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, 2020

☐ **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 11, 2020, the registrant had 69,863,681 shares of $0.01 par value common stock outstanding.

VERU INC.
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FORWARD LOOKING STATEMENTS

Certain statements included in this quarterly report on Form 10-Q which are not statements of historical fact are intended to be, and are hereby identified as, "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about 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 and plans, 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, 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 in regulatory approval of products under development;
- 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 VERU-111 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 at an early stage 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;
- government entities may take actions that directly or indirectly have the effect of limiting opportunities for VERU-111 as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments;
- product demand and market acceptance;
- 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;
- the risk that we will be affected by regulatory developments, including a reclassification of products;
- 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 and/or of our ability to supply product due to raw materialshortages, labor shortages, physical damage to our facilities, COVID-19 (including the impact of COVID-19 on suppliers of key raw materials), product testing, transportation delays or regulatory actions;
- our reliance on major customers and risks related to delays in payment of accounts receivable by major 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, including our 2018 South Africa 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 2018 South Africa tender award could be subject in the future to reallocation for potential local manufacturing initiatives, which could reduce the size of the award to us;
- 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, 2019 and Part II, Item 1A of this Form 10-Q. 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, 2020	September 30, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 15,394,423	$ 6,295,152
Accounts receivable, net	4,144,351	5,021,057
Inventory, net	5,194,442	3,647,406
Prepaid expenses and other current assets	2,125,730	1,843,297
Total current assets	26,858,946	16,806,912
Plant and equipment, net	315,456	351,895
Operating lease right-of-use assets	1,012,951	—
Deferred income taxes	8,628,006	8,433,669
Intangible assets, net	19,931,219	20,168,495
Goodwill	6,878,932	6,878,932
Other assets	1,562,126	988,867
Total assets	$ 65,187,636	$ 53,628,770
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,772,990	$ 3,124,751
Accrued research and development costs	2,277,491	2,475,490
Accrued compensation	2,196,043	1,597,197
Accrued expenses and other current liabilities	1,745,811	1,436,888
Credit agreement, short-term portion	6,599,095	5,385,649
Residual royalty agreement liability, short-term portion	356,346	—
Operating lease liability, short-term portion	425,136	—
Total current liabilities	17,372,912	14,019,975
Credit agreement, long-term portion	—	2,886,382
Residual royalty agreement liability, long-term portion	5,407,007	3,845,518
Operating lease liability, long-term portion	808,401	—
Deferred income taxes	292,740	296,605
Other liabilities	27,469	247,154
Total liabilities	23,908,529	21,295,634
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock; no shares issued and outstanding at June 30, 2020 and September 30, 2019	—	—
Common stock, par value $0.01 per share; 154,000,000 shares authorized, 72,047,385 and 67,221,951 shares issued and 69,863,681 and 65,038,247 shares outstanding at June 30, 2020 and September 30, 2019, respectively	720,474	672,220
Additional paid-in-capital	126,306,764	110,268,057
Accumulated other comprehensive loss	(581,519)	(581,519)
Accumulated deficit	(77,360,007)	(70,219,017)
Treasury stock, 2,183,704 shares, at cost	(7,806,605)	(7,806,605)
Total stockholders' equity	41,279,107	32,333,136
Total liabilities and stockholders' equity	$ 65,187,636	$ 53,628,770

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,	
	2020	2019	2020	2019
Net revenues	$ 10,321,754	$ 9,727,060	$ 30,842,874	$ 23,074,984
Cost of sales	3,802,636	3,155,902	9,618,163	7,250,895
Gross profit	6,519,118	6,571,158	21,224,711	15,824,089
Operating expenses:				
Research and development	4,436,496	4,866,114	13,666,730	10,138,524
Selling, general and administrative	3,475,474	3,547,046	11,034,904	10,663,884
Total operating expenses	7,911,970	8,413,160	24,701,634	20,802,408
Operating loss	(1,392,852)	(1,842,002)	(3,476,923)	(4,978,319)
Non-operating (expenses) income:				
Interest expense	(1,169,692)	(1,091,276)	(3,476,079)	(3,627,971)
Change in fair value of derivative liabilities	(169,000)	157,000	(94,000)	(246,000)
Other (expense) income, net	(53,334)	1,744	(63,369)	12,588
Total non-operating expenses	(1,392,026)	(932,532)	(3,633,448)	(3,861,383)
Loss before income taxes	(2,784,878)	(2,774,534)	(7,110,371)	(8,839,702)
Income tax expense (benefit)	240,502	(458)	30,619	117,207
Net loss	$ (3,025,380)	$ (2,774,076)	$ (7,140,990)	$ (8,956,909)
Net loss per basic and diluted common share outstanding	$ (0.05)	$ (0.04)	$ (0.11)	$ (0.14)
Basic and diluted weighted average common shares outstanding	66,728,782	62,917,362	65,709,139	62,745,355

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, 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 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, 2018	57,468,660	$ 574,687	$ 95,496,506	$ (581,519)	$ (58,201,651)	$ (7,806,605)	$ 29,481,418
Share-based compensation	—	—	417,256	—	—	—	417,256
Shares issued in connection with public offering of common stock, net of fees and costs	7,142,857	71,428	9,060,539	—	—	—	9,131,967
Issuance of shares pursuant to share-based awards	190,000	1,900	(1,900)	—	—	—	—
Net loss	—	—	—	—	(2,148,798)	—	(2,148,798)
Balance at December 31, 2018	64,801,517	648,015	104,972,401	(581,519)	(60,350,449)	(7,806,605)	36,881,843
Share-based compensation	—	—	496,209	—	—	—	496,209
Issuance of shares pursuant to share-based awards	166,667	1,667	198,333	—	—	—	200,000
Net loss	—	—	—	—	(4,034,035)	—	(4,034,035)
Balance at March 31, 2019	64,968,184	649,682	105,666,943	(581,519)	(64,384,484)	(7,806,605)	33,544,017
Share-based compensation	—	—	468,207	—	—	—	468,207
Sale of shares under common stock purchase agreement	2,000,000	20,000	3,580,000	—	—	—	3,600,000
Amortization of deferred costs	—	—	(101,981)	—	—	—	(101,981)
Issuance of shares pursuant to share-based awards	34,299	343	(343)	—	—	—	—
Net loss	—	—	—	—	(2,774,076)	—	(2,774,076)
Balance at June 30, 2019	67,002,483	$ 670,025	$ 109,612,826	$ (581,519)	$ (67,158,560)	$ (7,806,605)	$ 34,736,167

See notes to unaudited condensed consolidated financial statements.

VERU INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine Months Ended June 30,	
	2020	2019
OPERATING ACTIVITIES		
Net loss	$ (7,140,990)	$ (8,956,909)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	109,883	126,084
Amortization of intangible assets	237,276	231,926
Noncash change in right-of-use assets	240,282	—
Noncash interest expense	3,476,079	3,627,971
Share-based compensation	1,981,492	1,381,672
Deferred income taxes	(198,202)	20,413
Provision for obsolete inventory	227,982	112,498
Change in fair value of derivative liabilities	94,000	246,000
Other	7,500	148,674
Changes in current assets and liabilities:		
Decrease (increase) in accounts receivable	194,471	(791,272)
Increase in inventory	(1,775,018)	(941,188)
Increase in prepaid expenses and other assets	(4,794)	(68,578)
Increase (decrease) in accounts payable	648,239	(46,894)
Decrease in unearned revenue	—	(187,159)
Increase in accrued expenses and other current liabilities	556,330	566,557
Decrease in operating lease liabilities	(243,514)	—
Net cash used in operating activities	(1,588,984)	(4,530,205)
INVESTING ACTIVITIES		
Capital expenditures	(73,444)	(74,948)
Net cash used in investing activities	(73,444)	(74,948)
FINANCING ACTIVITIES		
Proceeds from sale of shares in public offering, net of fees	—	9,400,000
Payment of costs related to public offering	—	(268,033)
Proceeds from sale of shares under common stock purchase agreement	13,399,999	3,600,000
Installment payments on SWK credit agreement	(3,325,180)	(4,047,207)
Proceeds from stock option exercises	415,464	200,000
Proceeds from premium finance agreement	836,780	—
Installment payments on premium finance agreement	(555,920)	—
Cash paid for debt portion of finance lease	(9,444)	—
Net cash provided by financing activities	10,761,699	8,884,760
Net increase in cash	9,099,271	4,279,607
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	6,295,152	3,759,509
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 15,394,423	$ 8,039,116
Supplemental disclosure of noncash activities:		
Right-of-use assets recorded in exchange for lease liabilities	$ 1,253,233	$ —
Shares issued in connection with common stock purchase agreement	$ 680,937	$ —
Increase in other assets from accrued expenses	$ 50,284	$ —
Amortization of deferred costs related to common stock purchase agreement	$ 390,931	$ 101,981

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, 2019. The accompanying condensed consolidated balance sheet as of September 30, 2019 has been derived from our audited financial statements. The unaudited condensed consolidated statements of operations for the three and nine months ended June 30, 2020 and cash flows for the nine months ended June 30, 2020 are not necessarily indicative of the results to be expected for any future period or for the fiscal year ending September 30, 2020.

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. Prior to the completion of the October 31, 2016 acquisition (the "APP Acquisition") of APP through the merger of a wholly owned subsidiary of the Company into APP, the Company had been a single product company engaged in marketing, manufacturing and distributing a consumer healthcare product, the FC2 Female Condom/FC2 Internal Condom® (FC2). The completion of the APP Acquisition transitioned the Company into a biopharmaceutical company focused on oncology and urology with multiple drug products under clinical development. Most of the Company's net revenues during the three and nine months ended June 30, 2020 and 2019 were derived from sales of FC2.

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.

Leases: Leases are classified as either operating or finance leases at inception. A right-of-use (ROU) asset and corresponding lease liability are established at an amount equal to the present value of fixed lease payments over the lease term at the commencement date. The ROU asset includes any initial direct costs incurred and lease payments made at or before the commencement date and is reduced by lease incentive payments. The Company has elected not to separate the lease and nonlease components for all classes of underlying assets. The Company uses its incremental borrowing rate as the discount rate to determine the present value of the lease payments for leases that do not have a readily determinable implicit discount rate. The incremental borrowing rate is the rate of interest that the Company would be charged to borrow on a collateralized basis over a similar term and amount in a similar economic environment. The Company determines the incremental borrowing rates for its leases by adjusting the risk-free interest rate with a credit risk premium corresponding to the Company's credit rating.

Operating lease costs are recognized for fixed lease payments on a straight-line basis over the term of the lease. Finance lease costs are a combination of the amortization expense for the ROU asset and interest expense for the outstanding lease liability using the applicable discount rate. Variable lease payments are recognized when incurred based on occurrence or usage. Short-term leases with an initial term of 12 months or less are not recorded on the balance sheet; we recognize lease expense for short-term leases on a straight-line basis over the lease term.

Government grants: U.S. GAAP for profit-oriented entities does not define government grants nor is there specific guidance applicable to government grants. Under the Company's accounting policy for government grants and consistent with non-authoritative guidance, government grants are recognized as a reduction of the related expense. Government grants are recognized when there is reasonable assurance that the Company has met the requirements of the grant and there is reasonable assurance that the grant will be received. Grants that compensate the Company for expenses incurred are recognized as a reduction of the related expenses in the same period in which the expenses are recognized. The Company has elected to treat forgivable loans from a government as a government grant when it is probable that the Company will meet the terms for forgiveness of the loan.

Other comprehensive loss: Accounting principles generally require that recognized revenue, expenses, gains and losses be included in net loss. Although certain changes in assets and liabilities, such as foreign currency translation adjustments, are reported as a separate component of the equity section of the accompanying unaudited condensed consolidated balance sheets, these items, along with net loss, are components of other comprehensive loss. For the three and nine months ended June 30, 2020 and 2019, comprehensive loss is equivalent to the reported net loss.

Recently Issued Accounting Pronouncements: In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-02, *Leases (Topic 842)*, which requires that lessees recognize an ROU asset and a lease liability for all leases with lease terms greater than twelve months in the balance sheet. ASU 2016-02 distinguishes leases as either a finance lease or an operating lease, which affects how the leases are measured and presented in the statement of operations and statement of cash flows, and requires disclosure of key information about leasing arrangements. A modified retrospective transition approach is required upon adoption. In July 2018, the FASB issued ASU No. 2018-10, *Codification Improvements to Topic 842, Leases* to clarify the implementation guidance and ASU No. 2018-11, *Leases (Topic 842) Targeted Improvements.* This updated guidance provides an optional transition method, which allows for the initial application of the new accounting standard at the adoption date and the recognition of a cumulative-effect adjustment to the opening balance of retained earnings as of the beginning of the period of adoption. In December 2018, the FASB issued ASU 2018-20, *Leases (Topic 842): Narrow-Scope Improvements for Lessors* to address certain implementation issues facing lessors when adopting ASU 2016-02. In March 2019, the FASB issued ASU 2019-01, *Leases (Topic 842): Codification Improvements* to address, among other things, certain transition disclosure requirements subsequent to the adoption of ASU 2016-02.

The Company adopted the new lease accounting standard using the modified retrospective approach on October 1, 2019 and elected certain practical expedients, including the optional transition method that allows for the application of the new standard at its adoption date with no restatement of prior period amounts. We elected the package of practical expedients permitted under the transition guidance, which allowed us to not reassess our prior conclusions about lease identification, lease classification, and initial direct costs. Adoption of the new standard resulted in the recording of ROU assets and lease liabilities of approximately $1.2 million and $1.5 million, respectively, and the derecognition of prepaid expenses and operating lease deferred rent liabilities of $23,000 and $247,000, respectively, as of October 1, 2019 with zero cumulative-effect adjustment to retained earnings. The new standard did not materially impact our consolidated statement of operations or cash flows.

In June 2018, the FASB issued ASU 2018-07, *Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. The purpose of ASU 2018-07 is to expand the scope of *Topic 718, Compensation—Stock Compensation* (which previously only included share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The Company has issued share-based payments to nonemployees in the past but is not able to predict the amount of future share-based payments to nonemployees, if any. We adopted ASU 2018-07 effective October 1, 2019. The adoption of ASU 2018-07 did not have a material impact on our consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU 2019-12,*Income Taxes (Topic 740). Simplifying the Accounting for Income Taxes* The new guidance eliminates certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period, and the recognition of deferred tax liabilities for outside basis differences. It also clarifies and simplifies other aspects of the accounting for income taxes. ASU 2019-12 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. Early adoption is permitted. The adoption of ASU 2019-12 is not expected to have a material effect on our consolidated financial statements and related disclosures.

Note 2 – Liquidity

The Company has incurred quarterly operating losses since the fourth quarter of fiscal 2016 and anticipates that it will continue to consume cash and incur substantial net losses as it develops its drug candidates. Because of the numerous risks and uncertainties associated with the development of pharmaceutical products, the Company is unable to estimate the exact amounts of capital outlays and operating expenditures necessary to fund development of its drug candidates and obtain regulatory approvals. The Company's future capital requirements will depend on many factors.

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

Note 3 – Fair Value Measurements

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

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

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

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

Level 3 – Instruments with primarily unobservable value drivers.

We review the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels of certain securities within the fair value hierarchy. There were no transfers between Level 1, Level 2 and Level 3 during the nine months ended June 30, 2020 and 2019.

As of June 30, 2020 and September 30, 2019, 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 Company determines the fair value of hybrid instruments based on available market data using appropriate valuation models, considering all of the rights and obligations of each instrument. The Company estimates the fair value of hybrid instruments using various techniques (and combinations thereof) that are considered to be consistent with the objective of measuring fair value. In selecting the appropriate technique, the Company considers, among other factors, the nature of the instrument, the market risks that it embodies and the expected means of settlement. Estimating the fair value of derivative financial instruments requires the development of significant and subjective estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. Increases in fair value during a given financial quarter result in the recognition of non-cash derivative expense. Conversely, decreases in fair value during a given financial quarter would result in the recognition of non-cash derivative income.

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, 2020 and 2019:

	Nine Months Ended June 30,	
	2020	**2019**
Beginning balance	$ 3,625,000	$ 2,426,000
Change in fair value of derivative liabilities	94,000	246,000
Ending balance	$ 3,719,000	$ 2,672,000

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 usinga Monte Carlo simulation model to value the financial liabilities at inception and on subsequent valuation dates. This valuation model incorporates transaction details such as the contractual terms, expected cash outflows, expected repayment dates, probability of a change of control, expected volatility, and risk-free interest rates. A significant acceleration of the estimated repayment date or a significant decrease in the probability of a change of control event prior to repayment of the Credit Agreement, in isolation, would result in a significantly lower 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, 2020 and September 30, 2019:

		Weighted Average (range, if applicable)	
Valuation Methodology	**Significant Unobservable Input**	**June 30, 2020**	**September 30, 2019**
Monte Carlo Simulation	Estimated change of control dates	June 2021 to June 2022	September 2020 to December 2021
	Discount rate	13.3% to 14.9%	14.4% to 16.8%
	Probability of change of control	10% to 90%	10% 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 direct product sales of FC2 in the global publichealth sector, sales of FC2 in the U.S. prescription channel, and sales of PREBOOST® medicated wipes for prevention of premature ejaculation. The following table presents net revenues from these three categories:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2020	2019	2020	2019
FC2				
Public health sector	$ 4,254,197	$ 4,905,874	$ 11,197,635	$ 13,039,878
U.S. prescription channel	5,391,523	4,377,862	18,395,280	9,412,177
Total FC2	9,645,720	9,283,736	29,592,915	22,452,055
PREBOOST®	676,034	443,324	1,249,959	622,929
Net revenues	$ 10,321,754	$ 9,727,060	$ 30,842,874	$ 23,074,984

The following table presents net revenue by geographic area:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2020	2019	2020	2019
United States	$ 6,396,762	$ 5,548,987	$ 20,575,515	$ 11,234,870
South Africa	1,182,225	*	*	*
Zimbabwe	*	*	*	2,558,308
Other	2,742,767	4,178,073	10,267,359	9,281,806
Net revenues	$ 10,321,754	$ 9,727,060	$ 30,842,874	$ 23,074,984

*Less than 10% of total net revenues

The Company's performance obligations consist mainly of transferring control of products identified in the contracts which occurs either when: i) the product is made available to the customer for shipment; ii) the product is shipped via common carrier; or iii) the product is delivered to the customer or distributor, in accordance with the terms of the agreement. Some of the Company's contracts require the customer to make advanced payments prior to transferring control of the products. These advanced payments create a contract liability for the Company. The balances of the Company's contract liability, included in accrued expenses and other current liabilities on the accompanying unaudited condensed consolidated balances sheets, was approximately $249,000 at June 30, 2020 and September 30, 2019.

The Company records an unearned revenue liability if a customer pays consideration for product that was shipped by the Company but revenue recognition criteria have not been met under the terms of a contract. Unearned revenue is recognized as revenue after control of the product is transferred to the customer and all revenue recognition criteria have been met. The Company had no unearned revenue at June 30, 2020 or September 30, 2019.

The Company recognized revenue of $804,000 and $723,000 during the nine months ended June 30, 2020 and 2019, respectively, after satisfying its contract obligations and transferring control for previously recorded contract liabilities or unearned revenue.

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 is 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 180 days subsequent to clearance of the product by the Ministry of Health in Brazil. The Company classified approximately $800,000 and $300,000 of trade receivables with its distributor in Brazil as long-term as of June 30, 2020 and September 30, 2019, respectively, because payment was expected in greater than one year. The long-term portion of trade receivables is included in other assets on the accompanying unaudited condensed consolidated balance sheets.

The components of accounts receivable consist of the following at June 30, 2020 and September 30, 2019:

	June 30, 2020	September 30, 2019
Trade receivables, gross	$ 5,038,398	$ 5,410,165
Less: allowance for doubtful accounts	(25,643)	(33,143)
Less: allowance for sales and payment term discounts	(67,779)	(49,623)
Less: long-term trade receivables*	(800,625)	(306,342)
Accounts receivable, net	$ 4,144,351	$ 5,021,057

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

At June 30, 2020 and at September 30, 2019, no customers had a current accounts receivable balance that represented greater than 10% of current assets.

At June 30, 2020, three customers had an accounts receivable balance greater than 10% of net accounts receivable and long-term trade receivables, representing 76% of net accounts receivable and long-term trade receivables in the aggregate. At September 30, 2019, two customers had an accounts receivable balance greater than 10% of net accounts receivable and long-term trade receivables, representing 66% of net accounts receivable and long-term trade receivables 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 three months ended June 30, 2019, there were three customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 63% 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. For the nine months ended June 30, 2019, there were three customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 64% of the Company's net revenues in the aggregate.

The Company maintains an allowance for doubtful accounts for estimated losses resulting from theinability 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.

The table below summarizes the change in the allowance for doubtful accounts for thenine months ended June 30, 2020 and 2019:

	Nine Months Ended June 30,	
	2020	2019
Beginning balance	$ 33,143	$ 36,201
Charges to expense	—	—
Charge-offs	(7,500)	(3,058)
Ending balance	$ 25,643	$ 33,143

Recoveries of accounts receivable previously charged off are recorded when received. 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, 2020 and September 30, 2019:

	June 30, 2020	September 30, 2019
FC2:		
Raw material	$ 750,688	$ 426,590
Work in process	127,693	187,970
Finished goods	4,268,944	3,157,952
FC2, gross	5,147,325	3,772,512
Less: inventory reserves	(29,331)	(125,106)
FC2, net	5,117,994	3,647,406
PREBOOST®		
Finished goods	76,448	—
Inventory, net	$ 5,194,442	$ 3,647,406

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, 2020 and September 30, 2019:

	Estimated Useful Life	June 30, 2020	September 30, 2019
Plant and equipment:			
Manufacturing equipment	5 - 8 years	$ 2,766,179	$ 2,716,647
Office equipment, furniture and fixtures	3 - 10 years	819,140	795,228
Leasehold improvements	3 - 8 years	298,886	298,886
Total plant and equipment		3,884,205	3,810,761
Less: accumulated depreciation and amortization		(3,568,749)	(3,458,866)
Plant and equipment, net		$ 315,456	$ 351,895

Note 7 – Intangible Assets and Goodwill

Intangible Assets

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

	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Intangible assets with finite lives:			
Developed technology - PREBOOST®	$ 2,400,000	$ 706,876	$ 1,693,124
Covenants not-to-compete	500,000	261,905	238,095
Total intangible assets with finite lives	2,900,000	968,781	1,931,219
Acquired in-process research and development assets	18,000,000	—	18,000,000
Total intangible assets	$ 20,900,000	$ 968,781	$ 19,931,219

The gross carrying amounts and net book value of intangible assets are as follows at September 30, 2019:

	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Intangible assets with finite lives:			
Developed technology - PREBOOST®	$ 2,400,000	$ 523,172	$ 1,876,828
Covenants not-to-compete	500,000	208,333	291,667
Total intangible assets with finite lives	2,900,000	731,505	2,168,495
Acquired in-process research and development assets	18,000,000	—	18,000,000
Total intangible assets	$ 20,900,000	$ 731,505	$ 20,168,495

For the three months ended June 30, 2020 and 2019, amortization expense was approximately $79,000 and $77,000, respectively. For the nine months ended June 30, 2020 and 2019, amortization expense was approximately $237,000 and $232,000, respectively.

Goodwill

The carrying amount of goodwill at June 30, 2020 and September 30, 2019 was $6.9 million. There was no change in the balance during the nine months ended June 30, 2020 and 2019.

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 will be 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 the12-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 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 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 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, 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 certaincovenants, 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 completed12-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 allocatedbetween 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 will be adjusted to fair market value at each subsequent 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 in 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, 2020 and September 30, 2019, the Credit Agreement liability consisted of the following:

	June 30, 2020	September 30, 2019
Aggregate repayment obligation	$ 17,650,000	$ 17,650,000
Less: cumulative payments	(8,903,265)	(5,578,085)
Remaining repayment obligation	8,746,735	12,071,915
Less: unamortized discounts	(2,102,227)	(4,590,974)
Less: unamortized deferred issuance costs	(49,413)	(107,910)
Credit agreement, excluding embedded derivative liability, net	6,595,095	7,373,031
Add: embedded derivative liability at fair value (see Note 3)	4,000	899,000
Credit agreement, net	6,599,095	8,272,031
Credit agreement, short-term portion	(6,599,095)	(5,385,649)
Credit agreement, long-term portion	$ —	$ 2,886,382

The Company currently estimates the aggregate amount of quarterly revenue-based payments payable during the 12-month period subsequent to June 30, 2020 will be approximately $8.2 million under the Credit Agreement.

At June 30, 2020 and September 30, 2019, the Residual Royalty Agreement liability consisted of the following:

	June 30, 2020	September 30, 2019
Residual royalty agreement liability, fair value at inception	$ 346,000	$ 346,000
Add: accretion of liability using effective interest rate	1,702,353	773,518
Residual royalty agreement liability, excluding embedded derivative liability	2,048,353	1,119,518
Add: embedded derivative liability at fair value (see Note 3)	3,715,000	2,726,000
Total residual royalty agreement liability	5,763,353	3,845,518
Residual royalty agreement liability, short-term portion	(356,346)	—
Residual royalty agreement liability, long-term portion	$ 5,407,007	$ 3,845,518

The short-term portion of the Residual Royalty Agreement liability represents the aggregate of the estimated quarterly royalty payments payable during the 12-month period subsequent to June 30, 2020.

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, 2020 and 2019, interest expense related to the Credit Agreement and Residual Royalty Agreement was as follows:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2020	2019	2020	2019
Amortization of discounts	$ 782,169	$ 922,144	$ 2,488,747	$ 3,187,972
Accretion of residual royalty agreement	369,138	147,223	928,835	363,520
Amortization of deferred issuance costs	18,385	21,909	58,497	76,479
Interest expense	$ 1,169,692	$ 1,091,276	$ 3,476,079	$ 3,627,971

Premium Finance Agreement

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 is payable in three quarterly installments of principal and interest, which began on January 1, 2020. The balance of the insurance premium liability is $281,000 as of June 30, 2020 and is included in accrued expenses and other current liabilities on the accompanying unaudited condensed consolidated balance sheet.

Note 9 – Stockholders' Equity

Preferred Stock

The Company has 5,000,000 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, 2020 and September 30, 2019. The Company has 15,000 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, 2020 and September 30, 2019.

Common Stock Offering

On October 1, 2018, we completed an underwritten public offering of 7,142,857 shares of our common stock, at a public offering price of $1.40 per share. Net proceeds to the Company from this offering were $9.1 million after deducting underwriting discounts and commissions and costs paid by the Company. All of the shares sold in the offering were by the Company. The offering was made pursuant to the Company's 2017 shelf registration statement on Form S-3 (File No. 333-221120).

Common Stock Purchase Warrants

In connection with the closing of the APP Acquisition, the Company issued warrants to purchase up to 2,585,379 shares of the Company's common stock to Torreya Capital, the Company's financial advisor (the "Financial Advisor Warrants"). The Financial Advisor Warrants have a five-year term expiring October 31, 2021, a cashless exercise feature and a strike price equal to $1.93 per share. The Financial Advisor Warrants vested upon issuance. During the three months ended June 30, 2020, one of the Financial Advisor Warrants to purchase 258,538 shares of the Company's common stock was exercised using the cashless exercise feature, resulting in the issuance of 109,143 shares of common stock. As of June 30, 2020, an aggregate of 2,326,841 shares of common stock remain available for purchase under the Financial Advisor Warrants.

Aspire Capital Purchase Agreements

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.

In consideration for entering into the 2020 Purchase Agreement, 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.

Upon execution of the 2020 Purchase Agreement, the Company issued and sold 1,644,737 shares of common stock to Aspire Capital under the 2020 Purchase Agreement, resulting in proceeds to the Company of $5 million. As a result of this sale, we recorded approximately $153,000 of deferred costs to additional paid-in capital. The unamortized amount of deferred costs related to the 2020 Purchase Agreement of $578,000 at June 30, 2020 is included in other assets on the accompanying unaudited condensed consolidated balance sheet.

Effective June 26, 2020, upon the execution of the 2020 Purchase Agreement, the Company's prior purchase agreement with Aspire Capital dated December 29, 2017 (the "2017 Purchase Agreement") was terminated. Under the 2017 Purchase Agreement, the Company had the right, upon the terms and subject to the conditions and limitations set forth therein, from time to time in its sole discretion during the 36-month term of the 2017 Purchase Agreement, to direct Aspire Capital to purchase up to $15.0 million of the Company's common stock in the aggregate. As of the date of termination of the 2017 Purchase Agreement, the Company had sold an aggregate of 6,214,343 shares of common stock to Aspire Capital resulting in proceeds to the Company of $15.0 million.

During the nine months ended June 30, 2020, we sold2,497,333 shares of common stock to Aspire Capital under the 2017 Purchase Agreement resulting in proceeds to the Company of $8.4 million. As a result of these sales, we recorded approximately$238,000 of deferred costs to additional paid-in capital.

In consideration for entering into the 2017 Purchase Agreement, concurrently with the execution of the 2017 Purchase Agreement, the Company issued to Aspire Capital 304,457 shares of the Company's common stock. The shares of common stock issued as consideration were valued at approximately $347,000, 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 approximately $78,000, which total approximately $425,000, were recorded as deferred costs. All deferred costs related to the 2017 Purchase Agreementhave been amortized to additional paid-in capital as of June 30, 2020. The unamortized amount of deferred costs related to the 2017 Purchase Agreement of $238,000 at September 30, 2019 is included in other assets on the accompanying unaudited condensed consolidated balance sheet.

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, 2020 and 2019, we recorded share-based compensation expenses as follows:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2020	2019	2020	2019
Cost of sales	$ 7,743	$ 9,998	$ 38,713	$ 25,728
Selling, general and administrative	490,647	347,165	1,442,970	1,081,600
Research and development	186,924	111,044	499,809	274,344
Share-based compensation	$ 685,314	$ 468,207	$ 1,981,492	$ 1,381,672

Equity Plans

In March 2018, the Company's stockholders approved the Company's 2018 Equity Incentive Plan (the "2018 Plan").On March 24, 2020, the Company's stockholders approved an increase in the number of shares that may be issued under the 2018 Plan to 11.0 million. As of June 30, 2020, 5,881,998 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 of4.7 million shares are authorized for issuance under the 2017 Plan. As of June 30, 2020, 101,747 shares remain available for issuance under the 2017 Plan. The 2017 Plan replaced the Company's 2008 Stock Incentive Plan (the "2008 Plan"), andno 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 nine months ended June 30, 2020 and the three and nine months ended June 30, 2019. There were no options granted during the three months ended June 30, 2020

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2020	2019	2020	2019
Weighted Average Assumptions:				
Expected volatility	—	65.29%	63.13%	65.91%
Expected dividend yield	—	0.00%	0.00%	0.00%
Risk-free interest rate	—	2.23%	1.63%	2.37%
Expected term (in years)	—	6.0	5.9	5.9
Fair value of options granted	$ —	$ 0.97	$ 1.14	$ 0.92

During the three and nine months ended June 30, 2020 and 2019, 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, 2020:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2019	7,027,989	$ 1.58		
Granted	2,228,827	$ 1.97		
Exercised	(441,548)	$ 1.67		
Forfeited and expired	(195,434)	$ 1.55		
Outstanding at June 30, 2020	8,619,834	$ 1.68	8.01	$ 14,349,547
Exercisable at June 30, 2020	4,120,510	$ 1.53	7.17	$ 7,453,274

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, 2020 of $3.34, 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, 2020 and 2019 was approximately $1.1 million and $105,000, respectively. Cash received from options exercised during the nine months ended June 30, 2020 and 2019 was approximately $415,000 and $200,000, respectively. During the nine months ended June 30, 2020 and 2019, options to purchase 223,415 and 116,666 shares of common stock, respectively, were exercised using the cashless exercise feature available under the 2017 Plan and 2018 Plan, which resulted in the issuance of 143,958 and 34,299 shares of common stock, respectively.

As of June 30, 2020, the Company had unrecognized compensation expense of approximately $3.4 million related to unvested stock options. This expense is expected to be recognized over approximately three years.

Stock Appreciation Rights

In connection with the closing of the APP Acquisition, the Company issued stock appreciation rights based on50,000 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, 2020, 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 six years, which include the option to extend a lease when the Company is reasonably certain to exercise that option. The Company does not have any leases that have not yet commenced as of June 30, 2020. Certain of our lease agreements include variable lease payments for common area maintenance, real estate taxes, and insurance or based on usage for certain equipment leases. For one of our office space leases, the Company entered into a sublease, for which it receives sublease income. Sublease income is recognized as a reduction to operating lease costs as the sublease is outside of the Company's normal business operations. This is consistent with the Company's recognition of sublease income prior to the adoption of FASB ASC Topic 842.

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

	Three Months Ended June 30, 2020	Nine Months Ended June 30, 2020
Finance lease cost:		
Amortization of right-of-use assets	$ 2,178	$ 6,535
Interest on lease liabilities	1,238	4,097
Operating lease cost	124,326	378,006
Short-term lease cost	1,863	5,589
Variable lease cost	24,213	91,349
Sublease income	(45,382)	(135,071)
Total lease cost	$ 108,436	$ 350,505

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

The Company's operating lease ROU assets and the related lease liabilities are presented as separate line items on the accompanying unaudited condensed consolidated balance sheet as of June 30, 2020. The Company's finance lease ROU asset was$36,000 as of June 30, 2020 and is included in property and equipment, net on the accompanying unaudited condensed consolidated balance sheet. The current and long-term finance lease liabilities were $20,000 and $12,000, respectively, and are included in accrued expenses and other current liabilities and other liabilities, respectively, on the accompanying unaudited condensed consolidated balance sheet as of June 30, 2020.

Other information related to the Company's leases as ofJune 30, 2020 was as follows:

	June 30, 2020
Operating Leases	
Weighted-average remaining lease term	4.0
Weighted-average discount rate	12.02%
Finance Leases	
Weighted-average remaining lease term	1.7
Weighted average discount rate	13.86%

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

As of June 30, 2020, maturities of lease liabilities were as follows:

	Operating Leases	Finance Leases	Sublease Income
Fiscal year ended September 30,			
2020	$ 129,402	$ 5,432	$ 48,745
2021	431,061	22,199	198,668
2022	350,054	9,496	203,584
2023	295,258	—	190,749
2024	191,559	—	—
Thereafter	164,725	—	—
Total lease payments	1,562,059	37,127	$ 641,746
Less imputed interest	(328,522)	(4,261)	
Total lease liabilities	$ 1,233,537	$ 32,866	

Under FASB ASC 840, the lease accounting guidance prior to the Company's adoption of FASB ASC 842, the Company had net capital lease assets of $43,000 included in property and equipment, net and a related capital lease obligation of $42,000 included in accrued expenses and other current liabilities and other liabilities on the accompanying unaudited condensed consolidated balance sheet as of September 30, 2019.

Under FASB ASC 840, future minimum payments under operating leases consisted of the following as of September 30, 2019:

	Operating Leases	Sublease Income	Net Total
Fiscal year ended September 30,			
2020	$ 469,002	$ 193,753	$ 275,249
2021	433,751	198,668	235,083
2022	337,456	203,584	133,872
2023	114,493	190,749	(76,256)
2024	11,238	—	11,238
Total minimum lease payments	$ 1,365,940	$ 786,754	$ 579,186

The minimum lease payments presented above do not include real estate taxes, common area maintenance charges or insurance charges payable under the Company's operating leases for office and manufacturing facility space. These amounts are generally not fixed and can fluctuate from year to year.

Note 12 – Contingent Liabilities

The testing, manufacturing and marketing of consumer products by the Company and the clinical testing of our product candidates entail an inherent risk that product liability claims will be asserted against the Company. The Company maintains product liability insurance coverage for claims arising from the use of its products. The coverage amount is currently $10.0 million.

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 and tax credit carryforwards.

The Tax Cuts and Jobs Act of 2017 (the "Tax Act") repealed the alternative minimum tax (AMT) for corporations. The law provides that AMT carryovers can be utilized to reduce or eliminate the tax liability in subsequent years or to obtain a tax refund. The Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), which was enacted on March 27, 2020, accelerates the ability to claim a refund of the entire refundable credit to 2018 with an election when filing. The Tax Act previously allowed a 50% refundable credit for tax years beginning in 2018 through 2020, with a 100% credit refund in 2021. At June 30, 2020, the Company has $0.5 million of AMT credit carryovers in prepaid expenses and other current assets due to the expectation, as a result of the CARES Act, that the AMT credits will be refundable over the next year.

As of September 30, 2019, the Company had U.S. federal and state net operating loss carryforwards of $42.6 million and $25.8 million, respectively, for income tax purposes with $14.4 million and $19.9 million, respectively, expiring in years 2022 to 2038 and $28.2 million and $5.9 million, respectively, which can be carried forward indefinitely. The Company's U.K. subsidiary has U.K. net operating loss carryforwards of $61.7 million as of September 30, 2019, which can be carried forward indefinitely to be used to offset future U.K. taxable income.

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

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2020	2019	2020	2019
Income tax benefit at U.S. federal statutory rates	$ (584,825)	$ (582,652)	$ (1,493,179)	$ (1,856,337)
State income tax benefit, net of federal benefits	(45,268)	(138,089)	(115,615)	(439,952)
Non-deductible expenses	332,230	2,269	335,869	7,052
Effect of foreign income tax rates	(16,478)	43	49,908	(3,484)
Effect of global intangible low taxed income	85,522	2,554	101,642	66,182
Change in valuation allowance	415,449	716,442	1,097,900	2,367,633
Other, net	53,872	(1,025)	54,094	(23,887)
Income tax expense (benefit)	$ 240,502	$ (458)	$ 30,619	$ 117,207

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

	June 30, 2020	September 30, 2019
Deferred tax assets:		
Federal net operating loss carryforwards	$ 8,854,855	$ 8,971,569
State net operating loss carryforwards	1,686,902	1,689,536
Foreign net operating loss carryforwards – U.K.	10,600,648	10,486,476
Foreign capital allowance – U.K.	103,400	103,400
Share-based compensation	1,116,240	804,378
Interest expense	757,141	—
Other, net – U.K.	50,781	50,781
Other, net – U.S.	592,237	434,764
Gross deferred tax assets	23,762,204	22,540,904
Valuation allowance for deferred tax assets	(10,928,109)	(9,830,209)
Net deferred tax assets	12,834,095	12,710,695
Deferred tax liabilities:		
In-process research and development	(4,072,740)	(4,072,740)
Developed technology	(383,092)	(424,657)
Covenant not-to-compete	(53,872)	(65,993)
Other, net – Malaysia	17,251	(3,865)
Other, net – U.S.	(6,376)	(6,376)
Net deferred tax liabilities	(4,498,829)	(4,573,631)
Net deferred tax asset	$ 8,335,266	$ 8,137,064

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

	June 30, 2020	September 30, 2019
Deferred tax asset – U.K.	$ 8,610,759	$ 8,433,669
Deferred tax asset – Malaysia	17,247	—
Total deferred tax asset	$ 8,628,006	$ 8,433,669
Deferred tax liability – U.S.	$ (292,740)	$ (292,740)
Deferred tax liability – Malaysia	—	(3,865)
Total deferred tax liability	$ (292,740)	$ (296,605)

Note 14 – Paycheck Protection Program

The CARES Act established the Paycheck Protection Program (PPP), which authorizes forgivable loans to small businesses. Pursuant to the CARES Act, the PPP loan 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. During the three-month period ended June 30, 2020, the Company expended the funds received under the PPP in full on qualifying expenses, and maintained the conditions set forth by the CARES Act. The Company, given its use of the funds, believes it is probable that the PPP loan will be forgiven. 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 statement of operations for the three and nine months ended June 30, 2020.

The Company does not anticipate taking any action that would cause any portion of the PPP loan to be ineligible for forgiveness. However, to the extent that any amount is deemed unforgivable, such amount is payable over two years at an interest rate of 1% per annum, with a deferral of payments for the first six months.

Note 15 – Net Loss Per Share

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing net income by the weighted average number of common shares outstanding during the period after giving effect to all dilutive potential common shares that were outstanding during the period. Dilutive potential common shares consist of the incremental common shares issuable upon the exercise of stock options, stock appreciation rights and warrants, and the vesting of unvested restricted stock and restricted stock units. Due to our net loss for the periods presented, all potentially dilutive instruments were excluded because their inclusion would have been anti-dilutive. See Notes 9 and 10 for a discussion of our dilutive potential common shares.

Note 16 – Industry Segments

The Company currently operates in two reporting segments: Commercial and Research and Development. The Commercial segment consists of FC2 and PREBOOST®. The Research and Development segment consists of multiple drug products under clinical development for oncology and urology. 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 income (loss) by segment is as follows:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2020	2019	2020	2019
Commercial	$ 5,619,168	$ 5,263,796	$ 17,608,972	$ 11,424,718
Research and development	(4,436,496)	(4,853,344)	(13,549,652)	(10,103,528)
Corporate	(2,575,524)	(2,252,454)	(7,536,243)	(6,299,509)
Operating loss	$ (1,392,852)	$ (1,842,002)	$ (3,476,923)	$ (4,978,319)

All of our net revenues, which are primarily derived from the sale of FC2, are attributed to our Commercial 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 Commercial segment. 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 Inc. is an oncology and urology biopharmaceutical company with a focus on developing novel medicines for the management of prostate cancer.

The Company's prostate cancer pipeline includes VERU-111, VERU-100 and Zuclomiphene Citrate.

VERU-111 is an oral, first-in-class, new chemical entity that targets, crosslinks, and disrupts alpha and beta tubulin subunits of microtubules. VERU-111 is being evaluated in an open label Phase 1b and Phase 2 clinical study in men with metastatic castration and androgen-blocking agent resistant prostate cancer. The Phase 1b clinical study completed enrollment of 39 men and is ongoing. The Phase 2 clinical study is enrolling approximately 39 men who have metastatic castration resistant prostate cancer and who have also become resistant to novel androgen blocking agents, such as abiraterone or enzalutamide, but prior to proceeding to IV chemotherapy. VERU-111 is also being evaluated in a Phase 2 clinical trial to assess the efficacy of VERU-111 in combating COVID-19. Drugs like VERU-111 that target microtubules have broad antiviral activity by disrupting the intracellular transport of viruses such as SARS CoV-2, along microtubules. Microtubule trafficking is critical for viruses to cause infection. Furthermore, microtubule depolymerization agents that target alpha and beta tubulin subunits of microtubules also have strong anti-inflammatory effects including the potential to treat the cytokine release syndrome (cytokine storm) induced by the SARS-CoV-2 viral infection that seems to be associated with high COVID-19 mortality rates. The Company applied for grant funding through both The Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services (BARDA) and The Defense Advanced Research Projects Agency of the U.S. Department of Defense (DARPA) to expedite the clinical development program of VERU-111 for COVID-19. Both applications were not accepted because data from the Phase 2 clinical trial are not yet available. If the clinical results of the Phase 2 clinical trial are positive, the Company intends to reapply for grant funding through BARDA and DARPA. There can be no assurances that any such grant funding will be provided.

VERU-100 is a novel, proprietary peptide formulation designed to address the current limitations of commercially available androgen deprivation therapies (ADT) for advanced prostate cancer. VERU-100 is a long-acting gonadotropin-releasing hormone (GnRH) antagonist administered as a small volume, subcutaneous 3-month depot injection without a loading dose. VERU-100 immediately suppresses testosterone with no testosterone surge upon initial or repeated administration --- a problem which occurs with currently approved luteinizing hormone-releasing hormone (LHRH) agonists used for ADT. There are no GnRH antagonist depot formulations commercially approved beyond a one-month duration injection. A Phase 2 study to evaluate VERU-100 dosing is anticipated to begin in the fourth quarter of calendar year 2020.

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 is also advancing new drug formulations in its specialty pharmaceutical pipeline addressing unmet medical needs in urology such as TADFIN® for the administration of tadalafil 5mg and finasteride 5mg combination formulation dosed daily to treat urinary tract symptoms caused by benign prostatic hyperplasia (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 by finasteride alone. The Company had a successful pre-NDA meeting with the FDA and the expected submission of the NDA for TADFIN® is the fourth quarter of calendar year 2020 or early 2021. The Company is also developing a Tamsulosin XR formulation, which is a formulation of tamsulosin, the active ingredient in FLOMAX®, that the Company has designed to avoid the "food effect" inherent in currently marketed versions of the drug, allowing for potentially safer administration and improved patient compliance.

The Company's commercial products include FC2, an FDA-approved product for the dual protection against unintended pregnancy and sexually transmitted infections, and the PREBOOST® 4% benzocaine medicated individual wipe for the treatment of premature ejaculation. The Company's Female Health Company Division markets and sells FC2 commercially and in the public health sector both in the U.S. and globally. In the U.S., FC2 is available by prescription through the Company's multiple telemedicine and internet pharmacy partners and 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. PREBOOST® is marketed online in the U.S. through a marketing arrangement under the Roman® Swipes brand name by Roman Health Ventures Inc. Roman is a leading telemedicine company that sells men's health products via the internet website www.getroman.com.

In October 2016, we completed our acquisition of Aspen Park Pharmaceuticals (the "APP Acquisition"). Prior to the completion of the APP Acquisition, the Company had been a single product company, focused on manufacturing, marketing and selling FC2 in the public health sector. Most of the Company's net revenues are currently derived from sales of FC2 in the public health and commercial sectors.

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 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 maydelay 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.

The Phase 1b portion of our ongoing VERU-111 clinical trial is fully enrolled. As for the Phase 2 portion of the VERU-111 clinical trial, discontinuation would disrupt treatment of patients' advanced prostate cancer. Therefore, the VERU-111 Phase 2 study for metastatic castration resistant prostate cancer is currently enrolling as planned. However, there is a risk that changing circumstances relating to the COVID-19 pandemic may not allow our healthcare clinical trial investigators, their healthcare facilities, or other necessary parties to continue to participate in these trials through completion.

COVID-19 has had, and will likely continue to have, an impact on our operations. 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 continued social distancing requirements on May 4, 2020. The Company has had a sufficient quantity of FC2 outside of Malaysia to continue to satisfy customer demand, and with the facility reopening the Company does not expect to have issues with supply of FC2. The Company has adopted measures 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, andif the Company's Malaysian manufacturing facility 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 has recently been prioritizing production of surgical gloves 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 limited capacity, and the Company may also encounter issues shipping product into key markets or through freight or other carriers. The COVID-19 pandemic and related economic disruption may also adversely affect customer demand for FC2 and PREBOOST. For example, sales of FC2 could be impacted in the U.S. prescription market 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. During the quarter ended June 30, 2020, the COVID-19 pandemic did not have a material net impact on our consolidated operating results.

To protect the health and safety of our workforce, we have closed our offices in the United States and the United Kingdom and our personnel have 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. 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 more clear.

Sales of FC2 in the public health and commercial sectors

FC2 Public Health Sector. FC2's use is for the prevention of HIV/AIDS and other sexually transmitted diseases and family planning, and the global public health sector has been the Company's main 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 unwanted 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 either through UNFPA or 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 WHO, 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 Company began shipping units under this tender award in the third quarter of fiscal 2019.

The Company classified approximately $0.8 million and $0.3 million of trade receivables with its distributor in Brazil as long-term as of June 30, 2020 and September 30, 2019, respectively, because payment was expected in greater than one year.

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 Patient Protection and Affordable Care Act (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 partnering with fast-growing, highly reputable telemedicine firms (telemedicine being the remote diagnosis and treatment of patients by means of telecommunications technology) 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 Unit Sales. Details of the quarterly unit sales of FC2 for the last five fiscal years are as follows:

Period	2020	2019	2018	2017	2016
October 1 — December 31	10,070,700	7,382,524	4,399,932	6,389,320	15,380,240
January 1 — March 31	6,884,472	9,792,584	4,125,032	4,549,020	9,163,855
April 1 — June 30	10,532,048	10,876,704	10,021,188	8,466,004	10,749,860
July 1 — September 30	—	9,842,020	6,755,124	6,854,868	6,690,080
Total	27,487,220	37,893,832	25,301,276	26,259,212	41,984,035

Revenues. The Company's revenues are primarily derived from sales of FC2 in the global public health sector and the U.S. prescription channel. Other revenues are from sales of PREBOOST® (Roman® Swipes). 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 global public health sector agencies who purchase and/or distribute FC2 for use in preventing the transmission of HIV/AIDS and/or family planning and, in the U.S., telemedicine providers who sell into the prescription channel.

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.

Conducting research and development is central to our business model. Since the completion of the APP Acquisition 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 $4.4 million and $4.9 million for the three months ended June 30, 2020 and 2019, respectively. Our research and development expenses were $13.7 million and $10.1 million for the nine months ended June 30, 2020 and 2019, 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, 2020 COMPARED TO THREE MONTHS ENDED JUNE 30, 2019

The Company generated 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, compared to net revenues of $9.7 million and net loss of $2.8 million, or $(0.04) per basic and diluted common share, for the three months ended June 30, 2019. Net revenues increased 6% year over year.

FC2 net revenues represented 93% of total net revenues for the three months ended June 30, 2020. FC2 net revenues increased 4% year over year. There was a 3% decrease in total FC2 unit sales and an increase in FC2 average sales price per unit of 7%. The principal factor for the increase in the FC2 average sales price per unit compared to prior year was the increase in net revenues in the U.S. prescription channel. The Company experienced an increase of 23% in FC2 net revenues in the U.S. prescription channel and a decrease of 13% in FC2 net revenues in the global public health sector.

Cost of sales increased to $3.8 million in the three months ended June 30, 2020 from $3.2 million in the three months ended June 30, 2019 primarily due to an increase in labor and equipment maintenance costs and increased period costs 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.

Gross profit decreased slightly to $6.5 million in the three months ended June 30, 2020 from $6.6 million in the three months ended June 30, 2019. Gross profit margin for the 2020 period was 63% of net revenues, compared to 68% of net revenues for the 2019 period. The decrease in the gross profit margin is primarily due to an increase in labor and equipment maintenance costs and increased period costs 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.

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 decreased to $4.4 million in the three months ended June 30, 2020 from $4.9 million in the same period in fiscal 2019. The decrease is primarily due to the timing of costs associated with the in-process research and development projects and a reduction of payroll-related expenses due to the funds received under the Paycheck Protection Program of $0.1 million (see discussion below).

Selling, general and administrative expenses remained consistent at $3.5 million in the three months ended June 30, 2020 compared to the three months ended June 30, 2019, after taking into account the reduction in expenses of $0.4 million due to the funds received under the Paycheck Protection Program (see discussion below).

Interest expense, which consists of items related to the Credit Agreement and Residual Royalty Agreement, was $1.2 million in the three months ended June 30, 2020, which is comparable with $1.1 million in the three months ended June 30, 2019.

Expense associated with the change in fair value of the embedded derivatives related to the Credit Agreement and Residual Royalty Agreement was $0.2 million in the three months ended June 30, 2020 compared to income of $0.2 million in the three months ended June 30, 2019. The liabilities associated with embedded derivatives represent the fair value of the change of control provisions in the Credit Agreement and Residual Royalty Agreement. See Note 3 and Note 8 to the financial statements included in this report for additional information.

Income tax expense in the third quarter of fiscal 2020 was $0.2 million, compared to income tax benefit of $458 in the third quarter of fiscal 2019. The increase in the income tax expense of $0.2 million is primarily due to a decrease in the state income tax benefit of $93,000 related to the reduction in the overall effective state income tax rate, an increase of $0.1 million in global intangible low taxed income and an increase of $0.3 million in non-deductible expenses, partially offset by a decrease in the change in the valuation allowance of $0.3 million.

NINE MONTHS ENDED JUNE 30, 2020 COMPARED TO NINE MONTHS ENDED JUNE 30, 2019

The Company generated 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, compared to net revenues of $23.1 million and net loss of $9.0 million, or $(0.14) per basic and diluted common share, for the nine months ended June 30, 2019. Net revenues increased 34% year over year.

FC2 net revenues represented 96% of total net revenues for the nine months ended June 30, 2020. FC2 net revenues increased 32% year over year. There was a 2% decrease in total FC2 unit sales and an increase in FC2 average sales price per unit of 35%. The principal factor for the increase in the FC2 average sales price per unit compared to prior year was the increase in net revenues in the U.S. prescription channel. The Company experienced an increase in FC2 net revenues of 95% in the U.S. prescription channel and a decrease of 14% in FC2 net revenues in the global public health sector.

Cost of sales increased to $9.6 million in the nine months ended June 30, 2020 from $7.3 million in the nine months ended June 30, 2019 primarily due to an increase in labor, transportation, and equipment maintenance costs and increased period costs 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.

Gross profit increased to $21.2 million in the nine months ended June 30, 2020 from $15.8 million in the nine months ended June 30, 2019. The increase in net revenues in the U.S. prescription channel was offset by the increase in labor, transportation, and equipment maintenance costs and increased period costs 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. As a result, gross profit margin for the fiscal 2020 period was 69% of net revenues, which is unchanged from the fiscal 2019 period

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 $13.7 million in the nine months ended June 30, 2020 from $10.1 million in the same period in fiscal 2019. The increase is primarily due to increased costs associated with the in-process research and development projects and increased personnel costs.

Selling, general and administrative expenses increased to $11.0 million in the nine months ended June 30, 2020 from $10.7 million in the nine months ended June 30, 2019. The increase is primarily due to increased personnel, personnel costs, and related benefits.

Interest expense, which consists of items related to the Credit Agreement and Residual Royalty Agreement, was $3.5 million in the nine months ended June 30, 2020, which is comparable with $3.6 million in the nine months ended June 30, 2019.

Expense associated with the change in fair value of the embedded derivatives related to the Credit Agreement and Residual Royalty Agreement was $94,000 in the nine months ended June 30, 2020 compared to expense of $0.2 million in the nine months ended June 30, 2019. The liabilities associated with embedded derivatives represent the fair value of the change of control provisions in the Credit Agreement and Residual Royalty Agreement. See Note 3 and Note 8 to the financial statements included in this report for additional information.

Income tax expense in the first nine months of fiscal 2020 was $31,000, compared to income tax expense of $0.1 million in the first nine months of fiscal 2019. The decrease in the income tax expense of $87,000 is primarily due to a decrease in the change in the valuation allowance of $1.3 million, partially offset by a decrease in the income tax benefit of $0.7 million related to the decrease in the loss before income taxes during the current period and an increase of $0.3 million in non-deductible expenses.

Liquidity and Sources of Capital

Liquidity

Our cash on hand at June 30, 2020was $15.4 million, compared to $6.3 million at September 30, 2019.At June 30, 2020, the Company had working capital of $9.5 million and stockholders' equity of $41.3 million compared to working capital of $2.8 million and stockholders' equity of $32.3 million as of September 30, 2019. The increase in working capital is primarily due to the increase in cash on hand partially offset by an increase in the current portion of the Credit Agreement and Residual Royalty Agreement liabilities and the recognition of a current liability for operating leases as a result of the Company's adoption of the new lease accounting standard, as described in Note 1 to the financial statements included in this report.

We have incurred quarterly operating losses since the fourth quarter of fiscal 2016 and anticipate that we will continue to consume cash and incur substantial net losses as we develop our drug candidates. Because of the numerous risks and uncertainties associated with the development of pharmaceutical products, we are unable to estimate the exact amounts of capital outlays and operating expenditures necessary to fund development of our drug candidates and obtain regulatory approvals. Our future capital requirements will depend on many factors. See Part II, Item 1A of this Form 10-Q and Part I, Item 1A, "Risk Factors - Risks Related to Our Financial Position and Need for Capital" in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2019, for a description of certain risks that will affect our future capital requirements.

The Company believes its current cash position, cash expected to be generated from sales of the Company's commercial products, and its ability to secure equity financing or other financing alternatives are adequate to fund planned operations of the Company for the next 12 months. Such financing alternatives may include debt financing, common stock offerings, or financing involving convertible debt or other equity-linked securities and may include financings under the Company's current effective shelf registration statement on Form S-3 (File No. 333-239493). The Company intends to be opportunistic when pursuing equity or debt financing which could include selling common stock under the 2020 Purchase Agreement with Aspire Capital (see discussion below). See Part II, Item 1A of this Form 10-Q and Part I, Item 1A, "Risk Factors - Risks Related to Our Financial Position and Need for Capital" in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2019, for a description of certain risks related to our ability to raise capital on acceptable terms.

Operating activities

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 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.

Our operating activities used cash of $4.5 million in the nine months ended June 30, 2019. Cash used in operating activities included a net loss of $9.0 million, adjustments for noncash items totaling $5.9 million and changes in operating assets and liabilities of $1.5 million. Adjustments for noncash items primarily consisted of $3.6 million of noncash interest expense related to the Credit Agreement and Residual Royalty Agreement and $1.4 million of share-based compensation. The decrease in cash from changes in operating assets and liabilities included an increase in accounts receivable of $0.8 million and an increase in inventories of $0.9 million. These were partially offset by an increase in accrued expenses and other current liabilities of $0.6 million.

Investing activities

Net cash used in investing activities was $73,000 and $75,000 in the nine months ended June 30, 2020 and 2019, respectively, and was primarily 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 30,2020 was $10.8 million and consisted of $13.4 million from the sale of shares under the 2020 Purchase Agreement and 2017 Purchase Agreement with Aspire Capital (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.

Net cash provided by financing activities in the nine months ended June 30, 2019was $8.9 million and consisted of net proceeds from the underwritten public offering of the Company's common stock of $9.1 million (see discussion below) and $3.6 million from the sale of shares under the 2017 Purchase Agreement with Aspire Capital (see discussion below), less payments on the Credit Agreement (see discussion below) totaling $4.0 million.

Sources of Capital

Common Stock Offering

On October 1, 2018, we completed an underwritten public offering of 7,142,857 shares of our common stock, at a public offering price of $1.40 per share. Net proceeds to the Company from this offering were $9.1 million after deducting underwriting discounts and commissions and costs paid by the Company. All the shares sold in the offering were by the Company. The offering was made pursuant to the Company's 2017 shelf registration statement on Form S-3 (File No. 333-221120).

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 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 $3.3 million and $4.0 million during the nine months ended June 30, 2020 and 2019, 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, 2020 will be approximately $8.2 million under the Credit Agreement. The Company also estimates that it will begin making payments under the Residual Royalty Agreement during the 12-month period subsequent to June 30, 2020, and estimates such payments within that period to be approximately $0.4 million.

Aspire Capital Purchase Agreements

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.

Effective June 26, 2020, upon the execution of the 2020 Purchase Agreement, the 2017 Purchase Agreement with Aspire Capital was terminated. Under the 2017 Purchase Agreement, the Company had the right, from time to time and in its sole discretion during the 36-month term of the 2017 Purchase Agreement, to direct Aspire Capital to purchase up to $15.0 million of the Company's common stock in the aggregate. As of the date of termination of the 2017 Purchase Agreement, the Company sold a total of 6,214,343 shares of common stock to Aspire Capital under the 2017 Purchase Agreement for aggregate proceeds of $15.0 million. During the nine months ended June 30, 2020, the Company sold 2,497,333 shares of common stock to Aspire Capital under the 2017 Purchase Agreement resulting in proceeds to the Company of $8.4 million.

U.S. Small Business Administration's Paycheck Protection Program

In April 2020, the Company was approved for a loan under the U.S. Small Business Administration's (the "SBA") Paycheck Protection Program established by the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") in the amount of $0.5 million (the "PPP Loan"). The PPP Loan proceeds were received on April 20, 2020. The PPP Loan has a maturity of two years and bears interest at an annual rate of 1%. Payments on the PPP Loan are deferred for six months. Pursuant to the CARES Act, the PPP Loan 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. As of the date of this report, the Company has not terminated any employees in the U.S. due to the COVID-19 pandemic. The Company expended the funds received under the PPP Loan in full on qualifying expenses, and maintained the conditions set forth by the CARES Act. The Company does not anticipate taking any action that would cause any portion of the PPP Loan to be ineligible for forgiveness. However, to the extent that any amount is deemed unforgivable, such amount is payable over two years at an interest rate of 1% per annum, with a deferral of payments for the first six months.

Fair Value Measurements

As of June 30, 2020 and September 30, 2019, 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, expected cash outflows, expected repayment dates, probability of a change of control, expected volatility, and risk-free interest rates. 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, 2019. There have been no material changes to such exposures since September 30, 2019.

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, 2019. 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, 2019, except for the following additional risk factors. Additional risks that we do not yet know of or that we currently think are immaterial may also impair our business operations, and there is significant uncertainty regarding the COVID-19 pandemic and its impact on the economic environment and our business which could affect the risk factors set forth below and in the Form 10-K.

Due to the COVID-19 pandemic, we may find it difficultto effectively recruit new clinical trial patients in a timely manner and to partner with clinical trial investigators and sites, which could delay or prevent us from proceeding with, or otherwise adversely affect, clinical trials of our drug candidates.

Identifying and qualifying patients to participate in, and partnering with investigators and sites to run, clinical trials of our drug candidates is critical to the timely completion of our clinical trials. Patients may be unwilling to participate in our clinical trials because of the ongoing COVID-19 pandemic. The severe burden on healthcare systems caused by the COVID-19 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.

There is a risk that changing circumstances relating to the COVID-19 pandemic may not allow our healthcare clinical trial investigators, their healthcare facilities or other necessary parties to continue to participate in our clinical trials through completion or may delay the initiation of planned clinical trials. Any delays related to clinical trials could result in increased costs, delays in advancing our drug candidates, delays in testing the effectiveness of our drug candidates or termination of the clinical trials altogether.

Disruptions at the FDA caused by the COVID-19 pandemic could delay or prevent new drugs from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent the FDA from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

Disruptions at the FDA caused by the COVID-19 pandemic may slow the time necessary for new drugs to be reviewed and/or approved, which would adversely affect our business. In response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products through April 2020. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. The FDA has also prioritized the review of submissions relating to COVID-19. The FDA may adopt other restrictions or policy measures in response to the COVID-19 pandemic or issue guidance materially affecting the conduct of clinical trials. If global health concerns continue to prevent the FDA from conducting its regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

The COVID-19 pandemic has disrupted, and may continue to disrupt, our operations and the operations of our suppliers and customers.

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. The outbreak and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen.

If COVID-19 continues to spread and to affect economic activity in the United States and other markets in which we conduct business, we may experience disruptions that could severely impact our business, including:

- if our Malaysian manufacturing facility is closed again our ability to supply product to our customers could be disrupted;
- we may encounter labor or raw material shortages, transportation delays or other issues at our Malaysian manufacturing facility or to our various customers;
- our personnel may not be able to travel between our facilities in the United States, the United Kingdom and Malaysia, which may impact our ability to effectively oversee our international operations;
- customer demand for FC2 and PREBOOST may be adversely affected, including with respect to FC2 in the U.S. prescription market 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;
- our customers, including in the global public health sector, may reduce orders or delay paying their accounts receivable balances due to liquidity issues, spending priorities or other issues related to the COVID-19 pandemic;
- there may be limitations in employee resources, potentially including key executives, because of sickness of employees or their families or the desire of employees to avoid contact;
- we may face delays in receiving approval from the FDA or other applicable regulatory authorities in connection with our clinical trials;
- there may be delays or difficulties in enrolling patients in our clinical trials or in recruiting clinical site investigators and staff;
- there may be delays in clinical sitesreceiving the supplies and materials needed to conduct our clinical trials, including delays or interruptions in manufacturing and interruption in shipping;
- there may be changes in local regulations as part of a response to the COVID-19 outbreak which may require us to change the ways in which our clinical trials are conducted, to incur unexpected costs, or to discontinue the clinical trials altogether;
- healthcare resources may be diverted away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- key clinical trial activities may be interrupted, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or the clinical research organizations or clinical trial sites' own risks related to the COVID-19 outbreak, which could affect the integrity of clinical data or the conduct of the trial;
- participants enrolled in our clinical trials could acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- necessary interactions with local regulators, ethics committees and other important agencies and contractors may be delayed due to limitations in employee resources or forced furlough of government employees; and
- the FDA may refuse to accept data from clinical trials in affected geographies.

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. We do not yet know the full extent of any impact on our business or our operations, and it is possible that its effect on our business and operations will significantly worsen in the future.

COVID-19 and its impact on the economic environment and capital markets could adversely affect our access to capital when needed.

We expect to incur significant expenditures over the next several years to support our preclinical and clinical development activities, particularly with respect to clinical trials for certain of our drug candidates and to commence the commercialization of our drug candidates. Market volatility resulting from the COVID-19 pandemic or other factors could adversely affect our ability to access capital as and when needed and could also adversely affect the terms of a financing. If sales of FC2 decline due to the current economic environment, supply constraints or other issues, we may need additional financing to make up for reduced cash flows from our FC2 business. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate some of our research and development activities or we may be unable to take advantage of future business opportunities.

Our pursuit of a COVID-19 treatment candidate is at an early stage. We may be unable to produce a drug that successfully treats the virus in a timely manner, if at all.

In May 2020, we announced that we have received FDA permission to initiate a Phase 2 clinical trial to assess the efficacy of VERU-111, a microtubule depolymerization agent, in combating COVID-19. Our development of a COVID-19 treatment is in its early stages, and we may be unable to produce a drug that successfully treats the virus in a timely manner, if at all. We are also committing 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 surrounding the longevity and extent of coronavirus as a global health concern. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our treatment, if developed, may not be partially or fully effective. In addition, conducting a clinical trial of a COVID-19 treatment is challenging in the current environment due to a number of factors, including a large number of competitive clinical trials seeking to enroll COVID-19 patients, the high workload of hospital staff, and the difficulty of enrolling patients in intensive care or similar environments. These challenges may delay the clinical trial, increase its costs or otherwise adversely affect the clinical trial.

Government entities may take actions that directly or indirectly have the effect of limiting opportunitiesfor VERU-111 as a COVID-19 treatment.

Various government entities, including the U.S. government, are offering incentives, grants and contracts to encourage additional investment by commercial organizations into preventative and therapeutic agents against COVID-19, which may have the effect of increasing the number of competitors and/or providing advantages to competitors. Accordingly, there can be no assurance that we will be able to successfully establish a competitive market share if we develop a COVID-19 treatment. COVID-19 treatments may also be subject to government pricing controls, which could adversely affect the profitability of any COVID-19 treatment we are able to develop and commercialize.

We may not be entitled to forgiveness of our recently received PPP Loan, and our application for the PPP Loan could in the future be determined to have been impermissible or could result in damage to our reputation.

In April 2020, we received proceeds of approximately $540,000 from a loan under the Paycheck Protection Program of the CARES Act, a portion of which may be forgiven, which we intend to use to retain employees, maintain payroll and make lease and utility payments. The PPP Loan matures in April 2022 and bears interest at an annual rate of 1.0%. Commencing in November 2020, we are required to pay the lender equal monthly payments of principal and interest as required to fully amortize by April 2022 any principal amount outstanding on the PPP Loan as of October 2020. A portion of the PPP Loan may be forgiven by the SBA upon our application and upon documentation of expenditures in accordance with the SBA requirements. Under the CARES Act, loan forgiveness is available for the sum of documented payroll costs, covered rent payments, covered mortgage interest and covered utilities during the eight-week period beginning on the date of loan approval. Not more than 25% of the forgiven amount may be for non-payroll costs. The amount of the PPP Loan eligible to be forgiven is reduced if our full-time headcount declines or if salaries and wages for employees with salaries of $100,000 or less annually are reduced by more than 25%. We will be required to repay any portion of the outstanding principal that is not forgiven, along with accrued interest, in accordance with the amortization schedule described above, and we cannot provide any assurance that we will be eligible for loan forgiveness or that any amount of the PPP Loan will ultimately be forgiven by the SBA.

In order to apply for the PPP Loan, we were required to certify, among other things, that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. We made this certification in good faith after analyzing, among other things, our financial situation and access to alternative forms of capital, and believe that we satisfied all eligibility criteria for the PPP Loan, and that our receipt of the PPP Loan is consistent with the broad objectives of the Paycheck Protection Program of the CARES Act. The certification described above does not contain any objective criteria and is subject to interpretation. However, on April 23, 2020, the SBA issued guidance stating that it is unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith. The lack of clarity regarding loan eligibility under the Paycheck Protection Program has resulted in significant media coverage and controversy with respect to public companies applying for and receiving loans. If, despite our good-faith belief that we satisfied all eligible requirements for the PPP Loan, we are later determined to have violated any of the laws or governmental regulations that apply to us in connection with the PPP Loan, such as the False Claims Act, or it is otherwise determined that we were ineligible to receive the PPP Loan, we may be subject to penalties, including significant civil, criminal and administrative penalties, or damages or could be required to repay the PPP Loan in its entirety. In addition, our receipt of the PPP Loan may result in adverse publicity and damage to our reputation, and a review or audit by the SBA or other government entity or claims under the False Claims Act could consume significant financial and management resources.

Item 5. Other Information

Disclosure Pursuant to Item 5.02 of Form 8-K - Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers

On August 11, 2020, the Company's Board of Directors (the “Board”) approved an increase in the number of directors constituting the Board from five to six directors and, following the recommendation of the Board's Nominating and Corporate Governance Committee, appointed Grace Hyun, M.D. to fill the vacancy created thereby. Dr. Hyun has not been appointed to any committee of the Board at this time.

The Board has determined that Dr. Hyun is “independent” as defined under the listing standards of the NASDAQ Stock Market. There are no arrangements or understandings between Dr. Hyun and any other person pursuant to which she was appointed as a director. There are no transactions in which Dr. Hyun has an interest requiring disclosure under Item 404(a) of Regulation S-K of the Securities Act of 1933, as amended.

Item 6. Exhibits

Exhibit Number	Description
3.1	Amended and Restated Articles of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Form SB-2 Registration Statement (File No. 333-89273) filed with the SEC on October 19, 1999).
3.2	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 27,000,000 shares (incorporated by reference to Exhibit 3.2 to the Company's Form SB-2 Registration Statement (File No. 333-46314) filed with the SEC on September 21, 2000).
3.3	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 35,500,000 shares (incorporated by reference to Exhibit 3.3 to the Company's Form SB-2 Registration Statement (File No. 333-99285) filed with the SEC on September 6, 2002).
3.4	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 38,500,000 shares (incorporated by reference to Exhibit 3.4 to the Company's Form 10-QSB (File No. 1-13602) filed with the SEC on May 15, 2003).
3.5	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company designating the terms and preferences for the Class A Preferred Stock – Series 3 (incorporated by reference to Exhibit 3.5 to the Company's Form 10-QSB (File No. 1-13602) filed with the SEC on May 17, 2004).
3.6	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company designating the terms and preferences for the Class A Preferred Stock – Series 4 (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on November 2, 2016).
3.7	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company changing the corporate name to Veru Inc. and increasing the number of authorized shares of common stock to 77,000,000 shares (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on August 1, 2017).
3.8	Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 154,000,000 shares (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on March 29, 2019).
3.9	Amended and Restated By-Laws (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on May 4, 2018).
4.1	Amended and Restated Articles of Incorporation, as amended (same as Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7 and 3.8).
4.2	Articles II, VII and XI of the Amended and Restated By-Laws (included in Exhibit 3.9).
10.1	Common Stock Purchase Agreement, dated as of June 26, 2020, between the Company and Aspire Capital Fund, LLC (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on June 26, 2020).

10.2	Registration Rights Agreement, dated as of June 26, 2020, between the Company and Aspire Capital Fund, LLC (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on June 26, 2020).
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 endedJune 30, 2020, formatted in XBRL (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.

* 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 13, 2020

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

DATE: August 13, 2020

/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 13, 2020

/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 13, 2020

/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, 2020 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 13, 2020

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

Date: August 13, 2020

/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.