

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

CEL SCI CORP

Form: 10-Q

Date Filed: 2019-05-14

Corporate Issuer CIK: 725363

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

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 (d) OF
THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2019

OR

☐ 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 001-11889

CEL-SCI CORPORATION

Colorado

State or other jurisdiction incorporation

84-0916344

(IRS) Employer Identification Number

8229 Boone Boulevard, Suite 802

Vienna, Virginia 22182

Address of principal executive offices

(703) 506-9460

Registrant's telephone number, including area code

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) had been subject to such filing requirements for the past 90 days.

Yes ☒

No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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. (Check One):

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 defined in Exchange Act Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Class of Stock

No. Shares Outstanding

Date

Common

33,702,852

May 9, 2019

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	CVM	NYSE American

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CEL-SCI CORPORATION
CONDENSED BALANCE SHEETS
(UNAUDITED)

	MARCH 31, 2019	SEPTEMBER 30, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 5,514,013	\$ 10,310,044
Receivables	123,236	118,657
Prepaid expenses	355,948	364,622
Inventory used for R&D and manufacturing	761,012	645,238
Total current assets	6,754,209	11,438,561
Plant, property and equipment, net	16,086,828	16,218,851
Patent costs, net	243,253	258,093
Deposits	1,670,917	1,670,917
Total Assets	<u>\$ 24,755,207</u>	<u>\$ 29,586,422</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 4,158,732	\$ 5,743,913
Accrued expenses	287,890	205,310
Due to employees	1,010,015	764,941
Derivative instruments, current portion	-	2,498,606
Other current liabilities	13,984	14,029
Total current liabilities	5,470,621	9,226,799
Derivative instruments, net of current portion	4,727,929	6,818,458
Lease liability	13,444,394	13,379,962
Deferred income	126,849	126,795
Other liabilities	29,892	33,492
Total liabilities	23,799,685	29,585,506
Commitments and Contingencies		
STOCKHOLDERS' EQUITY		
Preferred stock, \$.01 par value-200,000 shares authorized; -0- shares issued and outstanding	-	-
Common stock, \$.01 par value - 600,000,000 shares authorized; 29,951,628 and 28,034,487 shares issued and outstanding at March 31, 2019 and September 30, 2018, respectively	299,517	280,346
Additional paid-in capital	337,449,398	331,312,184
Accumulated deficit	(336,793,393)	(331,591,614)
Total stockholders' equity	955,522	916
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 24,755,207</u>	<u>\$ 29,586,422</u>

See notes to condensed financial statements.

CEL-SCI CORPORATION
CONDENSED STATEMENTS OF OPERATIONS
SIX MONTHS ENDED MARCH 31, 2019 and 2018
(UNAUDITED)

	<u>2019</u>	<u>2018</u>
Grant income	\$ 277,183	\$ 210,586
Operating Expenses:		
Research and development	5,657,648	5,288,311
General & administrative	<u>3,960,597</u>	<u>4,074,723</u>
Total operating expenses	<u>9,618,245</u>	<u>9,363,034</u>
Operating loss	(9,341,062)	(9,152,448)
Other income	36,127	35,273
Gain on derivative instruments	4,589,135	196,585
Other non-operating gain (loss)	421,353	(22,109)
Interest expense, net	<u>(907,332)</u>	<u>(1,953,266)</u>
Net loss available to common shareholders	<u>\$ (5,201,779)</u>	<u>\$ (10,895,965)</u>
Net loss per common share		
BASIC	\$ (0.18)	\$ (0.81)
DILUTED	\$ (0.19)	\$ (0.81)
Weighted average common shares outstanding		
BASIC	28,543,417	13,403,878
DILUTED	28,548,818	13,403,878

See notes to condensed financial statements.

CEL-SCI CORPORATION
CONDENSED STATEMENTS OF OPERATIONS
THREE MONTHS ENDED MARCH 31, 2019 and 2018
(UNAUDITED)

	<u>2019</u>	<u>2018</u>
Grant income	\$ 150,769	\$ 114,271
Operating Expenses:		
Research and development	2,525,460	2,962,297
General & administrative	<u>1,931,909</u>	<u>1,375,410</u>
Total operating expenses	<u>4,457,369</u>	<u>4,337,707</u>
Operating loss	(4,306,600)	(4,223,436)
Other income	18,216	17,691
(Loss) gain on derivative instruments	(967,171)	1,154,815
Other non-operating loss	(730,823)	(768,810)
Interest expense, net	<u>(461,303)</u>	<u>(888,395)</u>
Net loss available to common shareholders	<u>\$ (6,447,681)</u>	<u>\$ (4,708,135)</u>
Net loss per common share		
BASIC	\$ (0.22)	\$ (0.31)
DILUTED	\$ (0.22)	\$ (0.31)
Weighted average common shares outstanding		
BASIC	29,113,910	15,210,296
DILUTED	29,113,910	15,210,296

See notes to condensed financial statements.

CEL-SCI CORPORATION
CONDENSED STATEMENTS OF CASH FLOWS
SIX MONTHS ENDED MARCH 31, 2019 and 2018
(UNAUDITED)

	2019	2018
Net loss	\$ (5,201,779)	\$ (10,895,965)
Adjustments to reconcile net income loss to net cash used in operating activities:		
Depreciation and amortization	316,083	308,259
Share-based payments for services	511,424	157,991
Equity based compensation	1,104,490	1,727,915
Common stock contributed to 401(k) plan	72,124	72,400
Shares issued for settlement of clinical research costs	1,290,000	1,247,400
Gain on derivative instruments	(4,589,135)	(196,585)
Amortization of debt discount	-	1,023,084
Capitalized lease interest	64,432	83,564
(Increase)/decrease in assets:		
Receivables	(4,579)	81,698
Prepaid expenses	(74,741)	42,748
Inventory used for R&D and manufacturing	(115,774)	42,211
Deposits	-	150,000
Increase/(decrease) in liabilities:		
Accounts payable	(1,489,234)	(541,767)
Accrued expenses	82,580	(33,966)
Due to employees	245,074	360,972
Other liabilities	(1,057)	2,638
Net cash used in operating activities	<u>(7,790,092)</u>	<u>(6,367,403)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of equipment	(160,920)	-
Expenditures for patent costs	<u>(67,661)</u>	<u>(1,113)</u>
Net cash used in investing activities	<u>(228,581)</u>	<u>(1,113)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock and warrants	-	7,127,141
Payments of stock issuance costs	(80,224)	(62,004)
Proceeds from exercises of warrants	3,305,387	-
Payments on obligations under capital lease	<u>(2,521)</u>	<u>(3,870)</u>
Net cash provided by financing activities	<u>3,222,642</u>	<u>7,061,267</u>
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(4,796,031)	692,751
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	<u>10,310,044</u>	<u>2,369,438</u>
CASH AND CASH EQUIVALENTS, END OF PERIOD	<u>\$ 5,514,013</u>	<u>\$ 3,062,189</u>

See notes to condensed financial statements.

CEL-SCI CORPORATION
CONDENSED STATEMENTS OF CASH FLOWS
SIX MONTHS ENDED MARCH 31, 2019 and 2018

SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:

	2019	2018
Capitalizable patent costs included in accounts payable	\$ -	\$ 8,137
Capital lease obligation included in accounts payable	\$ 428	\$ 402
Stock issuance costs included in accounts payable	\$ 10,000	\$ 68,374
Prepaid consulting services paid with issuance of common stock	\$ (83,415)	\$ 95,911
Notes payable converted into common shares	\$ -	\$ 184,300

Cash paid for interest expense	\$ 902,091	\$ 872,087
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See notes to condensed financial statements.

CEL-SCI CORPORATION
NOTES TO CONDENSED FINANCIAL STATEMENTS
THREE MONTHS ENDED MARCH 31, 2019 AND 2018 (UNAUDITED)

A. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed financial statements of CEL-SCI Corporation (the Company) are unaudited and certain information and footnote disclosures normally included in the annual financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been omitted pursuant to the rules and regulations of the Securities and Exchange Commission. While management of the Company believes that the disclosures presented are adequate to make the information presented not misleading, these interim condensed financial statements should be read in conjunction with the financial statements and notes included in the Company's annual report on Form 10-K for the year ended September 30, 2018.

In the opinion of management, the accompanying unaudited condensed financial statements contain all accruals and adjustments (each of which is of a normal recurring nature) necessary for a fair presentation of the Company's financial position as of March 31, 2019 and the results of its operations for the six and three months then ended. The condensed balance sheet as of September 30, 2018 is derived from the September 30, 2018 audited financial statements. Significant accounting policies have been consistently applied in the interim financial statements. The results of operations for the six and three months ended March 31, 2019 are not necessarily indicative of the results to be expected for the entire year.

The financial statements have been prepared assuming that the Company will continue as a going concern, but due to recurring losses from operations, which are expected for the foreseeable future, and future liquidity needs, there is substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Refer to discussion in Note B.

Summary of Significant Accounting Policies:

Research and Office Equipment and Leasehold Improvements – The leased manufacturing facility is recorded at total project costs incurred and is depreciated over the 20-year useful life of the building. Research and office equipment is recorded at cost and depreciated using the straight-line method over estimated useful lives of five to seven years. Leasehold improvements are depreciated over the shorter of the estimated useful life of the asset or the term of the lease. Repairs and maintenance which do not extend the life of the asset are expensed when incurred. The fixed assets are reviewed on a quarterly basis to determine if any of the assets are impaired.

Patents - Patent expenditures are capitalized and amortized using the straight-line method over the shorter of the expected useful life or the legal life of the patent (17 years). In the event changes in technology or other circumstances impair the value or life of the patent, appropriate adjustment in the asset value and period of amortization is made. An impairment loss is recognized when estimated future undiscounted cash flows expected to result from the use of the asset, and from its disposition, is less than the carrying value of the asset. The amount of the impairment loss would be the difference between the estimated fair value of the asset and its carrying value.

Research and Development Costs - Research and development costs are expensed as incurred. Management accrues Clinical Research Organization ("CRO") expenses and clinical trial study expenses based on services performed and relies on the CROs to provide estimates of those costs applicable to the completion stage of a study. Estimated accrued CRO costs are subject to revisions as such studies progress to completion. The Company charges revisions to estimated expense in the period in which the facts that give rise to the revision become known.

Income Taxes - The Company uses the asset and liability method of accounting for income taxes. Under the asset and liability method, deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating and tax loss carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Company records a valuation allowance to reduce the deferred tax assets to the amount that is more likely than not to be recognized. A full valuation allowance was recorded against the deferred tax assets as of March 31, 2019 and September 30, 2018.

On December 22, 2017, the "Tax Cuts and Jobs Act" (the "Tax Act"), was signed into law by the President of the United States (U.S.). The Tax Act includes significant changes to corporate taxation, including reduction of the U.S. corporate tax rate from 35% to 21%, effective January 1, 2018, limitation of the tax deduction for interest expense to 30% of earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks. The Company has accounted for the income tax effects of the Act in applying FASB ASC 740 to the current reporting period. Because the Company records a valuation allowance for its entire deferred income tax asset, there was no impact to the amounts reported in the Company's financial statements resulting from the Tax Act.

Derivative Instruments – The Company has entered into financing arrangements that consist of freestanding derivative instruments that contain embedded derivative features. The Company accounts for these arrangements in accordance with Accounting Standards Codification (ASC) 815, "Accounting for Derivative Instruments and Hedging Activities." In accordance with accounting principles generally accepted in the United States (U.S. GAAP), derivative instruments and hybrid instruments are recognized as either assets or liabilities in the balance sheet and are measured at fair value with gains or losses recognized in earnings or other comprehensive income depending on the nature of the derivative or hybrid instruments. The Company determines the fair value of derivative instruments and hybrid instruments based on available market data using appropriate valuation models giving consideration to all of the rights and obligations of each instrument. The derivative liabilities are re-measured at fair value at the end of each interim period.

Deferred Rent – Certain of the Company's operating leases provide for minimum annual payments that adjust over the life of the lease. The aggregate minimum annual payments are expensed on a straight-line basis over the minimum lease term. The Company recognizes a deferred rent liability for rent escalations when the amount of straight-line rent exceeds the lease payments, and reduces the deferred rent liability when the lease payments exceed the straight-line rent expense. For tenant improvement allowances and rent holidays, the Company records a deferred rent liability and amortizes the deferred rent over the lease term as a reduction to rent expense.

Leases – Leases are categorized as either operating or capital leases at inception. Operating lease costs are recognized on a straight-line basis over the term of the lease. An asset and a corresponding liability for the capital lease obligation are established for the cost of capital leases. The capital lease obligation is amortized over the life of the lease. For build-to-suit leases, the Company establishes an asset and liability for the estimated construction costs incurred to the extent that it is involved in the construction of structural improvements or takes construction risk prior to the commencement of the lease. Upon occupancy of facilities under build-to-suit leases, the Company assesses whether these arrangements qualify for sales recognition under the sale-leaseback accounting guidance. If a lease does not meet the criteria to qualify for a sale-leaseback transaction, the established asset and liability remain on the Company's balance sheet.

Stock-Based Compensation – Compensation cost for all stock-based awards is measured at fair value as of the grant date in accordance with the provisions of ASC 718 "Compensation – Stock Compensation." The fair value of stock options is calculated using the Black-Scholes option pricing model. The Black-Scholes model requires various judgmental assumptions including volatility and expected option life. The stock-based compensation cost is recognized on the straight-line allocation method as expense over the requisite service or vesting period.

Equity instruments issued to non-employees are accounted for in accordance with ASC 505-50, "Equity-Based Payments to Non-Employees." Accordingly, compensation is recognized when goods or services are received and is measured using the Black-Scholes valuation model. The Black-Scholes model requires various judgmental assumptions regarding the fair value of the equity instruments at the measurement date and the expected life of the options.

The Company has Incentive Stock Option Plans, Non-Qualified Stock Option Plans, a Stock Compensation Plan, Stock Bonus Plans and an Incentive Stock Bonus Plan. In some cases, these Plans are collectively referred to as the "Plans". All Plans have been approved by the stockholders.

The Company's stock options are not transferable, and the actual value of the stock options that an employee may realize, if any, will depend on the excess of the market price on the date of exercise over the exercise price. The Company has based its assumption for stock price volatility on the variance of daily closing prices of the Company's stock. The risk-free interest rate assumption was based on the U.S. Treasury rate at date of the grant with term equal to the expected life of the option. Forfeitures are accounted for when they occur. The expected term of options represents the period that options granted are expected to be outstanding and has been determined based on an analysis of historical exercise behavior. If any of the assumptions used in the Black-Scholes model change significantly, stock-based compensation expense for new awards may differ materially in the future from that recorded in the current period.

Vesting of restricted stock granted under the Incentive Stock Bonus Plan is subject to service, performance and market conditions and meets the classification of equity awards. These awards were measured at market value on the grant-dates for issuances where the attainment of performance criteria is likely and at fair value on the grant-dates, using a Monte Carlo simulation for issuances where the attainment of performance criteria is uncertain. The total compensation cost will be expensed over the estimated requisite service period.

New Accounting Pronouncements

In June 2018, the Financial Accounting Standards Board ("FASB") issued ASU 2018-07, *Compensation—Stock Compensation (Topic 718)*, ("ASU 2018-7"), which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost. Under current GAAP, non-employee share-based payment awards are measured at the fair value of the consideration received or the fair value of the equity instruments issued, whichever can be more reliably measured. Under ASU 2018-07, non-employee share-based payments would be measured at the grant-date fair value of the equity instruments an entity is obligated to issue when the good has been delivered or the service has been rendered and any other conditions necessary to earn the right to benefit from the instruments have been satisfied. Under current GAAP, the measurement date for equity classified non-employee share-based payment awards is the earlier of the date at which a commitment for performance by the counterparty is reached or the date at which the counterparty's performance is complete. Under ASU 2018-07, equity-classified nonemployee share-based payment awards are measured at the grant date. The definition of the term *grant date* is amended to generally state the date at which a *grantor* and a *grantee* reach a mutual understanding of the key terms and conditions of a share-based payment award. The amendments in this Update are effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. An entity should only remeasure liability-classified awards that have not been settled by the date of adoption and equity classified awards for which a measurement date has not been established through a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption. Upon transition, the entity is required to measure these non-employee awards at fair value as of the adoption date. The entity must not remeasure awards that are completed. The Company is currently evaluating the impact the adoption of the standard will have on the Company's financial position and results of operations.

In February 2016, the FASB issued ASU 2016-02, *Leases*, which will require most leases (except of leases with terms of less than one year) to be recognized on the balance sheet as an asset and a lease liability. Leases will be classified as an operating lease or a financing lease. Operating leases are expensed using the straight-line method whereas financing leases will be treated similarly to a capital lease under the current standard. The new standard will be effective for annual and interim periods, within those fiscal years, beginning after December 15, 2018, but early adoption is permitted. The new standard must be presented using the modified retrospective method beginning with the earliest comparative period presented. As permitted by the guidance, the Company has an option to retain the original lease classification and historical accounting for initial direct costs for leases existing prior to the adoption date. Furthermore, the Company will not have to reassess contracts entered into prior to the adoption date for the existence of a lease. The Company also has an option not to restate prior periods for the impact of the adoption of the new standard and may instead recognize a cumulative-effect adjustment to beginning retained earnings as of October 1, 2019 for any prior period income statement effects identified. The Company will evaluate the effect that adoption of this new standard will have on the Company's financial statements. The Company will evaluate the effect that adoption of this new standard on its financial statements and related disclosures.

The Company has considered all other recently issued accounting pronouncements and does not believe the adoption of such pronouncements will have a material impact on its financial statements.

B. OPERATIONS AND FINANCING

The Company has incurred significant costs since its inception for the acquisition of certain patented and unpatented proprietary technology and know-how relating to the human immunological defense system, patent applications, research and development, administrative costs, construction of laboratory facilities, and clinical trials. The Company has funded such costs with proceeds from loans and the public and private sale of its common stock. The Company will be required to raise additional capital or find additional long-term financing to continue with its research efforts. The ability to raise capital may be dependent upon market conditions that are outside the control of the Company. The ability of the Company to complete the necessary clinical trials and obtain FDA approval for the sale of products to be developed on a commercial basis is uncertain. Ultimately, the Company must complete the development of its products, obtain the appropriate regulatory approvals and obtain sufficient revenues to support its cost structure. The Company is taking cost-cutting initiatives, as well as exploring other sources of funding, to finance operations over the next 12 months. The Company believes that there is a high likelihood that it will continue to receive funds from warrant conversions in a way similar to the way it has substantial funds for the past 12 months. However, there can be no assurance that the Company will be able to raise sufficient capital to support its operations.

The Company is currently in the final stages of its large multi-national Phase 3 clinical trial for head and neck cancer with its partners TEVA Pharmaceuticals and Orient Europharma. To finance the study beyond the next twelve months, the Company plans to raise additional capital in the form of corporate partnerships, debt issuances and/or equity financings. The Company believes that it will be able to obtain additional financing because it has done so consistently in the past and because Multikine is a product in the Phase 3 clinical trial stage. However, there can be no assurance that the Company will be successful in raising additional funds on a timely basis or that the funds will be available to the Company on acceptable terms or at all. If the Company does not raise the necessary amounts of money, it may have to curtail its operations until it can raise the required funding.

The financial statements have been prepared assuming the Company will continue as a going concern, but due to the Company's recurring losses from operations and future liquidity needs, there is substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Since the Company launched its Phase 3 clinical trial for Multikine, the Company has incurred expenses of approximately \$53.5 million as of March 31, 2019 on direct costs for the Phase 3 clinical trial. The Company estimates it will incur additional expenses of approximately \$6.3 million for the remainder of the Phase 3 clinical trial. It should be noted that this estimate is based only on the information currently available in the Company's contracts with the Clinical Research Organizations responsible for managing the Phase 3 clinical trial and does not include other related costs, e.g., the manufacturing of the drug. This number may be affected by the rate of death accumulation in the study, foreign currency exchange rates, and many other factors, some of which cannot be foreseen today. It is therefore possible that the cost of the Phase 3 clinical trial will be higher than currently estimated.

Nine hundred twenty-eight (928) head and neck cancer patients have been enrolled and have completed treatment in the Phase 3 study. The study end point is a 10% increase in overall survival of patients between the two main comparator groups in favor of the group receiving the Multikine treatment regimen. The determination if the study end point has been met will occur when there are a total of 298 deaths in those two groups.

C. STOCKHOLDERS' EQUITY

The changes in stockholders' equity during the six months ended March 31, 2019 are as follows:

	Common Shares	Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total
BALANCES AT OCTOBER 1, 2018	28,034,487	\$ 280,346	\$ 331,312,184	\$ (331,591,614)	\$ 916
Warrant exercises	298,682	2,987	646,766	-	649,753
401(k) contributions paid in common stock	12,279	123	35,118	-	35,241
Stock issued to nonemployees for service	62,784	628	201,752	-	202,380
Shares returned for settlement of clinical research costs	(564,905)	(5,649)	5,649	-	-
Equity based compensation - employees	-	-	573,660	-	573,660
Net income	-	-	-	1,245,902	1,245,902
BALANCES AT DECEMBER 31, 2018	27,843,327	278,435	332,775,129	(330,345,712)	2,707,852
Warrant exercises	1,523,933	15,239	2,640,395	-	2,655,634
401(k) contributions paid in common stock	10,419	104	36,779	-	36,883
Stock issued to nonemployees for service	77,449	774	224,855	-	225,629
Equity based compensation - employees	(3,500)	(35)	530,865	-	530,830
Shares issued for settlement of clinical research costs	500,000	5,000	1,285,000	-	1,290,000
Stock issuance costs	-	-	(43,625)	-	(43,625)
Net loss	-	-	-	(6,447,681)	(6,447,681)
BALANCES AT MARCH 31, 2019	29,951,628	\$ 299,517	\$ 337,449,398	\$ (336,793,393)	\$ 955,522

The changes in stockholders' equity during the six months ended March 31, 2018 are as follows:

	Common Shares	Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total
BALANCES AT OCTOBER 1, 2017	11,903,133	\$ 119,031	\$ 296,298,401	\$ (299,754,409)	\$ (3,336,977)
Sale of common stock	1,289,478	12,895	2,437,105	-	2,450,000
401(k) contributions paid in common stock	18,984	190	35,690	-	35,880
Stock issued to nonemployees for service	13,705	137	25,270	-	25,407
Equity based compensation - employees	-	-	1,448,098	-	1,448,098
Net loss	-	-	-	(6,187,830)	(6,187,830)
BALANCES AT DECEMBER 31, 2017	13,258,051	132,581	300,975,618	(305,942,239)	(4,834,040)
Sale of common stock	2,501,145	25,011	4,652,130	-	4,667,141
401(k) contributions paid in common stock	25,901	259	36,261	-	36,520
Stock issued to nonemployees for service	124,082	1,241	227,254	-	228,495
Equity based compensation - employees	-	-	279,817	-	279,817
Conversion of notes payable and interest to common stock	55,373	554	108,746	-	109,300
Shares issued for settlement of clinical research costs	660,000	6,600	1,240,800	-	1,247,400
Stock issuance cost	-	-	(94,773)	-	(94,773)
Net loss	-	-	-	(4,708,135)	(4,708,135)
BALANCES AT MARCH 31, 2018	16,624,552	\$ 166,246	\$ 307,425,853	\$ (310,650,374)	\$ (3,058,275)

Stock options, stock bonuses and compensation granted by the Company as of March 31, 2019 are as follows:

Name of Plan	Total Shares Reserved Under Plans	Shares Reserved for Outstanding Options	Shares Issued	Remaining Options/Shares Under Plans
Incentive Stock Options Plans	138,400	123,558	N/A	385
Non-Qualified Stock Option Plans	3,387,200	3,010,476	N/A	335,619
Stock Bonus Plans	783,760	N/A	322,928	460,799
Stock Compensation Plan	134,000	N/A	115,590	18,410
Incentive Stock Bonus Plan	640,000	N/A	620,500	16,000

Stock options, stock bonuses and compensation granted by the Company as of September 30, 2018 are as follows:

Name of Plan	Total Shares Reserved Under Plans	Shares Reserved for Outstanding Options	Shares Issued	Remaining Options/Shares Under Plans
Incentive Stock Option Plans	138,400	123,558	N/A	385
Non-Qualified Stock Option Plans	3,387,200	3,036,569	N/A	309,526
Stock Bonus Plans	783,760	N/A	297,230	486,497
Stock Compensation Plan	134,000	N/A	118,590	15,410
Incentive Stock Bonus Plan	640,000	N/A	624,000	16,000

Stock option activity:

	Six Months Ended March 31,	
	2019	2018
Granted	500	10,300
Expired	2,400	24,379
Forfeited	24,193	1,393

	Three Months Ended March 31,	
	2019	2018
Granted	-	-
Expired	-	584
Forfeited	24,193	6,856

Employee stock based compensation expense includes the expense related to options issued or vested and restricted stock. Non-employee expense includes the expense related to options and stock issued to consultants expensed over the period of their service contracts. Stock based compensation expense is included in general and administrative expenses on the statements of operations.

Non-employee stock based compensation expense includes the value of shares and options issued under consulting arrangements. At March 31, 2019 and September 30, 2018, approximately \$124,000 and \$207,000, respectively, are included in prepaid expenses.

Warrants and Non-Employee Options

The following chart represents the warrants and non-employee options outstanding at March 31, 2019:

Warrant	Issue Date	Shares Issuable upon Exercise of Warrants	Exercise Price	Expiration Date
Series N	8/18/2008	85,339	\$ 3.00	2/18/2020
Series V	5/28/2015	810,127	\$ 19.75	5/28/2020
Series UU	6/11/2018	187,562	\$ 2.80	6/11/2020
Series W	10/28/2015	688,930	\$ 16.75	10/28/2020
Series X	1/13/2016	120,000	\$ 9.25	1/13/2021
Series Y	2/15/2016	26,000	\$ 12.00	2/15/2021
Series ZZ	5/23/2016	20,000	\$ 13.75	5/18/2021
Series BB	8/26/2016	16,000	\$ 13.75	8/22/2021
Series Z	5/23/2016	264,000	\$ 13.75	11/23/2021
Series FF	12/8/2016	68,048	\$ 3.91	12/1/2021
Series CC	12/8/2016	680,480	\$ 5.00	12/8/2021
Series HH	2/23/2017	20,000	\$ 3.13	2/16/2022
Series AA	8/26/2016	200,000	\$ 13.75	2/22/2022
Series JJ	3/14/2017	30,000	\$ 3.13	3/8/2022
Series LL	4/30/2017	26,398	\$ 3.59	4/30/2022
Series MM	6/22/2017	893,491	\$ 1.86	6/22/2022
Series NN	7/24/2017	539,300	\$ 2.52	7/24/2022
Series OO	7/31/2017	60,000	\$ 2.52	7/31/2022
Series QQ	8/22/2017	3,500	\$ 2.50	8/22/2022
Series GG	2/23/2017	200,000	\$ 3.00	8/23/2022
Series II	3/14/2017	216,500	\$ 3.00	9/14/2022
Series RR	10/30/2017	555,370	\$ 1.65	10/30/2022
Series KK	5/3/2017	213,870	\$ 3.04	11/3/2022
Series SS	12/19/2017	794,740	\$ 2.09	12/18/2022
Series TT	2/5/2018	1,210,827	\$ 2.24	2/5/2023
Series PP	8/28/2017	112,500	\$ 2.30	2/28/2023
Series WW	7/2/2018	69,225	\$ 1.63	6/28/2023
Series VV	7/2/2018	2,515,000	\$ 1.75	1/2/2024
Consultants	7/1/16 - 7/28/17	28,000	\$ 2.18-\$11.50	6/30/2019- 7/27/2027

* No current period changes to these warrants

1. Derivative Liabilities

The table below presents the fair value of the warrant liabilities at the balance sheet dates:

	March 31, 2019	September 30, 2018
Series S warrants	\$ -	\$ 33
Series V warrants	275,584	770,436
Series W warrants	383,053	999,081
Series Z warrants	372,936	487,767
Series ZZ warrants	21,577	34,215
Series AA warrants	287,206	380,474
Series BB warrants	20,720	28,456
Series CC warrants	1,440,026	1,779,724
Series DD warrants	-	1,249,287
Series EE warrants	-	1,249,287
Series FF warrants	154,318	188,921
Series GG warrants	500,478	607,228
Series HH warrants	48,174	58,816
Series II warrants	544,792	660,135
Series JJ warrants	72,716	88,642
Series KK warrants	543,463	656,930
Series LL warrants	62,886	77,632
Total warrant liabilities	<u>\$ 4,727,929</u>	<u>\$ 9,317,064</u>

The table below presents the gains/(losses) on the warrant liabilities for the six months ended March 31:

	2019	2018
Series S warrants	\$ 33	\$ 11,927
Series V warrants	494,852	(3,547)
Series W warrants	616,028	(24,131)
Series Z warrants	114,831	8,095
Series ZZ warrants	12,638	189
Series AA warrants	93,268	8,676
Series BB warrants	7,736	293
Series CC warrants	339,698	41,919
Series DD warrants	1,249,287	5,456
Series EE warrants	1,249,287	5,456
Series FF warrants	34,603	7,301
Series GG warrants	106,750	37,419
Series HH warrants	10,642	2,683
Series II warrants	115,343	50,608
Series JJ warrants	15,926	4,010
Series KK warrants	113,467	36,924
Series LL warrants	14,746	3,307
Net gain on warrant liabilities	<u>\$ 4,589,135</u>	<u>\$ 196,585</u>

The table below presents the gains/(losses) on the warrant liabilities for the three months ended March 31:

	2019	2018
Series S warrants	\$ -	\$ (1,141)
Series V warrants	(61,480)	94,766
Series W warrants	(10,822)	105,336
Series Z warrants	(89,290)	63,630
Series ZZ warrants	(1,685)	3,532
Series AA warrants	(63,951)	56,036
Series BB warrants	(4,374)	2,924
Series CC warrants	(325,908)	238,740
Series DD warrants	-	(27)
Series EE warrants	-	(27)
Series FF warrants	(34,459)	25,348
Series GG warrants	(106,032)	152,551
Series HH warrants	(10,309)	8,345
Series II warrants	(115,246)	229,414
Series JJ warrants	(15,536)	12,552
Series KK warrants	(114,628)	151,951
Series LL warrants	(13,451)	10,885
Net (loss)/gain on warrant liabilities	<u>\$ (967,171)</u>	<u>\$ 1,154,815</u>

The Company reviews all outstanding warrants in accordance with the requirements of ASC 815. This topic provides that an entity should use a two-step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. The warrant agreements provide for adjustments to the exercise price for certain dilutive events. Under the provisions of ASC 815, the warrants are not considered indexed to the Company's stock because future equity offerings or sales of the Company's stock are not an input to the fair value of a "fixed-for-fixed" option on equity shares, and equity classification is therefore precluded.

In accordance with ASC 815, derivative liabilities must be measured at fair value upon issuance and re-valued at the end of each reporting period through expiration. Any change in fair value between the respective reporting dates is recognized as a gain or loss.

Expiration of Derivative Liabilities

On December 10, 2018, 1,360,960 Series DD and 1,360,960 Series EE warrants, with an exercise price of \$4.50, expired.

On October 11, 2018, 327,729 Series S warrants, with an exercise price of \$31.25, expired.

No derivative liabilities expired during the three months ended March 31, 2019.

2. Securities Purchase Agreement

The Company has entered into several Securities Purchase Agreements (SPAs) with Ergomed plc, one of its Clinical Research Organizations responsible for managing the Phase 3 clinical trial, to facilitate a partial payment of amounts due Ergomed. Under the Agreements, the Company issued Ergomed shares of common stock as a forbearance fee in exchange for Ergomed's agreement to provisionally forbear collection of the payables in an amount equal to the net proceeds from the resales of the shares issued to Ergomed. Upon issuance, the Company expenses the full value of the shares as Other Non-Operating Gain/Loss and subsequently offsets the expense as amounts are realized through the resale by Ergomed and reduces accounts payable to Ergomed. Any amounts received from the resell of the shares in excess of the payables will be applied towards the satisfaction of any future amounts owed.

On December 31, 2018, the prior SPA expired. Pursuant to that arrangement, Ergomed returned all 564,905 unsold shares for cancellation. The par value of those shares was reclassified from Common Stock to Additional Paid-In Capital on the balance sheet.

On January 9, 2019, the Company entered into a new SPA under which it issued Ergomed 500,000 restricted shares of the Company's common stock valued at approximately \$1.3 million. This current SPA expires on December 31, 2019.

During the six months ended March 31, 2019 and 2018, respectively, the Company decreased Accounts Payable by approximately \$1.7 million and \$1.2 million through the resale of 545,324 and 684,541 shares.

The following table summarizes the Other Non-Operating Gains (Loss) for the six and three months ended March 31, 2019 and 2018 relating to these agreements:

	Six Months Ended		Three Months Ended	
	3/31/2019	3/31/2018	3/31/2019	3/31/2018
Amount realized through the resale of shares	\$ 1,711,353	\$ 1,225,291	\$ 559,177	\$ 478,590
Fair value of shares upon issuance	1,290,000	1,247,400	1,290,000	1,247,400
Other non-operating gain (loss)	<u>\$ 421,353</u>	<u>\$ (22,109)</u>	<u>\$ (730,823)</u>	<u>\$ (768,810)</u>

As of March 31, 2019, Ergomed holds 308,671 shares and may resell the shares or return the shares to the Company for cancellation until December 31, 2019.

3. Incentive Stock Bonus Plan

During the six and three months ended March 31, 2019, 3,500 shares of common stock issued from the 2014 Incentive Stock Bonus Plan were forfeited.

D. FAIR VALUE MEASUREMENTS

In accordance with ASC 820-10, “*Fair Value Measurements*,” the Company determines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company generally applies the income approach to determine fair value. This method uses valuation techniques to convert future amounts to a single present amount. The measurement is based on the value indicated by current market expectations with respect to those future amounts.

ASC 820-10 establishes a fair value hierarchy that prioritizes the inputs used to measure fair value. The hierarchy gives the highest priority to active markets for identical assets and liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement). The Company classifies fair value balances based on the observability of those inputs. The three levels of the fair value hierarchy are as follows:

- Level 1 – Observable inputs such as quoted prices in active markets for identical assets or liabilities
- Level 2 – Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and amounts derived from valuation models where all significant inputs are observable in active markets
- Level 3 – Unobservable inputs that reflect management’s assumptions

For disclosure purposes, assets and liabilities are classified in their entirety in the fair value hierarchy level based on the lowest level of input that is significant to the overall fair value measurement. The Company’s assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the placement within the fair value hierarchy levels.

The table below sets forth the assets and liabilities measured at fair value on a recurring basis, by input level, in the condensed balance sheet at March 31, 2019:

	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Derivative instruments	\$ -	\$ -	\$ 4,727,929	\$ 4,727,929

The table below sets forth the assets and liabilities measured at fair value on a recurring basis, by input level, in the condensed balance sheet at September 30, 2018:

	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Derivative instruments	\$ 33	\$ -	\$ 9,317,031	\$ 9,317,064

The following sets forth the reconciliation of beginning and ending balances related to fair value measurements using significant unobservable inputs (Level 3) for the three months ended March 31, 2019 and the year ended September 30, 2018:

	Six Months Ended March 31, 2019	Year Ended September 30, 2018
Beginning balance	\$ 9,317,031	\$ 2,020,629
Issuances	-	-
Exercises	-	(595,780)
Realized and unrealized (gains) and losses	(4,589,102)	7,892,182
Ending balance	<u>\$ 4,727,929</u>	<u>\$ 9,317,031</u>

The fair values of the Company’s derivative instruments disclosed above under Level 3 are primarily derived from valuation models where significant inputs such as historical price and volatility of the Company’s stock, as well as U.S. Treasury Bill rates, are observable in active markets.

E. COMMITMENTS AND CONTINGENCIES

Clinical Research Agreements

Under co-development and revenue sharing agreements with Ergomed, Ergomed agreed to contribute up to \$12 million towards the Company's Phase 3 Clinical Trial in the form of discounted clinical services in exchange for a single digit percentage of milestone and royalty payments, up to a specific maximum amount. The Company accounted for the co-development and revenue sharing agreements in accordance with ASC 808 "Collaborative Arrangements". The Company determined the payments to Ergomed are within the scope of ASC 730 "Research and Development." Therefore, the Company records the discount on the clinical services as a credit to research and development expense on its Statements of Operations. Since the inception of the agreement with Ergomed, the Company has incurred research and development expenses of approximately \$29.6million for Ergomed's services. This amount is net of Ergomed's discount of approximately \$9.9 million. During the six months ended March 31, 2019 and 2018, the Company recorded, net of Ergomed's discount, approximately \$1.5 million and \$1.7 million, respectively, as research and development expense related to Ergomed's services. During the three months ended March 31, 2019 and 2018, the Company recorded, net of Ergomed's discount, approximately \$0.7 million and \$0.8 million, respectively, as research and development expense related to Ergomed's services.

Lease Agreements

The Company leases a manufacturing facility near Baltimore, Maryland (the San Tomas lease). The building was remodeled in accordance with the Company's specifications so that it can be used by the Company to manufacture Multikine for the Company's Phase 3 clinical trial and sales of the drug if approved by the FDA. The lease is for a term of twenty years and requires annual base rent to escalate each year at 3%. The Company is required to pay all real estate and personal property taxes, insurance premiums, maintenance expenses, repair costs and utilities. The lease allows the Company, at its election, to extend the lease for two ten-year periods or to purchase the building at the end of the 20-year lease. The Company contributed approximately \$9.3 million towards the tenant-directed improvements, of which \$3.2 million is being refunded during years six through twenty through reduced rental payments. The landlord paid approximately \$11.9 million towards the purchase of the building, land and the tenant-directed improvements. The Company placed the building in service in October 2008.

The Company was deemed to be the owner of the building for accounting purpose under the build-to-suit guidance in ASC 840-40-55. In addition to tenant improvements the Company incurred, the Company also recorded an asset for tenant-directed improvements and for the costs paid by the lessor to purchase the building and to perform improvements, as well as a corresponding liability for the landlord costs. Upon completion of the improvements, the Company did not meet the "sale-leaseback" criteria under ASC 840-40-25, Accounting for Lease, Sale-Leaseback Transactions, and therefore, treated the lease as a financing obligation. Thus, the asset and corresponding liability were not de-recognized. As of March 31, 2019 and September 30, 2018, the leased building asset has a net book value of approximately \$15.8 and \$16.1 million, respectively, and the landlord liability has a balance of approximately \$13.4 million as of both balance sheet dates. The leased building is being depreciated using a straight-line method over the 20-year lease term to a residual value. The landlord liability is being amortized over the 20 years using the effective interest method. Lease payments allocated to the landlord liability are accounted for as debt service payments on that liability using the finance method of accounting per ASC 840-40-55.

The Company was required to deposit the equivalent of one year of base rent in accordance with the lease. When the Company meets the minimum cash balance required by the lease, the deposit will be returned to the Company. The approximate \$1.7 million deposit is included in non-current assets at March 31, 2019 and September 30, 2018.

Approximate future minimum lease payments under the San Tomas lease as of March 31, 2019 are as follows:

Six months ending September 30, 2019	\$ 907,000
Year ending September 30,	
2020	1,872,000
2021	1,937,000
2022	2,004,000
2023	2,073,000
2024	2,145,000
Thereafter	9,540,000
Total future minimum lease obligation	20,478,000
Less imputed interest on financing obligation	(7,034,000)
Net present value of lease financing obligation	<u>\$ 13,444,000</u>

The Company subleases a portion of its rental space on a month-to-month term lease, which requires a 30-day notice for termination. The sublease rental income for each of the six months ended March 31, 2019 and 2018 was approximately \$36,000. The sublease rental income for each of the three months ended March 31, 2019 and 2018 was approximately \$18,000.

The Company leases its research and development laboratory under a 60-month lease which expires February 28, 2022. The operating lease includes escalating rental payments. The Company is recognizing the related rent expense on a straight-line basis over the full 60-month term of the lease at the rate of approximately \$13,000 per month. As of March 31, 2019 and September 30, 2018, the Company has recorded a deferred rent liability of approximately \$14,000 and \$12,000, respectively.

The Company leases its office headquarters under a 60-month lease which expires June 30, 2020. The operating lease includes escalating rental payments. The Company is recognizing the related rent expense on a straight-line basis over the full 60-month term of the lease at the rate approximately \$8,000 per month. As of March 31, 2019 and September 30, 2018, the Company has recorded a deferred rent liability of approximately \$11,000 and \$14,000, respectively.

As of March 31, 2019, material contractual obligations, excluding the San Tomas lease, consisting of non-cancelable operating lease payments are as follows:

Six months ending September 30, 2019	\$ 130,000
Year ending September 30,	
2020	238,000
2021	163,000
2022	69,000
Total	<u>\$ 600,000</u>

The Company leases office equipment under a capital lease arrangement. The term of the capital lease is 60 months and expires on October 31, 2021. The monthly lease payment is \$505. The lease bears interest at an annual interest rate of 6.25%.

F. PATENTS

During the six months ended March 31, 2019 and 2018, no patent impairment charges were recorded. For the six and three months ended March 31, 2019, amortization of patent costs totaled approximately \$23,000 and \$11,000, respectively. For the six and three months ended March 31, 2018, amortization of patent costs totaled approximately \$19,000 and \$9,000, respectively. Approximate estimated future amortization expense is as follows:

Six months ending September 30, 2019	\$ 20,000
Year ending September 30,	
2020	39,000
2021	36,000
2022	31,000
2023	21,000
2024	18,000
Thereafter	78,000
Total	\$ 243,000

G. LOSS PER COMMON SHARE

The following tables provide the details of the basic and diluted loss per-share computations:

	<u>Six months ended March 31,</u>		<u>Three months ended March 31,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Loss per share - basic				
Net loss available to common shareholders - basic	\$ (5,201,779)	\$ (10,895,965)	\$ (6,447,681)	\$ (4,708,135)
Weighted average shares outstanding - basic	28,543,417	13,403,878	29,113,910	15,210,296
Basic loss per common share	<u>\$ (0.18)</u>	<u>\$ (0.81)</u>	<u>\$ (0.22)</u>	<u>\$ (0.31)</u>
Loss per share - diluted				
Net loss available to common shareholders - basic	\$ (5,201,779)	\$ (10,895,965)	\$ (6,447,681)	\$ (4,708,135)
Gain on derivatives ⁽¹⁾	(335,560)	-	-	-
Net loss available to common shareholders - diluted	<u>\$ (5,537,339)</u>	<u>\$ (10,895,965)</u>	<u>\$ (6,447,681)</u>	<u>\$ (4,708,135)</u>
Weighted average shares outstanding - basic	28,543,417	13,403,878	29,113,910	15,210,296
Incremental shares underlying dilutive "in the money" warrants ⁽¹⁾	5,401	-	-	-
Weighted average shares outstanding - diluted	<u>28,548,818</u>	<u>13,403,878</u>	<u>29,113,910</u>	<u>15,210,296</u>
Diluted loss per common share	<u>\$ (0.19)</u>	<u>\$ (0.81)</u>	<u>\$ (0.22)</u>	<u>\$ (0.31)</u>

⁽¹⁾ Includes series GG, II and KK for the six months ended March 31, 2019.

The gain on derivatives priced lower than the average market price during the period is excluded from the numerator and the related shares are excluded from the denominator in calculating diluted loss per share.

In accordance with the contingently issuable shares guidance of FASB ASC Topic 260, *Earnings Per Share*, the calculation of diluted net earnings (loss) per share excludes the following securities because their inclusion would have been anti-dilutive as of March 31:

	<u>2019</u>	<u>2018</u>
Options and Warrants	10,576,881	12,381,730
Unvested Restricted Stock	308,500	312,000
Convertible debt	-	1,077,982
Total	<u>10,885,381</u>	<u>13,771,712</u>

H. SUBSEQUENT EVENTS

Between April 1, 2019 and May 13, 2019, the Company received approximately \$7.6 million through the exercise of options and warrants to purchase shares of the Company's common stock.

On May 7, 2019, the Company received security purchase agreements for the purchase of 30,612 restricted shares of the Company's common stock at the closing price on May 6, 2019 of \$6.86 in the principal amount of approximately \$210,000 from five officers and directors of the Company.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Liquidity and Capital Resources

The Company's lead investigational therapy, Multikine® (Leukocyte Interleukin, Injection), is cleared for a Phase 3 clinical trial in advanced primary head and neck cancer by the regulators in twenty-four countries, including the U.S.

Multikine (Leukocyte Interleukin, Injection) is the full name of this investigational therapy, which, for simplicity, is referred to in this report as Multikine. Multikine is the trademark that the Company has registered for this investigational therapy, and this proprietary name is subject to FDA review under the Company's future anticipated regulatory submission for approval. Multikine has not been licensed or approved by the FDA or any other regulatory agency. Neither has its safety or efficacy been established for any use.

The Company also owns and is developing a pre-clinical technology called LEAPS (Ligand Epitope Antigen Presentation System).

All the Company's projects are under development. Consequently, the Company cannot predict when it will be able to generate any revenue from the sale of any of its products.

Since inception, the Company has financed its operations through the sale of equity securities, convertible notes, loans and certain research grants. The Company's expenses will continue to exceed its revenues as it continues the development of Multikine and brings other drug candidates into clinical trials. Until the Company becomes profitable, any or all of these financing vehicles or others may be utilized to assist in funding the Company's capital requirements.

Capital raised by the Company has been expended primarily for patent applications, research and development, administrative costs, and the construction of the Company's manufacturing and laboratory facilities. The Company does not anticipate realizing significant revenues until entering into licensing arrangements for its technology and know-how or until it receives regulatory approval to sell its products (which could take several years). Thus, the Company has been dependent upon the proceeds from the sale of its securities to meet all its liquidity and capital requirements and anticipates having to do so in the future.

The Company will be required to raise additional capital or find additional long-term financing to continue with its research efforts. The ability to raise capital may be dependent upon market conditions that are outside the control of the Company. The ability of the Company to complete the necessary clinical trials and obtain FDA approval for the sale of products to be developed on a commercial basis is uncertain. Ultimately, the Company must complete the development of its products, obtain the appropriate regulatory approvals and obtain sufficient revenues to support its cost structure. The Company is taking cost-cutting initiatives, as well as exploring other sources of funding, to finance operations over the next 12 months. However, there can be no assurance that the Company will be able to raise sufficient capital to support its operations.

Since the Company launched its Phase 3 clinical trial for Multikine, the Company has incurred expenses of approximately \$53.5 million as of March 31, 2019 on direct costs for the Phase 3 clinical trial. The Company estimates it will incur additional expenses of approximately \$6.3 million for the remainder of the Phase 3 clinical trial. It should be noted that this estimate is based only on the information currently available in the Company's contracts with the Clinical Research Organizations responsible for managing the Phase 3 clinical trial and does not include other related costs, e.g., the manufacturing of the drug. This number may be affected by the rate of death accumulation in the study, foreign currency exchange rates, and many other factors, some of which cannot be foreseen today. It is therefore possible that the cost of the Phase 3 clinical trial will be higher than currently estimated.

The Company uses two CRO's to manage the global Phase 3 study; ICON and Ergomed, who are both international leaders in managing oncology trials. As of September 2016, the study was fully enrolled with 928 patients.

Under a co-development agreement, Ergomed agreed to contribute up to \$12 million towards the study where it will perform clinical services in exchange for a single digit percentage of milestone and royalty payments, up to a specified maximum amount. Approximately \$9.9 million of these credits were realized as of March 31, 2019.

During the six months ended March 31, 2019, the Company's cash decreased by approximately \$4.8 million. Significant components of this decrease included net cash used to fund the Company's regular operations, including its Phase 3 clinical trial, of approximately \$7.8 million and approximately \$0.2 million to purchase long term assets. The decrease was offset by net proceeds from the exercise of warrants of approximately \$3.3 million. During the six months ended March 31, 2018, the Company's cash increased by approximately \$0.7 million. Significant components of this increase include net proceeds from the sale of the Company's stock of approximately \$7.1 million offset by net cash used to fund the Company's regular operations, including its Phase 3 clinical trial, of approximately \$6.4 million.

During the six months ended March 31, 2019, 1,822,615 warrants were exercised at a weighted average exercise price of \$1.81 for proceeds of approximately \$3.3 million. These exercises include 1,523,933 warrants exercised during the three months ended March 31, 2019 for proceeds of approximately \$2.7 million. No warrants were exercised during the six months ended March 31, 2018.

The Company has entered into several Securities Purchase Agreements (SPAs) with Ergomed plc, one of its Clinical Research Organizations responsible for managing the Phase 3 clinical trial, to facilitate a partial payment of amounts due Ergomed. Under the Agreements, the Company issued Ergomed shares of common stock in exchange for Ergomed's agreement to provisionally forbear collection of the payables in an amount equal to the net proceeds from the resales of the shares issued to Ergomed. During the six months ended March 31, 2019 and 2018, respectively, the Company decreased Accounts Payable by approximately \$1.7 million and \$1.2 million as a result of the sale of 545,324 and 684,541 shares by Ergomed. As of March 31, 2019, Ergomed holds 308,671 shares and may resell the shares or return the shares to the Company for cancellation until December 31, 2019. For more information regarding the SPAs refer to Note C above.

Inventory at March 31, 2019 increased by approximately \$116,000 as compared to September 30, 2018. In addition, receivables remained relatively constant, only increasing by approximately \$5,000. Receivables consist primarily of amounts due from the Company's partners for reimbursed clinical study costs related to its Phase 3 clinical trial and amounts to be reimbursed for costs related to its Small Business Innovation Research (SBIR) grant.

Results of Operations and Financial Condition

During the six months ended March 31, 2019, research and development expenses increased by approximately \$0.4 million compared to the six months ended March 31, 2018. During the three months ended March 31, 2019, research and development expenses decreased by approximately \$0.4 million compared to the three months ended March 31, 2018. The majority of the Company's research and development expense relates to its on-going Phase 3 clinical trial. The Company is continuing the Phase 3 clinical trial and research and development fluctuates based on the activity level of the clinical trial.

During the six months ended March 31, 2019, general and administrative expenses decreased by approximately \$0.1 million compared to the six months ended March 31, 2018. During the three months ended March 31, 2019, general and administrative expenses increased by approximately \$0.6 million compared to the three months ended March 31, 2018. The current quarter increase is primarily due to an increase in public relations costs of approximately \$0.3 million, of which approximately \$0.2 million relates to equity based compensation. The increase in equity based public relations cost is primarily the result of the timing of the expense recognized dependent upon the terms of each contract. In addition, the current quarter increase is due to an increase in employee stock based compensation of approximately \$0.3 million as a result of employee stock options granted subsequent to March 31, 2018.

The gain on derivative instruments of approximately \$4.6 million and \$0.2 million for the six months ended March 31, 2019 and 2018, respectively, is the result of the change in fair value of the derivative liabilities during the respective periods. The loss on derivative instruments of approximately \$1.0 million for the three months ended March 31, 2019 and the gain on derivative instruments of approximately \$1.2 million for the three months ended March 31, 2018 were the result of the change in fair value of the derivative liabilities during the respective quarters. These changes were caused mainly by fluctuation in the share price of the Company's common stock.

Other non-operating gain (loss) for the six and three months ended March 31, 2019 and 2018 is a result of shares issued to Ergomed to facilitate partial payments of amounts due to Ergomed under the SPA mentioned above. For more information regarding the SPAs refer to Note C above.

Net interest expense decreased by approximately \$1.0 million for the six months ended March 31, 2019 compared to the six months ended March 31, 2018. Net interest expense decreased by approximately \$0.4 million for the three months ended March 31, 2019 compared to the three months ended March 31, 2018. The prior periods included interest expense and the amortization of a discount on the notes payable that were converted by September 30, 2018.

Research and Development Expenses

The Company's research and development efforts involve Multikine and LEAPS. The table below shows the research and development expenses associated with each project.

	Six months ended March 31,		Three months ended March 31,	
	2019	2018	2019	2018
MULTIKINE	\$ 5,257,946	\$ 4,989,721	\$ 2,314,316	\$ 2,769,787
LEAPS	399,702	298,590	211,144	192,510
TOTAL	\$ 5,657,648	\$ 5,288,311	\$ 2,525,460	\$ 2,962,297

Clinical and other studies necessary to obtain regulatory approval of a new drug involve significant costs and require several years to complete. The extent of the Company's clinical trials and research programs are primarily based upon the amount of capital available to the Company and the extent to which the Company has received regulatory approvals for clinical trials. The inability of the Company to conduct clinical trials or research, whether due to a lack of capital or regulatory approval, will prevent the Company from completing the studies and research required to obtain regulatory approval for any products which the Company is developing. Without regulatory approval, the Company will be unable to sell any of its products. Since all the Company's projects are under development, the Company cannot predict when it will be able to generate any revenue from the sale of any of its products.

Critical Accounting Estimates and Policies

Management's discussion and analysis of the Company's financial condition and results of operations is based on its unaudited condensed financial statements. The preparation of these financial statements is based on the selection of accounting policies and the application of significant accounting estimates, some of which require management to make judgments, estimates and assumptions that affect the amounts reported in the financial statements and notes. The Company believes some of the more critical estimates and policies that affect its financial condition and results of operations are in the areas of operating leases and stock-based compensation. For more information regarding the Company's critical accounting estimates and policies, see Part II, Item 7 of the Company's Annual Report on Form 10-K for the year ended September 30, 2018. The application of these critical accounting policies and estimates has been discussed with the Audit Committee of the Company's Board of Directors.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

The Company does not believe that it has any significant exposures to market risk.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the direction and with the participation of the Company's management, including the Company's Chief Executive and Chief Financial Officer, the Company has conducted an evaluation of the effectiveness of the design and operation of its disclosure controls and procedures as of March 31, 2019. The Company maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in its periodic reports with the Securities and Exchange Commission is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and regulations, and that such information is accumulated and communicated to the Company's management, including its principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. The Company's disclosure controls and procedures are designed to provide a reasonable level of assurance of reaching its desired disclosure control objectives. Based on the evaluation, the Chief Executive and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective as of March 31, 2019.

Changes in Internal Control over Financial Reporting

There was no change in the Company's internal control over financial reporting that occurred during the quarter ended March 31, 2019 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting

PART II

ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds.

During the six months ended March 31, 2019 the Company issued 140,233 restricted shares of common stock to consultants for investor relations services.

The Company relied upon the exemption provided by Section 4(a)(2) of the Securities Act of 1933 with respect to the issuance of these shares. The individuals who acquired these shares were sophisticated investors and were provided full information regarding the Company's business and operations. There was no general solicitation in connection with the offer or sale of these securities. The individuals who acquired these shares acquired them for their own accounts. The certificates representing these shares bear a restricted legend which provides they cannot be sold except pursuant to an effective registration statement or an exemption from registration. No commission or other form of remuneration was given to any person in connection with the issuance of these shares.

ITEM 6. Exhibits

<u>Number</u>	<u>Exhibit</u>
31	Rule 13a-14(a) Certifications
32	Section 1350 Certifications

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.

CEL-SCI CORPORATION

Date: May 14, 2019

By: /s/ Geert Kersten

Geert Kersten
Principal Executive Officer*

* Also signing in the capacity of the Principal Accounting and Financial Officer.

CERTIFICATIONS

I, Geert Kersten, certify that:

1. I have reviewed this quarterly report on Form 10-Q of CEL-SCI Corporation;
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, considering 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15 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, 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 cause 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(s) and I have disclosed, based on our most recent evaluation of the internal control over financial reporting, to the registrant's auditors and the audit committee of the 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 significant role in the registrant's internal control over financial reporting.

May 14, 2019

By: /s/ Geert Kersten

Geert Kersten
Principal Executive Officer

CERTIFICATIONS

I, Geert Kersten, certify that:

1. I have reviewed this quarterly report on Form 10-Q of CEL-SCI Corporation;
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, considering 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15 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, 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 cause 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(s) and I have disclosed, based on our most recent evaluation of the internal control over financial reporting, to the registrant's auditors and the audit committee of the 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 significant role in the registrant's internal control over financial reporting.

May 14, 2019

By: /s/ Geert Kersten

Geert Kersten
Principal Financial Officer

In connection with the Quarterly Report of CEL-SCI Corporation (the "Company") on Form 10-Q for the period ended March 31, 2019 as filed with the Securities and Exchange Commission (the "Report"), Geert Kersten, the Principal Executive and Financial Officer of the Company, certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of the Company.

By: /s/ Geert Kersten
Geert Kersten
Principal Executive and
Principal Financial Officer

May 14, 2019
