CEL SCI CORP
Form 10-Q
February 09, 2017

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

FORM 10-Q
(Mark One)
QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 (d) OF
THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended December 31, 2016
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	84-0916344
State or other jurisdiction incorporation	(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, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check One):

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company

(Do not check if a smaller reporting company)

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	190,965,450	February 3, 2017

TABLE OF CONTENTS

PART I FINANCIAL INFORMATION

CEL-SCI CORPORATION
CONDENSED BALANCE SHEETS
(UNAUDITED)

ASSETS	DECEMBER 31, 2016	SEPTEMBER 30, 2016
CURRENT ASSETS:		
Cash and cash equivalents	$2,386,673	$2,917,996
Receivables	4,128	394,515
Prepaid expenses	866,987	981,677
Deposits - current portion	154,995	154,995
Inventory used for R&D and manufacturing	694,504	1,008,642
Deferred rent - current portion	415,003	429,821
Total current assets	4,522,290	5,887,646
RESEARCH AND OFFICE EQUIPMENT, net	229,676	226,216
PATENT COSTS, net	247,267	256,547
DEFERRED RENT - net of current portion	3,257,739	3,406,921
DEPOSITS	1,670,917	1,820,917
TOTAL ASSETS	$9,927,889	$11,598,247
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$2,741,353	$3,091,512
Accrued expenses	319,476	378,672
Due to employees	476,413	538,278
Derivative instruments, current portion	249,157	-
Other current liabilities	7,203	3,310
Total current liabilities	3,793,602	4,011,772
Derivative instruments - net of current portion	1,533,549	8,394,934
Deferred revenue	125,000	125,000
Other Liabilities	42,447	22,609
Total liabilities	5,494,598	12,554,315
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred stock, $.01 par value-200,000 shares authorized;		
-0- shares issued and outstanding	-	-
Common stock, $.01 par value - 600,000,000 shares authorized;		

190,931,286 and 155,962,079 shares issued and outstanding at December 31, 2016 and September 30, 2016, respectively	1,909,313	1,559,621
Additional paid-in capital	284,655,153	283,152,288
Accumulated deficit	(282,131,175)	(285,667,977)
Total stockholders' equity (deficit)	4,433,291	(956,068)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$9,927,889	$11,598,247

See notes to condensed financial statements.

CEL-SCI CORPORATION
CONDENSED STATEMENTS OF OPERATIONS
THREE MONTHS ENDED DECEMBER 31, 2016 and 2015
(UNAUDITED)

	2016	2015
GRANT INCOME AND OTHER	$17,258	$20,976
OPERATING EXPENSES:		
Research and development	4,024,856	5,169,507
General & administrative	1,407,009	634,601
Total operating expenses	5,431,865	5,804,108
OPERATING LOSS	(5,414,607)	(5,783,132)
GAIN ON DERIVATIVE INSTRUMENTS	8,928,312	8,122,960
INTEREST INCOME, NET	23,097	1,985
NET INCOME AVAILABLE TO COMMON SHAREHOLDERS	$3,536,802	$2,341,813
NET INCOME PER COMMON SHARE		
BASIC	$0.02	$0.02
DILUTED	$0.01	$0.02
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING		
BASIC	149,860,777	109,768,502
DILUTED	152,117,711	111,639,785

See notes to condensed financial statements.

CEL-SCI CORPORATION
CONDENSED STATEMENTS OF CASH FLOWS
THREE MONTHS ENDED DECEMBER 31, 2016 and 2015
(UNAUDITED)

	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$3,536,802	$2,341,813
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation and amortization	30,737	41,741
Issuance of common stock and options for services	78,553	329,195
Equity based compensation	312,375	427,910
Common stock contributed to 401(k) plan	38,372	40,995
Loss on retired equipment	1,187	115
Gain on derivative instruments	(8,928,312)	(8,122,960)
(Increase)/decrease in assets:		
Receivables	85,046	75,206
Deferred rent	164,000	176,825
Prepaid expenses	96,507	51,628
Inventory used for R&D and manufacturing	314,138	58,798
Deposits	150,000	150,000
Increase/(decrease) in liabilities:		
Accounts payable	(75,029)	(1,666,792)
Accrued expenses	(59,196)	280,032
Deferred revenue	-	(1,639)
Due to employees	17,110	(25,056)
Deferred rent liability	(1,496)	4,245
Net cash used in operating activities	(4,239,206)	(5,837,944)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of equipment	-	(14,831)
Net cash used in investing activities	-	(14,831)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock and warrants	3,709,931	10,550,538
Payments on obligations under capital lease	(2,048)	(2,194)
Net cash provided by financing activities	3,707,883	10,548,344
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(531,323)	4,695,569
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	2,917,996	5,726,682
CASH AND CASH EQUIVALENTS, END OF PERIOD	$2,386,673	$10,422,251

See notes to condensed financial statements.

5

CEL-SCI CORPORATION
CONDENSED STATEMENTS OF CASH FLOWS
THREE MONTHS ENDED DECEMBER 31, 2016 and 2015

SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:

	2016	2015
Decrease in receivable due under the litigation funding arrangement offset by the same amount payable to the legal firm providing the services	$305,341	$366,267
Research and office equipment included in accounts payable	-	6,814
Capital lease payments included in accounts payable	372	739
Property and equipment acquired through capital lease	26,104	-
Fair value of warrants issued in connection with public offering	2,316,084	5,060,771
Financing costs included in accounts payable	77,987	21,000
Prepaid consulting services paid with issuance of common stock	(18,183)	8,177
Cash paid for interest expense	$12	$33,260

See notes to condensed financial statements.

CEL-SCI CORPORATION
NOTES TO CONDENSED FINANCIAL STATEMENTS
THREE MONTHS ENDED DECEMBER 31, 2016 AND 2015 (UNAUDITED)

A.
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, 2016.

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 December 31, 2016 and the results of its operations for the three months then ended. The condensed balance sheet as of September 30, 2016 is derived from the September 30, 2016 audited financial statements. Significant accounting policies have been consistently applied in the interim financial statements and the annual financial statements. The results of operations for the three months ended December 31, 2016 and 2015 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 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 - 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.

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 December 31, 2016 and September 30, 2016.

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 remeasured at fair value at the end of each interim period as long as they are outstanding.

Deferred Rent (Asset) –Consideration paid, including deposits, related to operating leases is recorded as a deferred rent asset and amortized as rent expense over the lease term. Interest on the deferred rent is calculated at 3% on the funds deposited on the manufacturing facility and is included in deferred rent. This interest income will be used to offset future rent.

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. Historical data was used to estimate option exercise and employee termination within the valuation model. The expected term of options represents the period of time 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 February 2016, the FASB issued ASU 2016-02, Leases, which will require most leases (with the exception 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. The Company is currently evaluating the effect of the new standard on its financial statements and related disclosures.

B.
OPERATIONS AND FINANCING

The Company has incurred significant costs since its inception in connection with 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 in order to continue with its research efforts. Currently, the partial clinical hold has had a significant impact on the Company's market capital, and as such, may impact the Company's ability to attract new capital. To date, the Company has not generated any revenue from product sales. The ability of the Company to complete the necessary clinical trials and obtain US Food & Drug Administration (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 currently running a large multi-national Phase 3 clinical trial for head and neck cancer with its partners TEVA Pharmaceuticals and Orient Europharma. During the three months ended December 31, 2016, the Company raised approximately $3.7 million net proceeds from a public offering. To finance the study beyond the next twelve months, the Company plans to raise additional capital in the form of corporate partnerships, debt 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 will either have to slow or delay the Phase 3 clinical trial or even significantly curtail its operations until such time as it is able to raise the required funding. The Phase 3 study is currently on partial clinical hold by the FDA. The financial statements have been prepared assuming that the Company will continue as a going concern, but due to 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 spent approximately $36.0 million as of December 31, 2016 on direct costs for the Phase 3 clinical trial. The total remaining cash cost of the clinical trial is estimated to be approximately $13.5 million. 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 can be affected by the speed of enrollment, foreign currency exchange rates and many other factors, some of which cannot be foreseen. The Company has filed an amendment to the original Phase 3 protocol for it head and neck cancer study with the FDA to allow for this expansion in patient enrollment. Should the FDA allow the amended protocol filed with them to proceed, the remaining cost of the Phase 3 clinical trial will be higher. It is therefore possible that the cost of the Phase 3 clinical trial will be higher than currently estimated.

As of December 31, 2016, the Phase 3 clinical trial for Multikine was on a partial clinical hold.

If the partial clinical hold is not lifted, the Phase 3 study will not be able to be completed to its prespecified endpoints in a timely manner, if at all, and, if the Phase 3 study cannot be completed to its prespecified endpoints, the study would not be able to be used as the pivotal study supporting a marketing application in the United States, and at least one entirely new Phase 3 pivotal study would need to be conducted to provide the pivotal study supporting a marketing application in the United States. Even if the partial clinical hold is lifted, if it is not lifted in a timely fashion, the nature and duration of the partial clinical hold could irreparably harm the data from the Phase 3 study such that it may no longer be able to be used as the pivotal study supporting a marketing application in the United States. Even if the partial clinical hold is lifted in a timely fashion, it remains possible that the regulatory authorities could determine that the Phase 3 study is not sufficient to be used as a single pivotal study supporting a marketing application in the United States.

C.
STOCKHOLDERS' EQUITY

Stock options, stock bonuses and compensation granted by the Company as of December 31, 2016 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	3,460,000	1,648,966	N/A	1,511,334
Non-Qualified Stock Option Plans	9,680,000	6,563,284	N/A	2,389,098
Stock Bonus Plans	5,594,000	N/A	4,003,926	1,589,247
Stock Compensation Plan	3,350,000	N/A	2,087,257	1,229,692
Incentive Stock Bonus Plan	16,000,000	N/A	15,600,000	400,000

Stock options, stock bonuses and compensation granted by the Company as of September 30, 2016 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	3,460,000	1,648,966	N/A	1,511,334
Non-Qualified Stock Option Plans	9,680,000	6,940,321	N/A	2,059,261
Bonus Plans	5,594,000	N/A	3,161,211	2,431,962
Stock Compensation Plan	3,350,000	N/A	1,985,037	1,331,912
Incentive Stock Bonus Plan	16,000,000	N/A	15,600,000	400,000

Stock option activity:

	Three Months Ended December 31,	
	2016	2015
Granted	-	-
Expired	377,037	-

Forfeited	- 22,966

Stock-Based Compensation Expense

	Three months Ended December 31,	
	2016	2015
Employees	$312,375	$427,910
Non-employees	$78,553	$329,195

11

Employee 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.

Warrants and Non-employee Options

The following chart presents the outstanding warrants and non-employee options, listed by expiration date at December 31, 2016:

Warrant	Issue Date	Shares Issuable upon Exercise of Warrant	Exercise Price	Expiration Date	Reference
Series P	2/10/12	590,001	$4.50	3/6/17	
Series DD	12/8/16	34,024,000	$0.18	6/8/17	1
Series EE	12/8/16	34,024,000	$0.18	9/8/17	1
Series N	8/18/08	2,844,627	$0.53	8/18/17	
Series U	4/17/14	445,514	$1.75	10/17/17	1
Series S	10/11/13 -10/24/14	25,928,010	$1.25	10/11/18	1
Series V	5/28/15	20,253,164	$0.79	5/28/20	1
Series W	10/28/15	17,223,248	$0.67	10/28/20	1
Series X	1/13/16	3,000,000	$0.37	1/13/21	
Series Y	2/15/16	650,000	$0.48	2/15/21	
Series Z	5/23/16	6,600,000	$0.55	11/23/21	1
Series ZZ	5/23/16	500,000	$0.55	5/18/21	1
Series BB	8/26/16	400,000	$0.55	8/22/21	1
Series FF	12/8/16	1,701,200	$0.16	12/1/21	1
Series CC	12/8/16	17,012,000	$0.20	12/8/21	1
Series AA	8/26/16	5,000,000	$0.55	2/22/22	1
Consultants	3/6/12- 7/1/16	575,000	$0.37- $3.50	3/5/17- 6/30/19	2

1.

Derivative Liabilities

The table below presents the warrant liabilities and their respective balances at the balance sheet dates:

	December 31, 2016	September 30, 2016
Series S warrants	$490,040	$3,111,361
Series U warrants	-	-
Series V warrants	202,532	1,620,253
Series W warrants	132,254	1,799,858
Series Z warrants	101,817	970,604
Series ZZ warrants	6,725	70,609
Series AA warrants	84,092	763,661
Series BB warrants	5,916	58,588
Series CC warrants	455,931	-
Series DD warrants	72,353	-
Series EE warrants	176,804	-
Series FF warrants	54,242	-

Total warrant liabilities	$1,782,706	$8,394,934

The table below presents the gains on the warrant liabilities for the three months ended December 31:

	2016	2015
Series S warrants	$2,621,321	$2,826,153
Series U warrants	-	31,186
Series V warrants	1,417,721	3,240,506
Series W warrants	1,667,604	2,025,115
Series Z warrants	868,787	-
Series ZZ warrants	63,884	-
Series AA warrants	679,569	-
Series BB warrants	52,672	-
Series CC warrants	604,492	-
Series DD warrants	370,919	-
Series EE warrants	514,603	-
Series FF warrants	66,740	-
Net gain on warrant liabilities	$8,928,312	$8,122,960

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.

Issuance of additional Warrants

On December 8, 2016, the Company sold 34,024,000 shares of common stock and warrants to purchase common stock at a price of $0.125 in a public offering. The warrants consist of 17,012,000 Series CC warrants to purchase 17,012,000 shares of common stock, 34,024,000 Series DD warrants to purchase 34,024,000 shares of common stock and 34,024,000 Series EE warrants to purchase 34,024,000 shares of common stock. The Series CC warrants are immediately exercisable, expire in five-years from the offering date and have an exercise price of $0.20 per share. The Series DD warrants are immediately exercisable, expire in six-months from the offering date and have an exercise price of $0.18 per share. The Series EE warrants are immediately exercisable, expire in nine-months from the offering date and have an exercise price of $0.18 per share. In addition, the Company issued 1,701,200 Series FF warrants to purchase 1,701,200 shares of common stock to the placement agent. The FF warrants are exercisable at any time on or after June 8, 2017 and expire on December 1, 2021 and have an exercise price $0.15625. The net proceeds from this offering was approximately $3.7 million. The fair value of the Series CC, DD, EE and FF warrants of approximately $2.3 million on the date of issuance was recorded as a warrant liability.

Expiration of Warrants

On December 6, 2016, 2,625,000 Series R warrants, with an exercise price of $4.00, expired. The fair value of the Series R warrants was $0 on the date of expiration.

On December 22, 2015, 1,200,000 Series Q warrants, with an exercise price of $5.00, expired. The fair value of the Series Q warrants was $0 on the date of expiration.

2.
Options and shares issued to Consultants
The Company typically enters into consulting arrangements in exchange for common stock or stock options. During the three months ended December 31, 2016, the Company issued 372,492 shares of common stock, of which 270,000 were restricted shares. The common stock was issued with stock prices ranging between $0.09 and $0.29 per share. During the three months ended December 31, 2015, the Company issued 442,492 shares of common stock, of which 340,000 were restricted shares. The common stock was issued with stock prices ranging between $0.41 and $0.72 per share. Additionally, during the three months ended December 31, 2015, the Company issued a consultant 150,000 options to purchase common stock at $0.60 per share and a fair value of $0.30 per share. The aggregate values of the issuances of restricted common stock and common stock options are recorded as prepaid expenses and are charged to general and administrative expenses over the periods of service.

During the three months ended December 31, 2016 and 2015, the Company recorded total expense of approximately $79,000 and $329,000, respectively, relating to these consulting agreements. At December 31, 2016 and September 30, 2016, approximately $30,000 and $48,000, respectively, are included in prepaid expenses. As of December 31, 2016, the Company had 575,000 options outstanding, which were issued to consultants as payment for services. Of these 575,000 outstanding options, 475,000 were vested, all of which were issued from the Non-Qualified Stock Option plans.

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 December 31, 2016:

	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	$490,040	$-	$1,292,666	$1,782,706

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, 2016:

	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	$3,111,361	$-	$5,283,573	$8,394,934

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 December 31, 2016 and the year ended September 30, 2016:

	(3 months ended) December 31, 2016	(12 months ended) September 30, 2016
Beginning balance	$5,283,573	$6,323,032
Issuances	2,316,084	8,722,073
Realized and unrealized gains	(6,306,991)	(9,761,532)
Ending balance	$1,292,666	$5,283,573

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.
RELATED PARTY TRANSACTIONS

Effective August 31, 2016, Maximilian de Clara, the Company's then President and a director, resigned for health reasons. In payment for past services, the Company agreed to issue Mr. de Clara 650,000 shares of restricted stock; 325,000 shares upon his resignation and 325,000 on August 31, 2017. At December 31, 2016 and September 30, 2016, the fair value accrued for unissued shares was approximately $22,000 and $101,000, respectively.

On January 13, 2016, the de Clara Trust demanded payment on a note payable, of which the balance, including accrued and unpaid interest, was approximately $1.1 million. The de Clara Trust was established by Maximilian de Clara, the Company's former President and a director. The Company's Chief Executive Officer, Geert Kersten, is the trustee and a beneficiary. When the de Clara Trust demanded payment on the note, the Company sold 3,000,000 shares of its common stock and 3,000,000 Series X warrants to the de Clara Trust for approximately $1.1 million. Each warrant allows the de Clara Trust to purchase one share of the Company's common stock at a price of $0.37 per share at any time on or before January 13, 2021.

During the three months ended December 31, 2016 and 2015, the Company paid approximately $0 and $33,000, respectively, in interest expense to Mr. de Clara.

F.
COMMITMENTS AND CONTINGENCIES

Clinical Research Agreements

In March 2013, the Company entered into an agreement with Aptiv Solutions, Inc. (which was subsequently acquired by ICON Inc.) to provide certain clinical research services in accordance with a master service agreement. The Company will reimburse ICON for costs incurred. The agreement required the Company to make $600,000 in advance payments which are being credited against future invoices in $150,000 annual increments through December 2017. As of December 31, 2016, the total balance advanced is $150,000, which is classified as a current asset.

16

In April 2013, the Company entered into a co-development and revenue sharing agreement with Ergomed. Under the agreement, Ergomed will contribute up to $10 million towards the study in the form of offering discounted clinical services in exchange for a single digit percentage of milestone and royalty payments, up to a specific maximum amount. In October 2015, the Company entered into a second co-development and revenue sharing agreement with Ergomed for an additional $2 million, for a total of $12 million. The Company accounted for the co-development and revenue sharing agreement 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 Company entered into the co-development and revenue sharing agreement with Ergomed, it has incurred research and development expenses of approximately $20.4 million related to Ergomed’s services. This amount is net of Ergomed’s discount of approximately $6.6 million. During the three months ended December 31, 2016 and 2015, the Company recorded, net of Ergomed’s discount, approximately $1.3 million and $2.0 million, respectively, as research and development expense related to Ergomed’s services.

In October 2013, the Company entered into two co-development and profit sharing agreements with Ergomed. One agreement supports the Phase 1 study being conducted at the University of California, San Francisco, or UCSF, for the development of Multikine as a potential treatment for peri-anal warts in HIV/HPV co-infected men and women. The Phase 1 study originally started after the Company signed a cooperative research and development agreement with the U.S. Naval Medical Center, San Diego. In August 2016, the U.S. Navy discontinued this Phase 1 study because of difficulties in enrolling patients. The other agreement focuses on the development of Multikine as a potential treatment for cervical dysplasia in HIV/HPV co-infected women. Ergomed will assume up to $3 million in clinical and regulatory costs for each study.

The Company is currently involved in a pending arbitration proceeding, CEL-SCI Corporation v. inVentiv Health Clinical, LLC (f/k/a PharmaNet LLC) and PharmaNet GmbH (f/k/a PharmaNet AG). The Company initiated the proceedings against inVentiv Health Clinical, LLC, or inVentiv, the former third-party CRO, and are seeking payment for damages related to inVentiv’s prior involvement in the Phase 3 clinical trial of Multikine. The arbitration claim, initiated under the Commercial Rules of the American Arbitration Association, alleges (i) breach of contract, (ii) fraud in the inducement, and (iii) common law fraud. Currently, the Company is seeking at least $50 million in damages in its amended statement of claim.

In an amended statement of claim, the Company asserted the claims set forth above as well as an additional claim for professional malpractice. The arbitrator subsequently granted inVentiv’s motion to dismiss the professional malpractice claim based on the “economic loss doctrine” which, under New Jersey law, is a legal doctrine that, under certain circumstances, prohibits bringing a negligence-based claim alongside a claim for breach of contract. The arbitrator denied the remainder of inVentiv’s motion, which had sought to dismiss certain other aspects of the amended statement of claim. In particular, the arbitrator rejected inVentiv’s argument that several aspects of the amended statement of claim were beyond the arbitrator’s jurisdiction.

In connection with the pending arbitration proceedings, inVentiv has asserted counterclaims against the Company for (i) breach of contract, seeking at least $2 million in damages for services allegedly performed by inVentiv; (ii) breach of contract, seeking at least $1 million in damages for the alleged use of inVentiv's name in connection with publications and promotions in violation of the parties' contract; (iii) opportunistic breach, restitution and unjust enrichment, seeking at least $20 million in disgorgement of alleged unjust profits allegedly made by the Company as a result of the purported breaches referenced in subsection (ii); and (iv) defamation, seeking at least $1 million in damages for allegedly defamatory statements made about inVentiv. The Company believes inVentiv's counterclaims are meritless and intends to vigorously defend against them. However, if such defense is unsuccessful, and inVentiv successfully asserts any of its counterclaims, such an adverse determination could have a material adverse effect on the Company's business, results, financial condition and liquidity.

In October 2015 the Company signed an arbitration funding agreement with a company established by Lake Whillans Litigation Finance, LLC, a firm specializing in funding litigation expenses. Pursuant to the agreement, an affiliate of Lake Whillans provides the Company with up to $5 million in funding for litigation expenses to support its arbitration claims against inVentiv. The funding is available to the Company to fund the expenses of the ongoing arbitration and will only be repaid if the Company receives proceeds from the arbitration. During the three months ended December 31, 2015, the Company recognized a gain of approximately $1.1 million on the derecognition of legal fees to record the transfer of the liability that existed prior to the execution of the financing agreement from the Company to Lake Whillans. The gain on derecognition of legal fees is recorded as a reduction of general and administration expenses on the Statement of Operations. All related legal fees are directly billed to and paid by Lake Whillans. As part of the agreement with Lake Whillans, the law firm agreed to cap its fees and expenses for the arbitration at $5 million.

The arbitration hearing on the merits began on September 26, 2016.

Lease Agreements

The Company leases a building near Baltimore, Maryland. 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 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 December 31, 2016 and September 30, 2016.

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 Company receives approximately $6,000 per month in rent for the sub-leased space.

The Company leases its research and development laboratory under a 60 month lease which expires February 28, 2017. In September 2016, the lease was extended through 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 $11,000 per month. As of December 31, 2016 and September 30, 2016, the Company has recorded a deferred rent liability of approximately $1,000 and $2,000, 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 December 31, 2016 and September 30, 2016, the Company has recorded a deferred rent liability of approximately $18,000.

During the three months ended December 31, 2016, the Company leased 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 approximately 6.25% per annum. The Company’s previous equipment lease expired on September 30, 2016.

G.
PATENTS

During the three months ended December 31, 2016 and 2015, no patent impairment charges were recorded. For the three months ended December 31, 2016 and 2015, amortization of patent costs totaled approximately $9,000. The total estimated future amortization expense is as follows:

Nine months ending September 30, 2017	$27,433
Year ending September 30,	
2018	36,379
2019	34,676
2020	31,483
2021	28,183
2022	24,380
Thereafter	64,733
Total	$247,267

H.
EARNINGS PER COMMON SHARE

The following table provides the details of the basic and diluted earnings per-share computations:

	Three Months Ended December 31, 2016		
	Net Income	Weighted Average Shares	EPS
Basic earnings per share	$3,536,802	149,860,777	$0.02
Gain on derivatives (1)	(1,556,754)	2,256,934	
Dilutive earnings per share	$1,980,048	152,117,711	$0.01

(1) Includes certain Series CC, DD, EE and FF warrants.

	Three Months Ended December 31, 2015		
	Net Income	Weighted Average Shares	EPS
Basic earnings per share	$2,341,813	109,768,502	$0.02
Conversion of note payable	24,841	1,871,283	
Dilutive earnings per share	$2,366,654	111,639,785	$0.02

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 December 31:

	2016	2015
Options and Warrants	173,654,474	74,776,529
Unvested Restricted Stock	15,100,000	15,100,000
Total	188,754,474	89,876,529

I.
SUBSEQUENT EVENTS

The Company has evaluated subsequent events through the date these financial statements were filed and determined there are no subsequent events that require disclosure.

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. Multikine has been cleared by the regulators in twenty four countries around the world, including the U.S. FDA.

On September 26, 2016, the Company received verbal notice from FDA that the Phase 3 clinical trial in advanced primary head and neck cancer has been placed on clinical hold. At such time, enrollment in the Phase 3 study was 926 patients. Pursuant to this communication from FDA, patients currently receiving study treatments can continue to receive treatment, and patients already enrolled in the study will continue to be followed.

On October 21, 2016, the Company received a partial clinical hold letter from FDA and, on November 18, 2016, the Company submitted a response to FDA's partial clinical hold letter.

In its partial clinical hold letter, FDA identified the following specific deficiencies: a) FDA stated that there is an unreasonable and significant risk of illness or injury to human subjects and cited among other things the absence of prompt reports by the Company to the FDA of IDMC recommendations to close the study entirely (made in spring of 2014) or at least to close it to accrual of new patients (made in spring of 2016); b) FDA stated that the investigator brochure is misleading, erroneous, and materially incomplete; and c) FDA stated that the plan or protocol is deficient in design to meet its stated objectives. In its partial clinical hold letter, FDA also identified the information needed to resolve these deficiencies. In addition, FDA's partial clinical hold letter included two requests relating to quality information regarding the Company's investigational final drug product, which were noted by FDA as non-hold issues. The Company believes that its response submitted to FDA on November 18, 2016, addressed each of the deficiencies identified by FDA including detailing its belief that, under the applicable FDA guidance, there was no obligation to report the cited IDMC recommendations to the FDA at the time they were issued, and it also requested a face-to-face meeting with FDA, and outlined the Company's commitment to diligently work with FDA in an effort to have the partial clinical hold for the study lifted.

On December 8, 2016, FDA advised us that the Agency was denying the Company's request for a meeting at that time because FDA's review of the Company's November 18, 2016 response was ongoing. The Company also was advised that the Company would be receiving a letter addressing its November 18, 2016 response by December 18, 2016.

On December 16, 2016, FDA issued an Incomplete Response To Hold letter to the Company indicating that based on the Agency's preliminary review of the Company's November 18, 2016 submission, FDA has determined that it is not a complete response to all of the issues listed in FDA's clinical hold letter. FDA identified the following specific deficiencies: a) FDA stated that the Company did not provide the information identified as necessary to address FDA's statement that patients enrolled in the study are exposed to unreasonable and significant risk of illness or injury to human subjects; b) FDA stated that the Company did not provide the information identified as necessary to address FDA's statement that continued enrollment of patients in the study exposes the patients to unreasonable risks and FDA furthermore stated that the study is unlikely to demonstrate that the addition of the Company's investigational drug Multikine to the standard of care is superior to standard of care and thus should be terminated for futility; (c) FDA stated that the Company did not provide the information identified as necessary to address FDA's statement that the investigator brochure is misleading, erroneous, and materially incomplete; (d) FDA stated that the Company did not provide the information identified as necessary to address FDA's statement that the proposed revised clinical protocol is inadequate in design to meet its stated objectives and FDA furthermore stated that this deficiency cannot be addressed by further revisions to the protocol. In its incomplete response to hold letter, FDA also identified the steps

the Company must take to address these deficiencies. In addition, FDA's incomplete response to hold letter noted with respect to FDA's two requests relating to quality information regarding the Company's investigational final drug product, which the Company had been instructed by FDA to submit separately from the response to the partial clinical hold, which again were noted by FDA as non-hold issues, that the Company's November 18, 2016, submission had not included the information addressing these two requests.

The Company is reviewing all of its options in response to FDA's incomplete response to hold letter. As an initial matter, the Company plans to send FDA a request accompanied by the required complete meeting package for an in person meeting with the Agency to discuss all matters relating to the partial clinical hold, because, among other things, the Company believes that there may be some misunderstanding regarding its conduct of the Phase 3 clinical trial as well as some misinterpretation of some of the information contained in the response the Company submitted on November 18, 2016 to the partial clinical hold letter. Pending the scheduling of that FDA meeting and resolution of the partial clinical hold issues, the Company expects to prepare a comprehensive submission to FDA detailing its belief, accompanied by what the Company believes to be appropriate supporting data, records, and information reflecting that the Company has taken the steps necessary to address the specific deficiencies identified by FDA, including: a) demonstrating that patients enrolled in the study are not exposed to unreasonable and significant risk of illness or injury; b) demonstrating that continued enrollment of patients in the study does not expose the patients to unreasonable risks and that the study should not be terminated for futility; (c) demonstrating that a supplemented investigator brochure is not misleading, erroneous, or materially incomplete; (d) demonstrating that the proposed revised clinical protocol is adequate in design to meet its stated objectives and that this deficiency can be addressed by the proposed revisions to the protocol.

Subject to the partial clinical hold, the Company's estimate that the total remaining cash cost of the Phase 3 clinical trial, excluding any costs that will be paid by our partners, would be approximately $13.5 million. Should FDA lift the partial clinical hold and allow the amended protocol submitted to them to proceed, which requires an enrollment of up to 1,273 subjects, the remaining cost of the Phase 3 clinical trial will be higher than currently estimated. This is in addition to the approximately $36.0 million that the Company already had spent on the trial as of December 31, 2016. This number may be affected by the rate of any future patient enrollment, 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. If FDA will only lift the partial clinical hold with termination of the current study and initiation of a new clinical trial, any such new trial can only be initiated if permitted by FDA and as appropriate other regulatory authorities around the world after the requisite submissions are made to them, and the additional duration and costs of the Phase 3 clinical program would likely exceed those already incurred in connection with the Phase 3 clinical trial. If there is a need to conduct an additional Phase 3 pivotal study, any such requirement would have significant and severe material consequences for us and could impact our ability to continue as a going concern.

The Company will not be able to enroll any additional patients in the Phase 3 study unless FDA lifts the partial clinical hold. In addition, in the spring of 2016, the IDMC recommended to us that new patient enrollment should stop in the Phase 3 study, but patients already on study should continue to be treated and followed. Although the Company had expected to work through the concerns raised by the IDMC while the Company worked through the partial clinical hold with FDA, the IDMC informed us on December 13, 2016, that because the study is on partial clinical hold imposed by FDA, the IDMC has no formal recommendation regarding continuation of the trial at this time. If the partial clinical hold is not lifted by FDA or if it is determined by FDA that the study has been compromised, the study may be terminated, or if the partial clinical hold is lifted by FDA but the IDMC continues to recommend that enrollment not be allowed to continue, the study may be terminated by the Company.

If the partial clinical hold is not lifted, the Phase 3 study will not be able to be completed to its prespecified endpoints in a timely manner, if at all, and, if the Phase 3 study cannot be completed to its prespecified endpoints, the study would not be able to be used as the pivotal study supporting a marketing application in the United States, and at least one entirely new Phase 3 pivotal study would need to be conducted to provide the pivotal study supporting a marketing application in the United States. Even if the partial clinical hold is lifted, if it is not lifted in a timely fashion, the nature and duration of the partial clinical hold could irreparably harm the data from the Phase 3 study such that it may no longer be able to be used as the pivotal study supporting a marketing application in the United States. Even if the partial clinical hold is lifted in a timely fashion, it remains possible that the regulatory authorities could determine that the Phase 3 study is not sufficient to be used as a single pivotal study supporting a marketing application in the United States.

Multikine is also being used in a Phase I study at UCSF in HIV/HPV co-infected men and women with peri-anal warts.

Multikine (Leukocyte Interleukin, Injection) is the full name of this investigational therapy, which, for simplicity, is referred to in the remainder of 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 in connection with 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 of the Company’s projects are under development. As a result, 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 such time as the Company becomes profitable, any or all of these financing vehicles or others may be utilized to assist 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 laboratory facilities. The Company does not anticipate realizing significant revenues until it enters into licensing arrangements regarding its technology and know-how or until it receives regulatory approval to sell its products (which could take a number of years). As a result the Company has been dependent upon the proceeds from the sale of its securities to meet all of 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 in order 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. Additionally, the partial clinical hold may also impact the Company's ability to attract new capital. 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.

The Company estimates the total remaining cash cost of the Phase 3 trial, with the exception of the parts that will be paid by its licensees, Teva Pharmaceuticals and Orient Europharma, to be approximately $13.5 million. This is in addition to approximately $36 million which has been paid as of December 31, 2016. 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 can be affected by the speed of enrollment, rate of death of patients, 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 trial will be higher than currently estimated.

In April 2013, the Company announced that it had replaced the CRO running its Phase 3 clinical trial. This was necessary since the patient enrollment in the study dropped off substantially following a takeover of the CRO which caused most of the members of the CRO's study team to leave the CRO. The Company announced that it had hired two CRO's who will manage the global Phase 3 study; ICON and Ergomed, who are both international leaders in managing oncology trials. Both CRO's helped the Company expand the trial to over 80 clinical sites globally. As of December 31, 2016, the study has enrolled 926 patients.

Under a co-development agreement, Ergomed will 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, only from sales for head and neck cancer. Ergomed, a privately-held firm headquartered in Europe with global operations, has entered into numerous similar co-development agreements, including one with Genzyme (purchased by Sanofi in 2011 for over $20 billion). Ergomed will be responsible for the new patient enrollment.

During the three months ended December 31, 2016, the Company's cash decreased by approximately $531,000. Significant components of this decrease include net proceeds from the sale of the Company's stock of approximately $3.7 million offset by net cash used to fund the Company's regular operations, including its Phase 3 clinical trial, of approximately $4.2 million and payments on capital leases of approximately $2,000. During the three months ended December 31, 2015, the Company's cash increased by approximately $4.7 million. Significant components of this increase include net proceeds from the sale of the Company's stock of approximately $10.6 million offset by net cash used to fund the Company's regular operations, including its Phase 3 clinical trial, of approximately $5.8 million, purchases of equipment of approximately $15,000 and payments on capital leases of approximately $2,000.

On December 8, 2016, the Company sold 34,024,000 shares of common stock and warrants to purchase common stock at a price of $0.125 in a public offering. The warrants consist of 17,012,000 Series CC warrants to purchase 17,012,000 shares of common stock, 34,024,000 Series DD warrants to purchase 34,024,000 shares of common stock and 34,024,000 Series EE warrants to purchase 34,024,000 shares of common stock. The Series CC warrants are immediately exercisable, expire in five-years and have an exercise price of $0.20 per share. The Series DD warrants are immediately exercisable, expire in six-months and have an exercise price of $0.18 per share. The Series EE warrants are immediately exercisable, expire in nine-months and have an exercise price of $0.18 per share. In addition, the Company issued 1,701,000 Series FF warrants to purchase 1,701,000 shares of common stock to the placement agent. The FF warrants are exercisable at any time on or after June 8, 2017 and expire on December 1, 2021 and have an exercise price $0.15625. The net proceeds to CEL-SCI from this offering was approximately $3.7 million, excluding any future proceeds that may be received from the exercise of the warrants.

Inventory decreased by approximately $314,000 at December 31, 2016 as compared to September 30, 2016, due to the timing of supplies purchased and used in the manufacturing of Multikine for the Phase 3 clinical trial. In addition, receivables decreased by approximately $390,000, primarily due to the timing of payments reimbursed under the litigation funding arrangement noted above.

Results of Operations and Financial Condition

During the three months ended December 31, 2016, research and development expenses decreased by approximately $1.1 million compared to the three months ended December 31, 2015. The Company is continuing the Phase 3 clinical trial subject to the partial clinical hold, and research and development fluctuates based on the activity level of the clinical trial.

During the three months ended December 31, 2016, general and administrative expenses increased by approximately $772,000 compared to the three months ended December 31, 2015. This increase is primarily due to an approximate $1.1 million gain on de-recognition of legal fees to record the transfer of the liability from the Company to Lake Whillans that existed prior to the execution of the financing agreement. The gain on de-recognition of legal fees is recorded as a reduction of general and administrative expenses in the three months ended December 31, 2015, offset by an approximate $366,000 decrease in employee and non-employee stock compensation due to the decrease in the market value of the common stock and 70,000 fewer shares issued in the three months ended December 31, 2016.

The gain on derivative instruments of approximately $8.9 million for the three months ended December 31, 2016 was the result of the change in fair value of the derivative liabilities during the quarter. This change was caused by decreases in the share price of the Company's common stock.

Net interest income was approximately $23,000 for the three months ended December 31, 2016, which consisted of interest income earned on the Company's cash balances. Net interest income was approximately $2,000 for the three months ended December 31, 2015, which consisted of $25,000 of interest expense on the loan from the Company's president, offset by interest income of approximately $27,000 earned on the Company's cash balances.

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.

	Three months ended December 31,	
	2016	2015
MULTIKINE	$3,939,605	$5,074,425
LEAPS	85,251	95,082
TOTAL	$4,024,856	$5,169,507

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 of 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, 2016. 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 December 31, 2016. 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 have concluded that the Company's disclosure controls and procedures were effective as of December 31, 2016.

Changes in Internal Control over Financial Reporting

The Company's management, with the participation of the Chief Executive and Chief Financial Officer, has evaluated whether any change in the Company's internal control over financial reporting occurred during the first three months of fiscal year 2016. There was no change in the Company's internal control over financial reporting during the three months ended December 31, 2016.

PART II

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

During the three months ended December 31, 2016 the Company issued 270,000 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 our 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 certificate representing these shares bears a restricted legend providing that 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. (a) Exhibits

Number Exhibit	
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: February 9, 2017 By: /s/ Geert Kersten
Geert Kersten
Principal Executive Officer*

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