ADVANCED CELL TECHNOLOGY, INC.
Form 10-Q
May 08, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED March 31, 2014

OR

o **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: 0-50295

ADVANCED CELL TECHNOLOGY, INC.

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE	**87-0656515**
(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)	(I.R.S. EMPLOYER IDENTIFICATION NO.)

33 LOCKE DRIVE, MARLBOROUGH, MASSACHUSETTS 01752

(ADDRESS, INCLUDING ZIP CODE, OF PRINCIPAL EXECUTIVE OFFICES)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: **(508) 756-1212**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

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 definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer x	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class:	Outstanding at April 30, 2014:
Common Stock, $0.001 par value per share	2,852,780,910 shares

ADVANCED CELL TECHNOLOGY, INC. AND SUBSIDIARY

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PART I – FINANCIAL INFORMATION

ITEM 1. Financial Statements

ADVANCED CELL TECHNOLOGY, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

AS OF MARCH 31, 2014 AND DECEMBER 31, 2013

	March 31, 2014 (Unaudited)	December 31, 2013
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$4,005,217	$1,743.485
Other receivable	220,349	209,198
Deferred royalty fees, current portion	62,435	62,435
Prepaid expenses and other current assets	374,573	896,741
Total current assets	4,662,574	2,911,859
Property and equipment, net	814,018	753,576
Deferred royalty fees, less current portion	92,171	107,780
Other assets	68,365	68,801
Deferred costs	–	65,903
TOTAL ASSETS	$5,637,128	$3,907,919
LIABILITIES AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES:		
Accounts payable	$2,714,684	$2,285,331
Accrued expenses	2,929,297	3,545,713
Accrued settlement	3,780,515	4,086,619
Senior secured convertible debentures, current portion, net of discount of $108,229 and $225,324, at March 31, 2014 and December 31, 2013, respectively	1,091,771	2,174,676
Embedded conversion option liabilities, current portion	287,000	335,208
Loss contingency accrual	8,384,243	6,431,979
Unsettled warrant obligation	4,885,299	3,899,391
Deferred revenue, current portion	157,872	157,872
Total current liabilities	24,230,681	22,916,789
	–	1,162,447

Senior secured convertible debentures, less current portion, net of discount of $0 and $37,553 at March 31, 2014 and December 31, 2013, respectively		
Embedded conversion option liabilities, less current portion	–	327,792
Warrant and option derivative liabilities	373,771	284,799
Deferred revenue, less current portion	1,710,234	1,749,702
Total liabilities	26,314,686	26,441,529
Commitments and contingencies		
STOCKHOLDERS' DEFICIT:		
Preferred stock, Series B; $0.001 par value; 50,000,000 shares authorized, 1,000 shares issued and outstanding	1	1
Preferred stock, Series C; $0.001 par value; 50,000,000 shares authorized, 1,750 shares issued and outstanding	2	2
Common stock, $0.001 par value; 3,750,000,000 shares authorized, 2,799,148,271 and 2,640,264,975 shares issued and outstanding	2,799,149	2,640,265
Additional paid-in capital	333,694,620	322,683,874
Promissory notes receivable, net of discount of $1,630,149 and $2,018,321, at March 31, 2014 and December 31, 2013, respectively	(34,565,486)	(34,013,395)
Accumulated deficit	(322,605,844)	(313,844,357)
Total stockholders' deficit	(20,677,558)	(22,533,610)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$5,637,128	$3,907,919

The accompanying notes are an integral part of these consolidated financial statements.

ADVANCED CELL TECHNOLOGY, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE THREE MONTHS ENDED MARCH 31, 2014 AND 2013

	Three Months Ended March 31,	
	2014 (Unaudited)	2013 (Unaudited) As Restated (1)
Revenue (License fees and royalties)	$39,468	87,781
Cost of Revenue	15,609	34,359
Gross profit	23,859	53,422
Operating expenses:		
Research and development	2,507,844	3,098,559
General and administrative expenses	3,312,563	2,833,869
Litigation settlement contingency	1,901,538	–
Total operating expenses	7,721,945	5,932,428
Loss from operations	(7,698,086)	(5,879,006)
Non-operating income (expense):		
Interest and other income	54,890	1,777
Interest expense	(296,972)	(524,189)
Finance (cost) gain	(50,726)	336,880
Adjustments to fair value of unsettled warrant obligation	(985,908)	(613,032)
Adjustments to fair value of derivatives	287,028	166,933
Total non-operating expense	(991,688)	(631,631)
Loss before provision for income tax	(8,689,774)	(6,510,637)
Provision for income tax	–	–
Net loss	$(8,689,774)	$(6,510,637)
Weighted average shares outstanding:		
Basic and diluted	2,799,148,271	2,251,585,598
Loss per share:		
Basic and diluted	$(0.00)	$(0.00)

(1) See Note 2 “Restatement of Previously Issued Financial Statements” of Notes to Consolidated Financial Statements

The accompanying notes are an integral part of these consolidated financial statements

ADVANCED CELL TECHNOLOGY, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT

FOR THE THREE MONTHS ENDED MARCH 31, 2014

	Series B Preferred Stock		Series C Preferred Stock		Common Stock		Additional Paid-in Capital	Promissory Notes Receivable, net	Accu Defic
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance December 31, 2013	1,000	1	1,750	2	2,640,264,975	2,640,265	322,683,874	(34,013,395)	(313,8
Shares issued for settlements	–	–	–	–	43,373,609	43,374	2,356,626	–	–
Shares issued for services	–	–	–	–	1,222,687	1,223	91,252	–	–
Accrued dividends on Series B and C Preferred Stock	–	–	–	–	–	–	623,804	–	(623,8
Accretion of note receivable discount on Series B and C Preferred Stock	–	–	–	–	–	–	–	(552,091)	552,0
Option compensation charges	–	–	–	–	–	–	346,595	–	–
Issuance of 114,287,000 shares of common stock	–	–	–	–	114,287,000	114,287	7,592,469	–	–
Net loss for the three	–	–	–	–	–	–	–	–	(8,68

months ended March 31, 2014									
Balance, March 31, 2014 (unaudited)	1,000	$1	1,750	$2	2,799,148,271	$2,799,149	$333,694,620	$(34,565,486)	$(322,(

The accompanying notes are an integral part of these consolidated financial statements.

ADVANCED CELL TECHNOLOGY, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE THREE MONTHS ENDED MARCH 31, 2014 AND 2013

	Three Months Ended March 31,	
	2014 (Unaudited)	2013 (Unaudited) As Restated (1)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(8,689,774)	$(6,510,637)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	30,960	17,852
Amortization of deferred charges	15,609	34,359
Amortization of deferred revenue	(39,468)	(87,781)
Redeemable preferred stock dividend accrual	–	34,069
Stock based compensation	346,595	1,132,624
Amortization of deferred issuance costs	65,903	198,685
Amortization of discounts	154,648	171,157
Adjustments to fair value of warrant obligation	985,908	613,032
Adjustments to fair value of derivatives	(287,028)	(166,933)
Shares of common stock issued for compensation	92,475	420,955
Non-cash financing costs	1,952,264	(1,019,700)
Warrant and options issued for consulting services	–	10,418
Changes in operating assets and liabilities		
Other receivable	(11,151)	–
Prepaid expenses and other current assets	522,604	(382,327)
Accounts payable and other current liabilities	(493,167)	(2,742,221)
Net cash used in operating activities	(5,353,622)	(8,276,448)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(91,402)	(98,386)
Payment of lease deposits	–	(8,805)
Net cash used in investing activities	(91,402)	(107,191)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	7,706,756	5,253,221
Net cash provided by financing activities	7,706,756	5,253,221

NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	2,261,732	(3,130,418)
CASH AND CASH EQUIVALENTS, BEGINNING BALANCE	1,743,485	7,241,852
CASH AND CASH EQUIVALENTS, ENDING BALANCE	$4,005,217	$4,111,434
CASH PAID FOR:		
Interest	$51,578	$80,000
SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING ACTIVITIES:		
Accrued dividends on Series B and C Preferred Stock	$623,804	$563,676
Accretion of note receivable discount on Series B and C Preferred Stock	$552,091	$567,132
Issuance of 43,373,609 and 80,357,143 shares of common stock for accrued settlement	$2,400,000	$4,500,000

(1) See Note 2 “Restatement of Previously Issued Financial Statements” of Notes to Consolidated Financial Statements

The accompanying notes are an integral part of these consolidated financial statements.

ADVANCED CELL TECHNOLOGY, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. ORGANIZATIONAL MATTERS

The unaudited consolidated financial statements have been prepared by Advanced Cell Technology, Inc. and Subsidiary (collectively the "Company"), pursuant to the rules and regulations of the Securities and Exchange Commission. The information furnished herein reflects all adjustments (consisting of normal recurring accruals and adjustments) which are, in the opinion of management, necessary to fairly present the operating results for the respective periods. Certain information and footnote disclosures normally present in annual consolidated financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") have been omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and footnotes included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 1, 2014. The results for the three months ended March 31, 2014 are not necessarily indicative of the results to be expected for the full year ending December 31, 2014.

Organization and Nature of Business

The Company is a life science company, incorporated in the state of Delaware, focused on the emerging field of regenerative medicine. The Company's core business strategy is to develop and ultimately commercialize stem cell derived cell therapies and biologics that will deliver safe and efficacious patient therapies, and which can be manufactured at scale and are reimbursable at attractive levels. The Company is conducting several ongoing clinical trials for treating macular degeneration, and it has a preclinical development pipeline focused on products for eye diseases, autoimmune and inflammatory diseases, and wound healing. The Company has no therapeutic products currently available for sale and does not expect to have any therapeutic products commercially available for sale for a period of years, if at all. These factors indicate that the Company's ability to continue its research and development activities is dependent upon the ability of management to obtain additional financing as required.

2. RESTATEMENT OF PREVIOUSLY ISSUED CONSOLIDATED FINANCIAL STATEMENTS

On March 10, 2014, we concluded that our previously issued consolidated financial statements required a restatement for the years ended December 31, 2012 and 2011. We determined that a misapplication of accounting guidance

relating to certain warrants and an associated full-ratchet anti-dilution feature that was included in these warrants occurred. Additionally we concluded that we had an error with our stock compensation accounting as a result of having inadequate authorized, unissued shares available for our outstanding options in certain periods. As a result of these errors we determined that our financial statements for the following periods (the "Applicable Periods") required a restatement and could no longer be relied upon: the fiscal years ended December 31, 2009, December 31, 2010, December 31, 2011 and December 31, 2012; each quarterly period in 2011 and 2012; and the first three quarterly periods in its fiscal year ended December 31, 2013.

Warrant Accounting Issue

Two separate warrant agreements entered into in September 2005 contained a full ratchet, anti-dilution feature which entitled the holders to automatic adjustments in the number and purchase price of their shares, if the Company issued lower-priced shares between May 1, 2005 and January 15, 2009, (the "Pricing Period"). From the original date of the warrant until the exercise of the warrants in September 2006, the anti-dilution embedded derivative feature was properly accounted for and recorded at its fair value. From the date of exercise through the end of the pricing period, the full ratchet feature remained in effect but was not accounted for or recorded at its fair value, which resulted in an accounting error. In determining the proper accounting management performed a valuation of this full ratchet embedded derivative using a Monte Carlo simulation model.

Management further determined that as of the end of the pricing period an adjustment to the shares and purchase price of the shares should have taken place per the full ratchet anti-dilution feature of the agreement. As the matter went to litigation this contractual obligation was never settled and became fixed at 63.2 million shares with a floor price of $0.06. This unsettled warrant contractual obligation should have been recorded from the end of the pricing period until settlement with accounting treatment, under ASC 815, requiring mark-to-market adjustments at each reporting date. Management also continues to evaluate the application of ASC 450, Contingencies, for the year ended December 31, 2013, as it relates to the ongoing, previously disclosed, legal dispute between the Company and the warrant holders.

Due to the resulting financial statement impact within the years impacted, the Company has determined it is necessary to restate its financial statements for the Applicable Periods.

Stock Compensation Issue related to inadequate authorized and unissued shares to settle share based awards in shares

The Company examined periods being restated for the warrant liability issue to determine if authorized, unissued share availability was an issue in relation to instruments that have share based settlement requirements. Through this analysis it was determined that stock options were impacted in certain periods while other instruments such as warrants, convertible debt and preferred stock already had liability classification and therefore would not be impacted by inadequate authorized, unissued shares available.

It was determined that in Q1 2009, Q2 2009 and Q4 2011 options outstanding were impacted by the lack of authorized, unissued shares available. It was further determined that the date in which committed shares exceeded unauthorized was February 9, 2009 and that shortage of available shares ran through September 10, 2009, when additional authorized shares were approved. As for 2011, the share issue began on November 2, 2011 and ran through January 24, 2012, when additional authorized shares were approved.

As per the accounting requirements of ASC 718, the inadequate share issue caused the accounting to change from equity based to liability based accounting, with the vested options to be measured at fair value as a liability until such time as adequate shares were approved and the accounting for the stock compensation would revert back to equity based accounting.

This accounting error in treating the stock compensation as equity throughout these periods with inadequate authorized unissued shares, led the Company to re-measure all stock options impacted during these periods to effect the proper accounting treatment.

Due to the resulting financial statement impact within the years impacted, the Company has determined it is necessary to restate its financial statements for the Applicable Periods.

The following tables summarize the effects of the restatement on our previously issued condensed consolidated financial statements:

Summary of increases (decreases) in net loss (unaudited)

	Three months ended March 31, 2013
Net loss, as previously reported	$(6,413,041)
Net adjustments	
Research and development	(106,559)
General and administrative expenses	(8,005)
Adjustments to fair value of unsettled warrant obligation	16,968
Net loss, restated	$(6,510,637)
Basic loss per share:	
Net loss, as previously reported	$(0.00)
Net adjustments	
Research and development	(0.00)
General and administrative expenses	(0.00)
Adjustments to fair value of unsettled warrant obligation	0.00
Net loss, restated	$(0.00)
Diluted loss per share:	
Net loss, as previously reported	$(0.00)
Net adjustments	
Research and development	(0.00)
General and administrative expenses	(0.00)
Adjustments to fair value of unsettled warrant obligation	0.00
Net loss, restated	$(0.00)
Weighted average shares used in computing net loss per share:	
Basic	2,251,585,598
Diluted	2,251,585,598

Consolidated Statements of Operations (unaudited) for the three months ended March 31, 2013

	Three months ended March 31, 2013		
	As Previously Reported	Adjustments	As Restated
Revenue	$87,781		$87,781
Cost of revenue	34,359		34,359
Gross profit	53,422	–	53,422
Operating expenses:			
Research and development	2,992,000	106,559	3,098,559
General and administrative expenses	2,825,864	8,005	2,833,869
Total operating expenses	5,817,864	114,564	5,932,428
Loss from operations	(5,764,442)	(114,564)	(5,879,006)
Non-operating income (expense):			
Interest income	1,777		1,777
Interest expense and late fees	(524,189)		(524,189)
Finance gain (cost)	(293,120)	630,000	336,880
Fines and penalties	–		–
Gain on extinguishment of debt	–		–
Adjustments to fair value of unsettled warrant obligation	–	(613,032)	(613,032)
Adjustments to fair value of derivatives	166,933		166,933
Total non-operating expense	(648,599)	16,968	(631,631)
Loss before provision for income tax	(6,413,041)	(97,596)	(6,510,637)
Provision for income tax	–	–	–
Net loss	$(6,413,041)	$(97,596)	$(6,510,637)
Loss per share:			
Basic	$(0.00)	$(0.00)	$(0.00)
Diluted	(0.00)	(0.00)	(0.00)
Weighted average shares outstanding:			
Basic	2,251,585,598	2,251,585,598	2,251,585,598
Diluted	2,251,585,598	2,251,585,598	2,251,585,598

Consolidated Statement of Cash Flows Impact

The following table includes selected information from our consolidated statements of cash flows presenting previously reported and restated cash flows, for the three months ended March 31, 2013:

	For the three months ended March 31, 2013	
	As Previously Reported	As Restated
Net loss	$(6,413,041)	$(6,510,637)
Stock based compensation	1,018,060	1,132,624
Adjustments to fair value of unsettled warrant obligation	–	613,032
Non-cash financing costs	(389,700)	(1,019,700)
Net cash used in operating activities	(8,276,448)	(8,276,448)

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3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation —The Company follows accounting standards set by the Financial Accounting Standards Board , FASB. The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, GAAP. References to GAAP issued by the FASB in these footnotes are to the FASB Accounting Standards Codification,™ sometimes referred to as the Codification or ASC.

The accompanying consolidated financial statements have been prepared in conformity with GAAP which contemplate continuation of the company as a going concern. However, as of March 31, 2014, the Company has an accumulated deficit of $322.6 million. This and other factors, such as the Company's cash balance, raise substantial doubt about the Company's ability to continue as a going concern. The ability to continue as a going concern is dependent upon many factors, including the Company's ability to raise additional capital in a timely manner. The accompanying financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

Principles of Consolidation — The accounts of the Company and its wholly-owned subsidiary Mytogen, Inc. are included in the accompanying consolidated financial statements. All intercompany balances and transactions were eliminated in consolidation.

Segment Reporting —ASC 280, *"Segment Reporting"* requires use of the "management approach" model for segment reporting. The management approach model is based on the way a company's management organizes segments within the company for making operating decisions and assessing performance. The Company determined it has one operating segment. Disaggregation of the Company's operating results is impracticable, because the Company's research and development activities and its assets overlap, and management reviews its business as a single operating segment. Thus, discrete financial information is not available by more than one operating segment.

Use of Estimates — These consolidated financial statements have been prepared in accordance with GAAP and, accordingly, require management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Specifically, the Company's management has estimated loss contingencies related to outstanding litigation. In addition, Management has estimated variables used to calculate the Black-Scholes option pricing model used to value derivative instruments and the Company estimates the fair value of the embedded conversion option associated with the senior secured convertible debentures using a binomial lattice model as discussed below under "Fair Value Measurements". Also, management has estimated the expected economic life and value of the Company's licensed technology, the Company's net operating loss for tax purposes, share-based payments for compensation to employees, directors, consultants and investment banks, and the useful lives of the Company's fixed assets and its accounts receivable allowance. Actual results could differ from those estimates.

Cash and Cash Equivalents — Cash equivalents are comprised of certain highly liquid investments with maturities of three months or less when purchased. The Company maintains its cash in bank deposit accounts, which at times, may exceed federally insured limits. The Company has not experienced any losses related to this concentration of risk. As of March 31, 2014 and December 31, 2013, the Company had deposits in excess of federally-insured limits totaling $3,787,842 and $1,668,232, respectively.

Commitments and Contingencies — We are subject to various claims and contingencies related to lawsuits as well as commitments under contractual and other obligations. We recognize liabilities for contingencies and commitments when a loss is probable and can be reasonably estimated.

Relating to loss contingencies we accrue the best estimate of a loss within a range. If no estimate in a range is better than any other, the minimum amount is accrued. We disclose a reasonably possible loss in excess of the amount accrued, if applicable. For reasonably possible loss contingencies we disclose the nature of the loss contingency and give a range of the estimate of possible loss or state that an estimate cannot be made.

Grant Received — From time to time the Company participates in research grants both as an initiator of grants as well as a sub-recipient of grant funds. The Company incurs costs for the grant and is subsequently reimbursed for these expenses by grant receipts. The Company records such receipts as a reduction in research and development costs. For the three months ended March 31, 2014 and 2013, the Company recorded as a reduction in research and development costs, $0, and $60,022 respectively.

Grants Receivable — The Company periodically assesses its grants receivable for collectability on a specific identification basis. If collectability of an account becomes unlikely, the Company records an allowance for that doubtful account. Once the Company has exhausted efforts to collect, management writes off the grants receivable against the allowance it has already created.

Property and Equipment — The Company records its property and equipment at historical cost. The Company expenses maintenance and repairs as incurred. Upon disposition of property and equipment, the gross cost and accumulated depreciation are written off and the difference between the proceeds and the net book value is recorded as a gain or loss on sale of assets. In the case of certain assets acquired under capital leases, the assets are recorded net of imputed interest, based upon the net present value of future payments. Assets under capital lease are pledged as collateral for the related lease.

The Company provides for depreciation over the assets' estimated useful lives as follows:

Machinery & equipment	4 years
Computer equipment	3 years
Office furniture	4 years
Leasehold improvements	Lesser of lease life or economic life
Capital leases	Lesser of lease life or economic life

Patents — The Company follows ASC 350-30, *"General Intangibles Other than Goodwill,"* in accounting for its patents. ASC 350-30 provides that costs of internally developing, maintaining, or restoring intangible assets that are not specifically identifiable, that have indeterminate lives, or that are inherent in a continuing business and related to an entity as a whole, shall be recognized as an expense when incurred. The Company has expensed as research and development expense all costs associated with developing its patents.

Equity Method Investment — The Company follows ASC 323, *"Investments-Equity Method and Joint Ventures,"* in accounting for its investment in the joint venture. In the event the Company's share of the joint venture's net losses reduces the Company's investment to zero, the Company will discontinue applying the equity method and will not provide for additional losses unless the Company has guaranteed obligations of the joint venture or is otherwise committed to provide further financial support for the joint venture. If the joint venture subsequently reports net income, the Company will resume applying the equity method only after its share of that net income equals the share of net losses not recognized during the period the equity method was suspended.

Deferred Costs — Consist of the following:

(a) Payments, either in cash or share-based, made in connection with the sale of debentures which are amortized using the effective interest method over the lives of the related debentures. These deferred issuance costs are charged to financing costs when and if the related debt instrument is retired or converted early. The weighted average amortization period for deferred debt issuance costs is 48 months.

(b) Payments made to secure commitments under certain financing arrangements. These amounts are recognized in financing costs ratably over the period of the financing arrangements, and are recognized in financing costs immediately if the arrangement is cancelled, forfeited or the utility of the arrangement to the company is otherwise compromised.

(c) Payments made to financial institutions and consulting firms in order to provide financing related services. These costs are being amortized over the terms of the related agreements.

Long-Lived Assets— The Company follows ASC 360-10, *"Property, Plant, and Equipment,"* which established a "primary asset" approach to determine the cash flow estimation period for a group of assets and liabilities that represents the unit of accounting for a long-lived asset to be held and used. Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The carrying amount of a long-lived asset is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset. Long-lived assets to be disposed of are reported at the lower of carrying amount or fair value less cost to sell. Through March 31, 2014, the Company had not experienced impairment losses on its long-lived assets.

Fair Value Measurements — The Company applies the provisions of ASC 820-10, *"Fair Value Measurements and Disclosures."* ASC 820-10 defines fair value, and establishes a three-level valuation hierarchy for disclosures of fair value measurement that enhances disclosure requirements for fair value measures. For certain financial instruments, including cash and cash equivalents, grants receivable, prepaid expenses, accounts payable and accrued expenses, the carrying amounts approximate fair value due to their relatively short maturities. The carrying amount of senior secured convertible debentures approximates fair value as the interest rate charged on the debentures is based on the prevailing rate. The three levels of valuation hierarchy are defined as follows:

- Level 1 inputs to the valuation methodology are quoted prices for identical assets or liabilities in active markets.
- Level 2 inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, and inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the financial instrument.
- Level 3 inputs to the valuation methodology are unobservable and significant to the fair value measurement.

The Company analyzes all financial instruments with features of both liabilities and equity under ASC 480, *"Distinguishing Liabilities From Equity,"* and ASC 815, *"Derivatives and Hedging."* Derivative liabilities are adjusted to reflect fair value at each period end, with any increase or decrease in the fair value being recorded in results of operations as adjustments to fair value of derivatives. The effects of interactions between embedded derivatives are calculated and accounted for in arriving at the overall fair value of the financial instruments. In addition, the fair values of freestanding derivative instruments such as warrant and option derivatives are valued using the Black-Scholes model.

The Company uses Level 2 inputs for its valuation methodology for certain warrant derivative liabilities. The Company's derivative liabilities are adjusted to reflect fair value at each period end, with any increase or decrease in the fair value being recorded in results of operations as adjustments to fair value of derivatives.

The Company uses Level 3 inputs for its valuation methodology for the fair value of certain embedded conversion options and warrant and option derivative liabilities.

The Company estimates the fair value of the embedded conversion option associated with its 8% convertible debentures using a binomial lattice, which estimates and compares the present value of the principal and interest payments to the as converted value to determine whether the holder of the notes should convert the notes into the Company's common stock or continue to receive principal and interest payments. The Company uses this methodology to determine the beneficial conversion features because there are no observable inputs available with respect to the fair value.

The binomial lattice relies on the following Level 3 inputs: (1) expected volatility of our common stock; (2) potential discount for illiquidity of large blocks of our common stock, and (3) discount rate for contractual debt principal and interest payments. The fair value of the embedded beneficial conversion feature is estimated as the difference between the fair value of the notes with and without the conversion feature. The fair value of the notes without the conversion feature is determined using one Level 3 input, the discount rate for contractual debt interest and principal payments.

- The expected volatility of the Company's common stock is estimated from the historical volatility of daily returns in the Company's common stock price. The Company monitors the volatility of its common stock on a quarterly basis to observe trends that may impact the fair value of the notes.

- The discount for illiquidity is measured using an average-strike option that calculates the discount as the opportunity cost for not being able to sell a large block of the Company's common stock immediately at prevailing observable market prices. Inputs to the average-strike option model include the expected volatility of the Company's common stock and time to sell a large block of the Company's stock as Level 3 inputs and other observable inputs. The time to sell the stock is estimated considering the historical daily trading volume of our common stock and market maker estimates of the amount of shares that can be offered for sale above the normal the daily trading volume without depressing the price of the Company's common stock.

At March 31, 2014, the Company identified the following assets and liabilities that are required to be presented on the balance sheet at fair value:

Description	Fair Value As of March 31, 2014	Fair Value Measurements at March 31, 2014 Using Fair Value Hierarchy		
		Level 1	Level 2	Level 3
Warrant and option derivative liabilities	$373,771	$–	$ –	$373,771

Embedded conversion option liabilities	287,000	–	–	287,000
Unsettled warrant obligation	4,885,299	4,885,299	–	–
Total	$5,546,070	$4,885,299	$ –	$660,771

The following tables reconcile the change in fair value for measurements categorized within Level 3 of the fair value hierarchy:

	Embedded Conversion Option Liabilities
Balance at December 31, 2013	$ 663,000
Total (gains) or losses for the period included in earnings	(376,000)
Balance at March 31, 2014	$ 287,000

	Warrant and Option Derivative Liabilities
Balance at December 31, 2013	$ 284,799
Total (gains) or losses for the period included in earnings	88,972
Balance at March 31, 2014	$ 373,771

Gains and losses included in earnings for the three months ended March 31, 2014 are reported as follows:

	Adjustment to Fair Value of Derivatives
Total gain included in earnings	$ 376,000

	Warrant and Option Derivative Liabilities
Total loss included in earnings	$ 88,972

The following table provides quantitative information about measurements categorized within Level 3 of the fair value hierarchy:

Description	Fair Value at March 31, 2014	Valuation Technique	Unobservable Input	Value
Embedded conversion option liability	287,000	Binomial Lattice Model	Expected volatility of the Company's common stock	71.5%
			Discount for illiquidity of large blocks of the Company's common stock	2.0% to 6.7%
			Discount rate for contractual debt principal and interest payments	19.0%

Description	Fair Value at March 31, 2014	Valuation Technique	Unobservable Input	Value
Warrant and Option derivative liabilities	373,771	Black Scholes Model	Expected volatility of the Company's common stock	65% - 95%

For the three months ended March 31, 2014 and March 31, 2013 the Company recognized a gain of $287,028 and $166,933, respectively, for the changes in the valuation of derivative liabilities.

The Company did not identify any non-recurring assets and liabilities that were recorded at fair value during the periods presented.

Revenue Recognition and Deferred Revenue — The Company’s revenues are primarily generated from license and research agreements with collaborators. Licensing revenue is recognized on a straight-line basis over the shorter of the life of the license or the estimated economic life of the patents related to the license.

License fee revenue begins to be recognized in the first full month following the effective date of the license agreement. Deferred revenue represents the portion of the license and other payments received that has not been earned. Costs associated with the license revenue are deferred and recognized over the same term as the revenue. Reimbursements of research expense pursuant to grants are recorded in the period during which collection of the

reimbursement becomes assured, because the reimbursements are subject to approval.

In some cases, the Company is entitled to receive royalty payments from licensees. In such cases, the Company recognizes the royalties when they are earned and collectability of those royalty payments is reasonably assured.

In connection with its license agreements, the Company recorded $39,468 and $87,781 in license fee revenue for the three months ended March 31, 2014 and 2013, respectively, in its consolidated statements of operations, and the remainder of the license fees have been accrued in deferred revenue at March 31, 2014 and December 31, 2013, respectively.

Research and Development Costs — Research and development costs consist of expenditures for the research and development of patents and technology, which cannot be capitalized. The Company's research and development costs consist mainly of payroll and payroll related expenses, research supplies and research grants. Reimbursements of research expense pursuant to grants are recorded in the period during which collection of the reimbursement becomes assured, because the reimbursements are subject to approval. Research and development costs are expensed as incurred.

Share-Based Compensation — The Company records stock-based compensation in accordance with ASC 718, "Compensation – Stock Compensation." ASC 718 requires companies to measure compensation cost for stock-based employee compensation at fair value at the grant date and recognize the expense over the employee's requisite service period. The Company recognizes in the statement of operations the grant-date fair value of stock options and other equity-based compensation issued to employees and non-employees. There were 132,556,931 options outstanding as of March 31, 2014.

Income Taxes — Deferred income taxes are provided using the liability method whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carryforwards, and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of the changes in tax laws and rates of the date of enactment.

When tax returns are filed, it is highly certain that some positions taken would be sustained upon examination by the taxing authorities, while others are subject to uncertainty about the merits of the position taken or the amount of the position that would be ultimately sustained. The benefit of a tax position is recognized in the financial statements in the period during which, based on all available evidence, management believes it is more likely than not that the position will be sustained upon examination, including the resolution of appeals or litigation processes, if any. Tax positions taken are not offset or aggregated with other positions. Tax positions that meet the more-likely-than-not recognition threshold are measured as the largest amount of tax benefit that is more than 50 percent likely of being realized upon settlement with the applicable taxing authority. The portion of the benefits associated with tax positions taken that exceeds the amount measured as described above is reflected as a liability for unrecognized tax benefits in the balance sheets along with any associated interest and penalties that would be payable to the taxing authorities upon examination.

Applicable interest and penalties associated with unrecognized tax benefits are classified as additional income taxes in the statements of operations.

Net Loss Per Share — Earnings per share is calculated in accordance with the ASC 260-10, *"Earnings Per Share."* Basic earnings-per-share is based upon the weighted average number of common shares outstanding. Diluted earnings-per-share is based on the assumption that all dilutive convertible shares and stock options were converted or exercised. Dilution is computed by applying the treasury stock method. Under this method, options and warrants are assumed to be exercised at the beginning of the period (or at the time of issuance, if later), and as if funds obtained thereby were used to purchase common stock at the average market price during the period.

At March 31, 2014 and 2013, approximately 158,711,504 and 207,503,505 potentially dilutive shares, respectively, were excluded from the shares used to calculate diluted earnings per share as their inclusion would be anti-dilutive.

Concentrations and Other Risks — Currently, the Company's revenues are concentrated on a small number of license agreements with customers. Revenues are based on amortizing funds already received over contractual terms of agreements. Based on the insignificance of these revenues to the Company's operations and the nature of the agreements, any concentration of revenue among a small number of customers does not result in a risk to the Company.

Other risks include the uncertainty of the regulatory environment and the effect of future regulations on the Company's business activities. As the Company is a biotechnology research and development company, there is also the attendant risk that someone could commence legal proceedings over the Company's discoveries.

Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists* (ASU 2013-11). ASU 2013-11 clarifies guidance and eliminates diversity in practice on the presentation of unrecognized tax benefits when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists at the reporting date. This new guidance is effective on a prospective basis for fiscal years and interim reporting periods within those years, beginning after December 15, 2013. The adoption of ASU 2013-11 is not expected to have a material impact on consolidated results of operations, financial condition, or liquidity.

In February 2013, the FASB issued ASU No. 2013-02, Comprehensive Income (Topic 220) – *Reporting of Amounts Reclassified out of Accumulative Other Comprehensive Income* (ASU 2013-02), which replaces the presentation requirements for reclassifications out of accumulated other comprehensive income in ASU 2011-05 and ASU 2011-12. ASU 2013-02 requires an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component and to present significant amounts reclassified out of accumulated other comprehensive income by respective line items of net income if the amount reclassified is required to be reclassified to net income in its entirety. The adoption of this standard is not expected to have a material impact on consolidated results of operations, financial condition, or liquidity.

4. INVESTMENT IN JOINT VENTURE

On December 1, 2008, the Company and CHA Bio & Diostech Co., Ltd. (“CHA”), formed an international joint venture. The new company, Stem Cell & Regenerative Medicine International, Inc. (“SCRMI”), will develop human blood cells and other clinical therapies based on the Company’s hemangioblast program, one of the Company’s core technologies. Under the terms of the agreement, the Company purchased upfront a 33% interest in the joint venture, and will receive another 7% interest upon fulfilling certain obligations under the agreement over a period of 3 years. The Company’s contribution includes (a) the uninterrupted use of a portion of its leased facility at the Company’s expense, (b) the uninterrupted use of certain equipment in the leased facility, and (c) the release of certain of the Company’s research and science personnel to be employed by the joint venture. In return, for a 60% interest, CHA has agreed to contribute $150,000 cash and to fund all operational costs in order to conduct the hemangioblast program. Effective May 1, 2010, the Company was no longer obligated to provide laboratory space to SCRMI. As of March 31, 2014, the Company holds a 40% interest in the joint venture and CHA owns a 60% interest. The two partners to the joint venture are in negotiations on further funding of the joint venture, but there can be no assurances that an agreement will be reached. Any financial statement impact at this time is unclear should an agreement not be reached.

The Company has agreed to collaborate with the joint venture in securing grants to further research and development of its technology. Additionally, SCRMI has agreed to pay the Company a fee of $500,000 for an exclusive, worldwide license to the Hemangioblast Program. The Company recorded $7,353 and $7,353 in license fee revenue for the three months ended March 31, 2014 and 2013, respectively, in its accompanying consolidated statements of operations, and the balance of unamortized license fee of $344,363 and $351,715 is included in deferred revenue in the accompanying consolidated balance sheets at March 31, 2014 and December 31, 2013, respectively.

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On July 15, 2011, the Company and CHA entered into a binding term sheet, with the expectation of entering into a future definitive agreement, in which the joint venture was realigned around both product development rights and research responsibilities. Under the terms of the binding term sheet, SCRMI exclusively licensed the rights to the Hemangioblast Program to the Company for United States and Canada and expanded the jurisdictional scope of the license to CHA to include Japan (in addition to South Korea, which was already exclusively licensed to CHA). As part of the agreement, the scientists at SCRMI involved in the Hemangioblast Program were transferred to the Company, and SCRMI discontinued its research activity and became solely a licensing entity. The Company is obligated to meet a minimal research spending requirement of $6.75 million by July 31, 2014 in order to maintain its exclusive license, up to the point of filing an investigational new drug for a therapeutic product. Intellectual property rights created by the Company in the course of our research are subject to a non-exclusive license to CHA for Japan and South Korea, and to SCRMI to be sub-licensable under certain circumstances for countries other than the United States, Canada, Japan and South Korea. Pursuant to the agreement, the Company paid $820,000 to SCRMI which is recorded to “losses attributable to equity method investments.” By filing the investigational new animal drug application on September 12, 2013 with the Federal Drug Administration, the Company has met the commitment required to maintain its exclusive license.

The following table is a summary of key financial data for the joint venture as of and for the three months ended March 31, 2014 and 2013:

	March 31, 2014	2013
Current assets	$279,824	$213,375
Noncurrent assets	1,315,625	1,263,514
Current liabilities	313,042	310,267
Noncurrent liabilities	1,802,524	2,094,639
Net revenue	73,029	73,029
Net income	46,882	35,564

5. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at March 31, 2014 and December 31, 2013:

	March 31, 2014	December 31, 2013
Machinery & equipment(1)	$1,125,321	$1,086,800
Computer equipment	58,963	49,707
Office furniture	49,560	38,783
Leasehold improvements(1)	592,817	559,969

	1,826,661	1,735,259
Accumulated depreciation	(1,012,643)	(981,683)
Property and equipment, net	$814,018	$753,576

(1) The 2014 balances include approximately $141,733 in machinery & equipment and $354,308 in leasehold improvements that were not yet placed in service at March 31, 2014 and therefore had not started being depreciated as of that date.

Depreciation expense for the three months ended March 31, 2014 and 2013 amounted to $30,960 and $17,852, respectively.

6. ACCRUED SETTLEMENT

The accrued settlement is comprised of the following at March 31, 2014 and December 31, 2013:

	March 31, 2014	December 31, 2013
SEC Civil Action	$3,405,515	$4,086,619
SEC Section 16 Investigation	375,000	–
Total	$3,780,515	$4,086,619

SEC Civil Action

In May 2012, the Company was named as a defendant in a civil action brought by the Securities and Exchange Commission related to transactions involving the sale and issuance of the Company’s securities. The Securities and Exchange Commission alleges that Company violated Section 5(a) and 5(c) of the Securities Act of 1933 because certain sales of shares to outside organizations, completed in late 2008 and early 2009 under the Company’s former management, resulted in $3.5 million in proceeds to the Company, were neither registered under the Securities act nor subject to an exemption from registration under Section 3(a)(10) of the Securities Act of 1933, as amended. In addition, the Company is alleged to have violated Section 13(a) of the Exchange Act of 1934 because the Company did not disclose the sale and issuance of the shares to the Securities and Exchange Commission on a timely basis.

In December 2013, the Company settled the civil action. Under the terms of the settlement accepted by the SEC, the Company consented to entry of judgment under which it neither admits nor denies liability and has agreed to disgorgement of $3.5 million in proceeds from the transactions in question. In addition, the Company will pay approximately $587,000 in pre-judgment interest. The total amount due, approximately $4.1 million, will be paid over six equal quarterly installments. The first installment was placed into escrow in July 2013 and was applied immediately to the aggregate amount due. The next installment was due and paid in late April 2014. In addition, the settlement permanently restrains and enjoins the Company from violations of Sections 5(a) and 5(c) of the Securities Act, Section 13(a) of the Exchange Act and Rule 13a-11 under the Exchange Act.

SEC Section 16 Investigation

The Company was advised that the SEC was investigating transactions involving sales of shares of our common stock that the former Chief Executive Officer failed to report in a timely manner on Form 4 under Section 16 of the Exchange Act. The Company has discussed a resolution to the matter with the SEC and has recorded the $375,000 as the expected settlement amount.

7. CONVERTIBLE PROMISSORY NOTES

Senior Secured Convertible Debentures

The Debentures issued to the CAMOFI Parties pursuant to the Settlement Agreement have an effective date of December 31, 2012, accrue interest at the rate of 8% per annum and mature on June 30, 2015. The Company may pre-pay all or a portion of the amounts due under the Debentures prior to maturity without penalty. Both of the Debentures are convertible at the option of the holder at a price per share of common stock equal to 80% of VWAP of the ten consecutive trading days prior to the conversion date. The Company must make quarterly payments under the Debentures on the last day of each calendar quarter commencing on March 31, 2013 in the amount of $600,000. The quarterly payments may, at the option of the Company and subject to the satisfaction of certain conditions, be paid in shares of Common Stock. In such case, the conversion price for such payment will be based on the lesser of (i) the conversion price as defined in the agreement or (ii) 80% of the average of the 10 closing prices immediately prior to the date the quarterly payment is due. To secure its obligations under the Debentures, the Company granted a security interest in substantially all of the Company’s assets, including its intellectual property, to the CAMOFI Parties. The Debentures contain certain covenants customary for debt instruments of its kind.

The Company received conversion notices during the period from January 1, 2014 through March 31, 2014 for $2,400,000. The Company issued 43,373,609 shares of its common stock for these conversion notices.

As of March 31, 2014, the remaining outstanding redemption dates and amounts are as follows:

Redemption Date	Amount
6/30/2014	600,000
9/30/2014	600,000
	$1,200,000

The Company determined that the Debentures contained an embedded beneficial conversion feature as the Debentures are convertible at a price per share of common stock equal to 80% of VWAP of the ten consecutive trading days prior to the conversion date. The embedded beneficial conversion feature was modeled using a binomial lattice model, and the calculated value at March 31, 2014 and December 31, 2013 was $287,000 and $663,000, respectively. The Company recorded a gain of $376,000 for the change in the fair value of the embedded conversion option liability for the three months ended March 31, 2014.

At March 31, 2014, the Debentures could be converted into 18,324,690 shares of common stock based on a conversion price of $0.0655.

The Company recorded a debt discount of $725,000, which will be amortized over the life of the note using the effective interest rate of 22.9%. For the three months ended March 31, 2014, the Company amortized $154,648 of the debt discount and recorded it as interest expense. The unamortized discount at March 31, 2014 and December 31, 2013 was $108,229 and $262,877, respectively. The Company recorded interest expense of $51,440 for the three months ended March 31, 2014 based on the contractual interest rate.

8. LOSS CONTINGENCY ACCRUAL

The loss contingency accrual is comprised of the following at March 31, 2014 and December 31, 2013:

	March 31, 2014	December 31, 2013
Warrant holder litigation	$8,130,159	$6,228,621
Miscellaneous settlements	254,084	203,358

Total	$8,384,243	$6,431,979

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Warrant holder litigation

In connection with the unsettled warrant obligation (see Note 9), the holder has filed numerous lawsuits and in 2011 made a claim for approximately $28 million. In evaluating the need for a loss contingency accrual relating to the associated litigation, the Company determined that a loss was probable and the amount of loss was reasonably estimable, based on the facts and circumstances surrounding the litigation during the last quarter of 2013. The loss contingency represents the estimated number of shares to settle above a determined share amount necessary to settle the warrant share obligation plus an additional amount for potential interest charges.

While the Company believes it has meritorious defenses against the litigation, the ultimate resolution of the matter could result in a loss of up to approximately $25 million in excess of the amount currently accrued.

Miscellaneous settlements

The Company was not able to reach settlement agreements with all of holders of convertible promissory notes and warrants that were issued between 2005 and 2010. The Company has not been contacted by the remaining holders nor has it been able to reach them for potential settlement discussions. The holders in question held warrants, which expire in June 2014. If the Company is able to negotiate with the holders it anticipates that the number of shares to be issued will be similar to the settlements that have already been finalized as of December 31, 2012.

9. Unsettled Warrant obligation

The Company determined that it has an unsettled warrant obligation related to two warrant agreements entered into in 2005. The warrant agreement had anti-dilution ratchet provisions which the Company determined led to a contractual obligation, which became fixed on January 15, 2009, to issue approximately 63.2 million common shares. The Company further determined that those common shares represent a liability which should be recorded at fair value at each accounting period with changes to that fair value being recorded in earnings. Fair value is based on the share obligation multiplied by the stock price at the end of each reporting period, with a liability “floor” established, at $0.06 per share, based on the stock price at the time the ratchet provision was triggered. At March 31, 2014 and December 31, 2013 the liability has been recorded at $4,885,299 and $3,899,391, respectively. The Company recorded an expense of $985,908 for the three months ended March 31, 2014 due to the change in the fair value of the liability.

10. SERIES B PREFERRED STOCK

On November 2, 2009 (“Effective Date”), the Company entered into a preferred stock purchase agreement with Optimus Life Sciences Capital Partners, LLC (“Investor” or “Optimus”). Pursuant to the purchase agreement, the Company agreed to sell, and the Investor agreed to purchase, in one or more purchases from time to time at the Company’s sole discretion, (i) up to 1,000 shares of Series B preferred stock at a purchase price of $10,000 per share, for an aggregate purchase price of up to $10,000,000, and (ii) five-year warrants to purchase shares of the Company’s common stock with an aggregate exercise price equal to 135% of the purchase price paid by the Investor, at an exercise price per share as follows:

On the sixth (6th) Trading Day following the Tranche Notice Date, the Exercise Price of the Optimus Warrant shall be adjusted to equal the VWAP for the 5 trading days beginning on and including the Tranche Notice Date (as so adjusted, the “Adjusted Exercise Price”); and

If the Adjusted Exercise Price results in additional Warrant Shares being issuable to the Holder, such additional shares shall be delivered to the Holder within one Trading Day following the Adjustment Date. If the Adjusted Exercise Price results in less Warrant Shares being issuable to the Holder, the excess Warrant Shares shall be returned by the Holder to the Company within one Trading Day following on the Adjustment Date.

The Company agreed to pay to the Investor a commitment fee of $500,000, at the earlier of the closing of the first Tranche or the six month anniversary of the effective date, payable at the Company’s election in cash or common stock valued at 90% of the volume weighted average price of the Company’s common stock on the five trading days preceding the payment date. The $500,000 commitment fee was outstanding and was recorded in accrued expenses in the Company’s consolidated balance sheet at December 31, 2009. During 2010, the Company issued 50 shares of preferred stock as payment for the commitment fee.

During 2010, the Company delivered tranche notices to Optimus Life Sciences Capital Partners, LLC for delivery of a total of 1,000 shares under the Series B preferred stock for funding in the amount of $10,000,000 ($9,485,000 in cash proceeds, $500,000 of commitment fee applied, and $15,000 in legal fees).

During 2010, in connection with the funding, the Company issued 95,870,362 shares of its common stock upon exercise of the same number of warrants, which were granted simultaneously with the Company’s tranche notices. During 2010, the Company received secured promissory notes in the amount of $13,500,000 to settle the warrant exercise.

Dividends

Commencing on the date of the issuance of any shares of Series B preferred stock, Holders of Series B preferred stock will be entitled to receive dividends on each outstanding share of Series B preferred stock, which will accrue in shares of Series B preferred stock at a rate equal to 10% per annum from the issuance date compounded annually. Accrued dividends will be payable upon redemption of the Series B preferred stock. Accrued dividends were $3,921,881 and $3,587,748 at March 31, 2014 and December 31, 2013, respectively.

Redemption Rights

Upon or after the fourth anniversary of the initial issuance date, the Company will have the right, at the Company's option, to redeem all or a portion of the shares of the Series B preferred stock, at a price per share equal to 100% of the Series B liquidation value. The preferred stock may be redeemed at the Company's option, commencing 4 years from the issuance date at a price per share of (a) $10,000 per share plus accrued but unpaid dividends (the "Series B Liquidation Value"), or, at a price per share of: (x) 127% of the Series B Liquidation Value if redeemed on or after the first anniversary but prior to the second anniversary of the initial issuance date, (y) 118% of the Series B Liquidation Value if redeemed on or after the second anniversary but prior to the third anniversary of the initial issuance date, and (z) 109% of the Series B Liquidation Value if redeemed on or after the third anniversary but prior to the fourth anniversary of the initial issuance date.

Liquidation Rights

The preferred shares shall, with respect to dividend, rights upon liquidation, winding-up or dissolution, rank: (i) senior to the Company's common stock, and any other class or series of preferred stock of the Company, except Series A-1 Convertible Preferred Stock which shall rank senior in right of liquidation and pari passu with respect to dividends; and (ii) junior to all existing and future indebtedness of the Company.

If the Company determines to liquidate, dissolve or wind-up its business, it must redeem the Series B preferred stock at the prices set forth above. Upon any liquidation, dissolution or winding up of the Company the Holders of Series B preferred stock shall be first entitled to be paid out of the assets of the Company available for distribution to its stockholders an amount with respect to each share of Series B preferred stock equal to $10,000, plus any accrued and unpaid dividends.

The Company has classified the Series B redeemable preferred stock in the equity section in its consolidated balance sheets.

Related Secured Promissory Notes Receivable:

In accordance with the terms of the Series B preferred stock agreement, Optimus issued to the Company a secured promissory note in consideration for receiving warrants under each tranche. The value of each secured promissory note equals the value of the warrants that Optimus received. Interest on the notes accrues at 2% per year, compounding annually if the interest remains unpaid at the end of each year. The note is secured by freely tradable

marketable securities belonging to Optimus. Each promissory note matures on the fourth anniversary of its issuance.

In the event the Company redeems all or a portion of any shares of Series B preferred stock held by Optimus, the Company will be permitted to offset the full amount of such proceeds against amounts outstanding under the promissory notes. Accordingly, the Company included the discounted value of the secured promissory notes as a separate component of stockholders' deficit at March 31, 2014 and December 31, 2013.

The value of the secured promissory notes in the consolidated balance sheet was $13,819,771, net of discounts of $462,338 and accrued interest of $782,112 at March 31, 2014, reflecting a face value of $13,500,000. The value of the secured promissory notes in the consolidated balance sheet was $13,561,607, net of discounts of $654,559 and accrued interest of $716,166 at December 31, 2013, also reflecting a face value of $13,500,000. The Company determined that a 10% discount is appropriate, in order to consistently reflect the Company's cost of borrowing under the terms of the underlying Series B preferred stock that permits offset. The Company recorded an initial discount on the promissory notes in the amount of $3,519,238 during the year ended December 31, 2010. The Company accretes interest at 10% over the respective four-year terms of the promissory notes.

During the three months ended March 31, 2014 and March 31, 2013 the Company accreted interest on the promissory notes in the amount of $258,164 and $289,942, respectively, which was recorded in accumulated deficit during the period then ended. The Company recorded dividends on its Series B preferred stock during the three months ended March 31, 2014 and March 31, 2013 of $334,133 and $290,401, respectively. The accrued dividends are offset by the accretion of the note receivable discount.

As of March 31, 2014 and December 31, 2013, 1,000 shares of Series B preferred stock were outstanding. As of March 31, 2014, the Company has drawn the entire commitment of $10,000,000.

Below is a table showing the net settlement amount at March 31, 2014 and December 31, 2013:

	March 31, 2014	December 31, 2013
Face Value of Preferred Stock	$10,000,000	$10,000,000
Accrued Dividends	$3,921,881	$3,587,748
Redemption factor	100%	109%
Conversion price	$13,921,881	$14,810,645
Receivable	$14,282,109	$14,216,166
Net settlement (receivable) upon conversion	$(360,228)	$594,479

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11. SERIES C PREFERRED STOCK

On December 30, 2010 (the "Series C Effective Date"), the Company entered into a securities purchase agreement (the "Series C Purchase Agreement") with Socius CG II, Ltd., a Bermuda exempted company ("Socius"). Pursuant to the Series C Purchase Agreement:

- The Company agreed to sell, and Socius agreed to purchase, in one or more purchases from time to time (each such purchase, a "Series C Tranche") in the Company's sole discretion (subject to the conditions set forth therein), (i) up to 2,500 shares of Series C preferred stock at a purchase price of $10,000 per share, for an aggregate purchase price of up to $25,000,000, and (ii) a two-year warrant (the "Socius Warrant") obligating Socius to purchase shares of the Company's common stock with an aggregate exercise price equal to 20% of the purchase price paid by Socius for the Series C preferred stock sold in each Series C Tranche, at an exercise price per share equal to the closing bid price of the Company's common stock on the date the Company provides notice of such Series C Tranche (the "Series C Tranche Notice"). On each date that the Company delivers a Series C Tranche Notice to Socius, Socius shall also become obligated, pursuant to a right automatically vesting on such Series C Tranche Notice date, to purchase that number of shares of common stock (such shares of common stock, the "Additional Investment Shares") equal in dollar amount to 100% of the Series C Tranche amount set forth in the Series C Tranche Notice at a price per share equal to the closing bid price of the Company's common stock on the Series C Tranche Notice date.

- The Series C Purchase Agreement requires that, when the Company requests Socius to purchase a tranche of Series C preferred stock, the mandatory purchase by Socius of the related Additional Investment Shares must occur no later than sixty (60) calendar days following the Series C Tranche Notice date.

- The Socius Warrant was issued to Socius on December 30, 2010 (the "Closing Date") simultaneous with entering into the Series C Purchase Agreement. The Socius Warrant was issued with an initial exercise price per warrant of $0.16 per share and for a total of up to 31,250,000 shares, subject to adjustment as described therein. On January 10, 2011, Socius and the Company entered into a letter agreement in which the parties agreed that, following arms-length negotiations and notwithstanding anything to the contrary in the Socius Warrant, that the initial number of shares issuable under the Socius Warrant, subject to the adjustment mechanism set forth therein, was equal to 30,000,000.

- As required by the Series C Purchase Agreement, the Socius Warrant must be exercised for such number of shares of common stock equal in amount to 20% of the cumulative purchase price paid by Socius for the Series C preferred stock. The maximum amount of Series C preferred stock that Socius may become obligated to purchase under all Series C Tranches is $25,000,000. Assuming the maximum drawdown of $25,000,000 by the Company under the Series C Purchase Agreement, Socius would be required to exercise the Socius Warrant to purchase 20% of this total dollar amount, or $5,000,000 worth of the Company's common stock.

- The letter agreement entered into on January 10, 2011, modified the Socius Warrant only with respect to the initial number of underlying shares and expressly provides that, except as so modified, the Socius Warrant shall remain unchanged and shall continue in full force and effect.

- At the initial closing pursuant to the Series C Purchase Agreement, which occurred on the Closing Date, (i) Socius purchased 400 shares of Series C preferred stock and the Company received gross proceeds of $4,000,000. (ii) the Company delivered to Socius an initial warrant (the "Initial Warrant") obligating Socius to purchase shares of its common stock with an aggregate purchase price of $800,000, which shall be automatically exercisable on the date a registration statement for the resale of all shares of common stock issuable pursuant to the Series C Purchase Agreement is declared effective (which effectiveness occurred on April 13, 2011), with delivery of such shares made to Socius on the trading day immediately following the exercise date at a per-share price equal to the closing bid price of the Company's common stock on the delivery date, and (iii) Socius became obligated to purchase additional shares of common stock equal in aggregate dollar amount to $4,000,000 (such shares of common stock the "Initial Investment Shares"), with delivery of such shares made to Socius on the trading day immediately following the date the registration statement is declared effective at a price per share equal to the closing bid price of the Company's common stock on the delivery date.

- The Company agreed to pay to Socius a commitment fee of $1,250,000 (the "Commitment Fee"), at the earlier of the closing of the first Series C Tranche or the six month anniversary of the Series C Effective Date. This Commitment Fee is payable solely at the Company's election, in cash or in the alternative, in shares of common stock valued at 88% of the volume weighted average price of the Company's common stock on the 5 trading days preceding the payment date. If the Company elects to pay the Commitment Fee in shares of its common stock, no cash payment would be due as the issuance of shares would satisfy the Commitment Fee obligation in full. The Company issued 7,562,008 shares of its common stock on September 30, 2011 as full payment of the commitment fee.

- The Company agreed to use its best efforts to file within 60 days of the Series C Effective Date, and cause to become effective as soon as possible thereafter, a registration statement with the Securities and Exchange Commission for the resale of all shares of common stock issuable pursuant to the Series C Purchase Agreement, including the shares of common stock underlying the Socius Warrant, shares of the common stock issuable upon exercise of the Initial Warrant, shares of common stock issuable as Initial Investment Shares, shares of common stock issuable as Additional Investment Shares, and shares of common stock issuable in payment of the Commitment Fee.

- In the event that Socius does not comply with its obligations under the Series C Purchase Agreement (including its obligations to exercise the Socius Warrant), the Series C Purchase Agreement provides that, in addition to being entitled to exercise all rights provided therein or granted by law, the Company would be entitled to seek specific performance by Socius under the Series C Purchase Agreement and the Socius Warrant.

On December 30, 2010, in accordance with the Series C Purchase Agreement, the Company filed a certificate of designations for the Series C preferred stock with the Secretary of State of the State of Delaware. As previously reported, pursuant to the certificate of designations, the Series C preferred stock shall, with respect to dividend, rights upon liquidation, winding-up or dissolution, rank: (i) senior to the Company's common stock, and any other class or series of preferred stock of the Company (collectively, with any warrants, rights, calls or options exercisable for or convertible into such preferred stock, the "Junior Securities"); provided, however, the Series A-1 redeemable convertible preferred stock and Series B preferred stock (together, the "Senior Securities") shall rank senior in right of redemption, liquidation, and dividends; and (ii) junior to all existing and future indebtedness of the Company.

As of March 31, 2014 and December 31, 2013, the Company has drawn $17,500,000 of the $25,000,000 commitment, respectively.

Dividends

Commencing on the date of the issuance of any shares of Series C preferred stock, holders of Series C preferred stock will be entitled to receive dividends on each outstanding share of Series C preferred stock, which will accrue in shares of Series C preferred stock at a rate equal to 6% per annum from the issuance date compounded annually. Accrued dividends will be payable upon redemption of the Series C preferred stock. Accrued dividends were $2,744,524 and $2,454,853 at March 31, 2014 and December 31, 2013, respectively.

Redemption Rights

Upon or after the fourth anniversary of the initial issuance date, the Company will have the right, at the Company's option, to redeem all or a portion of the shares of the Series C preferred stock, at a price per share equal to 100% of the Series C liquidation value. The Series C preferred stock may be redeemed at the Company's option, commencing 4 years from the issuance date at a price per share of (a) $10,000 per share plus accrued but unpaid dividends (the "Series C Liquidation Value"), or, at a price per share of : (i) 136% of the Series C Liquidation Value if redeemed prior to the first anniversary of the initial issuance date, (ii) 127% of the Series C Liquidation Value if redeemed on or after the first anniversary but prior to the second anniversary of the initial issuance date, (iii) 118% of the Series C Liquidation Value if redeemed on or after the second anniversary but prior to the third anniversary of the initial issuance date, and (iv) 109% of the Series C Liquidation Value if redeemed on or after the third anniversary but prior to the fourth anniversary of the initial issuance date.

Termination and Liquidation Rights

If the Company determines to liquidate, dissolve or wind-up its business, it must redeem the Series C preferred stock at the prices set forth above. Upon any liquidation, dissolution or winding up of the Company, the holders of Series C preferred stock shall be first entitled to be paid out of the assets of the Company available for distribution to its stockholders an amount with respect to each share of Series C preferred stock equal to $10,000, plus any accrued and unpaid dividends.

Related Secured Promissory Notes Receivable:

As of March 31, 2014, Socius has issued $21,000,000 in notes receivable in accordance with the terms of the Series C Purchase Agreement.

Interest on the notes accrues at 2% per year, compounding annually if the interest remains unpaid at the end of each year. The notes are secured by freely tradable marketable securities belonging to Socius. Each promissory note matures on the fourth anniversary of its issuance.

In the event the Company redeems all or a portion of any shares of Series C preferred stock held by Socius, the Company will be permitted to offset the full amount of such proceeds against amounts outstanding under the promissory notes. Accordingly, the Company included the discounted value of the secured promissory notes as a separate component of stockholders' deficit at March 31, 2014 and December 31, 2013.

At March 31, 2014, the value of the secured promissory notes in the consolidated balance sheet was $20,745,715, net of discounts of $1,167,811 and accrued interest of $913,524, reflecting a face value of $21,000,000.

At December 31, 2013, the value of the secured promissory notes in the consolidated balance sheet was $20,451,788, net of discounts of $1,363,762 and accrued interest of $815,549, reflecting a face value of $21,000,000.

The Company determined that a 6% discount is appropriate, in order to consistently reflect the Company's cost of borrowing under the terms of the underlying Series C preferred stock that permits offset. The Company recorded an initial discount on the promissory notes in the amount of $1,968,050 during the year ended December 31, 2011 and an additional $1,026,809 of debt discounts during the year ended December 31, 2012 related to the fifth, sixth and seventh tranche notice. The Company accretes interest at 6% over the respective four-year terms of the promissory notes.

During the three months ended March 31, 2014 and March 31, 2013, the Company accreted interest on the promissory note in the amount of $293,927 and $277,290, respectively, which was recorded in accumulated deficit during the periods then ended. The Company recorded dividends on its Series C preferred stock during the three months ended March 31, 2014 and March 31, 2013 of $289,671 and $273,274, respectively. The accrued dividends are offset by the

accretion of the note receivable discount.

The Company has classified the Series C preferred stock in the equity section in its consolidated balance sheets. As of March 31, 2014 and December 31, 2013, 1,750 shares of Series C preferred stock were outstanding.

Below is a table showing the net settlement amount at March 31, 2014 and December 31, 2013:

	March 31, 2014	December 31, 2013
Face Value of Preferred Stock	$17,500,000	$17,500,000
Accrued Dividends	$2,744,524	$2,454,853
Redemption factor	109 %	109 %
Conversion price	$22,066,531	$21,750,790
Receivable	$21,913,526	$21,815,550
Net settlement (receivable) upon conversion	$153,005	$(64,760)

12. WARRANT SUMMARY

Warrant Activity

A summary of warrant activity for the three months ended March 31, 2014 is presented below:

	Number of Warrants	Weighted Average Exercise Price $	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (000)$
Outstanding, December 31, 2013	7,829,883	0.28	1.82	–
Granted	–	–		
Exercised	–	–		
Forfeited/Canceled	–	–		
Outstanding, March 31, 2014	7,829,883	0.28	1.58	
Exercisable, March 31, 2014	7,829,883	0.28	1.58	–

The aggregate intrinsic value in the table above is before applicable income taxes and is calculated based on the difference between the exercise price of the warrants and the quoted price of the Company’s common stock as of the reporting date.

The following table summarizes information about warrants outstanding and exercisable at March 31, 2014:

	Warrants Outstanding and Exercisable		
Exercise Price $	**Number of Shares**	**Weighted Average Remaining Life (Years)**	**Weighted Average Exercise Price $**
.10 - .11	3,239,247	0.68	0.10
.20 - .30	1,630,000	1.75	0.25
.38-.39	1,330,636	3.32	0.39
.40-.45	815,000	1.75	0.45
0.70	815,000	1.75	0.70
	7,829,883		

13. STOCKHOLDERS' DEFICIT TRANSACTIONS

From January 2, 2014 to March 31, 2014, Lincoln Park purchased 114,287,000 shares of common stock for cash proceeds of $7,706,756.

From January 27, 2014 to March 14, 2014, the Company issued an aggregate of 43,373,609 shares in settlement of $2,400,000 Debentures to the CAMOFI Parties as required by the Settlement Agreement.

On March 31, 2014, the Company issued various board members 1,222,687 shares of common stock valued at $92,475 as compensation for board services.

14. STOCK-BASED COMPENSATION

Stock Plans

Stock Plan	Options/Shares Issued	Options Outstanding	Options/Shares Available For Grant	Total Authorized
2004 Stock Plan	2,492,000	70,000	1,215,104	2,800,000
2004 Stock Plan II	1,301,161	1,071,161	–	1,301,161
2005 Stock Plan	164,326,391	131,415,770	417,512,392	581,838,783
	168,119,552	132,556,931	418,727,496	585,939,944

Stock Option Activity

A summary of option activity for the three months ended March 31, 2014 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding, December 31, 2013	118,278,611	$ 0.19	6.95	$ 10,319
Granted	15,750,000	0.08		
Exercised	–	–		
Forfeited/canceled	(1,471,680)	0.10		
Outstanding, March 31, 2014	132,556,931	0.18	7.08	50,411
Vested and expected to vest at March 31, 2014	129,256,746	$ 0.18	7.01	$ 50,411
Exercisable, March 31, 2014	107,170,890	$ 0.20	6.49	$ 50,411

The aggregate intrinsic value in the table above is before applicable income taxes and is calculated based on the difference between the exercise price of the options and the quoted price of the Company’s common stock as of the reporting date.

The following table summarizes information about stock options outstanding and exercisable at March 31, 2014.

	Options Outstanding			Options Exercisable		
Exercise Price	**Number of Shares**	**Weighted Average Exercise Price**	**Weighted Average Remaining Life (Years)**	**Number of Shares**	**Weighted Average Exercise Price**	**Weighted Average Remaining Life (Years)**
$0.05 - 0.079	22,980,714	$ 0.07	9.30	11,772,381	$0.07	9.28
0.08 - 0.09	40,010,878	0.09	7.16	25,833,170	0.09	5.75
0.10 - 0.157	26,710,496	0.14	7.35	26,710,496	0.14	7.35
0.185 - 0.21	25,760,833	0.19	6.48	25,760,833	0.19	6.48
0.25 - 0.45	11,071,161	0.36	6.56	11,071,161	0.36	6.56
0.85	5,417,849	0.85	0.15	5,417,849	0.85	0.15
$1.35 - 2.48	605,000	$2.02	1.63	605,000	$2.02	1.63
	132,556,931			107,170,890		

The assumptions used in calculating the fair value of options granted using the Black-Scholes option- pricing model for options granted during the three months ended March 31, 2014 are as follows:

	March 31, 2014	March 31, 2013
Risk-free interest rate	1.72 – 2.09%	0.76 - 0.78%
Expected life of the options	5.00 - 6.25 years	5.00 - 6.26 years
Expected volatility	112 - 148%	160%
Expected dividend yield	0%	0%
Expected forfeitures	13%	13%

The weighted average grant-date fair value for the options granted during the three months ended March 31, 2014 and 2013 was $0.0854 and $0.08, respectively.

Stock-based compensation expense to employees for the three months ended March 31, 2014 and 2013 was $346,595 and $1,132,625, respectively.

The compensation expense related to the unvested options as of March 31, 2014, was $1,771,262 which will be recognized over the weighted average period of 2.89 years.

15. SUBSEQUENT EVENTS

Lincoln Park

On various dates from April 1, 2014 through April 30, 2014, the Company received $3,252,482 from the issuance of 53,632,639 shares to Lincoln Park under the purchase agreement.

Camofi/Camhzn Debt

On April 15, 2014, the Company received a notice from CAMOFI of an Event of Default under Amortizing Senior Secured Convertible Notes, or Notes, due June 30, 2015 held by CAMOFI. The notice alerted the Company that due to the Company's failure to deliver shares of common stock issuable to the Holders within three days of a conversion event occurring in March 2014 under the Notes, an "Event of Default" under the Notes had occurred and the Holders were reserving all rights held by them arising from such Event of Default. Among these rights are the Holders' ability to declare as immediately due and payable the aggregate principal amount remaining under the Notes together with any other amounts owed under the Notes.

On April 29, 2014 CAMOFI notified the Company that it was accelerating the debt per its rights described above. On May 2, 2014 the Company paid the outstanding principal balance of the CAMOFI Notes of $1,200,000 and additional amounts due under the Mandatory Default Amount clause in the debenture agreement with CAMOFI, for a total payment of approximately $1,616,000.

SEC Section 16 Investigation Settlement

On May 2, 2014, the Company finalized a settlement with the SEC relating to the investigation of transactions involving sales of shares of our common stock that the former Chief Executive Officer failed to report in a timely manner on Form 4 under Section 16 of the Exchange Act. The Company has agreed to pay civil penalties of $375,000 by no later than July 15, 2015 and comply with certain other undertakings relating to review of its policies and procedures relating to Section 16 compliance.

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

Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially and adversely from those expressed or implied by such forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to our outlook or expectations for earnings, revenues, expenses, volatility of our common stock, financial condition or other future financial or business performance, strategies, expectations, or business prospects, or the impact of legal, regulatory or supervisory matters on our business, results of operations or financial condition.

Forward-looking statements can be identified by the use of words such as "estimate," "plan," "project," "forecast," "intend," "expect," "anticipate," "believe," "seek," "target" or similar expressions. Forward-looking statements reflect our judgment base on currently available information and involve a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled "Risk Factors" included elsewhere in this Form 10-Q and in our other filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 1, 2014. Additionally, there may be other factors that could preclude us from realizing the predictions made in the forward-looking statements. We operate in a continually changing business environment and new factors emerge from time to time. We cannot predict such factors or assess the impact, if any, of such factors on our financial position or results of operations. All forward-looking statements included in this Form 10-Q speak only as of the date of this Form 10-Q and you are cautioned not to place undue reliance on any such forward-looking statements. Except as required by law, we undertake no obligation to publicly update or release any revisions to these forward-looking statements to reflect any events or circumstances after the date of this Form 10-Q or to reflect the occurrence of unanticipated events.

Restatement

With this Quarterly Report on Form 10-Q, we have restated the following previously filed consolidated financial statements, data, and related disclosures:

(1) Our consolidated statements of operations for the three months ended March 31, 2013, and the related cash flows for the three months ended March 31, 2013 located in Part I, Item 1 of this Quarterly Report on Form 10-Q; and

(2) Our management's discussion and analysis of financial condition and results of operations as of and for the three months ended March 31, 2013, contained herein;

The restatement results from our review of accounting for a potentially unsettled warrant obligation and stock compensation accounting. See Note 2, "Restatement of Previously Issued Consolidated Financial Statements" of the Notes to Consolidated Financial Statements in Part I, Item 1, for a detailed discussion of the review and effect of the restatement.

The following discussion and analysis of our financial condition and results of operations incorporates the restated amounts. For this reason the data set forth in this section may not be comparable to discussions and data in our previously filed Quarterly Reports of Form 10-Q.

Overview

We are a biotechnology company focused on developing and commercializing human stem cell technology in the emerging fields of regenerative medicine and stem cell therapy. Principal activities to date have included obtaining financing, securing operating facilities, and conducting research and development. We have no therapeutic products currently available for sale and do not expect to have any therapeutic products commercially available for sale for a period of years, if at all. These factors indicate that our ability to continue research and development activities is dependent upon the ability of management to obtain additional financing as required. We are actively conducting clinical trials for treating dry age-related macular degeneration and Stargardt's macular degeneration. Our preclinical programs involve cell therapies for the treatment of other ocular disorders and for diseases outside the field of ophthalmology, including autoimmune, inflammatory and wound healing-related disorders. Our intellectual property portfolio includes pluripotent human embryonic stem cell-induced pluripotent stem cell platforms; and other cell therapy research programs.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based upon consolidated financial statements and condensed consolidated financial statements that we have prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make a number of estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses in the condensed consolidated financial statements and accompanying notes included in this report. We base our estimates on historical information, when available, and assumptions believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following accounting policies to be critical to the estimates used in the preparation of our financial statements.

Use of Estimates — These consolidated financial statements have been prepared in accordance with GAAP and, accordingly, require management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Specifically, the Company's management has estimated loss contingencies related to outstanding litigation. In addition, Management has estimated variables used to calculate the Black-Scholes option pricing model used to value derivative instruments and the Company estimates the fair value of the embedded conversion option associated with the senior secured convertible debentures using a binomial lattice model as discussed below under "Fair Value Measurements". Also, management has estimated the expected economic life and value of the our licensed technology, our net operating loss for tax purposes, share-based payments for compensation to employees, directors, consultants and investment banks, and the useful lives of the fixed assets and its accounts receivable allowance. Actual results could differ from those estimates.

Deferred Issuance Cost—Payments, either in cash or share-based payments, made in connection with the sale of debentures are recorded as deferred debt issuance costs and amortized using the effective interest method over the lives of the related debentures.

Fair Value Measurements—On January 1, 2008, we adopted FASB ASC 820-10, *"Fair Value Measurements and Disclosures."* FASB ASC 820-10 defines fair value, and establishes a three-level valuation hierarchy for disclosures of fair value measurement that enhances disclosure requirements for fair value measures. The carrying amounts reported in the consolidated balance sheets for receivables and current liabilities each qualify as financial instruments and are a reasonable estimate of their fair values because of the short period of time between the origination of such instruments and their expected realization and their current market rate of interest. The three levels of valuation hierarchy are defined as follows:

- Level 1 inputs to the valuation methodology are quoted prices for identical assets or liabilities in active markets.

- Level 2 inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, and inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the financial instrument.

- Level 3 inputs to the valuation methodology are unobservable and significant to the fair value measurement.

Management analyzes all financial instruments with features of both liabilities and equity under ASC 480, *"Distinguishing Liabilities From Equity"* and ASC 815, *"Derivatives and Hedging."* Derivative liabilities are adjusted to reflect fair value at each period end, with any increase or decrease in the fair value being recorded in results of operations as adjustments to fair value of derivatives. The effects of interactions between embedded derivatives are calculated and accounted for in arriving at the overall fair value of the financial instruments. In addition, the fair values of freestanding derivative instruments such as warrant and option derivatives are valued using the Black-Scholes model. The fair value of certain conversion features was calculated using a binomial model.

Revenue Recognition—Our revenue is generated from license and research agreements with collaborators. Licensing revenue is recognized on a straight-line basis over the shorter of the life of the license or the estimated economic life of the patents related to the license. Deferred revenue represents the portion of the license and other payments received that has not been earned. Costs associated with the license revenue are deferred and recognized over the same term as the revenue. Reimbursements of research expense pursuant to grants are recorded in the period during which collection of the reimbursement becomes assured, because the reimbursements are subject to approval.

Stock Based Compensation—We record stock-based compensation in accordance with ASC 718, "Compensation – Stock Compensation." ASC 718 requires companies to measure compensation cost for stock-based employee compensation at fair value at the grant date and recognize the expense over the employee's requisite service period. We recognize in the statement of operations the grant-date fair value of stock options and other equity-based compensation issued to employees and non-employees.

Comparison of Three months Ended March 31, 2014 and 2013

	Three Months Ended March 31, 2014	2013 As Restated	$ Change	% Change
Revenue	$39,468	$87,781	$(48,313)	(55.0)%
Cost of revenue	15,609	34,359	18,750	54.6%
Gross profit	23,859	53,422	(29,563)	(55.3)%
Research and development expenses:				
-R&D expenses, excluding non-cash, stock option compensation	2,422,659	2,504,821	(82,162)	(3.3)%
- Non-cash, stock option compensation	85,185	593,738	(508,553)	(85.7)%
Total Research and Development	2,507,844	3,098,559	(590,715)	(19.1)%
General and administrative expenses:				
-G&A expenses, excluding non-cash, stock option compensation	2,958,678	1,827,859	1,130,819	61.9%
-Non-cash, stock option compensation	353,885	1,006,010	(652,125)	(64.8)%
Total General and Administrative	3,312,563	2,833,869	478,694	16.9%
Litigation settlement contingency	1,901,538	-	1,901,538	100%
Non-operating expense	(991,688)	(631,631)	(360,057)	(57.0)%
Net loss	$(8,689,774)	$(6,510,637)	$(2,179,137)	(33.5)%

Revenue

Revenue relates to license fees and royalties collected that are being amortized over the period of the license granted. Revenue was $39,468 for the three months ended March 31, 2014, which was a decrease of $48,313 or 55.0% compared to the three months ended March 31, 2013. The decrease is due to license agreements that expired in 2013. The deferred revenue balance of $1,868,106, as of March 31, 2014, is being amortized and recorded to revenue over approximately 12 years.

Research and Development Expenses

Research and development, or R&D expenses, consist mainly of payroll and payroll related expenses for our scientific staff, services attained in connection with our ongoing clinical trials and pre-clinical programs, our R&D and GMP facilities, and research supplies and materials. R&D expenditures, excluding non-cash, stock option compensation expense, decreased from $2,504,821 for the three months ended March 31, 2013 to $2,422,659 for the three months

ended March 31, 2014, for a decrease of $82,162 or 3.3%. The decrease in R&D expenditures was primarily due to a decrease in legal costs related to intellectual property of approximately $270,000 and a decrease in pre-clinical and clinical trial costs of approximately $206,000 offset by increases in payroll and related expenses of approximately $215,000, increases in costs for consultants of approximately $117,000 and increases in occupancy costs due to additional lab and manufacturing space of approximately $42,000.

R&D expenses related to non-cash, stock option compensation decreased from $593,738 for the three months ended March 31, 2013 to $85,185 for the three months ended March 31, 2014, for a decrease of $508,553, or 85.7%. This decrease is related to the final vesting of options in 2013 of our chief scientific officer's options associated with his employment contract, for a decrease of approximately $317,000. Additionally, in 2013 new grants vested 20% upfront and subsequently over a 24 month period, whereas new grants in 2014 had no upfront vesting and vest over a 48 month period, resulting in higher stock compensation expense for the three months ended March 31, 2013 as compared to the same period in 2014.

Our R&D expenses are primarily associated with basic and pre-clinical research and our clinical development programs, exclusively in the field of human stem cell therapies and regenerative medicine. Our focus is on development of our technologies in cellular reprogramming, reduced complexity applications, and stem cell differentiation. These expenses represent both pre-clinical and clinical development costs and costs associated with support activities such as quality control and regulatory processes. The cost of our research and development personnel is the most significant category of R&D expense; however, we also incur expenses with third parties, including license agreements, sponsored research programs and consulting expenses.

We do not segregate R&D costs by project because our research is focused exclusively on human stem cell therapies as a unitary field of study. Although we have three principal areas of focus for our research, these areas are intertwined and have not yet matured to the point where they are separate and distinct projects. The intellectual property, scientists and other resources dedicated to these efforts are not separately allocated to individual projects, since the research is conducted on an integrated basis.

We expect that R&D expenses to increase modestly from quarter to quarter for the foreseeable future. The rate of increase for any given quarter will be impacted by the timing of enrollment, and treatment of clinical trial patients along with interim results of our many pre-clinical programs. The amount and timing of these fluctuations can be difficult to predict due to the uncertainty inherent in the timing and extent of progress in our research programs, initiation of new clinical trials and rate of progression of existing clinical trials. In addition, the results from our basic research and pre-clinical trials, as well as the results of trials of similar therapeutics under development by others, will influence the number, size and duration of current and future trials. As our research efforts mature, we will continue to review the direction of our research based on an assessment of the value of possible commercial applications emerging from these efforts. Based on this continuing review, we expect to establish discrete research programs and evaluate the cost and potential for cash inflows from commercializing products, partnering with others in the biotechnology or pharmaceutical industry, or licensing the technologies associated with these programs to third parties.

We believe that it is not possible at this stage to provide a meaningful estimate of the total cost to complete our ongoing projects and bring any proposed products to market. The use of human embryonic stem cells as a therapy is an emerging area of medicine, and it is not known what clinical trials will be required by the FDA in order to gain marketing approval. Costs to complete could vary substantially depending upon the projects selected for development, the number of clinical trials required and the number of patients needed for each study. It is possible that the completion of these studies could be delayed for a variety of reasons, including difficulties in enrolling patients, delays in manufacturing, incomplete or inconsistent data from the pre-clinical or clinical trials, and difficulties evaluating the trial results. Any delay in completion of a trial would increase the cost of that trial, which would harm our results of operations. Due to these uncertainties, we cannot reasonably estimate the size, nature nor timing of the costs to complete, or the amount or timing of the net cash inflows from our current activities. Until we obtain further relevant pre-clinical and clinical data, we will not be able to estimate our future expenses related to these programs or when, if ever, and to what extent we will receive cash inflows from resulting products.

General and Administrative Expenses

General and Administrative, or G&A, costs, consist mainly of payroll and payroll related expenses, legal costs relating to corporate matters and litigation, and fees for consultants, service providers and other administrative costs. G&A expenditures, excluding non-cash, stock option compensation expense, increased from $1,827,859 for the three months ended March 31, 2013 to $2,958,678 for the three months ended March 31, 2014, for an increase of $1,130,819 or 61.9%. The increase in G&A expenditures was primarily due to an increase in legal costs related to intellectual property matters of approximately $304,000 and in corporate legal fees of approximately $267,000. The increase in corporate legal expenses is due primarily to our efforts to resolve outstanding non-routine legal issues. Also contributing to the increase in G&A spending was an increase in salary and wage costs as the severance costs for our former Chief Executive Officer, of approximately $345,000, were expensed in the period. Additionally, costs related to accounting and professional fees increased by approximately $136,000.

G&A expenses related to non-cash, stock option compensation decreased from $1,006,010 for the three months ended March 31, 2013 to $353,885 for the three months ended March 31, 2014, for a decrease of $652,125, or 64.8%. This decrease is related to the final vesting of options in 2013 of the former Chief Executive Officer's options associated with his employment contract, for a decrease of approximately $531,000. Additionally, in 2013 new grants vested 20% upfront and subsequently over a 24 month period, whereas new grants in 2014 had no upfront vesting and vest over a 48 month period, resulting in higher stock compensation expense for the three months ended March 31, 2013 as compared to the same period in 2014.

Litigation Settlement Contingency

In connection with the unsettled warrant obligation and the need for a loss contingency accrual relating to the associated litigation, the Company determined that a loss was probable and the amount of loss was reasonably estimable, based on the facts and circumstances surrounding the litigation during the last quarter of 2013. The loss contingency amount for the first quarter of 2014 represents the change from the last quarter in 2013 to the estimated number of shares to settle multiplied by the stock price at the end of the quarter plus an additional amount for potential interest charges.

Other Income (Expense)

	2014	2013 As Restated	$ Change	% Change
Interest and other income	$54,890	$1,777	$53,113	2988.9 %
Interest expense	(296,972)	(524,189)	227,217	43.3 %
Finance (cost) gain	(50,726)	336,880	(387,606)	(115.1)%
Adjustments to fair value of unsettled warrant obligation	(985,908)	(613,032)	(372,876)	(60.8)%
Adjustments to fair value of derivatives	287,028	166,933	120,095	71.9 %
Total non-operating expense	$(991,688)	$(631,631)	$(360,057)	

Interest expense for the three months ended March 31, 2014 compared to the three months ended March 31, 2013 decreased by $227,217 to $296,972 for the three months ended March 31, 2014 compared to $524,189 for the three months ended March 31, 2013. The decrease is due to the discontinuation of interest expense on the Volation and JMJ Financial debt in 2013 and a lower principal balance on the CAMOFI debt in 2014 as compared to 2013.

The change in finance costs during the three months ended March 31, 2014, compared to that of the same period in 2013, relates primarily to warrants that were canceled as part of the Settlement Agreement with the CAMOFI Parties in 2013, resulting in a gain of approximately $390,000.

Adjustments to fair value of unsettled warrant obligation for the three months ended March 31, 2014 as compared to the three months ended March 31, 2013 increased by $372,876. The fair value account adjusts the 63.2 million shares which are contractually obligated by the change in the stock price for each period. The increase in expense resulted from the stock price increasing from approximately $0.06 to $0.08 for the three months ended March 31, 2014 compared to a smaller increase during the same period in 2013, from approximately $0.06 to $0.07.

Adjustment to fair value of derivatives was a gain of $287,028 for the three months ended March 31, 2014 compared to a gain of $166,933 for the three months ended March 31, 2013. The change of $120,095 is primarily due to the valuation of the derivative related to the CAMOFI debentures and the fact that the time to maturity is reduced as well as the outstanding balance of the debt.

Liquidity and Capital Resources

Cash Flows

The following table sets forth a summary of our cash flows for the periods indicated below:

	Three Months Ended March 31,	
	2014	2013
Net cash used in operating activities	$(5,353,622)	$(8,276,448)
Net cash used in investing activities	(91,402)	(107,191)
Net cash provided by financing activities	7,706,756	5,253,221
Net increase (decrease) in cash and cash equivalents	2,261,732	(3,130,418)
Cash and cash equivalents at the end of the period	$4,005,217	4,111,434

Operating Activities

Our net cash used in operating activities during the three months ended March 31, 2014 and 2013 was $5,353,622and $8,276,448, respectively. Net cash used in operating activities decreased in the three months ended March 31, 2014 period compared to the same period in 2013 period despite a larger net loss by approximately $2.1 million and a smaller add back to cash for non-cash compensation expense, including the value of common stock issued for compensation of approximately $1.2 million. Drivers of improved net cash used in operations for the 2014 period were changes in operating assets and liabilities, which improved in 2014 by approximately $3.1 million over the 2013 period and also by an add back to cash for non-cash financing cost generating approximately $3.0 million in improved cash flow in 2014 as compared to 2013. The non-cash financing costs was primarily related to the change in the non-cash warrant holder litigation expense.

Cash Used in Investing Activities

Cash used in investing activities during the three months ended March 31, 2014 and 2013 was $91,402 and $107,191, respectively. Our cash used in investing activities during the three months ended March 31, 2014 was attributed to the purchase of fixed assets.

Cash Flows from Financing Activities

On September 19, 2012, we entered into a purchase agreement, or Purchase Agreement, with Lincoln Park Capital Fund, LLC or Lincoln Park. Pursuant to the Purchase Agreement, we have the right to sell to Lincoln Park up to $35,000,000 in shares of our common stock. Upon signing the Purchase Agreement, Lincoln Park purchased 10,000,000 shares of our common stock for $800,000 as the initial purchase. In addition, we issued 8,750,000 shares of common stock to Lincoln Park as a commitment fee.

Upon the satisfaction of the conditions set forth in the Purchase Agreement, including the registration statement for the resale of the shares issued thereunder being declared effective by the Securities and Exchange Commission (which effectiveness occurred on November 6, 2012), we have the right over a 36-month period to sell up to an additional $34.2 million worth of shares of our common stock to Lincoln Park, upon the terms set forth in the Purchase Agreement. Pursuant to the Purchase Agreement, the purchase price of such common stock will be based on the prevailing market price of our common stock immediately preceding the time of sales, with us having the ability to control the timing and amount of any future sales, if any, of common stock to Lincoln Park. There are no upper limits to the price Lincoln Park may pay to purchase our common stock. Lincoln Park shall not have the right or the obligation to purchase any shares of common stock on any business day that the closing price of our common stock is below a floor price as provided in the Purchase Agreement. The purchase price means, with respect to any regular purchase, the lower of: (i) the lowest sale price on the applicable purchase date and (ii) the arithmetic average of the three (3) lowest closing sale prices for the common stock during the ten (10) consecutive business days ending on the business day immediately preceding such purchase date (in each case, to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction that occurs on or after the date of this Purchase Agreement. However, the purchase price cannot be below $0.03.

Cash flows provided by financing activities during the three months ended March 31, 2014 and 2013 was $7,706,756 and $5,253,221, respectively. During the three months ended March 31, 2014, we received $7,706,756 from the issuance of 114,287,000 shares to Lincoln Park as part of the $35,000,000 Purchase Agreement.

We plan to fund our operations for the foreseeable future from the following sources:

- As of March 31, 2014, we have approximately $4,005,217 in cash.

- As of March 31, 2014, $6,574,539 is available to us through the Lincoln Park financing arrangement.

- We continue to repay our debt obligations through the issuance of shares of our common stock, enabling us to use our cash resources to fund our operations.

We believe that our current cash balance, and the $6,574,539 available to us under the Lincoln Park financing arrangement, will be sufficient to fund our operations into the second half of 2014. This belief is based on the assumption that our stock price does not realize any significant or prolonged decreases. Our ability to fund our operations through the Lincoln Park arrangement is highly dependent on our stock price. A significant decline in our share price could force us to curtail our operations in part, or entirely. We are continually in discussions with potential investors and collaborators to explore alternative sources of dilutive and non-dilutive funding, so that we may either extend our ability to fund operations through 2014, and beyond. In addition to exploring new sources of funding we have established contingency budget plans where we can scale back programs and costs to extend our company operations and increase the time to secure proper financing throughout 2014.

On a long term basis, we have no expectation of generating any meaningful revenues from our product candidates for a substantial period of time and will rely on raising funds in capital transactions to finance our research and development programs. Our future cash requirements will depend on many factors, including the pace and scope of our research and development programs, the costs involved in filing, prosecuting and enforcing patents, and other costs associated with commercializing our potential products. We intend to seek additional funding primarily through public or private financing transactions, and, to a lesser degree, new licensing or scientific collaborations, grants from governmental or other institutions, and other related transactions. If we are unable to raise additional funds, we will be forced to either scale back our business efforts or curtail our business activities entirely. We cannot assure you that public or private financing or grants will be available on acceptable terms, if at all. Several factors will affect our ability to raise additional funding, including, but not limited to, the volatility of our common stock.

We cannot assure you that public or private financing or grants will be available on acceptable terms, if at all. Several factors will affect our ability to raise additional funding, including, but not limited to, the volatility of our common stock. If we are unable to raise additional funds, we will be forced to either scale back our business efforts or curtail our business activities entirely.

Off-Balance Sheet Arrangements

We do not maintain any off-balance sheet arrangements, transactions, obligations or other relationships with unconsolidated entities that would be expected to have a material current or future effect upon our financial condition or results of operations.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is limited primarily to interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because a significant portion of our investments are in short-term debt securities issued by the U.S. government and institutional money market funds. The primary objective of our investment activities is to preserve principal. Due to the nature of our marketable securities, we believe that we are not exposed to any material market risk. We do not have any derivative financial instruments or foreign currency instruments. If interest rates had varied by 10% in the quarter ended March 31, 2014, it would not have had a material effect on our results of operations or cash flows for that period.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our principal executive and financial officer after evaluating the effectiveness of our "disclosure controls and procedures" (as defined in the Exchange Act Rule 13a- 15(e) or Rule 15d-15(e)), with the participation of our management has concluded that as of the end of the period covered by this Quarterly Report on Form 10-Q our disclosure controls and procedures were effective and were designed to ensure that information we are required to disclose in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is accumulated and communicated to management including our principal executive and financial officer as appropriate to allow timely decisions regarding required disclosure and is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms. It should be noted that any system of controls is designed to provide reasonable but not absolute assurances that the system will achieve its stated goals under all reasonably foreseeable circumstances. Our principal executive and financial officer has concluded that our disclosure controls and procedures as of the end of the period covered by this report are effective at a level that provides such reasonable assurances.

We carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and principal financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of March 31, 2014. Based upon that evaluation, the chief executive and principal financial officer concluded that the Company’s disclosure controls and procedures are effective.

Changes in Internal Control over Financial Reporting

As previously described in Item 9A “Controls and Procedures” in our Annual Report on Form 10-K filed for the year ended December 31, 2013, we identified a material weakness in internal controls over financial reporting relating our accounting of derivatives, specifically embedded derivatives relating to anti-dilution ratchet provisions. This material weakness contributed to material post-closing adjustments and restatement of prior period financial statements, which were reflected in the financial statements for the three years ended December 31, 2013.

In connection with the review, we identified a control deficiency relating to the application of applicable accounting literature related to accounting for derivatives. Specifically, the control deficiency related to our interpretation of the FASB Accounting Standards Codification for derivatives (ASC 815) in determining the proper accounting treatment for an embedded derivative with anti-dilution ratchet provisions. The warrant agreement was entered into in 2005 and the applicable ratchet provision extended through January 2009. The resulting unissued share obligation remained an issue through Q3 2013.

Management, with the input, oversight, and support of the Audit Committee has identified and taken the following steps, which management believes have corrected the material weakness described above subsequent to December 31, 2013:

- in June 2013, we hired a new Chief Financial Officer, who has extensive experience leading the accounting and finance functions at publicly traded companies and adds accounting expertise to our staff. For several years we had outsourced many accounting duties and the previous CEO acted as the company CFO as well;
- in November 2013, we hired a new Corporate Controller, who has extensive experience leading the accounting and finance functions at publicly traded companies and adds accounting expertise to our staff; and
- in December 2013, we engaged external advisors knowledgeable in many technical accounting matters, including derivatives to assist us in the interpretation of key technical accounting standards and associated interpretations and the determination of how to adequately apply such standards.

Additionally, we plan to enhance our training programs to ensure that our accounting personnel have the competence and the on-going accounting and financial reporting training necessary for their assigned duties, including specific technical training courses related to derivative accounting and other complex accounting issues.

Other than described above, there were no changes in our internal control over financial reporting that occurred during the first quarter of 2014 that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In the ordinary course of business, we are party to litigation matters. We included a discussion of certain legal proceedings in Part I, Item 3, of our Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 1, 2014 (the "2013 Form 10-K"). During the quarter ended March 31, 2014, there were no material developments to the legal proceedings disclosed in the 2013 Form 10-K.

ITEM 1A. RISK FACTORS

This Quarterly Report on Form 10-Q contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forward-looking statements that we make or that are made on our behalf, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our capital resources, our ability to successfully develop and commercialize therapeutic products, the progress and timing of our clinical programs, the safety and efficacy of our product candidates, risks associated with regulatory filings, risks associated with determinations made by regulatory agencies, the potential clinical benefits and market potential of our product candidates, future development efforts, patent protection, effects of healthcare reform, reliance on third parties, and other risks set forth below. You should carefully consider the risks described below, including information in the section of this document entitled "Forward Looking Statements." An investment in the Company's common stock involves a high degree of risk. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected, the value of our common stock could decline, and you may lose all or part of your investment. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also impair our business operations.

Those risk factors below denoted with a "" are newly added or have been materially updated from our Annual Report on 10-K filed with the SEC on April 1, 2014.*

Risks Related to our Early Stage of Development and Capital Resources

We have a history of operating losses and we may not achieve future revenues or operating profits.

We have generated modest revenue to date from our operations. Historically we have had net operating losses each year since our inception. As of December 31, 2013, we have an accumulated deficit of $313,844,357 and a stockholders' deficit of $22,533,610. We incurred net losses of $31,022,248, $34,584,115, and $55,192,803 for the years ended December 31, 2013, 2012, and 2011, respectively. We have limited current potential sources of income from licensing fees and we do not generate significant revenue from any other source. Additionally, even if we are able to commercialize our technologies or any products or services related to our technologies if approved, it is not certain that they will result in revenue or profitability.

Our business is at an early stage of development and we may not develop therapeutic products that can be commercialized.

Our most advanced product candidates are in Phase I/II clinical trials and we don't have any products that are currently in the marketplace. Our potential therapeutic products will require extensive preclinical and clinical testing prior to regulatory approval in the United States and other countries and may additionally require post-authorization outcome studies. We may not be able to obtain regulatory approvals in some cases, or commence or continue clinical trials for some of our products, or commercialize any products. Any of our therapeutic and product candidates may prove to have undesirable and unintended side effects or other characteristics that could cause adverse effects on patient safety, efficacy or cost-effectiveness that could prevent or limit their therapeutic use, commercialization or acceptance in the medical community. Any product using any of our technologies may fail to provide the intended therapeutic benefits, or even achieve therapeutic benefits equal to or better than the standard of treatment at the time of testing or production, or may not be safe for use in humans. In addition, we will need to determine whether any of our potential products can be manufactured in commercial quantities or at an acceptable cost, with or without third-party support. Our efforts may not result in a product that can be or will be marketed successfully. Physicians may not prescribe our products, and patients or third party payors may not accept or reimburse for use of our products. For these reasons we may not be able to generate product revenues.

We have never generated any revenue from product sales and may never be profitable.

We have limited clinical testing, regulatory, manufacturing, marketing, distribution and sales experience capabilities which may limit our ability to generate revenues. Due to the early stage of our therapeutic products, including regenerative medical therapies and stem cell therapy-based programs, we have not yet invested significantly in marketing, distribution or product sales resources. We cannot assure you that we will be able to develop any of these resources successfully or as expediently as necessary, either alone or with strategic partners. We do not anticipate generating revenues from product sales for several years or more, if ever. Our ability to generate future revenues from product sales will depend on, among other things, our success in:

- commencing, continuing and completing research and preclinical and clinical development of our therapeutic candidates;
- seeking and obtaining regulatory and marketing approvals for therapeutic candidates, and the manufacturing process for generating those candidates for which we complete clinical studies;
- developing a scalable, reproducible, globally scalable and fully GMP compliant manufacturing process for our therapeutic candidates;
- establishing and maintaining supply and manufacturing relationships with third parties that can satisfy our needs for products and services that meet our required specifications to support clinical development and the market demand for our therapeutic candidates, if approved;
- launching and commercializing therapeutic candidates for which we obtain regulatory and marketing approval, either by collaborating with a partner or, if launched independently, by establishing a marketing, sales and distribution infrastructure;
- obtaining market acceptance of our therapeutic candidates as a viable treatment of the targeted conditions in question;
- adequately addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure, as needed;
- identifying and validating new therapeutic candidates;

- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;

- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and

- attracting, hiring and retaining qualified personnel.

Even if one or more of the therapeutic candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate, including costs related to additional clinical studies, and such costs may exceed our estimates. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. The inability to do so will inhibit or harm our ability to generate revenues or operate profitably.

We have determined that material weaknesses exist in our system of internal control over financial reporting, which could have a material impact on our business.

Our ability to implement our business plan and comply with regulations requires an effective planning and management process. We expect that we will need to improve existing operational and financial systems, procedures and controls, and implement new ones, to manage our future business effectively. Any implementation delays, or disruption in the transition to new or enhanced systems, procedures or controls, could harm our ability to forecast sales, manage our supply chain, and record and report financial and management information on a timely and accurate basis.

Furthermore we are required to maintain internal control over financial reporting adequate to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements in accordance with generally accepted accounting principles. In connection with the restatement of certain of our financial statements for fiscal years December 31, 2009, 2010, 2011, and 2012, for each quarter in our fiscal years ended December 31, 2011 and December 31, 2012, and for the first three quarters of the fiscal year ended December 31, 2013, we determined that we have a material weakness as of December 31, 2013, namely that our controls over the evaluation and review of complex and non-routine transactions were not effective.

Due to these material weaknesses, we have concluded that as of December 31, 2013, our internal controls over financial reporting were not effective. Until these complex and non-routine control deficiencies are fully remediated, it may be more difficult for us to manage our business, our results of operations could be harmed, our ability to report results accurately and on time could be impaired, investors may lose faith in the reliability of our statements, and the price of our securities may be materially impacted. We cannot assure you whether, or when, the control deficiencies that are identified as material weaknesses will be fully remediated.

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We do not expect that our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. Over time, controls may become inadequate because changes in conditions or deterioration in the degree of compliance with policies or procedures may occur. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. As a result, we cannot assure you that significant deficiencies or material weaknesses in our internal control over financial reporting will not be identified in the future. A material weakness means a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the registrant's annual or interim financial statements will not be prevented or detected on a timely basis.

Any failure to maintain or implement required new or improved controls, or any difficulties that we encounter in their implementation, could result in additional significant deficiencies or material weaknesses, cause us to fail to timely meet our periodic reporting obligations, or result in material misstatements in our consolidated financial statements. Any such failure could adversely affect the results of periodic management evaluations and annual auditor attestation reports regarding disclosure controls and the effectiveness of our internal control over financial reporting.

The restatement of our historical financial statements has already consumed a significant amount of our time and resources and may have a material adverse effect on our business and stock price.

As described earlier, we have restated certain of our financial statements. The restatement process was highly time and resource-intensive and involved substantial attention from management and significant legal and accounting costs. Although we have now completed the restatement, we cannot guarantee that we will have no inquiries from the SEC or other entities regarding our restated financial statements or matters relating thereto.

Any future inquiries from the SEC as a result of the restatement of our historical financial statements will, regardless of the outcome, likely consume a significant amount of our resources in addition to those resources already consumed in connection with the restatement itself.

Further, many companies that have been required to restate their historical financial statements have experienced a decline in stock price and stockholder lawsuits related thereto.

We currently have an Interim President while we search for a permanent Chief Executive Officer.

During the first quarter of 2014, we executed a separation by mutual release agreement with our Chief Executive Officer, pursuant to which our CEO's employment ended effective immediately. As a result, the board of directors formed a CEO search committee and is currently conducting a search. While we expect to recruit a new CEO in the coming months, we cannot assure you that the process will be concluded in a timely fashion. The search for and transition to a permanent CEO could be disruptive to our business, growth, financial condition and profitability. We believe each member of our senior management team is important to our success and the unexpected loss of any of these persons could impair our day-to-day operations as well as our strategic direction.

Our primary source of liquidity is our financing arrangement with Lincoln Park, and changes in our share price directly affect our ability to fund our operations.

We currently rely on our share purchase arrangement with Lincoln Park Capital Fund, LLC, or Lincoln Park, to fund our ongoing operations. Pursuant to the Purchase Agreement with Lincoln Park, the purchase price of such common stock sold to Lincoln Park is based on the prevailing market price of our common stock immediately preceding the time of sales; we control the timing and amount of any future sales, if any, of common stock. There are no upper limits to the price Lincoln Park may pay to purchase our common stock. The purchase price in most cases is directly derived from the prevailing market price of our common stock on OTCBB. Though the purchase price cannot be less than $0.03, this arrangement means that our prevailing share price directly affects the number of shares we need to issue to Lincoln Park at any given time to fund short-term operations. The number of shares issuable under our Certificate of Incorporation and the number of shares to be registered for sale to Lincoln Park are both limited, and a share price that falls and stays too low would make it difficult or impossible to fund our operations through sales of shares to Lincoln Park due to these limitations.

As of May 6, 2014, we have access to approximately $3.1 million in capital under our arrangement with Lincoln Park.

We have a limited operating history on which investors may evaluate our operations and prospects for profitable operations.

If we continue to suffer losses as we have in the past, investors may not receive any return on their investment and may perhaps lose their entire investment. Our prospects must be considered speculative in light of the risks, expenses and difficulties frequently encountered by companies in their early stages of development, particularly in light of the uncertainties relating to the new, competitive and rapidly evolving markets in which we anticipate we will operate. A substantial risk is involved in investing in us because, as an early stage company, we have fewer resources than an established company, our management may be more likely to make mistakes at such an early stage, and we may be more vulnerable operationally and financially to any mistakes that may be made, as well as to external factors beyond our control. We also have no experience bringing therapeutics candidates through the regulatory approval process to commercialization, and we operate with little budgetary margin for error. To attempt to address these risks, we must,

among other things, further develop our technologies, products and services, successfully implement our research, development, marketing and commercialization strategies, respond to competitive developments and attract, retain and motivate qualified personnel. Any failure to achieve any of the forgoing would result in an inability to achieve profitability.

We are subject to litigation that will be costly to defend or pursue and uncertain in its outcome.

Our business may bring us into conflict with our licensees, licensors or others with whom we have contractual or other business relationships, or with our competitors or others whose interests differ from ours. If we are unable to resolve those conflicts on terms that are satisfactory to all parties, we may become involved in litigation brought by or against us. That litigation is likely to be expensive and may require a significant amount of management's time and attention, at the expense of other aspects of our business. The outcome of litigation is always uncertain, and in some cases could include judgments against us that require us to pay damages, enjoin us from certain activities or otherwise affect our legal or contractual rights, which could have a significant adverse effect on our business.

A significant adverse determination in any claim against us could adversely affect our operating results or financial condition. For example, as previously disclosed by us, we received a copy of the claim, or the Claim, by Gary D. Aronson's Creditor, or the Claimant, in the amount of $27,909,706, dated July 13, 2011, against the Estate of William Caldwell, who at the time of his death was our Chief Executive Officer and Chairman of the Board of Directors. The Claim states Mr. Caldwell's liability arises under a cause of action against us for violations of the Exchange Act, including Section 10(b) of the Exchange Act. In the Claim, the Claimant alleges that in September 2005, he entered into a Settlement Agreement with us pursuant to which he received a warrant to purchase shares of our common stock and that, among other thing, in reliance on misinformation provided to him by the Decedent he exercised his warrant to purchase the such common stock at an inflated price and received fewer shares than he was owed by us under the terms of his warrant. The Claim also alleges that we breached the terms of the warrant by not timely issuing stock after the warrant was exercised, and that we failed to provide proper notice of certain events that allegedly triggered the Claimant's purported rights to additional shares under the warrant. On August 23, 2011, Gary Aronson filed suit in federal court in Massachusetts against us and Wilmington Trust, N.A., as Special Administrator of the Estate of Decedent William Mackay Caldwell, which reasserts allegations made in the Claim. On August 25, 2011, John S. Gorton filed a substantially similar lawsuit. Aronson and Gorton then filed substantially similar First Amended Complaints. We together with Decedent moved to dismiss Aronson's and Gorton's First Amended Complaints. On July 16, 2012, a United States Magistrate Judge issued a report and recommendation concerning our and Decedent's motions to dismiss. The district court adopted the report and recommendation, dismissing all claims, including those asserting material misrepresentations in violation of the Exchange Act, except for one breach-of-contract claim against us concerning a warrant allegedly issued to William Woodward in breach of the warrants issued to Aronson and Gorton. Aronson and Gorton filed motions for leave to file Second Amended Complaints on October 23, 2012 and October 25, 2012. We did not oppose the motions. The Second Amended Complaints, deemed filed as of November 9 and 12, 2012, reasserted the claim for breach of contract with respect to the Woodward warrant, as well as new breach-of-contract claims against us related to a warrant allegedly issued to Deron Colby, an alleged extension of the exercise periods for stock warrants issued to Andwell, LLC and Nancy Burrows, and alleged stock sales in 2008. We moved to dismiss the second, third, and fourth counts of the Second Amended Complaints on November 30, 2012. A United States Magistrate Judge issued a report and recommendation concerning the motion to dismiss. The district court adopted the report and recommendation, denying the motions to dismiss as to the second and third counts of the Second Amended Complaints, and granting the motion to dismiss the fourth count with leave to amend. On September 25 and 26, 2013, Aronson and Gorton filed their Third Amended Complaints. On October 15, 2013, we answered Aronson's Third Amended Complaint and moved to dismiss Gorton's Third Amended Complaint for lack of subject-matter jurisdiction.

In addition, in mid-April of 2014 we received a notice of default from CAMOFI Master LDC and CAMZHN Master LDC stating that a failure by us to deliver shares of common stock issuable to this investors under convertible debentures held by these investors event resulted in an event of default under the debentures. In late April 2014, these investors delivered a notice to us stating that all amounts payable under the debentures, subject to adjustment as set forth therein, were immediately due and payable in accordance with their terms. The investors also demanded damages to which we believe they were not entitled and that they did not incur. On May 2, 2014, we paid these holders an amount that we believe satisfies all of our obligations under the debentures. However, there can be no assurance that the holders of the debentures will agree with our position that we have satisfied all of our obligations under the debentures and not pursue additional monetary or other damages.

The amount we may be required to pay, in cash or in stock, in connection with any claim or default event may prove to exceed our estimated reserves and, in the case of payment in the form of stock, may prove to be highly dilutive to our stockholders. Should any judgment or settlement occur that exceeds our estimate, or a new claim arise, or if we become aware of additional information that requires us to adjust our estimation of potential exposure, we may need to adjust our overall reserve and, depending on the amount, such adjustment could be material and adversely affect our operating results or financial condition.

We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

As of March 31, 2014, we had 39 full-time employees. As we mature and undertake the activities required to further develop and commercialize our therapeutic candidates, we may expand our full-time employee base and hire more consultants and contractors. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We will require substantial additional resources to fund our operations and to develop our product candidates. If we cannot find additional capital resources, we will have difficulty in operating as a going concern and growing our business.

We currently operate with limited resources. On March 31, 2014, we had a cash balance of approximately $4.0 million, and approximately $6.6 million in capital remained available under our arrangement with Lincoln Park. Based upon current business activities, existing cash resources and our ability to sell shares to Lincoln Park, we forecast having sufficient cash and access to capital to enable us to operate into the second half of 2014. We could make these capital resources last longer, though, that would require the implementation of significant cost-cutting measures. These measures may include reducing our staff and cancelling development programs. Our future capital requirements will depend on many factors, including the:

- progress and costs of pre-clinical development and laboratory testing and clinical trials;
- time and costs involved in obtaining regulatory approvals;
- number of product candidates we pursue;
- costs involved in filing and prosecuting patent applications and enforcing or defending patent claims; and
- the costs associated with commercializing our product candidates if they receive regulatory approval, including the cost and timing of developing sales and marketing capabilities, or entering into strategic collaboration with others relating to the commercialization of our product candidates.

Other than our arrangement with Lincoln Park, we have no sources of debt or equity capital committed for funding. We can provide no assurance that we will be successful in any funding effort. The timing and degree of any future capital requirements will depend on many factors, including:

- our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- the accuracy of the assumptions underlying our estimates for capital needs in 2013 and beyond as well as for the clinical studies of our therapy candidates;
- scientific progress in our research and development programs;

- the magnitude and scope of our research and development programs;

- our progress with preclinical development and clinical trials;

- the time and costs involved in obtaining regulatory approvals;

- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; and

- the number and type of therapeutic candidates that we pursue.

Our ability to execute our business strategy and sustain our infrastructure at our currently planned levels will be impacted by whether or not we have sufficient funds. Depending on market conditions and our ability to maintain financial stability, we may not have access to additional funds on reasonable terms or at all. Any inability to obtain additional funds when needed would have an adverse effect on our business and on our ability to operate on an ongoing basis.

Our independent auditor's report for the fiscal year ended December 31, 2013 includes an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern.

Due to the uncertainty of our ability to meet our current operating and capital expenses, in their report on our audited annual financial statements as of and for the year ended December 31, 2013, our independent auditors included an explanatory paragraph regarding concerns about our ability to continue as a going concern. Recurring losses from operations raise substantial doubt about our ability to continue as a going concern. If we are unable to continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. In addition, the inclusion of an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern and our lack of cash resources may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights.

We may seek additional capital through a combination of private and public equity offerings, debt financings and collaboration, strategic and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder.

Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

Risks Relating to Technology

We are dependent on new and unproven technologies.

Our risks as an early stage company are compounded by our heavy dependence on unproven technologies. If these technologies do not produce satisfactory results in the clinical trial setting and/or are unable to gain regulatory approval, our business may be harmed. We have not shown an ability to bring any therapeutic candidate through the regulatory process to marketing approval. Given the unproven nature of our technology and potential product candidates, the FDA or other regulatory agency may require additional clinical data or manufacturing practices than that required of other conventional therapies. Additionally some of our technologies and potential revenue sources involve ethically sensitive and controversial issues which could become the subject of legislation or regulations materially restricting our development programs, future sales and marketing and other operations and, therefore, harm our financial condition and operating results.

We may not be able to commercially develop our technologies and proposed product lines, which, in turn, would significantly harm our ability to earn revenues and result in a loss of investment.

Our ability to commercially develop our technologies may be limited in part by a number of factors including, but not limited to, general economic conditions, the success of our research and pre-clinical and field testing, the availability of collaborative partners willing and able finance our work in pursuing applications of cell therapy technologies, and

technological or other developments in the biomedical field which may render out technologies obsolete or competitively unattractive. We may not pursue one or more commercialization strategies at all if we cannot locate a collaborative partner or entity willing to fund research and development or if we cannot agree to acceptable terms governing a potential development or marketing collaboration. Our decisions regarding the ultimate products and/or services we pursue could have a significant adverse effect on our ability to earn revenue if we misinterpret trends, underestimate development costs and/or pursue wrong products or services. Any of these factors either alone or in concert could materially harm our ability to earn revenues or could result in a loss of any investment in us.

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.

We are engaged in activities in the biotechnology field, which is characterized by extensive research efforts and rapid technological progress. If we fail to anticipate or respond adequately to technological developments, our ability to operate profitably could suffer. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization and market penetration than us. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors. We cannot assure you that research and discoveries by other biotechnology, agricultural, pharmaceutical or other companies will not render our technologies or potential products or services uneconomical or result in products superior to those we develop or that any technologies, products or services we develop will be preferred to any existing or newly-developed technologies, products or services.

We are aware that several companies and non-profit entities are working on various RPE formulations for treating macular degeneration. For example, Pfizer, Regenerative Patch Technologies and the Riken Center for Developmental Biology (Japan) have publicly stated that each is working towards clinical trials of RPE patches (sheets of cells) for treating wet AMD, and have also stated that they believe their formulations of RPE cells could potentially be used for treating dry AMD. Cell Cure Neurosciences Ltd. (Israel) has previously announced that it is developing RPE cell formulations for dry AMD.

Other cell types are also being developed for subretinal use in treating various forms of macular degeneration. StemCells Inc. recently commenced treating dry AMD patients with purified human neural stem cells. Bioheart, Inc. sponsors an active clinical trial for treating dry AMD with adipose stem cell (ASC), while the University of California Davis and Retinal Associates of South Florida are the sponsors of FDA approved pilot studies to determine whether it would be safe and feasible to inject CD34+ stem cells from bone marrow into the eye as treatment for patients who are irreversibly blind from various retinal conditions including dry AMD. Neurotech, Inc. recently completed a phase I study testing the safety of injecting encapsulated cells that express CNTF in dry AMD patients, while Janssen Research & Development, LLC suspended its safety study of umbilical cord stem cells administered subretinally in dry AMD patients.

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The biotechnology industries are characterized by rapidly evolving technology and intense competition. Our competitors include major multinational pharmaceutical companies, specialty biotechnology companies and chemical and medical products companies operating in the fields of regenerative medicine, cell therapy, tissue engineering and tissue regeneration.

Many of these companies are well-established and possess technical, research and development, financial and sales and marketing resources significantly greater than ours. In addition, certain smaller biotech companies have formed strategic collaborations, partnerships and other types of joint ventures with larger, well established industry competitors that afford these companies' potential research and development and commercialization advantages. Academic institutions, governmental agencies and other public and private research organizations are also conducting and financing research activities which may produce products directly competitive to those we are developing. Moreover, many of these competitors may be able to obtain patent protection, obtain FDA and other regulatory approvals and begin commercial sales of their products before we do.

The diseases and medical conditions we are targeting have no effective long-term therapies. Nevertheless, we expect that our technologies and products will compete with a variety of therapeutic products and procedures offered by major pharmaceutical companies. Many pharmaceutical and biotechnology companies are investigating new drugs and therapeutic approaches for the same purposes, which may achieve new efficacy profiles, extend the therapeutic window for such products, alter the prognosis of these diseases or prevent their onset.

We believe that our products, when and if successfully developed, will compete with these products principally on the basis of improved and extended efficacy and safety and their overall economic benefit to the health care system. Competition for any stem cell products that we may develop may be in the form of existing and new drugs, other forms of cell transplantation, ablative and simulative procedures and gene therapy. We believe that some of our competitors are also trying to develop stem and progenitor cell-based technologies. We expect that all of these products will compete with our potential stem cell products based on efficacy, safety, cost and intellectual property positions. We may also face competition from companies that have filed patent applications relating to the use of genetically modified cells to treat disease, disorder or injury. In the event our therapies should require the use of such genetically modified cells, we may be required to seek licenses from these competitors in order to commercialize certain of our proposed products, and such licenses may not be granted.

If we develop products that receive regulatory approval, they would then have to compete for market acceptance and market share. For certain of our potential products, an important success factor will be the timing of market introduction of competitive products. This timing will be a function of the relative speed with which we and our competitors can develop products, complete the clinical testing and approval processes and supply commercial quantities of a product to market. These competitive products may also impact the timing of clinical testing and approval processes by limiting the number of clinical investigators and patients available to test our potential products.

Our competition includes both public and private organizations and collaborations among academic institutions and large pharmaceutical companies, most of which have significantly greater experience and financial resources than we do.

Private and public academic and research institutions also compete with us in the research and development of therapeutic products based on human embryonic and adult stem cell technologies. In the past several years, the pharmaceutical industry has selectively entered into collaborations with both public and private organizations to explore the possibilities that stem cell therapies may present for substantive breakthroughs in the fight against disease.

Many of our competitors have significantly greater experience than we have in the development, pre-clinical testing and human clinical trials of biotechnology and pharmaceutical products, in obtaining FDA and other regulatory approvals of such products and in manufacturing and marketing such products.

Accordingly our competitors may succeed in obtaining FDA approval for products more rapidly or effectively than we can. Our competitors may also be the first to discover and obtain a valid patent to a particular stem cell technology which may effectively block all others from doing so. It will be important for us or our collaborators to be the first to discover any stem cell technology that we are seeking to discover. Failure to be the first could prevent us from commercializing all of our research and development affected by that discovery. Additionally, if we commence commercial sales of any products, we will also be competing with respect to manufacturing efficiency and sales and marketing capabilities, areas in which we have no experience.

Risks Related to Intellectual Property

Certain aspects of our business are dependent upon maintaining licenses with respect to key technology; if we are unable to obtain or protect intellectual property rights related to our product candidates, we may not be able to compete effectively in our markets.

Several of the patents we utilize are licensed to us by third parties. These licenses are subject to termination under certain circumstances (including, for example, our failure to make minimum royalty payments or to timely achieve spending, development and commercialization benchmarks). The loss of any of such licenses, or the conversion of such licenses to non-exclusive licenses, could harm our operations and/or enhance the prospects of our competitors. Certain of these licenses also contain restrictions, such as limitations on our ability to grant sublicenses that could materially interfere with our ability to generate revenue through the licensing or sale to third parties of important and valuable technologies that we have, for strategic reasons, elected not to pursue directly. The possibility exists that in the future we will require further licenses to complete and/or commercialize our proposed products. We cannot assure you that we will be able to acquire any such licenses on a commercially viable basis.

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Certain parts of our technology are not protectable by patent.

Certain parts of our know-how and technology are not patentable. To protect our proprietary position in such know-how and technology, we require all employees, consultants, advisors and collaborators to enter into confidentiality and invention ownership agreements with us. We cannot assure you, however, that these agreements will provide meaningful protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure. Further, in the absence of patent protection, competitors who independently develop substantially equivalent technology may harm our business.

Patent litigation presents an ongoing threat to our business with respect to both outcomes and costs.

Companies in the life science industry typically obtain patents and frequently engage in substantial intellectual property litigation. Our products and technologies could infringe on the rights of others. If a third party successfully asserts a claim for infringement against us, we may be liable for substantial damages, be unable to sell products using that technology, or have to seek a license or redesign the related product. These alternatives may be uneconomical or impossible. Intellectual property litigation could be costly, result in product development delays and divert the efforts and attention of management from our business. We may also be unable to obtain licenses needed to develop its technology or for certain intellectual property needed to develop and commercialize its products.

In addition to our ability to avoid infringing the proprietary rights of others, our success will also depend, in part, on our ability to maintain protection for our products and technologies under the patent laws of the United States and other countries. Our patent rights could be challenged by others, or if issued, could later be deemed invalid or unenforceable. Patent prosecution, related proceedings, and litigation in the U.S. and in other countries may be expensive, time consuming and ultimately unsuccessful. In addition, patents issued by foreign countries may afford less protection than is available under U.S. patent law and may not adequately protect our proprietary information. We have previously been involved in patent interference litigation, and it is possible that further litigation or patent office proceedings (such as oppositions, observations and/or reexaminations) over one or more of our own patent filings could arise. We could incur substantial litigation costs or costs associated with patent office proceedings in defending ourselves against suits or other actions brought against us or in suits in which we may assert our patents against others. If the outcome of any such litigation or patent office proceeding is unfavorable, our business could be materially adversely affected. The expiration of patents on which we rely for protection of key products could diminish our competitive advantage and adversely affect its business and prospects. Our competitors may independently develop proprietary technologies and processes that design around the coverage our patents.

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering one of our therapeutic candidates, the defendant could counterclaim that the patent covering our therapeutic candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of

several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the United States Patent and Trademark office, or USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our therapeutic candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our therapeutic candidates. Such a loss of patent protection would have a material adverse impact on our business.

Without additional capital, we may not have the resources to adequately defend or pursue such litigation or patent office proceedings. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock.

We may not be able to protect our proprietary technology, which could harm our ability to operate profitably.

The biotechnology and pharmaceutical industries place considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend, to a substantial degree, on our ability to obtain and enforce patent protection for our products, preserve any trade secrets and operate without infringing the proprietary rights of others. We cannot assure you that:

- we will succeed in obtaining any patents in a timely manner or at all, or that the breadth or degree of protection of any such patents will protect our interests, or that such patents would even be enforceable;
- the use of our technology will not infringe on the proprietary rights of others;
- patent applications relating to our potential products or technologies will result in the issuance of any patents or that, if issued, such patents will afford adequate protection to us or not be challenged invalidated or infringed;
- if issued, patents might not be declared as unenforceable or invalid by operation of law;

- patents will not issue to other parties, which may be infringed by our potential products or technologies; and

- we will continue to have the financial resources necessary to prosecute our existing patent applications, pay maintenance fees on patents and patent applications, or file patent applications on new inventions.

We are aware of certain patents that have been granted to others and certain patent applications that have been filed by others with respect to iPS cells and embryonic stem cells, and other stem cell technologies. The fields in which we operate have been characterized by significant efforts by competitors to establish dominant or blocking patent rights to gain a competitive advantage, and by considerable differences of opinion as to the value and legal legitimacy of competitors' purported patent rights and the technologies they actually utilize in their businesses.

Patents obtained by other persons may result in infringement claims against us that are costly to defend and which may limit our ability to use the disputed technologies and prevent us from pursuing research and development or commercialization of potential products.

A number of other pharmaceutical, biotechnology and other companies, universities and research institutions have potentially relevant to or required in the manufacturing, storage, sale or use of our expected products. In the case of pending patent application, we cannot predict which, if any, of such applications will issue as patents or the claims that might be allowed. We are aware that a number of companies have filed patent applications, which in some cases have resulted in issued patents, relating to the generation, formulation and uses of various stem cells, as well as RPE cells, photoreceptor progenitor cells, and mesenchymal stem cells.

If third party patents or patent applications contain claims infringed by us or any strategic partner or other licensee of our products, such as for the manufacturing, storage, sale or use of our expected products, and such patent claims are ultimately determined to be valid and enforceable against us or our licensees, there can be no assurance that we would be able to obtain licenses to these patents at a reasonable cost, if at all, or be able to develop or obtain alternative technology. If we are unable to obtain such licenses at a reasonable cost, we may not be able to develop some products commercially. We may be required to defend ourselves in court against allegations of infringement of third party patents. Patent litigation is very expensive and could consume substantial resources and create significant uncertainties. An adverse outcome in such a suit could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties, or require us or our licensees to cease using such technology.

Changes in U.S. patent law and in patent law in other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore obtaining and enforcing biotechnology patents is costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings and rulings from the European Patent Office Board of Appeals have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations, including potentially relating to the patentability of cells and tissues generated from hESC lines. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, and equivalents bodies in other major markets, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may not be able to adequately defend against piracy of intellectual property in foreign jurisdictions.

Considerable research in the areas of stem cells, cell therapeutics and regenerative medicine is being performed in countries outside of the United States, and a number of potential competitors are located in these countries. The laws protecting intellectual property in some of those countries may not provide adequate protection to prevent our competitors from misappropriating our intellectual property. Several of these potential competitors may be further along in the process of product development and also operate large, company-funded research and development programs. As a result, our competitors may develop more competitive or affordable products, or achieve earlier patent protection or product commercialization than we are able to achieve. Competitive products may render any products or product candidates that we develop obsolete.

Regulatory Risks

We cannot market our product candidates until we receive regulatory approval; even if we complete the necessary preclinical and clinical studies, we cannot predict when or if we will obtain regulatory approval to commercialize a product candidate or the approval may be for a more narrow indication than we expect.

Development of our products is subject to extensive regulation by governmental authorities in the United States and other countries. The process of obtaining regulatory approval is lengthy, expensive and uncertain. In the United States, the FDA imposes substantial requirements on the introduction of biological products and many medical devices through lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Satisfaction of these requirements typically takes several years and the time required to do so may vary substantially based upon the type and complexity of the biological product or medical device.

Product candidates that we believe should be classified as medical devices for purposes of the FDA regulatory pathway may be determined by the FDA to be biologic products subject to the satisfaction of significantly more stringent requirements for FDA approval. Any difficulties that we encounter in obtaining regulatory approval may have a substantial adverse impact on our business and cause our stock price to significantly decline.

If we fail to obtain regulatory approval of any of our product candidates for at least one indication, we will not be permitted to market our product candidates and may be forced to cease our operations. Even if our product candidates demonstrate safety and efficacy in clinical studies, the regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval at all. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on any approved indications. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical studies and the review process. Regulatory agencies also may approve a treatment candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our treatment candidates.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

Even if we obtain regulatory approval in a jurisdiction, the regulatory authority may still impose significant restrictions on the indicated uses or marketing of our product candidates, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Conditions of approval, such as limiting the category of patients who can use the product, may significantly impact our ability to commercialize the product and may make it difficult or impossible for us to market a product profitably. In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with good manufacturing practices, or GMP, and adherence to commitments made to the FDA in the approval process. If we or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, problems with the facility where the product is manufactured or manufacturing issues, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

FDA approval of our products may also entail ongoing requirements for post-marketing studies, or limit how or to whom the Company can sell its products. Even if we obtain regulatory approval, labeling, promotional and manufacturing activities are subject to continual scrutiny by the FDA, state regulatory agencies and, in some circumstances, the Federal Trade Commission. In addition, FDA enforcement policy prohibits the marketing of approved products for unapproved, or off-label, uses. These regulations and the FDA’s and other third-party payers interpretation of them could materially increase the Company’s expenses, impair its ability to effectively market its products, and limit our revenue.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. In addition, if our product candidates are approved by the FDA or other regulatory authorities for the treatment of any indications, regulatory labeling may specify that our product candidates may be used in conjunction with other therapies. The occurrence of any of these events or penalties may

inhibit our ability to commercialize our product candidates and generate revenues.

Once obtained, regulatory approvals may be withdrawn and can be expensive to maintain.

Regulatory approval may be withdrawn for a number of reasons, including the later discovery of previously unknown problems with the product. Regulatory approval may also require costly post-marketing follow-up studies, and failure of our product candidates to demonstrate sufficient efficacy and safety in these studies may result in either withdrawal of marketing approval or severe limitations on permitted product usage. In addition, numerous additional regulatory requirements relating to, among other things, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping will also apply. Furthermore, regulatory agencies subject a marketed product, its manufacturer and the manufacturer's facilities to continual review and periodic inspections. Compliance with these regulatory requirements is time-consuming and requires the expenditure of substantial resources.

If any of our product candidates is approved, we will be required to report certain adverse events involving our products to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning the advertisement and promotional labeling of our products. As a result, even if we obtain necessary regulatory approvals to market our product candidates for any indication, any adverse results, circumstances or events that are subsequently discovered could require that we cease marketing the product for that indication or expend additional money, time and effort to ensure full compliance, which could have an adverse effect on our business or results of operations.

If our products do not comply with applicable laws and regulations our business will be harmed.

Any failure by us, or by any third parties that may manufacture or market our products, to comply with the law, including statutes and regulations administered by the FDA or other U.S. or foreign regulatory authorities, could result in, among other things, warning letters, fines and other civil penalties, suspension of regulatory approvals and the resulting requirement that we suspend sales of our products, refusal to approve pending applications or supplements to approved applications, export or import restrictions, interruption of production, operating restrictions, closure of the facilities used by us or third parties to manufacture our product candidates, injunctions or criminal prosecution. Any of the foregoing actions could have an adverse effect on our business.

The Company may incur substantial liabilities from product liability claims.

If we obtain FDA approval to conduct human clinical trials for any of its products, it will face the risk of product liability exposure related to such testing. Such risks will be even greater if any of our products are sold commercially. An individual may bring a claim against us if one of its products causes, or merely appears to have caused some causal relationship to, an injury. If we cannot successfully defend itself against a product liability claim, it may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- a clinical hold on further patient testing in the trial;
- damage to our reputation and decreased demand for its products;
- withdrawal of participants from our clinical trials;
- substantial costs of arising from the defense of the claim;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- increased difficulty in entering into strategic relationships.

The commercial success of any current or future product candidate will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community, and our products may not be accepted in the marketplace.

If we are successful in obtaining regulatory approval for any of our product candidates, the degree of market acceptance of those products will depend on many factors, including:

- Our ability to provide acceptable evidence of, and the perception of patients and the healthcare community, including third party payors, of, the potential advantages of our product candidates relative to existing treatment methods;

- The incidence and severity of any adverse side effects of our product candidates;
- The availability and efficacy of alternative treatments;
- The labeling requirements imposed by the FDA and foreign regulatory agencies on our products and related marketing materials, including the scope of approved indications and any safety warnings;
- Our ability to obtain sufficient third party insurance coverage or reimbursement for our product candidates;
- The inclusion of our products on insurance company coverage policies;
- The willingness and ability of patients and the healthcare community to adopt new technologies;
- Public opinion and acceptance of stem cell therapy in general, including media coverage and activism by religious, social or political groups;
- The procedure time associated with the use of our product candidates, including time between and frequency of dosage;
- Our ability to manufacture or obtain from third party manufacturers sufficient quantities of our product candidates with acceptable quality and at an acceptable cost to meet demand; and
- Internal or external marketing and distribution support for our products.

We cannot predict or guarantee that physicians, patients, healthcare insurers, third party payors or health maintenance organizations, or the healthcare community in general, will accept or utilize any of our product candidates. Failure to achieve market acceptance would limit our ability to generate revenue and would have a material adverse effect on our business. In addition, if any of our product candidates achieve market acceptance, we may not be able to maintain that market acceptance over time if competing products or technologies are introduced that are received more favorably or are more cost-effective.

Restrictions on the use of human embryonic stem cells, the ethical, legal and social implications of stem cell research, and negative public opinion about stem cell therapy may damage public perception of our therapeutic candidates and could prevent us from developing or gaining acceptance for commercially viable products.

Some of our most important programs involve the use of stem cells that are derived from human embryos. The use of human embryonic stem cells gives rise to ethical, legal and social issues regarding the appropriate derivation of these cells. In the event that our research related to human embryonic stem cells becomes the subject of adverse commentary or publicity or increased scrutiny by governmental or regulatory organizations, our business could be harmed or otherwise substantially impaired, and the market price for our common stock could be significantly harmed. Some political and religious groups have voiced opposition to our technology and practices. We use stem cells derived from human embryos that have been created for in vitro fertilization procedures but are no longer desired or suitable for that use and are donated with appropriate informed consent for research use. Many research institutions, including some of our scientific collaborators, have adopted policies regarding the ethical use of human embryonic tissue. These policies may have the effect of limiting the scope of research conducted using human embryonic stem cells, thereby impairing our ability to conduct research in this field.

Governmental regulations and laws could change.

There can be no assurance that our operations will not be restricted by any future legislative or administrative efforts by politicians or groups opposed to the development of human embryonic stem cell technology or nuclear transfer technology. Additionally, the scope of the Dickey–Wicker Amendment, a 16-year-old ban on U.S. federal funding for activity related to the harm or destruction of an embryo, was recently under review by the federal courts and while it was determined not to preclude funding of human embryonic stem cell research by the federal government, there can be no assurance that it will not be challenged again or the language modified by Congress so as to restrict government funding of human embryonic stem cell research. Judicial review of this or other U.S. federal or state laws, the occurrence and results of which are difficult to predict with any certainty, could result in a more restrictive interpretation of those laws than is previously the case, and may limit or require us to terminate certain of our research and therapeutic programs.

Because we or our collaborators must obtain regulatory approval to market our products in the United States and other countries, we cannot predict whether or when we will be permitted to commercialize our products.

Federal, state and local governments in the United States and governments in other countries have significant regulations in place that govern many of our activities. We are or may become subject to various federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances used in connection with our research and development work. The preclinical testing and clinical trials of the products that we or our collaborators develop are subject to extensive government regulation that may prevent us from creating

commercially viable products from our discoveries. In addition, the sale by us or our collaborators of any commercially viable product will be subject to government regulation from several standpoints, including manufacturing, advertising and promoting, selling and marketing, labeling and distributing.

If, and to the extent that, we are unable to comply with these regulations, our ability to earn revenues will be materially and negatively impacted. The regulatory process, particularly in the biotechnology field, is uncertain, can take many years and requires the expenditure of substantial resources. Biological drugs and non-biological drugs are rigorously regulated. In particular, proposed human pharmaceutical therapeutic product candidates are subject to rigorous preclinical and clinical testing and other requirements by the FDA in the United States and similar health authorities in other countries in order to demonstrate safety and efficacy. We may never obtain regulatory approval to market our proposed products.

Our products may not receive FDA approval, which would prevent us from commercially marketing our products and producing revenues.

The FDA and comparable government agencies in foreign countries impose substantial regulations on the manufacture and marketing of pharmaceutical products through lengthy and detailed laboratory, pre-clinical and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Satisfaction of these regulations typically takes several years or more and varies substantially based upon the type, complexity and novelty of the proposed product. We cannot assure you that FDA approvals for any products developed by us will be granted on a timely basis, if at all. Any such delay in obtaining, or failure to obtain, such approvals could have a material adverse effect on the marketing of our products and our ability to generate product revenue.

We may not be able to obtain required approvals in countries other than the United States.

The requirements governing the conduct of clinical trials and cell culturing as well as the marketing approval process for our product candidates outside the United States vary widely from country to country. Foreign approvals may take longer to obtain than FDA approvals and can require, among other things, additional testing and different clinical trial designs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval processes. Some foreign regulatory agencies also must approve prices of the products. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. We may not be able to file for regulatory approvals and may not receive necessary approvals to market our product candidates in any foreign country. If we fail to comply with these regulatory requirements or fail to obtain and maintain required approvals in any foreign country, we will not be able to sell our product candidates in that country and our ability to generate revenue will be adversely affected.

Financial Risks

We may not be able to raise the required capital to conduct our operations and develop and commercialize our products.

We require substantial additional capital resources in order to conduct our operations and develop and commercialize our products and run our facilities. We will need significant additional funds, a collaborative partner, or both, to finance the research and development activities of our therapies and potential products. Accordingly, we are continuing to pursue additional sources of financing. Our future capital requirements will depend upon many factors, including:

- The continued progress and cost of our research and development programs;
- The progression, timing and results of our pre-clinical studies and clinical trials;
- The time and costs involved in obtaining regulatory clearance;
- The costs in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- The costs of developing sales, marketing and distribution channels and our ability to sell the therapies/products if developed;
- The costs involved in establishing manufacturing capabilities for commercial quantities of our proposed products;
- Competing technological and market developments;
- Market acceptance of our proposed products;
- Costs associated with defending any litigation or regulatory investigations, including SEC investigations, investor litigation, or litigation regarding potential infringement by us of third-party intellectual property rights;
- The costs for recruiting and retaining employees and consultants; and

· The costs for educating and training physicians about our proposed therapies/products.

Additional financing through strategic collaborations, public or private equity financings or other financing sources may not be available on acceptable terms, or at all. Additional equity financing could result in significant dilution to our shareholders. Further, if additional funds are obtained through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies, product candidates or products that we would otherwise seek to develop and commercialize on our own. If sufficient capital is not available, we may be required to delay, reduce the scope of or eliminate one or more of our programs or potential products, any of which could have an adverse effect on our financial condition or business prospects.

Risks Related to Third Party Reliance

We depend on third parties to assist us in the conduct of our preclinical studies and clinical trials, and any failure of those parties to fulfill their obligations could result in costs and delays and prevent us from obtaining regulatory approval or successfully commercializing our product candidates on a timely basis, if at all.

We engage consultants and contract research organizations to help design, and to assist us in conducting, our preclinical studies and clinical trials and to collect and analyze data from those studies and trials. The consultants and contract research organizations we engage interact with clinical investigators to enroll patients in our clinical trials. As a result, we depend on these consultants and contract research organizations to perform the studies and trials in accordance with the investigational plan and protocol for each product candidate and in compliance with regulations and standards, commonly referred to as “good clinical practice”, for conducting, recording and reporting results of clinical trials to assure that the data and results are credible and accurate and the trial participants are adequately protected, as required by the FDA and foreign regulatory agencies. We may face delays in our regulatory approval process if these parties do not perform their obligations in a timely or competent fashion or if we are forced to change service providers.

We depend on our collaborators to help us develop and test our proposed products, and our ability to develop and commercialize products may be impaired or delayed if collaborations are unsuccessful.

Our strategy for the development, clinical testing and commercialization of our proposed products requires that we enter into collaborations with corporate partners, licensors, licensees and others. We are dependent upon the subsequent success of these other parties in performing their respective responsibilities and the continued cooperation of our partners. Under agreements with collaborators, we may rely significantly on such collaborators to, among other things:

- Design and conduct advanced clinical trials in the event that we reach clinical trials;
- Fund research and development activities with us;
- Pay us royalties or fees upon the achievement of milestones; and
- Market with us any commercial products that result from our collaborations.

Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators' resources that will be devoted to supporting our research and development activities related to or any diligence obligations on the part of these collaborators under our collaborative agreements with them. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us. The development and commercialization of potential products will be delayed if collaborators fail to conduct these activities in a timely manner, or at all. In addition, our collaborators could terminate their agreements with us and we may not receive any development or milestone payments. If we do not achieve milestones set forth in the agreements, or if our collaborators breach or terminate their collaborative agreements with us, our business may be materially harmed

Our reliance on the activities of our non-employee consultants, research institutions, and scientific contractors, whose activities are not wholly within our control, may lead to delays in development of our proposed products.

We rely extensively upon and have relationships with scientific consultants at academic and other institutions, some of whom conduct research at our request, and other consultants with expertise in clinical development strategy or other matters. These consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. We have limited control over the activities of these consultants and, except as otherwise required by our collaboration and consulting agreements to the extent they exist, can expect only limited amounts of their time to be dedicated to our activities. These research facilities may have

commitments to other commercial and non-commercial entities. We have limited control over the operations of these laboratories and can expect only limited amounts of time to be dedicated to our research goals.

Preclinical & Clinical Product Development Risks

We have limited experience in conducting and managing preclinical development activities, clinical trials and the application process necessary to obtain regulatory approvals.

Our limited experience in conducting and managing preclinical development activities, clinical trials and the application process necessary to obtain regulatory approvals might prevent us from successfully designing or implementing a preclinical study or clinical trial. If we do not succeed in conducting and managing our preclinical development activities or clinical trials or in obtaining regulatory approvals, we might not be able to commercialize our product candidates, or might be significantly delayed in doing so, which will materially harm our business.

Our ability to generate revenues from any of our product candidates will depend on a number of factors, including our ability to successfully complete clinical trials, obtain necessary regulatory approvals and implement our commercialization strategy. In addition, even if we are successful in obtaining necessary regulatory approvals and bringing one or more product candidates to market, we will be subject to the risk that the marketplace will not accept those products. We may, and anticipate that we will need to, transition from a company with a research and development focus to a company capable of supporting commercial activities and we may not succeed in such a transition.

Because of the numerous risks and uncertainties associated with our product development and commercialization efforts, we are unable to predict the extent of our future losses or when or if we will become profitable.

Our failure to successfully commercialize our product candidates or to become and remain profitable could depress the market price of our common stock and impair our ability to raise capital, expand our business, diversify our product offerings and continue our operations.

None of the products that we are currently developing has been approved for marketing by the FDA or any similar regulatory authority in any foreign country, and may never be so approved. Our approach of using cell-based therapy for the treatment of retinal diseases such as Startgardt's disease and dry AMD is risky and unproven and no products using this approach have received regulatory approval in the United States or Europe.

We believe that no other company has yet been successful in its efforts to obtain regulatory approval in the United States or Europe of a cell-based therapy product for the treatment of retinal disease or degeneration in humans. Cell-based therapy products, in general, may be susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy or other characteristics that may prevent or limit their approval by regulators or commercial use. Many companies in the industry have suffered significant setbacks in advanced clinical trials, despite promising results in earlier trials. If our clinical trials are unsuccessful or significantly delayed, or if we do not complete our clinical trials while achieving sufficiently satisfactory results, we will not receive regulatory approval for or be able to commercialize our product candidates.

Our lead product candidates, our therapeutic Retinal programs for Startgardt's disease and Dry AMD, have been in Phase I Clinical Trials and have not yet received market approval from the FDA or any similar foreign regulatory authority for any indication.

We cannot market any product candidate until regulatory agencies grant approval or licensure. In order to obtain regulatory approval for the sale of any product candidate, we must, among other requirements, provide the FDA and similar foreign regulatory authorities with preclinical and clinical data that demonstrate to the satisfaction of regulatory authorities that our product candidates are safe and effective for each indication under the applicable standards relating to such product candidate. The preclinical studies and clinical trials of any product candidates must comply with the regulations of the FDA and other governmental authorities in the United States and similar agencies in other countries. Our therapeutic Retinal programs may never receive market approval from the FDA or any similar foreign regulatory authority.

In addition, we may experience numerous unforeseen events during, or even if approved for clinical trials, as a result of, the clinical trial process that could delay or prevent regulatory approval and/or commercialization of our product candidates, including the following:

- The FDA or similar foreign regulatory authorities may find that our product candidates are not sufficiently safe or effective or may find our cell culturing processes or facilities unsatisfactory;

- Officials at the FDA or similar foreign regulatory authorities may interpret data from preclinical studies and clinical trials differently than we do;

- Our clinical trials may produce negative or inconclusive results or may not meet the level of statistical significance required by the FDA or other regulatory authorities, and we may decide, or regulators may require us, to conduct additional preclinical studies and/or clinical trials or to abandon one or more of our development programs;

- The FDA or similar foreign regulatory authorities may change their approval policies or adopt new regulations;

- There may be delays or failure in obtaining approval of our clinical trial protocols from the FDA or other regulatory authorities or obtaining institutional review board approvals or government approvals to conduct or continue clinical trials at current or prospective sites;

- We, or regulators, may suspend or terminate our clinical trials because the participating patients are being exposed to unacceptable health risks or undesirable side effects;

- We may experience difficulties in managing multiple clinical sites;

- Enrollment in our clinical trials for our product candidates may occur more slowly than we anticipate, or we may experience high drop-out rates of subjects in our clinical trials, resulting in significant delays;

- We may be unable to manufacture or obtain from third party manufacturers sufficient quantities of our product candidates for use in clinical trials; and

- Our product candidates may be deemed unsafe or ineffective, or may be perceived as being unsafe or ineffective, by healthcare providers for a particular indication.

Any failure or delay in obtaining regulatory approval will negatively affect our financial results and harm our business.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On March 31, 2014, we issued various board members 1,227,687 shares of common stock valued at $92,475 as compensation for board services.

We relied on the exemption from registration provided by Section 4(a)2 of the Securities Act, with respect to each of the issuances of unregistered securities set forth above.

ITEM 6. EXHIBITS

Exhibit	**Description**
31.1	Section 302 Certification of Principal Executive Officer.*
31.2	Section 302 Certification of Principal Financial Officer.*
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350.*
101.SCH	XBRL Schema Document*
101.CAL	XBRL Calculation Linkbase Document*
101.DEF	XBRL Definition Linkbase Document*
101.LAB	XBRL Label Linkbase Document*
101.PRE	XBRL Presentation Linkbase Document*

* Filed herewith

SIGNATURE

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 hereunto duly authorized.

ADVANCED CELL TECHNOLOGY, INC.

By: /s/ Edward Myles
Edward Myles
Interim President, CFO & Executive Vice President of Corporate Development
Dated: May 8, 2014 (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)