting the AR tumor suppressor pathway to be studied prospectively in a 3rd line metastatic setting in the Phase 3 ARTEST registration clinical trial of enobosarm monotherapy versus active control (exemestane ⌖ everolimus or a SERM) for the treatment of AR+ ER+ HER2- metastatic breast cancer patients who have failed a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor.

We intend to also conduct a Phase 2 clinical study to evaluate the efficacy and safety of enobosarm plus CDK4/6 inhibitor, abemaciclib, combination therapy versus an alternative estrogen blocking agent (fulvestrant or an aromatase inhibitor) in subjects with AR+ ER+ HER2- metastatic breast cancer who have failed first line CDK4/6 inhibitor, palbociclib, plus an estrogen blocking agent (non-steroidal aromatase inhibitor or fulvestrant) and have an AR nuclei staining ≥ 40% in breast cancer tissue. We plan to enroll approximately 106 subjects in this Phase 2 clinical study which is expected to commence in the second half of calendar year 2021.

*Sabizabulin for the treatment of taxane resistant metastatic triple negative breast cancer*

Metastatic triple negative breast cancer (TNBC) is an aggressive form of breast cancer that occurs in approximately 15% of all breast cancers. This form of breast cancer does not express ER, progesterone receptor (PR), or HER2 and is resistant to endocrine therapies. The first line of treatment usually includes IV taxane chemotherapy. Almost all women will eventually develop taxane resistance. Sabizabulin is an oral, first-in-class, new chemical entity that targets and inhibits microtubules to disrupt the cytoskeleton. Sabizabulin is not a substrate for P-glycoprotein drug resistance protein. Over expression of P-glycoprotein is a common mechanism that results in taxane resistance in TNBC. Preclinical studies in human triple negative breast cancer grown in animal models demonstrate that sabizabulin significantly inhibits cancer proliferation, migration, metastases, and invasion of triple negative breast cancer cells and tumors that have become resistant to paclitaxel (taxane). Using the safety information from the Phase 1b and Phase 2 sabizabulin prostate cancer clinical studies in a total of approximately 80 men, the Company plans to meet with the FDA in calendar year 2021 and to commence a Phase 2b clinical study in the second half of calendar year 2021 to evaluate sabizabulin in women with metastatic TNBC. The planned Phase 2b clinical study will evaluate daily oral dosing of sabizabulin for TNBC in a three-arm study of sabizabulin monotherapy, sabizabulin + Trodelvy® (sacituzumab govitecan-hziy) combination therapy, and Trodelvy monotherapy (control arm) in approximately 156 women with metastatic TNBC that have become resistant to at least two systemic chemotherapies including a taxane IV chemotherapy.

Trodelvy® (sacituzumab govitecan-hziy) is a registered trademark of Gilead Sciences, Inc.

**Sabizabulin for the treatment of hospitalized COVID-19 patients at high risk for acute respiratory distress syndrome (ARDS)**

Sabizabulin is a novel once-a-day orally dosed small molecule that has both broad anti-inflammatory and anti-viral properties which may serve as a two-pronged approach to the treatment of COVID-19 virus infection and the subsequent debilitating inflammatory effects that can lead to ARDS and death.

We conducted a double-blind, randomized, placebo-controlled Phase 2 clinical trial evaluating daily oral once-a-day dosing of sabizabulin 18mg versus placebo in approximately 40 hospitalized COVID-19 patients who were at high risk for ARDS. This trial was conducted in 5 sites across the United States. Patients that were hospitalized with documented evidence of COVID-19 infection with symptoms and who were at high risk for ARDS were enrolled. Subjects received either sabizabulin 18mg or placebo as well as standard of care for 21 days or until released from the hospital. The primary efficacy endpoint was the proportion of patients that were alive without respiratory failure at Day 29. On February 8, 2021, we announced positive results from this Phase 2 clinical trial evaluating sabizabulin for the treatment of hospitalized patients with COVID-19 who were high risk for ARDS. For the primary endpoint in hospitalized patients in a modified intent to treat population, sabizabulin treatment compared to placebo had a statistically significant and clinically meaningful improvement in the proportion of patients with treatment failures (death or alive with respiratory failure) being 5.6% in the sabizabulin treated group (n=18) and 30% in the placebo treated group (n=20) at Day 29. This represents an 81% relative reduction in treatment failures and shows statistical significance with p=0.05. Sabizabulin was tolerated with a good safety profile.

In February 2021, the FDA agreed to advancing sabizabulin into Phase 3 clinical registration trial. The Phase 3 clinical trial is a double-blind randomized (2:1) placebo-controlled trial evaluating daily oral doses of 9mg sabizabulin for 21 days versus placebo in 300 hospitalized patients (200 subjects will be treated with sabizabulin and 100 subjects will receive placebo) who tested positive for the SARS-CoV-2 virus and who are at high risk for ARDS. The primary efficacy endpoint will be proportion of patients alive at Day 60. Secondary endpoints will include proportion of patients alive without respiratory failure, days in ICU, days on mechanical ventilations, days in the hospital, and viral load. The Company is currently enrolling patients in its sabizabulin for COVID-19 Phase 3 pivotal study. The Company has selected clinical sites in the U.S., Brazil, Argentina, Colombia, and Mexico. The Company anticipates completion of the Phase 3 trial during the fourth calendar quarter of 2021.

The Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services (BARDA) and Veru have had several meetings to discuss possible grant funding for the Phase 3 study and manufacturing scale up.

**Sexual Health Division**

The Company's Sexual Health Division includes a drug candidate, TADFIN™, for the treatment of benign prostatic hyperplasia (BPH) and a commercial product, 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.

TADFIN™ (tadalafil 5mg and finasteride 5mg combination capsule) is being developed to treat urinary tract symptoms caused by BPH. Tadalafil (CIALIS®) is currently approved for treatment of BPH and erectile dysfunction and finasteride is currently approved for treatment of BPH (finasteride 5mg PROSCAR®) and male pattern hair loss (finasteride 1mg PROPECIA®). The co-administration of tadalafil and finasteride has been shown to be more effective for the treatment of BPH than finasteride alone. The Company had a successful pre-New Drug Application (NDA) meeting with the FDA and submitted the NDA for TADFIN™ in February 2021. An NDA was filed by the FDA in April 2021 with a PDUFA date in December 2021. If approved, TADFIN™ is expected to be marketed and distributed by telemedicine (telemedicine being the remote diagnosis and treatment of patients by means of telecommunications technology) and telepharmacy channels. The Company's Sexual Health Business segment will include future revenues for TADFIN™, if approved. Costs associated with the development of TADFIN™ are currently included in our Research and Development segment.

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

Most of the Company's net revenues during the three and nine months ended June 30, 2021 and 2020 were derived from sales of FC2 in the commercial and public health sectors.

**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 and was a commercial product in the Company's Sexual Health Division during fiscal 2020. 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, $2.5 million payable 12 months after closing and $2.5 million payable 18 months after closing.

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. We have experienced, and continue to experience, some temporary disruptions to our manufacturing facility due to the implementation of government policies. On March 16, 2020, the Malaysian government issued an order closing non-essential businesses in that country due to the COVID-19 pandemic. As a result, the sole facility where the Company manufactures FC2 was unable to manufacture or ship product starting March 16, 2020. Because FC2 is a health product, the Company received an exemption to reopen the facility with limited staff to ship existing inventory on March 27, 2020, to reopen for manufacturing with 50% of the regular number of workers and social distancing requirements on April 20, 2020 and to return to 100% of the regular number of workers but with continued social distancing requirements on May 4, 2020. 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. Furthermore, the Company has enrolled staff in a vaccination program that has commenced and is ongoing. 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 had and continues to have a sufficient quantity of FC2 inventory both inside and outside of Malaysia to satisfy customer demand. We do not anticipate that the recent closure, or currently ongoing reduced operating capacity, will have a material impact to the Company's consolidated operating results in the fourth quarter of fiscal 2021 or 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 and nine months ended June 30, 2021.

To protect the health and safety of our workforce, we have closed our offices in the United States and the United Kingdom to non-essential staff and our personnel have largely been working remotely. Travel between our facilities in the United States, the United Kingdom and Malaysia has also been restricted. As of the date of this report, our operations have not been significantly impacted by such remote work requirements and travel restrictions.

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.

Sales of FC2 in the public health and commercial sectors

*FC2 Commercial Sector.* In 2017, the Company began expanding access to FC2 in the U.S. by making it available by prescription. With a prescription, FC2 is covered by most insurance companies with no copay under the ACA and the laws of 20+ states prior to enactment of the ACA. In 2018, we dissolved our small-scale marketing and sales program to focus our efforts in accessing fast-growing, highly reputable telemedicine firms to bring our much-needed FC2 product to patients with a prescription in a cost-effective and highly convenient manner. As a result of these efforts, the Company now supplies FC2 to telemedicine providers in the U.S. prescription channel. The Company is working to develop supply and distributor relationships with additional telemedicine and other providers.

*FC2 Global Public Health Sector.* FC2's use is for the prevention of HIV/AIDS and the transmission of other sexually transmitted diseases and prevention of unintended pregnancies, and the global public health sector has been an important market for FC2. Within the global public health sector, various organizations supply critical products such as FC2, at no cost or low cost, to those who need but cannot afford to buy such products for themselves.

FC2 has been distributed in the U.S. and 149 other countries. A significant number of countries with the highest demand potential are in the developing world. The incidence of HIV/AIDS, other sexually transmitted infections and unintended pregnancy in these countries represents a remarkable potential for significant sales of a product that benefits some of the world's most underprivileged people. However, conditions in these countries can be volatile and result in unpredictable delays in program development, tender applications and processing orders.

The Company is working to further develop a global market and distribution network for FC2 by maintaining relationships with global public health sector groups and completing strategic arrangements with companies with the necessary marketing and financial resources and local market expertise.

The Company currently has a limited number of customers for FC2 in the global public health sector who generally purchase in large quantities. Over the past few years, significant customers have included large global agencies, such as UNFPA, USAID, the Brazil Ministry of Health through Semina Indústria e Comércio Ltda (Semina), the Company's distributor in Brazil, and the Republic of South Africa health authorities that purchase through the Company's various local distributors. Other customers include ministries of health or other governmental agencies, which either purchase directly or via in-country distributors, and NGOs.

Purchasing patterns for FC2 in the public health sector vary significantly from one customer to another and may reflect factors other than simple demand. For example, some governmental agencies purchase FC2 through a formal procurement process in which a tender (request for bid) is issued for either a specific or a maximum unit quantity. Tenders also define the other elements required for a qualified bid submission (such as product specifications, regulatory approvals, clearance by the World Health Organization, unit pricing and delivery timetable). Bidders have a limited period of time in which to submit bids. Bids are subjected to an evaluation process which is intended to conclude with a tender award to the successful bidder. The entire tender process, from publication to award, may take many months to complete, including administrative actions or appeals. A tender award indicates acceptance of the bidder's price rather than an order or guarantee of the purchase of any minimum number of units. Many governmental tenders are stated to be "up to" the maximum number of units, which gives the applicable government agency discretion to purchase less than the full maximum tender amount. Orders are placed after the tender is awarded; there are often no set dates for orders in the tender and there are no guarantees as to the timing or amount of actual orders or shipments. Orders received may vary from the amount of the tender award based on a number of factors including vendor supply capacity, quality inspections and changes in demand. Administrative issues, politics, bureaucracy, exchange rate risk, process errors, changes in leadership, funding priorities and/or other pressures may delay or derail the process and affect the purchasing patterns of public health sector customers. As a result, the Company may experience significant quarter-to-quarter sales variances in the global public health sector due to the timing and shipment of large orders of FC2.

On August 27, 2018, the Company announced that through six of its distributors in the Republic of South Africa, the Company had received a tender award to supply 75% of a tender covering up to 120 million female condoms over three years. The tender was extended until January 2022. The Company began shipping units under this tender award in the third quarter of fiscal 2019 and we have shipped approximately 14.0 million units through June 30, 2021. In October 2020, the Company was awarded up to 20 million units through its distributor in Brazil under the new Brazil female condom tender. These units are expected to be delivered over two years. 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 June 30, 2021.

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

| **Period** | **2021** | **2020** | **2019** | **2018** | **2017** |
|---|---|---|---|---|---|
| October 1 — December 31 | 12,318,988 | 10,070,700 | 7,382,524 | 4,399,932 | 6,389,320 |
| January 1 — March 31 | 8,189,552 | 6,884,472 | 9,792,584 | 4,125,032 | 4,549,020 |
| April 1 — June 30 | 11,201,588 | 10,532,048 | 10,876,704 | 10,021,188 | 8,466,004 |
| July 1 — September 30 | | 5,289,908 | 9,842,020 | 6,755,124 | 6,854,868 |
| Total | 31,710,128 | 32,777,128 | 37,893,832 | 25,301,276 | 26,259,212 |

*Revenues*. Most of the Company's net revenues during the three and nine months ended June 30, 2021 and 2020 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) 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 recently seen an increase in the cost of the nitrile polymer used to produce FC2 and may experience increases in other material costs due to the impact of COVID-19 and increased inflation. Our costs of sales and gross margins may be adversely impacted if we are unable to pass along cost increases to our customers.

On August 7, 2021, the Company learned that a fire had occurred at the manufacturing site used by our supplier to produce component sheaths for FC2. The preliminary analysis by the supplier indicates that production will be impacted for at least two months before it can restart. We have robust levels of inventory of FC2 in our U.S. warehouses and of FC2 and component sheaths in our facility in Malaysia. As a result, we believe that this supply disruption will have no impact on sales of FC2 in the fourth quarter of fiscal 2021 and, based on historic ordering and our forecasts, we believe that it will not have a significant impact on sales of FC2 in the first quarter of fiscal 2022. Given our inventory position, and the initial guidance given to us by our supplier at this stage, we expect any impact from this temporary disruption would be limited to the global public health sector market and that it would have no impact on sales in the U.S. market.

Conducting research and development is central to our business model. The Company’s Research and Development segment includes multiple products 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 $11.2 million and $4.4 million for the three months ended June 30, 2021 and 2020, respectively, and $24.4 million and $13.7 million for the nine months ended June 30, 2021 and 2020, respectively. We expect to continue this trend of increased expenses relating to research and development due to advancement of multiple drug candidates.

Results of Operations

THREE MONTHS ENDED JUNE 30, 2021 COMPARED TO THREE MONTHS ENDED JUNE 30, 2020

The Company generated net revenues of $17.7 million and net loss of $2.7 million, or $(0.03) per basic and diluted common share, for the three months ended June 30, 2021, compared to net revenues of $10.3 million and net loss of $3.0 million, or $(0.05) per basic and diluted common share, for the three months ended June 30, 2020. Net revenues increased 71% over the prior period.

FC2 net revenues increased 83% year over year. There was a 6% increase in total FC2 unit sales and an increase in FC2 average sales price per unit of 72%. 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 76% of total FC2 net revenues in the current year period compared to 56% of total FC2 net revenues in the prior year period. The Company experienced an increase of 150% in FC2 net revenues in the U.S. prescription channel and a decrease of 2% in FC2 net revenues in the global public health sector.

Cost of sales remained consistent at $3.8 million in the three months ended June 30, 2021 compared to the three months ended June 30, 2020. The cost per unit decreased due to decreased labor costs and period costs in the prior year period of approximately $0.3 million resulting from decreased production due to the temporary shutdown of the Company's manufacturing facility in Malaysia as a result of the COVID-19 pandemic in the prior year.

Gross profit increased to $13.9 million in the three months ended June 30, 2021 from $6.5 million in the three months ended June 30, 2020. Gross profit margin for the fiscal 2021 period was 79% of net revenues, compared to 63% of net revenues for the fiscal 2020 period. The increase in the gross profit margin is primarily due to an increase in net revenues in the U.S. prescription channel and a decrease in labor costs.

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 a significant increase in revenue from sales in the U.S. prescription channel, which is helping grow net revenues quarter to quarter and year to year.

Research and development expenses increased to $11.2 million in the three months ended June 30, 2021 from $4.4 million in the same period in fiscal 2020. The increase is primarily due to increased costs associated with the multiple in-process research and development projects and increased personnel costs. During the fiscal 2021 period, the Company initiated two Phase 3 clinical trials and one Phase 2 clinical trial with additional clinical trial initiations coming. This ongoing clinical trial activity has resulted in increased costs. Additionally, in the fiscal 2020 period, research and development expenses were reduced by $0.1 million due to the funds received under the Paycheck Protection Program. See Note 14 to the financial statements included in this report for additional information related to the Paycheck Protection Program.

Selling, general and administrative expenses increased to $5.6 million in the three months ended June 30, 2021 from $3.5 million in the three months ended June 30, 2020. The increase is due primarily to increased personnel and share-based compensation costs. Additionally, in the fiscal 2020 period, selling, general and administrative expenses were reduced by $0.4 million due to the funds received under the Paycheck Protection Program. See Note 14 to the financial statements included in this report for additional information related to the Paycheck Protection Program.

Interest expense, which consists of items related to the Credit Agreement and Residual Royalty Agreement, was $1.3 million in the three months ended June 30, 2021, which is comparable with $1.2 million in the three months ended June 30, 2020.

Expense associated with the change in fair value of the embedded derivatives related to the Credit Agreement and Residual Royalty Agreement was $1.3 million in the three months ended June 30, 2021, compared to expense of $0.2 million in the three months ended June 30, 2020. 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 derivatives is due to an increase in projected FC2 net revenues in future periods and decreases in the discount rates. See Note 3 and Note 8 to the financial statements included in this report for additional information.

Income tax benefit in the third quarter of fiscal 2021 was $2.9 million, compared to income tax expense of $0.2 million in the third quarter of fiscal 2020. The increase in the income tax benefit of $3.1 million is primarily due to the benefit recognized from the increasing the value of the U.K. net operating losses due to the increase in the U.K. tax rates from 19% to 25%.

NINE MONTHS ENDED JUNE 30, 2021 COMPARED TO NINE MONTHS ENDED JUNE 30, 2020

The Company generated net revenues of $45.6 million and net income of $11.7 million, or $0.16 per basic common share and $0.14 per diluted common share, for the nine months ended June 30, 2021, compared to net revenues of $30.8 million and net loss of $7.1 million, or $(0.11) per basic and diluted common share, for the nine months ended June 30, 2020. Net revenues increased 48% over the prior period.

FC2 net revenues increased 51% year over year. There was a 15% increase in total FC2 unit sales and an increase in FC2 average sales price per unit of 31%. 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 74% of total FC2 net revenues in the current year period compared to 62% of total FC2 net revenues in the prior year period. The Company experienced an increase of 79% in FC2 net revenues in the U.S. prescription channel and an increase of 6% in FC2 net revenues in the global public health sector.

Cost of sales increased to $10.0 million in the nine months ended June 30, 2021 from $9.6 million in the nine months ended June 30, 2020 primarily due to an increase in unit sales partially offset by a decrease in labor, equipment maintenance, and transportation costs.

Gross profit increased to $35.6 million in the nine months ended June 30, 2021 from $21.2 million in the nine months ended June 30, 2020. Gross profit margin for the fiscal 2021 period was 78% of net revenues, compared to 69% of net revenues for the fiscal 2020 period. The increase in the gross profit margin is primarily due to an increase in net revenues in the U.S. prescription channel and a decrease in labor, equipment maintenance, and transportation costs.

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 a significant increase in revenue from sales in the U.S. prescription channel, which is helping grow net revenues quarter to quarter and year to year.

Research and development expenses increased to $24.4 million in the nine months ended June 30, 2021 from $13.7 million in the same period in fiscal 2020. The increase is primarily due to increased costs associated with the multiple in-process research and development projects and increased personnel costs. During the fiscal 2021 period, the Company initiated two Phase 3 clinical trials and one Phase 2 clinical trial with additional clinical trial initiations coming. This ongoing clinical trial activity has resulted in increased costs. Additionally, in the fiscal 2020 period, research and development expenses were reduced by $0.1 million due to the funds received under the Paycheck Protection Program. See Note 14 to the financial statements included in this report for additional information related to the Paycheck Protection Program.

Selling, general and administrative expenses increased to $14.7 million in the nine months ended June 30, 2021 from $11.0 million in the nine months ended June 30, 2020. The increase is due primarily to increased personnel costs, patent-related legal costs, and increased insurance costs. Additionally, in the fiscal 2020 period, selling, general and administrative expenses were reduced by $0.4 million due to the funds received under the Paycheck Protection Program. See Note 14 to the financial statements included in this report for additional information related to the Paycheck Protection Program.

During the first quarter 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 consists of items related to the Credit Agreement and Residual Royalty Agreement, was $3.7 million in the nine months ended June 30, 2021, which is comparable with $3.5 million in the nine months ended June 30, 2020.

Expense associated with the change in fair value of the embedded derivatives related to the Credit Agreement and Residual Royalty Agreement was $2.0 million in the nine months ended June 30, 2021, compared to expense of $94,000 in the nine months ended June 30, 2020. 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 derivatives is due to an increase in projected FC2 net revenues in future periods and decreases in the discount rates. See Note 3 and Note 8 to the financial statements included in this report for additional information.

Income tax benefit in the first nine months of fiscal 2021 was $2.8 million, compared to income tax expense of $31,000 in the first nine months of fiscal 2020. The increase in the income tax benefit of $2.8 million is primarily due to the benefit recognized from the increasing the value of the U.K. net operating losses due to the increase in the U.K. tax rates from 19% to 25%.

Liquidity and Sources of Capital

***Liquidity***

Our cash and cash equivalents on hand at June 30, 2021 was $123.2 million, compared to $13.6 million at September 30, 2020. At June 30, 2021, the Company had working capital of $137.2 million and stockholders' equity of $155.0 million compared to working capital of $12.3 million and stockholders' equity of $30.1 million as of September 30, 2020. The increase in working capital is primarily due to the increase in cash on hand and an increase in prepaid 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 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, 2020 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 commercial product are adequate to fund planned operations of the Company for at least 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 shelf registration statement on Form S-3 (File No. 333-239493) or under a new registration statement.

*Operating activities*

Operating activities used cash of $14.8 million in the nine months ended June 30, 2021. Cash from operating activities included net income of $11.7 million, adjustments to reconcile net income to net cash provided by operating activities totaling a reduction of $17.9 million and changes in operating assets and liabilities of $8.5 million. Adjustments to net income primarily consisted of $18.4 million related to the gain on sale of the PREBOOST® business, $2.9 million of interest paid in excess of interest expense, and $2.9 million of deferred income taxes, partially offset by $3.7 million of share-based compensation and $2.0 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 $9.6 million and an increase in accounts receivable of $3.1 million, partially offset by an increase in accrued expenses and other current liabilities of $2.8 million.

Our operating activities used cash of $1.6 million in the nine months ended June 30, 2020. Cash used in operating activities included a net loss of $7.1 million, adjustments for noncash items totaling $6.2 million and changes in operating assets and liabilities of $0.6 million. Adjustments for noncash items primarily consisted of $3.5 million of noncash interest expense and $2.0 million of share-based compensation. The decrease in cash from changes in operating assets and liabilities included an increase in inventories of $1.8 million, partially offset by an increase in accounts payable of $0.6 million and an increase in accrued expenses and other current liabilities of $0.6 million.

*Investing activities*

Net cash from investing activities was $14.8 million in the nine months ended June 30, 2021, attributed to $15.0 million received from the sale of the Company's PREBOOST® business.

Net cash used in investing activities in the nine months ended June 30, 2020 was $73,000 and was associated with capital expenditures at our U.K. and Malaysia locations.

*Financing activities*

Net cash provided by financing activities in the nine months ended June 30, 2021 was $109.5 million and primarily consisted of proceeds from the underwritten public offering of the Company's common stock, net of fees and costs paid through June 30, 2021, of $108.0 million (see discussion below) and proceeds from stock option exercises of $1.5 million.

Net cash provided by financing activities in the nine months ended June 30, 2020 was $10.8 million and consisted of $13.4 million from the sale of shares under common stock purchase agreements with Aspire Capital Fund, LLC (see discussion below), proceeds from the Premium Finance Agreement of $0.8 million, which were used to finance the Company's directors and officers liability insurance premium, and proceeds from stock option exercises of $0.4 million, less payments on the Credit Agreement (see discussion below) of $3.3 million and payments on the Premium Finance Agreement of $0.6 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 $107.9 million after deducting underwriting discounts and commissions and costs incurred by the Company through June 30, 2021. 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 recourse of the Lenders and the Agent for obligations under the Credit Agreement is limited to assets relating to FC2. On May 13, 2019, the Company entered into an amendment to the Credit Agreement (the "Second Amendment") which included a reduction to the percentages to be used to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar year 2019, a return to the original percentages to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar year 2020 and an increase to the percentages to be used to calculate the quarterly revenue-based payments due on product revenue from net sales of FC2 during calendar year 2021 and thereafter until the loan has been repaid.

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 commencing after the Lenders would have received their return premium based on the return premium and calculation of revenue-based payments under the Credit Agreement without taking into account the amendments effected by the Second Amendment. 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 Credit Agreement, or (ii) mutual agreement of the parties.

The Company made total payments under the Credit Agreement of $6.4 million and $3.3 million during the nine months ended June 30, 2021 and 2020, respectively. As a result of the Second Amendment, the Company currently estimates the aggregate amount of quarterly revenue-based payments payable during the 12-month period subsequent to June 30, 2021 will be approximately $0.9 million under the Credit Agreement. The Company began making payments under the Residual Royalty Agreement during the quarter ended June 30, 2021, totaling $0.3 million during the period. The Company currently estimates the aggregate amount of quarterly revenue-based payments payable during the 12-month period subsequent to June 30, 2021 will be approximately $3.7 million under the Residual Royalty Agreement.

*Aspire Capital Purchase Agreement*

On June 26, 2020, the Company entered into a common stock purchase agreement (the "2020 Purchase Agreement") with Aspire Capital Fund, LLC (Aspire Capital) which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right, from time to time in its sole discretion during the 36-month term of the 2020 Purchase Agreement, to direct Aspire Capital to purchase up to $23.9 million of the Company's common stock in the aggregate. Upon execution of the 2020 Purchase Agreement, the Company issued and sold to Aspire Capital under the 2020 Purchase Agreement 1,644,737 shares of common stock at a price per share of $3.04, for an aggregate purchase price of $5,000,000. Other than the 212,130 shares of common stock issued to Aspire Capital in consideration for entering into the 2020 Purchase Agreement and the initial sale of 1,644,737 shares of common stock, the Company has no obligation to sell any shares of common stock pursuant to the 2020 Purchase Agreement and the timing and amount of any such sales are in the Company's sole discretion subject to the conditions and terms set forth in the 2020 Purchase Agreement. As of June 30, 2021, 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). Effective June 26, 2020, upon the execution of the 2020 Purchase Agreement, the Company's prior purchase agreement with Aspire Capital was terminated.

Fair Value Measurements

As of June 30, 2021 and September 30, 2020, 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 determined the fair value of the embedded derivatives at inception and on subsequent valuation dates using a Monte Carlo simulation model. This valuation model incorporates transaction details such as the contractual terms of the instruments and assumptions including projected FC2 revenues, expected cash outflows, expected repayment dates, probability and estimated dates of a change of control, expected volatility, and risk-free interest rates and applicable credit risk. The assumptions used in calculating the fair value of financial instruments represent the Company's best estimates, but these estimates involve inherent uncertainties and the application of management judgment. 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, 2020. There have been no material changes to such exposures since September 30, 2020.

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, 2020. 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, 2020.

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). |
| 31.1 | Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. * |
| 31.2 | Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. * |

| | |
|---|---|
| 32.1 | Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002). *, ** |
| 101 | The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, formatted in iXBRL (Inline Extensible Business Reporting Language): (1) the Unaudited Condensed Consolidated Balance Sheets, (2) the Unaudited Condensed Consolidated Statements of Operations, (3) the Unaudited Condensed Consolidated Statements of Stockholders' Equity, (4) the Unaudited Condensed Consolidated Statements of Cash Flows and (5) the Notes to the Unaudited Condensed Consolidated Financial Statements. |
| 104 | Cover Page Interactive Data File (formatted as iXBRL and contained in Exhibit 101). |

* Filed herewith

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

**SIGNATURES**

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

**VERU INC.**

DATE: August 12, 2021

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

DATE: August 12, 2021

/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: August 12, 2021

/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: August 12, 2021

/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 June 30, 2021 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: August 12, 2021

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

Date: August 12, 2021

/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.