ADVANCED CELL TECHNOLOGY, INC.
Form 10-Q
November 10, 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 September 30, 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 November 4, 2014:
Common Stock, $0.001 par value per share	34,393,658 shares

ADVANCED CELL TECHNOLOGY, INC. AND SUBSIDIARY

INDEX

PART I – FINANCIAL INFORMATION

ITEM 1. Financial Statements

ADVANCED CELL TECHNOLOGY, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

AS OF September 30, 2014 AND DECEMBER 31, 2013 (UNAUDITED)

	September 30, 2014	December 31, 2013
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$7,812,497	$1,743,485
Other receivables	9,240	209,198
Deferred royalty fees, current portion	62,436	62,435
Prepaid expenses and other current assets	468,538	896,741
Total current assets	8,352,711	2,911,859
Property and equipment, net	780,112	753,576
Deferred royalty fees, less current portion	60,952	107,780
Other assets	53,924	68,801
Deferred costs	–	65,903
TOTAL ASSETS	$9,247,699	$3,907,919
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$2,183,564	$2,285,331
Accrued expenses	1,907,858	3,545,713
Accrued settlement	2,415,307	4,086,619
Senior secured convertible debentures, current portion, net of discount of $225,324 at December 31, 2013	–	2,174,676
Embedded conversion option liabilities, current portion	–	335,208
Loss contingency accrual	–	6,431,979
Unsettled warrant obligation	–	3,899,391
Deferred revenue, current portion	157,873	157,872
Total current liabilities	6,664,602	22,916,789
	–	1,162,447

Senior secured convertible debentures, less current portion, net of discount of $37,553 at December 31, 2013		
Embedded conversion option liabilities, less current portion	–	327,792
Warrant and option derivative liabilities	228,792	284,799
Deferred revenue, less current portion	1,631,295	1,749,702
Total liabilities	8,524,689	26,441,529
Commitments and contingencies (Note 3)		
STOCKHOLDERS' EQUITY (DEFICIT):		
Preferred stock, Series B; $0.001 par value; 50,000,000 shares authorized, 0 and 1,000 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively.	–	1
Preferred stock, Series C; $0.001 par value; 50,000,000 shares authorized, 0 and 1,750 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	–	2
Common stock, $0.001 par value; 37,500,000 shares authorized, 34,358,658 and 26,402,650 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	34,359	26,403
Additional paid-in capital	342,998,141	325,297,736
Promissory notes receivable, net of discount of $2,018,321 at December 31, 2013	–	(34,013,395)
Accumulated deficit	(342,309,490)	(313,844,357)
Total stockholders' equity (deficit)	723,010	(22,533,610)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$9,247,699	$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 AND NINE MONTHS ENDED SEPTEMBER 30, 2014 AND 2013 (UNAUDITED)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013 As restated (1)	2014	2013 As restated (1)
Revenue (License fees and royalties)	$39,467	$39,468	$118,404	$185,517
Cost of revenue	15,608	15,609	46,825	66,827
Gross profit	23,859	23,859	71,579	118,690
Operating expenses:				
Research and development	2,415,475	3,061,332	7,641,944	8,668,077
General and administrative expenses	1,588,563	3,220,434	7,076,875	9,174,230
Loss on settlement of litigation	–	–	13,468,547	–
Total operating expenses	4,004,038	6,281,766	28,187,366	17,842,307
Loss from operations	(3,980,179)	(6,257,907)	(28,115,787)	(17,723,617)
Non-operating income (expense):				
Interest income	–	162,548	55,840	165,340
Interest expense	(69)	(271,021)	(429,573)	(1,165,438)
Other gain (loss)	221,581	19,002	(172,656)	(522,404)
Adjustment to fair value of unsettled warrant obligation	–	455,034	18,959	(714,151)
Gain on extinguishment of debt	–	–	–	438,587
Adjustments to fair value of derivatives	42,207	146,609	719,007	371,255
Total non-operating income (expense)	263,719	512,172	191,577	(1,426,811)
Loss before provision for income tax	(3,716,460)	(5,745,735)	(27,924,210)	(19,150,428)
Provision for income tax	–	–	–	–
Net loss	$(3,716,460)	$(5,745,735)	$(27,924,210)	$(19,150,428)
Preferred stock dividend	672,197	603,357	1,889,192	1,758,753
Net loss applicable to common stock	(4,388,657)	(6,349,092)	(29,813,402)	(20,909,181)
Weighted average shares outstanding:				
Basic and diluted	33,607,563	25,731,913	30,188,521	24,513,912
Net loss applicable to common share:				
Basic and diluted	$(0.13)	$(0.25)	$(0.99)	$(0.85)

(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' EQUITY (DEFICIT)

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2014 (UNAUDITED)

	Series B Preferred Stock		Series C Preferred Stock		Common Stock		Additional Paid-in	Promissory Notes Receivable	Accumulated	Total Stockh Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	net	Deficit	(Defic
Balance December 31, 2013	**1,000**	**$1**	**1,750**	**$ 2**	**26,402,650**	**$26,403**	**$325,297,736**	**$(34,013,395)**	**$(313,844,357)**	**$(22,5**
Shares issued for settlements	–	–	–	–	4,273,737	4,724	25,973,326	–	–	25,97
Shares issued for services	–	–	–	–	27,229	27	198,282	–	–	198,3
Accrued dividends on Series B and C Preferred Stock	–	–	–	–	–	–	1,442,082	–	(1,442,082)	–
Accretion of note receivable discount on Series B and C Preferred Stock	–	–	–	–	–	–	–	(1,348,269)	1,348,269	–
Redemption of Series B and C Preferred Stock	(1,000)	(1)	(1,750)	(2)	–	–	(34,984,680)	35,361,664	(447,110)	(70,1
Stock based compensation	–	–	–	–	–	–	1,036,859	–	–	1,036
	–	–	–	–	3,649,000	3,649	24,034,542	–	–	24,03

Issuance of 3,649,000 shares of common stock in financing arrangement (net of issuance costs of $698,926)										
Adjustment for 1/100 reverse stock split	–	–	–	–	6,042	6	(6)	–	–	–
Net loss for the nine months ended September 30, 2014	–	–	–	–	–	–	–	–	(27,924,210)	(27,9
Balance, September 30, 2014	–	**$–**	–	**$–**	**34,358,658**	**$34,359**	**$342,998,141**	**$–**	**$(342,309,490)**	**$723,0**

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 NINE MONTHS ENDED SEPTEMBER 30, 2014 AND 2013 (UNAUDITED)

	Nine Months Ended September 30,	
	2014	2013 As Restated (1)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(27,924,210)	$(19,150,428)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	109,357	64,320
Amortization of deferred charges	46,825	96,828
Amortization of deferred revenue	(118,404)	(185,467)
Stock based compensation	1,036,859	3,059,298
Amortization of deferred issuance costs	65,903	403,160
Amortization of discounts of senior secured convertible debentures	262,877	414,396
Changes in fair value of derivatives	(719,007)	(371,255)
Shares of common stock issued for services	198,309	1,272,363
Non-cash financing costs	(203,358)	(830,233)
Loss on settlement of litigation	13,468,547	–
Changes in the fair value of unsettled warrant obligation	(18,959)	714,151
Gain on debt extinguishment	–	(438,587)
Warrants and options issued for consulting services	–	32,550
Other	–	43,873
Changes in operating assets and liabilities:		
Prepaid expenses, other assets and other receivables	643,036	(776,281)
Accounts payable and other liabilities	(3,410,934)	(1,759,433)
Net cash used in operating activities	(16,563,159)	(17,410,745)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(135,891)	(586,091)
Payment of lease deposits	–	(36,895)
Net cash used in investing activities	(135,891)	(622,986)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from issuance of common stock	24,038,191	16,844,532
Principal repayment of senior secured convertible debentures	(1,200,000)	(600,000)
Redemption of 250 shares of Series B Preferred Stock, net	(70,129)	–
Net cash provided by financing activities	22,768,062	16,244,532

NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	6,069,012	(1,789,199)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	1,743,485	7,241,852
CASH AND CASH EQUIVALENTS, END OF PERIOD	$7,812,497	$5,452,653
CASH PAID FOR:		
Interest	$100,793	$–
Income taxes	$–	$–
SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING ACTIVITIES:		
Accrued dividends on Series B and C Preferred Stock	$1,442,082	$1,758,754
Accretion of note receivable discount on Series B and C Preferred Stock	$1,348,270	$1,776,742
Issuance of 4,273,737 and 1,002,835 shares of common stock for accrued settlement	$25,977,600	$5,700,000
Conversion of Series A Preferred stock for 275,229 shares of common stock	$–	$1,912,837
Issuance of 106,008 shares of common stock as commitment financing fee	$698,926	$–

(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. ORGANIZATION AND BASIS OF PRESENTATION

Organization and Nature of Business

Advanced Cell Technology, Inc., and Subsidiary (collectively, the "Company") is a biotechnology company incorporated in the state of Delaware, are focused on the development of novel cell-based therapies. The Company's therapeutic area of focus is ophthalmology and the Company's most advanced products are in clinical trials for the treatment of dry age-related macular degeneration, Stargardt's macular degeneration and myopic macular degeneration. The Company is also developing several pre-clinical cell therapies for the treatment of other ocular disorders. Additionally, the Company also has a number of pre-clinical stage assets in disease areas outside the field of ophthalmology, including autoimmune, inflammatory and wound healing-related disorders. The Company's intellectual property portfolio includes pluripotent human embryonic stem cell, or hESC; induced pluripotent stem cell, or iPSC, platforms; and other cell therapy research programs. The corporate headquarters and principal laboratory and manufacturing facilities are located in Marlborough, Massachusetts.

Basis of Presentation

The unaudited consolidated financial statements have been prepared 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 nine months ended September 30, 2014 are not necessarily indicative of the results to be expected for the full year ending December 31, 2014.

2. RESTATEMENT OF PREVIOUSLY ISSUED CONSOLIDATED FINANCIAL STATEMENTS

On March 10, 2014, the Company concluded that its previously issued consolidated financial statements required a restatement for the years ended December 31, 2012 and 2011. The Company 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 the Company concluded that it had an error with its stock compensation accounting as a result of having inadequate authorized, unissued shares available for its outstanding options in certain periods. As a result of these errors the Company determined that its 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 warrant. 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, on a pre-reverse stock split basis. 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.

Due to the resulting financial statement impact within the years impacted, the Company determined it was 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 the first and second quarter of 2009 and the fourth quarter of 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 determined it was necessary to restate its financial statements for the Applicable Periods.

The following tables summarize the effects of the restatement on the Company’s previously issued condensed interim consolidated financial statements:

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

	Three months ended September 30, 2013	Nine months ended September 30, 2013
Net loss, as previously reported	$(5,705,122)	$(18,729,509)
Net adjustments		
Research and development	(163,079)	(382,671)
General and administrative expenses	(8,568)	(26,097)
Adjustments to fair value of unsettled warrant obligation	131,034	(12,151)
Net loss, restated	$(5,745,735)	$(19,150,428)
Basic and diluted loss per share:		
Net loss, as previously reported	$(0.22)	$(0.76)
Net adjustments		
Research and development	(0.01)	(0.02)
General and administrative expenses	(0.00)	(0.00)
Adjustments to fair value of unsettled warrant obligation	0.01	(0.00)
Net loss, restated	$(0.22)	$(0.78)
Weighted average shares used in computing net loss per share:		
Basic and diluted	25,731,913	24,513,912

Consolidated Statements of Operations (unaudited) for the three months ended September 30, 2013

	Three months ended September 30, 2013		
	As Previously Reported	Adjustments	As Restated
Revenue	$39,468	–	$39,468
Cost of revenue	15,609	–	15,609
Gross profit	23,859	–	23,859
Operating expenses:			
Research and development	2,898,253	163,079	3,061,332
General and administrative expenses	3,211,866	8,568	3,220,434
Total operating expenses	6,110,119	171,647	6,281,766
Loss from operations	(6,086,260)	(171,647)	(6,257,907)
Non-operating income (expense):			
Interest income	162,548	–	162,548
Interest expense and late fees	(271,021)	–	(271,021)
Finance gain (cost)	343,002	(324,000)	19,002
Adjustments to fair value of unsettled warrant obligation	–	455,034	455,034
Adjustments to fair value of derivatives	146,609	–	146,609
Total non-operating expense	381,138	131,034	512,172
Loss before provision for income tax	(5,705,122)	(40,613)	(5,745,735)
Provision for income tax	–	–	–
Net loss	$(5,705,122)	$(40,613)	$(5,745,735)
Loss per share:			
Basic	$(0.22)	$(0.00)	$(0.22)
Diluted	(0.22)	(0.00)	(0.22)
Weighted average shares outstanding:			
Basic	25,731,913	–	25,731,913
Diluted	25,731,913	–	25,731,913

Consolidated Statements of Operations (unaudited) for the nine months ended September 30, 2013

	Nine months ended September 30, 2013		
	As Previously Reported	Adjustments	As Restated
Revenue	$185,517	–	$185,517
Cost of revenue	66,827	–	66,827
Gross profit	118,690	–	118,690
Operating expenses:			
Research and development	8,285,406	382,671	8,668,077

General and administrative expenses	9,148,133	26,097	9,174,230
Total operating expenses	17,433,539	408,768	17,842,307
Loss from operations	(17,314,849)	(408,768)	(17,723,617)
Non-operating income (expense):			
Interest income	165,340	–	165,340
Interest expense and late fees	(1,165,438)	–	(1,165,438)
Finance gain (cost)	(637,257)	702,000	64,743
Fines and penalties	(587,147)	–	(587,147)
Gain on extinguishment of debt	438,587	–	438,587
Adjustments to fair value of unsettled warrant obligation	–	(714,151)	(714,151)
Adjustments to fair value of derivatives	371,255	–	371,255
Total non-operating expense	(1,414,660)	(12,151)	(1,426,811)
Loss before provision for income tax	(18,729,509)	(420,919)	(19,150,428)
Provision for income tax	–	–	–
Net loss	$(18,729,509)	$(420,919)	$(19,150,428)
Loss per share:			
Basic	$(0.76)	$(0.02)	$(0.78)
Diluted	(0.76)	(0.02)	(0.78)
Weighted average shares outstanding:			
Basic	24,513,912	–	24,513,912
Diluted	24,513,912	–	24,513,912

Consolidated Statement of Cash Flows Impact

The following table includes selected information from the Company's consolidated statements of cash flows presenting previously reported and restated cash flows, for the nine months ended September 30, 2013:

	For the nine months ended September 30, 2013	
	As Previously Reported	As Restated
Net loss	$(18,729,509)	$(19,150,428)
Stock based compensation	2,650,530	3,059,298
Adjustments to fair value of unsettled warrant obligation	–	714,151
Non-cash financing costs	(128,233)	(830,233)
Net cash used in operating activities	(17,410,745)	(17,410,745)

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 September 30, 2014, the Company has an accumulated deficit of $342.3 million. 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 Company entered into an agreement for a $30 million equity line arrangement in late June 2014. The accompanying financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

On August 28, 2014, the Company effected a 100-to-1 reverse stock split of its common stock. Unless otherwise noted, all references in these financial statements to number of shares, price per share and weighted average number of shares outstanding of common stock have been adjusted to reflect the reverse stock split on a retroactive basis. The split was also applied to any outstanding equity-based awards.

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.

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. 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 September 30, 2014 and December 31, 2013, the Company had deposits in excess of federally-insured limits totaling $7,784,714 and $1,668,232, respectively.

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

Relating to loss contingencies the Company accrues 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. The Company discloses a reasonably possible loss in excess of the amount accrued, if applicable. For reasonably possible loss contingencies, the Company discloses the nature of the loss contingency and provides a range of the estimate of possible loss or state that an estimate cannot be made.

Included in the accounts payable balance as of September 30, 2014 and December 31, 2013 is approximately $1,200,000, primarily related to the acquisition of Mytogen which the Company expects to settle within the coming year.

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 and nine months ended September 30, 2014, the Company had no research grants recorded. For the three and nine months ended September 30, 2013, the Company recorded $40,010 and $160,054, respectively, as a reduction in research and development costs.

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 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 September 30, 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 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 the Company's common stock; (2) potential discount for illiquidity of large blocks of the Company's 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 the Company's 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 September 30, 2014, the Company identified the following liabilities that are required to be presented on the balance sheet at fair value:

Description	Fair Value As of September 30, 2014	Fair Value Measurements at September 30, 2014 Using Fair Value Hierarchy		
		Level 1	Level 2	Level 3
Warrant and option derivative liabilities	$ 228,792	$ –	$ –	$ 228,792
Total	$ 228,792	$ –	$ –	$ 228,792

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

	Warrant and Option Derivative Liabilities
Balance at December 31, 2013	$ 284,799
Total (gains) for the period included in earnings	(56,007)
Balance at September 30, 2014	$ 228,792

	Embedded Conversion Option Liabilities
Balance at December 31, 2013	$ 663,000
Total (gains) for the period included in earnings	(663,000)
Balance at September 30, 2014	$ –

Gains and losses included in earnings for the nine months ended September 30, 2014 are reported as follows:

	Warrant and Option Derivative Liabilities

Total gain included in earnings	$ 56,007

	Embedded Conversion Option Liabilities
Total gain included in earnings	$ 663,000

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

Description	Fair Value at September 30, 2014	Valuation Technique	Unobservable Input	Value
Warrant and Option derivative liabilities	$ 228,792	Black Scholes Model	Expected volatility of the Company's common stock	70% - 80%

For the three and nine months ended September 30, 2014, the Company recognized a gain of $42,207 and $719,007, respectively, for the changes in the valuation of derivative liabilities. For the three and nine months ended September 30, 2013 the Company recognized a gain of $146,609 and $371,255, 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 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 $39,467 and $118,404 in license fee revenue for the three and nine months ended September 30, 2014, respectively, in its consolidated statements of operations, and recorded $39,468 and $185,517 in license fee revenue for the three and nine months ended September 30, 2013, respectively.

The remainder of the license fees are reflected in deferred revenue at September 30, 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. The Company's research and development costs consist mainly of payroll and payroll related expenses, research supplies, research grants and clinical trial costs. 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.

In certain circumstances, the Company is required to make advance payments to vendors for goods or services that will be received in the future for use in research and development activities. In such circumstances, the advance payments are deferred and are expensed when the activity has been performed or when the goods have been received.

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 2,194,046 options and 468,000 restricted stock units ("RSUs") outstanding as of September 30, 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, based on the weight of available evidence, 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 at 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 the weight of 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 loss-per-share is based upon the weighted average number of common shares outstanding. Unless considered anti-dilutive, 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.

Potentially dilutive shares include stock options, warrants and RSUs. At September 30, 2014 and 2013, approximately 2,735,815 and 1,858,668 potentially dilutive shares, respectively, were excluded from the shares used to calculate diluted earnings per share as their inclusion would be anti-dilutive.

Recent Accounting Pronouncements - During the nine months ended September 30, 2014, the Financial Accounting Standards Board (FASB) issued ASU No. 2014-15, Presentation of Financial Statement-Going Concern (Subtopic 205-40) – *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The new standard requires a company to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern or to provide related footnote disclosures. The new standard will be effective for the Company on January 1, 2017. The Company is currently evaluating the potential impact that the new standard may have on its financial statements and related disclosures.

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 work towards developing human blood cells and other clinical therapies based on the Company's hemangioblast program. Under the terms of the agreement, the Company purchased upfront a 33% interest in the joint venture, and has received 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 September 30, 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 $22,059 in license fee revenue for the three and nine months ended September 30, 2014, respectively, and $7,353 and $22,059 in license fee revenue for the three and nine months ended September 30, 2013, respectively, in the consolidated statements of operations, and the balance of unamortized license fee of $329,657 and $351,715 is included in deferred revenue in the accompanying consolidated balance sheets at September 30, 2014 and December 31, 2013, respectively.

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 its 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 as “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 nine months ended September 30, 2014 and 2013:

	September 30,	
	2014	2013
Current assets	$257,334	$189,866
Noncurrent assets	1,280,989	1,227,201
Current liabilities	293,760	294,165
Noncurrent liabilities	1,656,467	1,948,582
Net revenue	219,087	219,087
Net income	$155,095	$137,901

5. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at September 30, 2014 and December 31, 2013:

	September 30, 2014	December 31, 2013
Machinery & equipment	$1,139,008	$1,086,800
Computer equipment	68,825	49,707
Office furniture	57,105	38,783
Leasehold improvements	606,212	559,969
	1,871,150	1,735,259
Accumulated depreciation	(1,091,038)	(981,683)
Property and equipment, net	$780,112	$753,576

Depreciation expense for the three and nine months ended September 30, 2014 amounted to $45,013 and $109,357, respectively. Depreciation expense for the three and nine months ended September 30, 2013 amounted to $26,618 and $64,320, respectively.

6. ACCRUED SETTLEMENT

The accrued settlement is comprised of the following at September 30, 2014 and December 31, 2013:

	September 30, 2014	December 31, 2013
SEC Civil Action	$2,040,307	$4,086,619
SEC Section 16 Investigation	375,000	–
Total	$2,415,307	$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 (the "SEC") 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 (the "Securities Act") 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, 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 SEC 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 to the aggregate amount due upon the acceptance by the SEC of the settlement agreement. The next installment was due and paid in April 2014 and the most recent payments were due and paid in July and October 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

In April 2013, it was determined that Gary Rabin, the Company's former Chief Executive Officer, failed to report 27 transactions in a timely manner on Form 4 under Section 16 of the Exchange Act in which Mr. Rabin sold shares of the Company's common stock that took place between February 7, 2011 and January 10, 2013. The SEC then investigated the unreported transactions involving sales of shares of the Company's common stock. In September 2014, the Company settled the SEC action arising from the SEC's investigation. Under the terms of the settlement accepted by the SEC, the Company consented to the entry of order under which it neither admits nor denies liability and has agreed to pay a civil penalty of $375,000, which has been previously accrued for, by July 2015. In addition, the settlement requires the Company to engage an independent Section 16 compliance consultant, provide Section 16(a) training to each Section 16(a) reporting person, and provide a certification of compliance that each of the preceding requirements were completed. The settlement also requires the Company to cease and desist from committing or causing any violations and any future violations of Section 17(a)(2) of the Securities Act, Sections 13(a) and 14(a) of the Exchange Act, and Rules 12b-20, 13a-1, and 14a-9 thereunder. The terms of this settlement require the Company to allocate financial and management resources to complying with the settlement's terms, which may have adverse effect on our business. Also, if the SEC deems us to not have complied with any portion of the settlement, it may issue additional fines or sanctions against us which may limit our ability to issue securities or otherwise conduct our business as currently conducted.

7. CONVERTIBLE PROMISSORY NOTES

CAMOFI Senior Secured Convertible Debentures

On January 11, 2013, the Company entered into a settlement agreement and mutual release ("the Settlement Agreement") with CAMOFI Master LDC ("CAMOFI") and CAMHZN Master LDC ("CAMHZN" and together with CAMOFI, the "CAMOFI Parties"), relating to the lawsuit between the CAMOFI Parties, as plaintiffs, and the Company, as defendant, in the Supreme Court of New York. Pursuant to the Settlement Agreement the Company issued Debentures in the principal amount of $4,732,781 and $1,267,219 to CAMOFI and CAMHZN, respectively (together the "Debentures").

The Debentures had 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 the volume weighted average price ("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 their kind.

On April 29, 2014, the Company received an Acceleration Notice from the CAMOFI Parties of a declaration that the aggregate principal amount remaining under the Debentures subject to adjustment as set forth therein, together with any other amounts owed under the Debentures were immediately due and payable in accordance with their terms. The Acceleration Notice followed the delivery of a notice to the Company on April 15, 2014 stating that, due to the Company's failure to deliver shares of common stock issuable to the CAMOFI Parties within three days of a conversion event, an "Event of Default" had occurred and the CAMOFI Parties were reserving all rights held by them arising from such Event of Default. At the time of the conversion event, the Company determined not to deliver the shares to the CAMOFI Parties in order to comply with applicable securities laws. The Company later delivered the shares to the CAMOFI Parties in compliance with applicable securities laws, prior to the delivery of the Default Notice.

On May 2, 2014, the Company paid to the CAMOFI Parties an aggregate amount of approximately $1,616,000 calculated in accordance with the payment acceleration provisions of the Debentures and satisfying the Company's obligations under the Debentures. The payment represented the remaining $1,200,000 in principal amount due and an

additional amount of approximately $416,000, which represented penalties, interest and legal cost reimbursement to the CAMOFI Parties. With the payment, the Company satisfied in full its obligations under the Debentures and the terms of the Settlement Agreement and Mutual Release dated as of December 31, 2012 pursuant to which the Debentures were issued in January 2013. The Company received correspondence from the CAMOFI Parties stating that the CAMOFI Parties believe the aggregate amount due to be different than the amount the Company paid. The Company believes that the Company's interpretation of the Debentures is accurate and complete.

The Debentures had 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 had a calculated value at December 31, 2013 of $663,000. The Company recorded a gain of $663,000 for the change in the fair value of the embedded conversion option liability for the nine months ended September 30, 2014 as the derivative was recorded at $0 at September 30, 2014 with the retirement of the remaining debentures.

The Company recorded a debt discount of $725,000, which was to be amortized over the life of the Debentures using the effective interest rate of 22.9%. The unamortized discount balance of $108,229 was written off to interest expense with the retirement of the remaining outstanding Debentures.

8. LOSS CONTINGENCY ACCRUAL

The loss contingency accrual is comprised of the following at September 30, 2014 and December 31, 2013:

	September 30, 2014	December 31, 2013
Warrant holder litigation	$ –	$6,228,621
Miscellaneous settlements	–	203,358
Total	$ –	$6,431,979

Warrant holder litigation

On June 4, 2014, the Company entered into a settlement agreement (the "June 2014 Agreement") with each of Gary D. Aronson ("Aronson"), John S. Gorton, individually and as trustee of the John S. Gorton Separate Property Trust dated March 3, 1993 ("Gorton"), herronlaw apc, attorneys for Aronson ("Herron"), Miller and Steele LLP, attorneys for Gorton ("Miller/Steele") and Michael A. Bourke, attorney for both Aronson and Gorton ("Bourke"). The June 2014 Agreement relates to previously disclosed lawsuits filed against the Company by each of Aronson and Gorton in August 2011 in the United States District Court for the District of Massachusetts claiming that the Company breached an anti-dilution provision contained in warrants held by each of Aronson and Gorton as a result of certain transactions between the Company and other third-party investors.

Pursuant to the June 2014 Agreement, in exchange for dismissal of the lawsuit by the warrant holders, the Company issued 3,840,000 shares of its common stock. On the date of the execution of the June 2014 Agreement, the shares were valued at $6.14 per share for a total value of $23,577,600. With the settlement the Company reversed the existing accruals recorded for warrant holder litigation under loss contingency as well as under the underlying unsettled warrant obligation. As a result the Company recorded a loss on settlement of litigation of $0 and $13,468,547 for the three and nine months ended September 30, 2014, respectively. (see Note 9).

At December 31, 2013, the Company had determined that a loss was probable and the amount of loss was reasonably estimable, based on the facts and circumstances surrounding the litigation with Aronson and Gorton during the last quarter of 2013. The loss contingency represented 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.

Miscellaneous settlements

The Company was not able to exercise 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. As of September 30, 2014, the Company believes the probability of a future settlement to be remote and therefore has removed the loss contingency related to these settlements.

9. Unsettled Warrant obligation

The Company determined that it had an unsettled warrant obligation related to two warrant agreements entered into in 2005. The warrant agreements contained “full ratchet” anti-dilution 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 on a pre-reverse stock split basis. 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 on a pre-reverse stock split basis, based on the stock price at the time the anti-dilution provision was triggered. At December 31, 2013, the liability had been recorded at $3,899,391.

In June 2014, the warrant holder litigation with Aronson and Gorton was settled as the Company entered into a settlement agreement with the parties, thus eliminating the unsettled warrant obligation accrual at June 30, 2014 (see Note 8). The Company conducted a final valuation of the 63.2 million shares, on a pre-reverse stock split basis, of unsettled warrant obligation on the day of settlement, June 4, 2014, and the liability was adjusted to $3,880,431 before being adjusted for the settlement. For the nine months ended September 30, 2014, the Company recorded a gain of $18,959 through earnings related to the above matter.

10. SERIES B PREFERRED STOCK

On November 2, 2009 (the "Effective Date"), the Company entered into a preferred stock purchase agreement with Optimus Life Sciences Capital Partners, LLC ("Optimus"). Pursuant to the purchase agreement, the Company agreed to sell, and Optimus agreed to purchase, in one or more purchases from time to time at the Company's sole discretion (each, a "Series B Tranche"), (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 Optimus a commitment fee of $500,000, at the earlier of the closing of the first Series B 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 delivered tranche notices to Optimus 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 $0 and $3,587,748 at September 30, 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 Series B 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.

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 and exercising 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 December 31, 2013.

June 2014 Redemption

In June 2014 the Company redeemed 250 shares of the Series B preferred stock, all of which were upon or after the fourth anniversary of their initial issuance date, representing three separate tranches. As part of the redemption, the promissory notes receivable balances for these tranches were netted against the accrued dividends payable, with the net dividend payable balance of $70,129 being paid out in cash and a charge being recorded to stockholders equity.

August 2014 Redemption

On August 7, 2014, the Company redeemed the remaining 750 shares of its Series B Preferred Stock and the associated outstanding dividends payable from Optimus in exchange for (i) cancellation of the secured promissory notes and associated accrued interest of $10,874,257 issued to the Company by Optimus and (ii) $25,000 cash. The difference on the redemption of $112,978 was recorded as a credit to accumulated deficit.

During the three and nine months ended September 30, 2014 the Company accreted interest on the promissory notes in the amount of $22,373 and $578,543, respectively, and during the three and nine months ended September 30, 2013, the Company accreted interest on the promissory notes in the amount of $315,546 and $917,504, respectively, which was recorded in accumulated deficit during the periods then ended. The Company recorded dividends on its Series B preferred stock during the three and nine months ended September 30, 2014 of $103,927 and $735,508 respectively and during the three and nine months ended September 30, 2013 of $316,154 and $919,273, respectively. The accrued dividends are offset by the accretion of the note receivable discount.

Following this redemption, we have zero shares of Series B Preferred Stock outstanding as of September 30, 2014. As of December 31, 2013, 1,000 shares of Series B preferred stock were outstanding.

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 December 31, 2013, the Company had drawn $17,500,000 of the $25,000,000 commitment.

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 $2,454,853 at December 31, 2013.

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:

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 December 31, 2013.

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.

August 2014 Redemption

On August 7, 2014, the Company redeemed the remaining 1,750 shares of its Series C Preferred Stock and the associated outstanding dividends payable from Socius in exchange for (i) cancellation of the secured promissory notes and associated accrued interest of $22,186,899, issued to the Company by Socius and (ii) $25,000 cash. Following this repurchase, the Company has zero shares of Series C Preferred Stock outstanding. The difference on the redemption of $560,088 was recorded as a debit to accumulated deficit.

During the three and nine months ended September 30 2014, the Company accreted interest on the promissory note in the amount of $172,158 and $769,726, respectively, and during the three and nine months ended September 30, 2013, the Company accreted interest on the promissory note in the amount of $295,494 and $859,238, 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 and nine months ended September 30, 2014, of $121,160 and $706,574, respectively and recorded dividends of $287,203 and $839,480 during the three and nine months ended September 30, 2013, 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 September 30, 2014 and December 31, 2013, 0 and 1,750 shares of Series C preferred stock were outstanding, respectively.

12. WARRANT SUMMARY

Warrant Activity

A summary of warrant activity for the nine months ended September 30, 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	78,299	28.00	1.82	–
Granted	–	–	–	–
Exercised	–	–	–	–
Forfeited/Canceled	(4,530)	10.00	–	–
Outstanding, September 30, 2014	73,769	28.95	1.16	–
Exercisable, September 30, 2014	73,769	28.95	1.16	–

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 September 30, 2014:

	Warrants Outstanding and Exercisable		
Exercise Price $	**Number of Shares**	**Weighted Average Remaining Life (Years)**	**Weighted Average Exercise Price $**
10.00	27,863	0.25	10.00
20.00 – 30.00	16,300	1.25	25.00
38.00 – 39.00	13,306	2.82	38.51
45.00	8,150	1.25	45.00
70.00	8,150	1.25	70.00

73,769

13. STOCKHOLDERS' EQUITY (DEFICIT) TRANSACTIONS

On September 19, 2012 the Company entered into a purchase agreement with Lincoln Park Capital, LLC ("Lincoln Park"). Pursuant to the purchase agreement, the Company had the right to sell to Lincoln Park up to $35,000,000 in shares of its common stock. On June 18, 2014, the Company completed the last sale of common stock to Lincoln Park under this agreement. The Company determined that it was prudent to enter into another, similar agreement with Lincoln Park.

On June 27, 2014, the Company entered into a purchase agreement with Lincoln Park pursuant to which the Company has the right to sell to Lincoln Park up to $30,000,000 in shares of its common stock, subject to certain limitations set forth in the purchase agreement.

On June 27, 2014, the Company and Lincoln Park also entered into a registration rights agreement, pursuant to which the Company is required to file a registration statement with the SEC to register the resale of the shares of common stock issued and issuable to Lincoln Park on a best efforts basis, pursuant to the purchase agreement.

Upon the satisfaction of the conditions set forth in the purchase agreement, including the registration statement being declared effective by the SEC, the Company has the right over a 36-month period commencing in June 2014 to sell up to $30,000,000 million worth of shares of its 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 the Company's common stock immediately preceding the time of sales, with the Company controlling 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 the Company's 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 the Company's 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 execution of the purchase agreement). Due to the 100-to-1 reverse stock split of the Company's common stock effected in August 2014, as of September 30, 2014, the purchase price cannot be below $1.00.

The purchase agreement contains customary representations, warranties, covenants, closing conditions and indemnification and termination provisions by, among and for the benefit of the parties. Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of the Company's common stock. The purchase agreement may be terminated by the Company at any time at its discretion without any cost to the Company.

In consideration for entering into the purchase agreement, the Company issued to Lincoln Park 106,008 shares of its common stock as a commitment fee. At the time of issuance, the Company's common stock had a fair value of $6.59 per share, for a total commitment fee of $698,926. The shares related to the commitment fee have been issued in reliance on an exemption from registration under the Securities Act of 1933, as amended pursuant to Section 4(a)(2) thereof and Regulation D promulgated thereunder, and will be registered for resale on the registration statement that the Company must file pursuant to the purchase agreement and the registration rights agreement. The shares related to the commitment fee are fully earned as of the date of the agreement. There were no other considerations given to Lincoln Park for entering into this agreement with the Company.

From January 1, 2014 to September 30, 2014, Lincoln Park purchased 3,542,991 shares of common stock for cash proceeds of $24,038,191. Of the shares purchased, 2,269,750 shares of common stock were sold to Lincoln Park pursuant to the 2012 Lincoln Park purchase agreement, for total proceeds of $14,281,295 and 1,273,241 shares of common stock were sold to Lincoln Park pursuant to the 2014 purchase agreement for total proceeds of $9,756,896.

From January 27, 2014 to September 30, 2014, the Company issued an aggregate of 4,273,737 shares in settlements of disputes, including 3,840,000 shares in settlement of the Aronson-Gorton warrant holder litigation valued at $23,577,600 and 433,737 shares in settlement of $2,400,000 Debentures to the CAMOFI Parties as required by the Settlement Agreement.

During the nine months ended September 30, 2014, the Company issued various board members 27,229 shares of common stock valued at $198,309 as compensation for board services.

On August 28, 2014, the Company completed a 100-to-1 reverse stock split of its common stock. Unless otherwise noted, all references in these financial statements to number of shares, price per share and weighted average number of shares outstanding of common stock have been adjusted to reflect the reverse stock split on a retroactive basis. The split was also applied to any outstanding equity-based awards.

14. STOCK-BASED COMPENSATION

Stock Plans

Stock Plan	Options/Shares Issued	Options Outstanding	Options/Shares Available For Grant	Total Authorized
2004 Stock Plan	24,220	–	–	–
2004 Stock Plan II	4,100	1,800	8,912	13,012
2005 Stock Plan	2,989,346	2,192,246	2,829,042	5,818,388
	3,017,666	2,194,046	2,837,954	5,831,400

Stock Option Activity

A summary of option activity for the nine months ended September 30, 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	1,182,795	$ 19.22	6.95	$ 10,319
Granted	1,115,250	7.90		
Exercised	–	–		
Forfeited/canceled	(103,999)	29.65		
Outstanding, September 30, 2014	2,194,046	12.97	8.23	388,208
Vested and expected to vest at September 30, 2014	2,042,304	$ 13.34	8.11	$ 350,819
Exercisable, September 30, 2014	1,026,801	$ 18.72	6.47	$ 100,601

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 September 30, 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)**
$5.00 – 7.99	642,358	$ 6.97	9.50	143,066	$6.89	8.81
8.00 – 10.00	956,427	8.84	8.75	288,474	9.43	6.24
10.10 – 15.70	202,501	15.25	6.71	202,501	15.25	6.71
15.80 – 21.00	256,345	19.45	5.98	256,345	19.45	5.98
22.00 – 45.00	101,800	37.28	6.64	101,800	37.28	6.64
46.00 – 85.00	28,565	85.00	0.34	28,565	85.00	0.34
$86.00 – 248.00	6,050	$202.33	1.12	6,050	$202.33	1.12
	2,194,046			1,026,801		

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 September 30, 2014 are as follows:

	September 30, 2014	September 30, 2013
Risk-free interest rate	0.02 – 2.29%	0.76 - 1.91%
Expected life of the options	5.00 - 6.25 years	5.00 - 6.50 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 nine months ended September 30, 2014 and 2013 was $7.50 and $8.00, respectively.

Stock-based compensation expense to employees for the three and nine months ended September 30, 2014 was $470,653 and $1,036,859 and for the three and nine months ended September 30, 2013 was $1,028,243 and 3,059,298, respectively.

The compensation expense related to the unvested options as of September 30, 2014, was $7,665,298 which will be recognized over the weighted average period of 2.49 years.

Restricted Stock Units

Restricted stock units are not included in issued and outstanding common stock until the shares are vested and released. The table below summarizes activity relating to Restricted Stock Units for the nine months ended September 30, 2014:

	Number of Shares Underlying Restricted Stock Units	Weighted Average Grant-Date Fair Value per Share	Weighted Average Remaining Recognition Period (in years)	Aggregate Intrinsic Value
Outstanding, December 31, 2013	–	$ –	–	$–
Granted	468,000	7.25		
Outstanding, September 30, 2014	468,000	7.25	2.9	3,467,880
Unearned stock-based compensation expense of outstanding restricted stock units	$ 3,358,900			

(a) The aggregate intrinsic value in this table was calculated based on the positive difference between the closing market value of our common stock on September 30, 2014 ($7.41) and the purchase price of the underlying Restricted Stock Units

15. SUBSEQUENT EVENTS

On various dates from October 1, 2014 through October 31, 2014, Lincoln Park purchased 35,000 shares of common stock for cash proceeds to the Company of $241,850.

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 and nine months ended September 30, 2013, and the related cash flows for the three and nine months ended September 30, 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 and nine months ended September 30, 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 the development and commercialization of novel cell-based therapies. Our therapeutic area of focus is ophthalmology and our most advanced products are in clinical trials for the treatment of dry age-related macular degeneration, Stargardt's macular degeneration and myopic macular degeneration. We are also developing several pre-clinical cell therapies for the treatment of other ocular disorders. Additionally, we have a number of pre-clinical stage assets in disease areas outside the field of ophthalmology, including autoimmune, inflammatory and wound healing-related disorders. We have unique scientific leadership, research and clinical competencies which we believe provide opportunities for innovation and development in regenerative medicine.

We pursue differentiation approaches to generating transplantable tissues both in-house and through collaborations with other researchers who have particular interests in, and skills related to, cellular differentiation. Our research in this area includes projects focusing on developing many different cell types that may be used to treat a range of diseases within ophthalmology and other therapeutic areas. Control of differentiation and the culture and growth of stem and differentiated cells are important current areas of research and development for us.

Ophthalmology Programs

We are developing a pipeline of stem cell derived therapeutics which may have use as treatment for degenerative diseases of the eye. In some instances, stem cell derived therapies may repair and replace damaged tissue in the eye, permitting restoration of otherwise lost vision or prevention of further vision loss. As our understanding of the underlying pathophysiology of ocular disease increases, we believe we will have additional opportunities to develop other therapeutic products for the ophthalmology market.

Macular Degeneration Programs

The largest indication involving macular degeneration is “age-related macular degeneration”, or AMD. AMD is the leading cause of blindness and visual impairment in adults over fifty years of age. It is estimated that the clinically detectable AMD patient population in North America and Europe includes about 25-30 million people across the range of disease, from early-stage to late-stage, or legal blindness. AMD represents one of the largest unmet medical needs in medicine today in terms of the lack of useful therapeutics. There is an exponential rise in prevalence and incidence rates with age, with the prevalence rates of late-stage AMD quadruple every decade of life after the age of 40. Based on population aging trends, a recent article in *The Lancet* has projected that globally the number of people with AMD in 2020 will be about 196 million, increasing to 288 million by 2040.

Retinal pigment epithelium, or RPE, is a single-cell-thick layer of pigmented cells that form part of the blood/ocular barrier. The presence and integrity of the RPE layer is required for normal vision. The RPE layer is positioned between the photoreceptor cell layer of the retina and the Bruch’s membrane and choroid, a layer filled with blood vessels. Because the photoreceptors see no direct blood supply, it is the role of the RPE layer to transport nutrients and oxygen to the photoreceptor cells, as well as to supply, recycle, and detoxify products involved with the phototransduction process – the process by which the photoreceptors turn light into a signal to be propagated along the optic nerve to the brain. In particular, the RPE layer serves as the transport layer that maintains the structure of the photoreceptor environment by acting as an intermediary between the nerve layer and blood vessels, supplying small molecules, transporting ions and water from the blood vessels to the photoreceptor layer. The RPE cells take up nutrients such as glucose, retinol (Vitamin A), and fatty acids from the blood and deliver these nutrients to photoreceptors. The RPE layer also prevents the buildup of toxic metabolites around the nerve cells by transporting the metabolites to the blood. In addition, the RPE cells are able to secrete a variety of growth and survival factors helping to maintain the structural integrity and organization of the photoreceptors.

As the name implies, age-related macular degeneration usually affects older adults, with loss of central vision required for reading, driving and other important activities of daily living due to chronic damage of the central retina. It occurs in “dry” (aka “atrophic” or “geographic”) and “wet” (aka “neovascular” or “exudative”) forms. In the case of dry AMD, the dis process appears to begin with loss (death) of RPE cells followed by some period of photoreceptor atrophy and inactivity, and eventually, photoreceptor death. For most dry AMD patients, gradual loss of central vision occurs first. Wet AMD is often an end-stage manifestation seen in approximately 10% - 15% of dry AMD patients, with the loss of the RPE layer and its ability to maintain the Bruch’s membrane function as a barrier resulting in failure of the membrane’s integrity and abnormal blood vessels penetrating into the subretinal space with ensuing rapid loss of vision. In addition to AMD, other forms of macular degenerative diseases exist which, even if the underlying causes are different, appear to follow a similar course of RPE cell loss followed by atrophy, inactivity and ultimately death of the photoreceptor. These include, for example, an inherited juvenile onset form of macular degeneration called Stargardt’s Macular Degeneration, or SMD.

It had been reported in scientific journal articles that a portion of the RPE layer can be transplanted from one part of the eye to the macula (“translocation”) to allow rescue of photoreceptor function. Other investigators utilized fetal RPE

cells for allogeneic transplants into the eyes of AMD patients. In some instances, the investigators observed improvements in visual acuity in patients receiving the transplanted RPE cells. Although limited in their potential as a therapeutic modality, the RPE translocation and fetal RPE cells transplant studies represent an important proof-of-principle regarding the use of the RPE as treatment for vision loss secondary to macular degeneration.

Our research has indicated that RPE cells generated from pluripotent stem cell sources, such as an hESC line, may potentially solve the sourcing of transplantable RPE cells for treating macular degenerative conditions. It is possible that the area in which the RPE layer exists will maintain its relative immune-privilege in dry AMD patients. If so, the need for donor matching is not likely to be a significant limitation and a single and scalable allogeneic source of RPE cells, one that can be manufactured in culture, might provide a therapeutic solution for the millions of patients affected by this disease. We have created a GMP-compliant hESC master stem cell bank and a GMP protocol for manufacturing of human RPE cells from our hESC master bank. Extensive animal testing of the human RPE cells generated in culture has been conducted and has established that when injected into the eyes of test animals as a suspension of cells, the human RPE cells were able to home to areas of damage in the RPE layer, with engraftment and recapitulation of the correct anatomical structure in the back of the eye of the animals. As published in the journal *Stem Cells*, we have also demonstrated that in animal models of macular degeneration, not only did the human RPE cells reform the correct structure, but also that the injection of the cells resulted in preservation of the photoreceptor layer and its function. That is, the injected human RPE cells repaired and restored the function of the RPE layer in animal models of disease.

This data, along with safety data we collected on the human RPE cells, or our RPE Program, formed the basis of several Investigational New Drug, or IND, applications filed with the U.S. Food and Drug Administration, or FDA, and an Investigational Medicinal Product Dossier, or IMPD, relied upon by the U.K. Medicines and Healthcare Products Regulatory Agency. It also served as the basis of our clinical trials using RPE cells in patients with SMD and dry AMD.

We believe that the results from the SMD and dry AMD clinical trials are promising. Preliminary results for the first dry AMD and first SMD patient were published in early 2012 in *The Lancet*. This publication reported that there were no serious adverse events due to the injected RPE cells, which is the primary endpoint of the Phase 1 aspect of these trial. The trial sites have provided regular follow-up on all of the patients, and have been able to include data relating to the engraftment and persistence of the injected cells as well the impact on visual acuity. The preliminary data suggest that the injected cells are well tolerated and appear generally to be capable of engrafting at the site of injection, forming the appropriate anatomical monolayer structure around the injected area. Visual acuity improvement was observed to varying degrees in several of these very late-stage patients, a result that was not anticipated in the original design of these studies.

In October 2014, we announced that Phase 1/2 clinical data published online in *The Lancet* demonstrate positive long-term safety results using our RPE cells for the treatment of SMD and AMD. The publication features data from 18 U.S.-based patients with at least six months of post-transplant follow-up. These two studies provide the first evidence of the mid- to long-term safety, survival, and potential biologic activity of pluripotent stem cell progeny into humans with any disease. In addition to showing no adverse safety issues related to the transplanted tissue, anatomic evidence confirmed successful engraftment of the RPE cells, which included increased pigmentation at the level of the RPE layer after transplantation in 13 of 18 patients.

Based on the data published in *The Lancet* in October 2014, and the continued safety profile observed in all 38 patients that have been treated, to date, with our experimental therapy, we plan to initiate a Phase 2 study for SMD in the fourth quarter of 2014. We plan to initiate a Phase 2 trial for dry AMD in the second quarter of 2015. Both phase 2 trials will be open-label, fellow-eye controlled, dose-escalation multi center studies. The studies have been designed with two primary endpoints; 1) change from month 1 to month 12 in average best corrected visual acuity, or 2) rate of change in the area of atrophy from baseline to 18 months post-transplant. The current plan is to enroll 100 patients in the SMD trial and between 40 and 50 in the AMD trial. The purpose of the SMD trial is to test the efficacy and safety, and to assess relevant functional and anatomical parameters of transplant, of our hESC-derived RPE cells. The purpose of the dry AMD trial is to evaluate systemic immunosuppressive regimens and to explore efficacy parameters of our hESC-derived RPE cells.

To support this plan we intend to expand our clinical operations capabilities. We currently work with four clinical sites in the US and two in the UK. We plan to expand the number of sites to approximately 20 in the US and 10 in Europe. In addition, we are expanding the network of consultants and service providers we contract and we also plan to expand our internal workforce. These expansions and the increased spending that will result from these expanded capabilities is consistent with our previously stated plans to transition to become a product development company.

In February 2013, we announced that our clinical partner, the Jules Stein Eye Institute at the University of California, Los Angeles had received approval of its Investigator IND Application to initiate a Phase 1/2 study using our RPE cells to treat myopic macular degeneration, or MMD, a form of macular degeneration that can occur in association with severe forms of myopia. Myopia, or nearsightedness, is the most common eye disorder in the world, and is a significant global public health concern. Myopic macular degeneration seems to be associated with stress on the RPE layer as a consequence of elongation of the eyeball in myopic patients. The stress can induce fissures in the RPE layer, leading to RPE cell death and ultimately macular dystrophy and degeneration. It is an important public health issue lacking safe and effective treatments. Overall, MMD is reported to be the seventh-ranking cause of legal blindness in the United States, the fourth-ranking cause in Hong Kong and the second in parts of China and Japan. In June 2014, we announced that Jules Stein Eye Institute has initiated the trial. The actual enrollment of patients in this trial has been delayed by technical considerations to maximize patient safety. We expect to begin treatment of patients in the first half of 2015.

As we continue to manage our clinical trials and expand the indications for which our RPE cell therapy is being investigated, we have also begun to take the steps to define our final product formulation, as well as to lay the early

ground work to support appropriate pricing, coverage and reimbursement programs. We believe that our RPE therapy provides pricing justification across all categories of consideration by Medicare, Medicaid, National Health Service (UK) and private payors. Our program related to RPE cell therapy for the treatment of SMD has been granted Orphan Drug status in both the U.S. and Europe, which could accordingly lead to provide regulatory market exclusivity and potential FDA grant opportunities.

Photoreceptor Progenitor Program

Photoreceptors mediate the first step in vision, capturing light which, in turn, is converted into nerve signals to the brain. Photoreceptor atrophy, and subsequent cell death and permanent loss of photoreceptors, is seen as a consequence of macular degenerative diseases including AMD and SMD. Loss of photoreceptors is also a consequence to inherited retinal diseases such as retinitis pigmentosa, and acquired conditions such as diabetes. We recognize the potential value of being able to repair the retina with replacement photoreceptor cells derived from pluripotent stem cell sources such as iPSCs and hESCs. We believe those therapies can provide the basis for new approaches for treating a wide variety of retinal degenerations in diseases where photoreceptors malfunction and/or die, either alone or in combination with our RPE therapy.

We have developed a human photoreceptor progenitor cell which we believe is unique with respect to both the markers they express as well as their plasticity, meaning that they can differentiate into both rods and cones, and therefore provide a viable source of new photoreceptors for retinal repair. In addition, our photoreceptor progenitors appear to secrete neuroprotective factors, and have the ability to phagocytose (digest) such materials as the drusen deposits that build up in the eyes of dry AMD patients, and so may provide additional benefits beyond forming new photoreceptors when injected into the subretinal space in the eyes of patients. We will continue our preclinical investigation in animal models, establish appropriate correlation between integration of the transplanted cells and visual function in the animals, and then consider preparation of an IND and/or IMPD application to commence clinical studies with these cells. As part of our evaluation of this program, we will consider, among other things, the data generated from pre-clinical studies, our understanding of the potential market opportunity, and our ability to allocate capital resources to adequately fund the program to the next milestone.

Retinal Ganglion Cell Progenitor Program

In the United States alone, approximately 100,000 people are legally blind from glaucoma. The proven treatments include drug therapy or surgery to lower intraocular pressure; however, many patients lose vision despite receiving these treatments. In glaucoma, retinal ganglion cells degenerate before photoreceptors are lost. We are currently conducting pre-clinical research and development activities regarding differentiation of stem cells into retinal ganglion cells and demonstration of the ability of those cells to protect against elevated intraocular pressure in glaucoma models. We have succeeded in generating a unique human ganglion progenitor cell which, when injected in animal models of glaucoma, appear to protect against damage. We will continue our preclinical investigation in animal models, establish appropriate correlation between integration and visual function in the animals, and then consider preparation of an IND and/or IMPD application to commence clinical studies with these cells. As part of our evaluation of this program, we will consider, among other things, the data generated from pre-clinical studies, our understanding of the potential market opportunity, and our ability to allocate capital resources to adequately fund the program to the next milestone.

Corneal Endothelial Program

We have been able to generate sheets of corneal endothelial cells, with Descemet membrane, from hESCs. These endothelial sheets, which resemble fetal cornea in cell density, and thickness and durability of the tissue graft, could serve as the transplanted tissue in Descemet's Stripping with Endothelial Keratoplasty. In culture, our corneal endothelial cells have all the hallmarks, both marker expression and morphology, of native human corneal endothelium. We are testing these cells in several animal models of corneal diseases. We will continue our pre-clinical investigation in animal models, with the goal of establishing that the transplanted tissue functions correctly in the animals, and then consider preparation of an IND and/or IMPD application to commence clinical studies with these cells. As part of our evaluation of this program, we will consider, among other things, the data generated from pre-clinical studies, our understanding of the potential market opportunity, and our ability to allocate capital resources to adequately fund the program to the next milestone.

Other Programs

In addition to our ophthalmology programs we are investing resources into other programs where we feel that we can leverage our expertise in cellular and developmental biology to generate allogeneic therapies that have the potential to improve health care in other prevalent degenerative diseases and diseases of aging. At the core of our pipeline planning are approaches intended to address large unmet medical needs with allogeneic stem cell-derived therapeutics. The criteria for prioritizing these programs include stem cell capability, competitive landscape within the therapeutic area and severity/prevalence of the therapeutic area. We also utilize a proof-of-concept, or POC, approach in our product development process, testing our candidate therapies in relevant animal models of human disease in order to assess the likelihood of success when it comes time to try those therapies in human patients. Our POC approach

allows us to focus only on the most promising projects by verifying the science behind many ideas early in the development process while terminating those programs with a low probability of success.

Mesenchymal Stem Cells

Pluripotent stem-cell derived mesenchymal stem cells, or MSCs regulate immune and inflammatory responses, providing therapeutic potential for treating diseases characterized by the presence of an inflammatory component, which makes them an attractive tool for the cellular treatment of autoimmunity and inflammation. Their underlying molecular mechanisms of action together with their clinical benefit — for example, in autoimmunity — are, in our opinion, being revealed by an increasing number of clinical trials and preclinical studies of MSCs. The immunosuppressive/ immunomodulatory activity of these cells allows MSCs to be transplanted nearly universally, i.e., as an allogeneic cell therapy, without matching between donors and recipients. MSCs' universality, along with the ability to manufacture and store these cells long-term, present a unique opportunity to produce an "off-the-shelf" cellular therapy ready for treatment of diseases in both acute and chronic settings.

The current source of MSCs for therapeutic applications are isolated from cord blood and adult sources such as bone marrow and adipose (fat) tissue. However, once isolated from the source, the MSCs present in these sources do not propagate well in cell culture. Rather, the cells undergo replicative senescence, or "aging," within only a few passages (i.e., after a limited number of population doublings of cells through cell division). Accordingly, the number of doses of MSCs that can be generated from each donor is limited, and the process using adult MSC sources is consequently high-touch, and therefore riskier.

We believe we have succeeded at creating a differentiated MSC product by producing the cells in culture from a pluripotent stem cell source. Our cell culture process permits us to manufacture large scale quantities of MSCs from a renewable stem cell source, potentially eliminating the sourcing issues attendant with relying on adult sources of these cells. The stem-cell-sourced manufacturing process is scalable for global commercialization of MSC therapies, and should prove to be less costly (particularly at commercial scale) when compared to the adult-sourced, and cord blood-sourced, MSC products in development by other companies.

In our preliminary testing of our stem cell-derived MSCs in animal models of autoimmune disease, we have noted another differentiating feature of our cells, relative to other MSCs we have tested. The MSCs generated using our proprietary manufacturing approach seem to be more potent with respect to suppressing autoimmune responses in certain diseases models when compared to the equivalent dose of bone marrow MSCs. This potency was dependent on the number of passages in culture our MSCs had been through, with the earlier passage MSCs retaining the greatest potency. This correlates with reports in the scientific literature which suggest that adult MSCs lose potency as they are propagated in culture, and reports indicating that MSC from young adult donors are more potent than MSC from elderly donors. Being derived from embryonic stem cells, the early-passage MSCs we are testing for potential therapeutic uses seem to represent the earliest and most potent stage of biological development for MSCs, a stage that cannot be obtained from adult sources.

Our goal is to conduct a limited number of preclinical proof-of-concept studies, and based on those results, advance certain of these MSC discovery programs into IND-enabling pre-clinical studies and perhaps file IND applications, as circumstances dictate. We will evaluate opportunities for strategic partnering relationships, out-licensing or other commercial transactions with large pharmaceutical and biotech companies at various stages in these preclinical programs with an eye towards mitigating our overall cost of these 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, our 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.

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. 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.

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, such as members of our scientific advisory board and board of directors. The valuation of stock-based compensation awards is determined at the date of grant using the Black-Scholes option pricing model (the "Black-Scholes Model"). This model requires inputs such as the expected term of the option, expected volatility, and risk-free interest rate. Further, the forfeiture rate also impacts the amount of aggregate compensation. These inputs are subjective and generally require significant analysis and judgment to develop. To establish an estimate of expected term, we consider the vesting period and contractual period of the award and our historical experience of stock option exercises, post-vesting cancellations and volatility. To establish an estimate of forfeiture rate, we consider our historical experience of option forfeitures and terminations. The risk-free rate is based on the yield available on United States Treasury zero-coupon issues. We review our valuation assumptions quarterly and, as a result, it is likely we will change our valuation assumptions used to value stock-based awards granted in future periods.

Comparison of Three Months Ended September 30, 2014 and 2013

	Three Months Ended September 30,			
	2014	2013 As Restated	$ Change	% Change
Revenue	$39,467	$39,468	$(1)	–
Cost of revenue	15,608	15,609	1	–
Gross profit	23,859	23,859	–	–

Research and development expenses:					
-R&D expenses, excluding non-cash, stock- based compensation	2,237,471	2,476,547	(239,076)	(9.7)	%
- Non-cash, stock-based compensation	178,004	584,785	(406,781)	(69.6)	%
Total Research and Development	2,415,475	3,061,332	(645,857)	(21.1)	%
General and administrative expenses:					
-G&A expenses, excluding non-cash, stock- based compensation	1,240,158	2,308,067	(1,067,909)	(46.3)	%
-Non-cash, stock-based compensation	348,405	912,367	(563,962)	(61.8)	%
Total General and Administrative	1,588,563	3,220,434	(1,631,871)	(50.7)	%
Loss on settlement of litigation	–	–	–	–	
Non-operating income (expense)	263,719	512,172	(248,453)	(48.5)	%
Net loss	$(3,716,460)	$(5,745,735)	$2,029,275	35.3	%

Revenue

Revenue relates to license fees and royalties collected that are being amortized over the period of the license granted. Revenue was basically unchanged from the prior year for the three months ended September 30 at $39,467. The deferred revenue balance of $1,789,168, as of September 30, 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, manufacturing, clinical and regulatory staff, services attained in connection with our ongoing clinical trials and pre-clinical programs, our R&D and manufacturing facilities, and research supplies and materials. R&D expenditures, excluding non-cash, stock-based compensation expense, decreased from $2,476,547 for the three months ended September 30, 2013 to $2,237,471 for the three months ended September 30, 2014, for a decrease of $239,076 or 9.7%. The decrease in R&D expenditures was primarily due to the reduction of accrued expenses from prior periods that were reversed in the current period as we deemed that we had been legally released from such liabilities. Aside from this adjustment of approximately $269,000, R&D expenses increased by approximately $30,000 due to an increase in payroll and other compensation costs of approximately $182,000 and also due to increases in costs related to outside consultants of approximately $89,000. These increases were offset by decreases in lab supply costs of $104,000 and a decrease in pre-clinical and clinical costs of approximately $124,000, primarily due to lower clinical trial patient enrollment in the period.

R&D expenses related to non-cash, stock-based compensation decreased from $584,785 for the three months ended September 30, 2013 to $178,004 for the three months ended September 30, 2014, for a decrease of $406,781, or 69.6%. This decrease is related to the final vesting of options and restricted stock 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 September 30, 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 R&D 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 will increase from quarter to quarter for the foreseeable future. This planned increase will be driven primarily by our expansion of our clinical operations capabilities as we initiate and scale our phase 2 programs for SMD and AMD. We currently work with four clinical sites in the US and two in the UK. We plan to expand the number of sites to approximately 20 in the US and 10 in Europe. In addition, we are expanding the network of consultants and service providers we contract and we also plan to expand our internal workforce. These expansions and the increased spend that will result from these expanded capabilities is consistent with our previously stated plans to transition to a product development company. 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 U.S Food and Drug Administration, or 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 –based compensation expense, decreased from $2,308,067 for the three months ended September 30, 2013 to $1,240,158 for the three months ended September 30, 2014, for a decrease of $1,067,909 or 46.3%. The decrease in G&A expenditures was primarily due to the reduction of accrued expenses from prior periods that were reversed in the current period as we deemed that we had been legally released from such liabilities. In addition to the reversed accruals of approximately $566,000, G&A also decreased because of a decrease in legal costs of approximately $662,000 related to the final settlement of a number of legacy corporate matters. A decrease in investor relations' costs of approximately $123,000 also contributed to the decrease in G&A spending. These decreases were partially offset by increases in payroll and other compensation costs of approximately $138,000, consulting and professional services costs of approximately $50,000, D&O insurance costs of approximately $42,000, and rent and facility costs of approximately $52,000.

G&A expenses related to non-cash, stock-based compensation decreased from $912,367 for the three months ended September 30, 2013 to $348,405 for the three months ended September 30, 2014, for a decrease of $563,962, or 61.8%. This decrease is related to the final vesting of options and restricted stock 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 September 30, 2013 as compared to the same period in 2014.

Although we have recently hired a Chief Commercial Officer, we expect G&A expense to remain consistent with that of recent periods over the next several quarters.

Other Income (Expense)

	2014	2013 As Restated	$ Change	% Change
Interest income	$–	$162,548	$(162,548)	(100.0)%
Interest expense	(69)	(271,021)	270,952	(100.0)%
Other gain	221,581	19,002	202,579	1,066.1%
Adjustments to fair value of unsettled warrant obligation	–	455,034	(455,034)	(100.0)%
Adjustments to fair value of derivatives	42,207	146,609	(104,402)	(71.2)%
Total non-operating income (expense)	$263,719	$512,172	$(248,453)	

Interest expense for the three months ended September 30, 2014 compared to the three months ended September 30, 2013 decreased by $270,952 to $69. The decrease is due to the discontinuation of interest expense on our previously outstanding debt obligations to Volation Capital, JMJ Financial, and entities affiliated with Centrecourt Management in 2013.

The increase in other gain during the three months ended September 30, 2014, compared to that of the same period in 2013, relates primarily to items included as part of the accrued loss contingency that were deemed no longer to be likely to be settled as of September 30, 2014.

Adjustments to fair value of unsettled warrant obligation was settled at June 4, 2014 and therefore had no activity in the current quarter.

Adjustment to fair value of derivatives was a gain of $42,207 for the three months ended September 30, 2014 compared to a gain of $146,609 for the three months ended September 30, 2013. The change of $104,402 is primarily due to retirement of the derivatives associated with the Camofi debt in 2014 and therefore less derivative instruments are being re-valued for the three months ended September 30, 2014 as compared to the same period in 2013.

Comparison of Nine Months Ended September 30, 2014 and 2013

	Nine Months Ended September 30, 2014	2013 As Restated	$ Change	% Change
Revenue	$118,404	$185,517	$(67,113)	(36.2)%
Cost of revenue	46,825	66,827	20,002	(29.9)%
Gross profit	71,579	118,690	(47,111)	(39.7)%
Research and development expenses:				
-R&D expenses, excluding non-cash, stock-based compensation	7,288,611	6,954,023	334,588	4.8 %
- Non-cash, stock-based compensation	353,333	1,714,054	(1,360,721)	(79.4)%
Total Research and Development	7,641,944	8,668,077	(1,026,133)	(11.8)%
General and administrative expenses:				
-G&A expenses, excluding non-cash, stock-based compensation	6,195,039	6,416,822	(221,783)	(3.5) %
-Non-cash, stock-based compensation	881,836	2,757,408	(1,875,572)	(68.0)%
Total General and Administrative	7,076,875	9,174,230	(2,097,355)	(22.9)%
Loss on settlement of litigation	(13,468,547)	–	(13,468,547)	(100)%
Non-operating income (expense)	191,577	(1,426,811)	1,618,388	113.4 %
Net loss	$(27,924,210)	$(19,150,428)	$(8,773,782)	45.8 %

Revenue

Revenue was $118,404 for the nine months ended September 30, 2014, which was a decrease of $67,113 or 36.2% compared to the nine months ended September 30, 2013. The decrease is due to license agreements that expired in 2013. Deferred revenue of $1,789,168, as of September 30, 2014, will be amortized and recorded to revenue over approximately 12 years.

Research and Development Expenses

R&D expenditures, excluding non-cash, stock-based compensation expense, increased from $6,954,023 for the nine months ended September 30, 2013 to $7,288,611 for the nine months ended September 30, 2014, for an increase of $334,588 or 4.8%. The increase in R&D expenditures was primarily due to an increase in payroll and other compensation costs of approximately $886,000. For the nine months ended September 30, 2014, we increased our clinical staff to prepare for the expansion of our clinical trials into phase 2. Other increases in costs related to outside

consultants of approximately $249,000 to support our preparation of phase 2 clinical trials, an increase in rent and facilities costs of approximately $34,000 and additional costs for dues and subscriptions of approximately $51,000. These increases were partially offset by the reduction of accrued expenses from prior periods that were reversed in the current period as we deemed that we had been legally released from such liabilities. In addition to the reversed accruals of approximately $269,000, there was also a decrease in license costs of approximately $200,000, which related to a one-time 2013 license fee for an agreement with Allele and a decrease in pre-clinical and clinical costs of approximately $462,000, primarily due to lower patient enrollment in the period.

R&D expenses related to non-cash, stock-based compensation decreased from $1,714,054 for the nine months ended September 30, 2013 to $353,333 for the nine months ended September 30, 2014, for a decrease of $1,360,721, or 79.4%. This decrease is related to the final vesting of options and restricted stock in 2013 of our chief scientific officer’s options associated with his employment contract, for a decrease of approximately $951,000. 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 nine months ended September 30, 2013 as compared to the same period in 2014.

We expect that R&D expenses will increase from period to period, for the foreseeable future. This planned increase will be driven primarily by our expansion of our clinical operations capabilities as we initiate and scale our phase 2 programs for SMD and AMD. We currently work with four clinical sites in the US and 2 in the UK. We plan to expand the number of sites to approximately 20 in the US and 10 in Europe. In addition, we are expanding the network of consultants and service providers we contract and we also plan to expand our internal workforce. These expansions and the increased spend that will result from these expanded capabilities is consistent with our previously stated plans to transition to become a product development company. Our spending is 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.

General and Administrative Expenses

G&A expenditures, excluding non-cash, stock-based compensation expense, decreased from $6,416,822 for the nine months ended September 30, 2013 to $6,195,039 for the nine months ended September 30, 2014, for a decrease of $221,783 or 3.5%. The decrease in G&A expenditures was primarily due to the reduction of accrued expenses from prior periods that were reversed in the current period as we deemed that we had been legally released from such liabilities. The reversed accruals of approximately $566,000 were partially offset by an increase in payroll and other compensation costs of approximately $534,000. Payroll costs were higher partly due to a full nine months of costs for a Chief Financial Officer in 2014 versus three and a half months during the same period in 2013. Other increases were related to audit, professional and consultant fees associated with financial restatement costs of approximately $331,000, an increase in recruiting costs of $183,000 mainly related to recruitment of the CEO, an increase in costs of rent and facilities of approximately $145,000 and increased Directors and Officers insurance costs of approximately $91,000. These increases were partially offset by decreases in legal costs of approximately $619,000 and investor relations costs of approximately $364,000.

G&A expenses related to non-cash, stock-based compensation decreased from $2,757,408 for the nine months ended September 30, 2013 to $881,836 for the nine months ended September 30, 2014, for a decrease of $1,875,572, or 68.0%. This decrease is related to the final vesting of options and restricted stock in 2013 of the former chief executive officer’s options associated with his employment contract, for a decrease of approximately $1,593,000. 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 nine months ended September 30, 2013 as compared to the same period in 2014.

Although we have recently hired a Chief Commercial Officer, we expect G&A expense to remain relatively consistent with that of recent periods over the next several quarters.

Loss on settlement of litigation

The loss on settlement of litigation relates to the settlement in June 2014 of the warrant holder litigation. The total value of the litigation settlement was recorded at $23,577,600 based on a 3,840,000 share settlement valued at $6.14 per share. Offsetting this charge was the reversal of previously recorded accruals related to the unsettled warrant obligation and loss contingency.

Other Income (Expense)

	2014	2013	$ Change	% Change
		As Restated		
Interest income	$55,840	$165,340	$(109,500)	(66.2)%
Interest expense	(429,573)	(1,165,438)	735,865	63.1 %
Other loss	(172,656)	(522,404)	349,748	66.9 %
Adjustments to fair value of unsettled warrant obligation	18,959	(714,151)	733,110	102.7 %
Gain on the extinguishment of debt	–	438,587	(438,587)	(100.0)%
Adjustments to fair value of derivatives	719,007	371,255	347,752	93.7 %
Total non-operating expense	$191,577	$(1,426,811)	$1,618,388	

Interest expense for the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013 decreased by $735,865 to $429,573. 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 decrease in other loss during the nine months ended September 30, 2014, compared to that of the same period in 2013, relates primarily to the recording of SEC related fines in 2013 and also to items included as part of the accrued loss contingency that were deemed no longer to be likely to be settled as of September 30, 2014.

Adjustments to fair value of unsettled warrant obligation was a gain of $18,959 for the nine months ended September 30, 2014 as compared to a loss of $714,151 for the nine months ended September 30, 2013 resulting in an increase to other income of $733,110. The fair value account adjusts the 63.2 million shares, on a pre-reverse stock split basis, which are contractually obligated by the change in the stock price for each period. The increase in other income resulted from the stock price decreasing from approximately $6.17 at December 31, 2013 to $6.14 at June 4, 2014 when the obligation was settled, whereas in 2013, during the period of December 31, 2012 to September 30, 2013, the stock price increased from approximately $5.57 to $7.13 per share.

Adjustment to fair value of derivatives was a gain of $719,007 for the nine months ended September 30, 2014 compared to a gain of $371,255 for the nine months ended September 30, 2013. The change is mainly due to the valuation of the derivative related to the CAMOFI debentures being revalued to $0 with the retirement of the debentures, resulting in a gain of approximately $663,000 for the nine months ended September 30, 2014.

Liquidity and Capital Resources

Cash Flows

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

	Nine Months Ended September 30,	
	2014	2013
Net cash used in operating activities	$(16,563,159)	$(17,410,745)
Net cash used in investing activities	(135,891)	(622,986)
Net cash provided by financing activities	22,768,062	16,244,532
Net increase (decrease) in cash and cash equivalents	6,069,012	(1,789,199)
Cash and cash equivalents at the end of the period	$7,812,497	$5,452,653

Operating Activities

Our net cash used in operating activities during the nine months ended September 30, 2014 and 2013 was $16,563,159 and $17,410,745, respectively. Net cash used in operating activities for the nine months ended September 30, 2014 includes the loss from operations of $28,951,808, partially offset by non-cash expenses such as the loss on settlement of litigation of $13,468,547. Excluding the loss on settlement of litigation, the operating loss for the nine months ended September 30, 2014 was $15,554,840, a decrease of $2,287,467, as compared to the same period in 2013. Partially offsetting this decrease in cash used in operating activities was the amount of loss that related to stock-based compensation. For the nine months ended September 30, 2014 the Company incurred $1,036,861 in stock-based compensation expense, as compared to $3,059,928 for the nine months ended September 30, 2013. During the nine months ended September 30, 2014, there was approximately $2,768,000 of cash used from changes in operating assets and liabilities, whereas during the nine months ended September 30, 2013 there was approximately $2,536,000 of cash used from changes in operating assets and liabilities, for a difference of approximately $232,000. This difference in the change in operating assets and liabilities was comprised of a decrease in cash used in operating activities of approximately $1,419,000 due to a change in current assets, offset by an increase in cash used from operating activities of approximately $1,652,000 due to a change in current liabilities.

Cash Used in Investing Activities

Cash used in investing activities during the nine months ended September 30, 2014 and 2013 was $135,891 and $622,986, respectively. Our cash used in investing activities during the nine months ended September 30, 2014 was due to purchases of property and equipment of $135,891. For the nine months ended September 30, 2013 the purchases of property and equipment were $586,091, primarily driven by our facility build-out. As part of the facility build-out in 2013 we incurred approximately $320,000 in leasehold improvements and approximately $225,000 in purchases of capital equipment.

Cash Flows from Financing Activities

On September 19, 2012, we entered into a purchase agreement, or the 2012 Purchase Agreement, with Lincoln Park Capital Fund, LLC, or Lincoln Park. Pursuant to the 2012 Purchase Agreement, we had the right to sell to Lincoln Park up to $35,000,000 in shares of our common stock. In June 2014 we had completed the last sale of common stock to Lincoln Park under the $35,000,000 Purchase Agreement.

On June 27, 2014, we entered into a new purchase agreement, or the 2014 Purchase Agreement with Lincoln Park pursuant to which we have the right to sell to Lincoln Park up to $30,000,000 in shares of its common stock, subject to certain limitations set forth in the purchase agreement.

On June 27, 2014, we also entered into a registration rights agreement, or the Registration Rights Agreement with Lincoln Park, pursuant to which we are required to file a registration statement, or the Registration Statement, on a best efforts basis, with the Securities and Exchange Commission to register the resale of the shares of common stock issued and issuable to Lincoln Park pursuant to the 2014 Purchase Agreement.

Upon the satisfaction of the conditions set forth in the 2014 Purchase Agreement, including the Registration Statement being declared effective by the Securities and Exchange Commission (which effectiveness occurred on July 21, 2014), we obtained the right over a 36-month period to sell up to $30,000,000 worth of shares of our common stock to Lincoln Park based upon the terms set forth in the 2014 Purchase Agreement. Pursuant to the 2014 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 our controlling 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 of $1.00, as adjusted under the 2014 Purchase Agreement due to the 100-to-1 reverse split of our common stock effected in August 2014.

Cash provided by financing activities during the nine months ended September 30, 2014 and 2013 was $22,768,062 and $16,244,532, respectively. The cash provided by financing activities during the nine months ended September 30, 2014 included $24,038,191 from the sale of common stock to Lincoln Park. The Lincoln Park sale included 2,269,750 shares of common stock sold to Lincoln Park pursuant to the 2012 Lincoln Park purchase agreement, for total proceeds of $14,281,295 and 1,273,241 shares of common stock sold to Lincoln Park pursuant to the 2014 purchase agreement for total proceeds of $9,756,896.

During the same period in 2013, cash provided by financing activities included $16,844,532 of proceeds from the sale of common stock to Lincoln Park.

During the nine months ended September 30, 2014, we repaid $1,200,000 on the CAMOFI senior secured convertible debentures.

During the nine months ended September 30, 2014, we redeemed 1,000 shares of Series B preferred stock which resulted in a cash use of $70,129.

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

- As of September 30, 2014, we have approximately $7,812,497 in cash.

- As of September 30, 2014, $20,243,104 is available to us through the June 27, 2014 Lincoln Park financing arrangement, subject to certain limitations.

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 must 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 believe that our current cash balance, and the $20,243,104 available to us under the Lincoln Park financing arrangement, will be sufficient to fund our operations into the second half of 2015. 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 funding which may or may not result in immediate and substantial dilution to the our stockholders, so that we may either extend our current cash runway beyond the second half of 2015 or accelerate the rate of investment in our many clinical and pre-clinical programs.

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 September 30, 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 were not 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 September 30, 2014. Based upon that evaluation, the chief executive and principal financial officer concluded that our disclosure controls and procedures were not effective and have been subject to a number of remediation steps.

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 the third quarter of 2013.

Management, with the input, oversight, and support of the Audit Committee has identified and taken the following steps, which management believes will assist us in the identification and resolution of technical accounting matters and will enable us to remediate 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; and

- in August 2014, we hired an Accounting Manager who has more than five years of progressive experience at PricewaterhouseCoopers. He brings additional capabilities to our finance and accounting organization and will assist us in identifying complex accounting positions and in determining the appropriate treatment.

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 third 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, or the 2013 Form 10-K.

In April 2013, it was determined that Gary Rabin, our former Chief Executive Officer, failed to report 27 transactions in a timely manner on Form 4 under Section 16 of the Exchange Act in which Mr. Rabin sold shares of our common stock that took place between February 7, 2011 and January 10, 2013. The SEC then investigated the unreported transactions. In September 2014, we settled the SEC action arising from the SEC's investigation. Under the terms of the settlement accepted by the SEC, we consented to the entry of order under which we neither admit nor deny liability and agreed to pay a civil penalty of $375,000, which has been previously accrued for, by July 2015. In addition, the settlement requires us to engage an independent Section 16 compliance consultant, provide Section 16(a) training to each Section 16(a) reporting person, and provide a certification of compliance that each of the preceding requirements were completed. The settlement also requires us to cease and desist from committing or causing any violations and any future violations of Section 17(a)(2) of the Securities Act, Sections 13(a) and 14(a) of the Exchange Act, and Rules 12b-20, 13a-1, and 14a-9 thereunder.

Other than as set forth above, during the quarter ended September 30, 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, the fact that we have no product revenue and no products approved for marketing; our limited operating history; the need for and limited sources of future capital; potential failures or delays in obtaining regulatory approval of products; risks inherent in the development and commercialization of potential products; reliance on new and unproven technology in the development of products; the need to protect our intellectual property; the challenges associated with conducting and enrolling clinical trials; the risk that the results of clinical trials may not support our drug candidate claims; even if approved, the risk that physicians and patients may not accept or use our products; our reliance on third parties to conduct its clinical trials and to formulate and manufacture its product candidates; economic conditions general; the safety and efficacy of our product candidates;

risks associated with obtaining regulatory approvals; 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 our 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 Relating 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. As of September 30, 2014, we have an accumulated deficit of $342,309,490 and stockholders' equity of $723,010. 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 being prepared for use in Phase 2 clinical trials and we do not have any products that are currently in the marketplace. Though we have recently released clinical data from our Phase I/II clinical trial regarding the safety and tolerability of sub-retinal transplantation of human embryonic stem cell-derived RPE cells transplanted into patients with SMD and dry AMD, our potential therapeutic products will require additional extensive preclinical and clinical testing prior to any possible 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 for any of our products (see the subsection entitled “Regulatory Risks” below), or commence or continue clinical trials for any 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. Clinical trial results that we view as positive or proof of safety and/or efficacy may not be viewed in the same manner by regulators or potential collaborators. 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, patients may not use our products, or third-party payors may not cover or provide adequate reimbursement for 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 regulatory, manufacturing, marketing, distribution or product sales resources. We cannot assure you that we will be able to invest or develop any of these resources successfully or as expediently as necessary, either alone or with strategic partners, to generate revenue. Our ability to become profitable depends upon our ability to generate revenue. We do not anticipate generating revenues from product sales for the foreseeable future, if ever. Our ability to generate future revenues from product sales depends heavily on our success in:

- continuing and completing research and preclinical and clinical development of our therapeutic candidates, including Phase 2 trials of our RPE cell therapies for the treatment of SMD and dry AMD;

- seeking and obtaining regulatory and marketing approvals for therapeutic candidates for which we complete clinical studies;

- developing a sustainable, scalable, reproducible, and transferable manufacturing process for our therapeutic candidates;

- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate (in amount and quality) products and services 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 sales force, marketing and distribution infrastructure;

- obtaining market acceptance of our therapeutic candidates as a viable treatment option;

- 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, to cover our existing and future products;

- obtaining and maintaining coverage and adequate reimbursement from third-party payors;

- having appropriate freedom-to-operate with respecting to manufacturing, using and selling our existing and future products; 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.

Our ability to generate revenues depends on obtaining regulatory approvals for our products.

In order to successfully commercialize a product, we or our potential partners will be required to conduct tests and successfully complete clinical trials needed in order to meet regulatory requirements and to obtain applicable regulatory approvals. The costs of developing and obtaining regulatory approvals for therapeutics can be substantial. Our ability to commercialize any of our products in development is dependent upon the success of development efforts in clinical studies. If these clinical trials fail to produce satisfactory results, or if we are unable to maintain the financial and operational capability to complete these development efforts, we may be unable to generate revenues. Even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize products successfully. For example, if the approval process takes too long, we may miss market opportunities, have diminished or exhausted relevant patent rights, and give other companies the ability to develop competing products or establish market dominance. Additionally, the terms of any approvals may not have the scope or breadth needed for us to commercialize products successfully.

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

As of September 30, 2014, we had 36 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 have determined that material weaknesses exist in our system of internal control over financial reporting, which have in the past, and could in the future, result in a material misstatement of our annual and interim financial statements, which could have a material impact on our business and share price.

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.

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.

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 to fund our ongoing operations. Pursuant to the 2014 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 $1.00, subject to adjustment as set forth in the Purchase Agreement, 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 sellable 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.

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.

The biotechnology industry in general, and research and development efforts in particular, is capital-intensive. 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 of our short- and long-term capital needs, including capital needed to fund 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 (with such dilution potentially being immediate and substantial), 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 agencies may require additional clinical data or manufacturing practices than that required of 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 to finance our work in pursuing applications of cell therapy technologies, and technological or other developments in the biomedical field which may render our 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..

State and/or country regulations relating to use and sale of products derived from human embryonic stem cells may limit the markets we can penetrate.

Our product candidates consist of cells derived from an immortal human embryonic stem cell line. Certain states have, or have shown interest in, restricting or even banning embryonic stem cell research. Similarly, there are certain countries that restrict or ban human embryonic stem cell research. The laws and guidances surrounding human embryonic stem cell research continue to evolve and change, and this may affect our ability to penetrate these markets.

We may not be able to maintain our human embryonic stem cell line that is used for the manufacture of our product candidates reliably and cost-effectively, and we may not be able to grow those cells at sufficient scale to continue development or commercialize our product candidates.

Operations with human cells, even with a stable, immortal hESC line, can be subject to conditions and influences that we may not be able to control. Cells could be lost due to contamination, equipment failure or improper installation or operation of equipment or laboratory technician error. Storage facilities could also be affected by labor shortages, natural disasters, power failures and numerous other factors that could result in the loss of all or a portion of our cell banks. It is also possible that the cells will simply cease to function, or that materials we use in manufacturing the cells could contain viruses or other pathogens, which would result in contamination of the cells. While we take precautions to prevent the cells from ceasing to function or becoming contaminated, long-term maintenance of hESC for our purpose has not been demonstrated and we could encounter unforeseen complications, including contamination, which could result in infection in patients. In addition, if not all the cells respond to the directed differentiation cues as expected, it is possible that residual hESC could result in the potential for formation of hESC-derived teratoma, a benign tumor comprised of tissues not normally present at the site that might arise due to uncontrolled, off-target growth of the cells.

As we increase production to support future development and if approved, commercialization, we may experience significant scale-up issues, which may cause quality and cost problems and our business could be materially harmed

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.

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 (which may or may not be on favorable terms) 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 under economically viable terms 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.

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 and/or the practice of our technology may infringe other third party patents, 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 were the first to file patent applications for these inventions;
- we were the first to make the inventions covered by each of our pending patent applications;
- any patents issued to us will cover our products as ultimately developed;
- the term of any patents issued to us can be extended under the provisions of patent term extension afforded by U.S. law or similar provisions in foreign countries, where available;

- there is no prior art of which we are not aware that may affect the validity or enforceability of a patent claim;

- there is no prior art of which we are aware, which we do not believe affects the validity or enforceability of a patent claim, but which, nonetheless, ultimately may be found to affect the validity or enforceability of a patent claim;

- 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 induced pluripotent stem cells, 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 patents or patent applications 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, and their uses as therapeutics. 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.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In this event, competitors might be able to enter the market earlier than would otherwise have been the case.

Risks Related to Clinical Development

The risk of failure of clinical development is high. Clinical studies are expensive, time-consuming, uncertain and susceptible to change, delay or termination. Any delay or failure in obtaining required approvals could have a material adverse effect on our business.

Before obtaining marketing approval from regulatory authorities for sale of our products, we must conduct extensive clinical studies to demonstrate the safety and efficacy of such product in humans for the desired indications. We do not currently have marketing approval for any products. We are planning to initiate Phase 2 clinical studies for some of our product candidates, initially pursuing treatment of several forms of macular degeneration, such as SMD, dry-AMD and MMD. However, clinical testing is expensive and can take many years to complete, its outcome is inherently uncertain and it will take years to obtain approval, if at all. It is impossible to predict when or if any of our product candidates for which we may seek marketing approval will prove be deemed by the FDA to be safe and effective enough to receive regulatory approval for the desired indications.

Despite promising results in earlier clinical studies, including the trials for macular degeneration and Stargardt's macular dystrophy, the results from our clinical studies may not demonstrate safety and effectiveness to the satisfaction of the FDA. and may not be predictive of the outcome of later stage trials.

Even if we conclude that the results from our clinical studies demonstrate the safety and effectiveness of our product candidates, FDA may not agree with us or could also conclude that the clinical study results are not clinically meaningful, that there were human errors in the conduct of the clinical study, or that for some other reason the clinical study results are inadequate to support approval. Clinical trial results are subject to varying interpretation. Numerous other factors could affect the timing, cost or outcome of our development efforts, including the following:

- conditions imposed on us by regulatory authorities regarding the scope or design of our clinical studies;

- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical study sites;

- failure to obtain, or delays in obtaining, the required regulatory approvals for the facilities or the processes used to manufacture our product candidates or any changes to such processes;

- insufficient or inadequate supply or quality of product candidates being tested or other necessary materials necessary to conduct our clinical studies;

- delays in the testing, validation, manufacturing and delivery of our product candidates to the clinical sites;

- problems in engaging institutional review boards, or IRBs, to oversee trials or problems in obtaining or maintaining IRB approval of studies at each clinical study site;

- delays in recruiting and enrolling suitable patients to participate in our clinical studies in conformity with required protocols or projected timelines;

- imposition of a clinical hold on our studies by regulatory agencies;

- failure by our CROs, other third parties or us to adhere to clinical study requirements, comply with regulatory requirements or meet their contractual obligations to us in a timely manner;

- failure to perform in accordance with the FDA's good clinical practices, or GCP, or applicable regulatory guidelines in other countries;

- delays in having patients complete participation in a study or return for post-treatment follow-up;

- clinical study sites or patients dropping out of a study;

- occurrence of undesirable side effects or other unexpected adverse results;

- discovery of serious or unexpected toxicities or side effects experienced by study participants or other safety issues;

- occurrence of serious adverse events associated with the product being tested that are viewed to outweigh its potential benefits;

- negative or inconclusive results from our clinical studies or the clinical studies of others for similar product being tested or inability to generate statistically significant data confirming the efficacy of the product being tested;

- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;

- changes in the regulatory environment, including pricing, coverage and reimbursement, that make development no longer desirable;

- delays in filing or acceptance of a supplement to our Biologics License Application, or BLA; or

- failure or delays in obtaining pricing, coverage and reimbursement approvals.

Any inability to successfully complete pre-clinical and clinical development could result in additional costs to us or impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, clinical study delays could also shorten any periods during which we may have the exclusive right to commercialize our products or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our products and may harm our business and results of operations.

If side effects are identified during the time our products candidates are in development or after they are approved and on the market, we may choose to or be required to perform lengthy additional clinical trials, discontinue development of the affected product candidate, change the labeling of any such products, or withdraw any such products from the market, any of which would hinder or preclude our ability to generate revenues.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. The side effects could affect patient recruitment or the ability of enrolled

patients to complete any ongoing clinical trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Even if any of our product candidates receives marketing approval, as greater numbers of patients use a product following its approval, an increase in the incidence of side effects or the incidence of other post-approval problems that were not seen or anticipated during pre-approval clinical trials could result in a number of potentially significant negative consequences, including:

- regulatory authorities may withdraw their approval of the product;

- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;

- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;

- we could be sued and held liable for harm caused to patients; and

- our reputation may suffer.

Any of these events could substantially increase the costs and expenses of developing, commercializing and marketing any such product candidates or could harm or prevent sales of any approved products.

We rely on third parties to conduct, supervise and monitor our clinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such studies.

We do not independently conduct our own clinical studies but rather rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to perform this function. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it could delay our product development activities.

Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our pre-clinical and clinical studies are conducted in accordance with the study plan and protocols and legal, regulatory, and scientific standards. We and our third party contractors are required to comply with requirements for good clinical practices, or GCP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under current good manufacturing practice, or cGMP, regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

The performance of these third parties may be adversely affected by various issues, including less advanced medical infrastructure, lack of familiarity with conducting clinical studies using U.S. standards, insufficient training of personnel and communication difficulties. We remain responsible for ensuring that each of our clinical studies is conducted in accordance with the general investigational plan and protocols for the study. Moreover, the FDA requires us to comply with GCP, for conducting, recording and reporting the results of clinical studies to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of patients in clinical studies are protected. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical studies in accordance with regulatory requirements or our stated study plans and protocols, we will not be able to obtain, or may be delayed in obtaining, the necessary regulatory approvals and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

If our clinical studies fail to demonstrate safety and effectiveness to the satisfaction of the FDA or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to

complete, the development and commercialization of our product candidates.

If the results of our clinical studies are inconclusive or if there are safety concerns or adverse events associated with the product being tested, we may:

- be delayed in obtaining marketing approval for such product, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to changes with the way such product is administered;
- be required to perform additional clinical studies to support approval or be subject to additional post-marketing testing requirements;

- have regulatory authorities withdraw their approval of such product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy, or REMS;

- be subject to the addition of labeling statements, such as warnings or contraindications;

- be sued; or

- experience damage to our reputation.

Even if the results of our clinical studies are favorable, the time required to obtain FDA and other approvals is unpredictable, and often can take years following the commencement of clinical studies. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all.

The FDA or any other regulatory authority may deny or delay an approval because it is not satisfied with the structure or conduct of clinical studies or due to its assessment of the data we supply. A regulatory authority, for instance, may not believe that we have adequately addressed negative safety issues. Clinical data is subject to varied interpretations, and regulatory authorities may disagree with our assessments of data. In any such case, a regulatory authority could insist that we provide additional data, which could substantially delay or even prevent commercialization efforts, particularly if we are required to conduct additional pre-approval clinical studies.

Clinical studies also require the review and oversight of IRBs, which approve and continually review clinical investigations and protect the rights and welfare of human subjects. An inability or delay in obtaining IRB approval could prevent or delay the initiation and completion of clinical studies, and the FDA may decide not to consider any data or information derived from a clinical investigation not subject to initial and continuing IRB review and approval.

Any of the foregoing could have a material adverse effect on our business, results of operations and financial condition.

If we fail to obtain or maintain orphan exclusivity for our products, our competitors may sell products to treat the same conditions, and our revenues will be reduced.

The FDA has designated MA09-hRPE cells as an orphan drug for the treatment of Stargardt's Macular Dystrophy. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity.

Even if orphan drug designation has been granted, we may not be the first to obtain marketing approval for this indication due to the uncertainties associated with developing biological products. Further, even if we obtain orphan drug exclusivity, that exclusivity may not effectively protect our product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is safer, more effective, or makes a major contribution to patient care. Orphan exclusivity neither shortens the

development time or regulatory review time, nor gives the product any advantage in the regulatory review or approval process. Orphan exclusive marketing rights may be lost if the FDA later determines that the request for designation was materially defective, if the manufacturer is unable to assure sufficient quantity of the product, or if a second applicant demonstrates its product is “clinically superior” to the original orphan drug.

Finally, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity and/or scope of patents relating to our competitors’ products. The availability of our competitors’ products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

We may find it difficult to enroll patients in our clinical studies, which could delay or prevent our clinical studies.

Identifying and qualifying patients to participate in our clinical studies is critical to our success. The timing of our clinical studies depends on the speed at which we can recruit patients to participate. If we have difficulty enrolling a sufficient number of patients to conduct our clinical studies as planned, we may need to delay, limit or terminate ongoing or planned clinical studies, any of which would have an adverse effect on our business.

Patient enrollment is affected by a number of factors including:

- severity of the disease under investigation;
- design of the study protocol;
- size of the patient population;
- eligibility criteria for the study in question;
- perceived risks and benefits of the product being tested;
- proximity and availability of clinical study sites for prospective patients;
- availability of competing therapies and clinical studies;
- efforts to facilitate timely enrollment in clinical studies;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

We may experience difficulties with patient enrollment for our clinical studies due to the small patient populations for our proposed products. For example, the process of finding and diagnosing patients may prove costly. Additionally, patients may be unwilling to participate in our studies due to negative publicity from adverse events in the biotechnology or other industries or for other reasons, such as concerns about the requirement of surgery with its attendant risks including infection, bleeding, loss of vision, loss of eye, death due to complication, increased risk of infection or malignancy due to immunosuppression, need for randomization of the eye to be treated and embryonic stem cell based therapy. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a study, to complete our clinical studies in a timely manner.

Our employees, consultants and commercial partners may engage in misconduct or other improper activities, including insider trading and non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, consultants and commercial partners may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates the regulations of the FDA and non-U.S. regulators, including those laws requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the United States and abroad or laws that require the true, complete

and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

We are subject to federal and state fraud and abuse laws, health information privacy and security laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

There are numerous U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims and physician transparency laws. Our relationships with providers and hospitals are subject to scrutiny under these laws. We may also be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;

- HIPAA, which created federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the PPACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, which is defined broadly to include other healthcare providers, and teaching hospitals and ownership and investment interests held by physicians and their immediate family members;

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers;

- state laws that require manufacturers to comply with the industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and

- state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

These laws, among other things, constrain our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential

purchasers of our products. We have a variety of arrangements with our customers that could implicate these laws. Due to the breadth of these laws, the narrowness of statutory exceptions and safe harbors available, and the range of interpretations to which they are subject to, it is possible that some of our current or future practices might be challenged under one or more of these laws. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could harm our business, financial condition and results of operations.

In addition, recent healthcare reform legislation has strengthened these laws. For example, the PPACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them to have committed a violation. Moreover, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations, any of which could negatively impact our ability to operate our business and our results of operations.

Healthcare policy changes, including legislation reforming the United States healthcare system, may have a material adverse effect on our financial condition and results of operations.

The PPACA makes changes that are expected to significantly impact the pharmaceutical, biological product and medical device industries. The PPACA, among other things, established annual fees and taxes on manufacturers of certain branded prescription drugs and biological products and included coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. In addition, the PPACA established an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. The IPAB has broad discretion to propose policies to reduce health care expenditures, which may have a negative impact on payment rates for services, including our products. The IPAB proposals may impact payments for hospital services beginning in 2020.

In addition, other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will remain in effect until 2024 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012, or the ATRA, was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The full impact on our business of the PPACA and the other new laws is uncertain. Nor is it clear whether other legislative changes will be adopted or how such changes would affect our industry generally or our ability to successfully commercialize any of our product candidates.

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 we 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 our 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.

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.

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.

Licensure of our products may not be available even if safety and efficacy is demonstrated in clinical trials.

Regulatory requirements for cell therapies, including manufacturing operations, can be different from one jurisdiction to the next in which are or intend to carry out clinical trials. The implementation or interpretation of the rules and regulations relating to manufacturing processes and source materials may occasionally be changed by the regulators, or modified or replaced by other governmental action. Our ability to obtain market authorization or the equivalent in any given jurisdiction may be dependent on our ability to demonstrate compliance with the rules and regulations covering source materials and manufacturing requirements in those jurisdictions, which we may not be able to meet.

MA09-hRPE cells for the treatment of Stargardt's Macular Dystrophy, or any other product candidate for which we seek approval as a biologic, may face competition sooner than anticipated.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCI Act, as part of the Patient Protection and Affordable Care Act, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing reference product. Under the BPCI Act, an application for a biosimilar product cannot be approved by the FDA until twelve years after the original reference product was

approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement the BPCI Act may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

While products approved under a BLA should qualify for the twelve-year period of exclusivity, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the approved BLA product to be a reference product for competing products, potentially creating the opportunity for competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our potential reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Our products may be used by physicians for indications that are not approved by the FDA. If the FDA finds that we marketed our products in a manner that promoted off-label use, we may be subject to civil or criminal penalties.

We plan to pursue FDA approval of product candidates for other indications other than age-related macular degeneration and Stargardt's macular dystrophy, including: myopic macular degeneration; retinal degenerative conditions; diabetic retinopathy; retinal vascular disorders; macular dysfunction, glaucoma, non-infectious uveitis and inflammatory diseases of the retina and choroid Under the Federal Food, Drug, and Cosmetic Act and other laws, we are prohibited from promoting any products for which we may obtain approval for off-label uses. This means that we may not make claims about the safety or effectiveness of a product or product candidate candidates outside of the approved indication and we may not proactively discuss or provide information on the off-label uses of products or product candidates with very specific and limited exceptions. Physicians, however, may lawfully choose prescribing products for off-label uses in the practice of medicine.

A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies, and even criminal sanctions. There can be no assurance that any of our clinical trials will generate data necessary to support approval of any of our product candidates. Should the FDA determine, however, that our activities constitute the promotion of off-label use, the FDA could bring action to prevent us from distributing products for the off-label use and could impose fines and penalties on us and our executives. In addition, failure to follow FDA rules and guidelines relating to promotion and advertising can result in, among other things, the FDA's refusal to approve a product, the suspension or withdrawal of an approved product from the market, product recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecutions.

If the Office of Inspector General within the Department of Health and Human Services, the Department of Justice, or DOJ, or another federal or state agency determines that we have promoted off-label use of our products, we may be subject to various penalties, including civil or criminal penalties, and the off-label use of our products may result in injuries that lead to product liability suits, which could be costly to our business.

In addition to the FDA restrictions on marketing of approved products, several other types of state and federal healthcare laws have been applied by DOJ and state attorneys general to restrict certain marketing practices in the pharmaceutical industry. While physicians may prescribe products for off-label uses and indications other than the approved indications for use, if other federal or state regulatory authorities determine that we have engaged in off-label promotion through remuneration, kickbacks or other monetary benefits to prescribers, we may be subject to civil or criminal penalties and could be prohibited from participating in government healthcare programs such as Medicaid and Medicare. In addition, government agencies or departments could conclude that we have engaged in off-label promotion and, potentially, caused the submission of false claims. Even if we are successful in resolving such matters without incurring penalties, responding to investigations or prosecutions will likely result in substantial costs and could significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results, financial condition and ability to finance our operations. In addition, the off-label use of our products may increase the risk of injury to patients, and, in turn, the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention and result in substantial damage awards against us.

Risks Related to Competition

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.

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.

In the general area of cell-based therapies (including both allogeneic and autologous cell therapies), we compete with a variety of companies, most of whom are specialty biotechnology companies, such as, Genzyme Corporation, StemCells, Inc., Inc., Viacell, Inc., Biotime, Inc. (and its subsidiary Cell Cure Neurosciences, Ltd.), Regenerative Patch Technologies, Inc., ISCO, MG Biotherapeutics, Pfizer, GlaxoSmithKline, Novartis, Roche, Celgene, Baxter Healthcare, Mesoblast, Osiris Therapeutics and Cytori.

Each of these companies is well-established and have substantial technical and financial resources compared to us. However, as cell-based products are only just emerging as medical therapies, many of our direct competitors are smaller biotechnology and specialty medical products companies. These smaller companies may become significant competitors through rapid evolution of new technologies. Any of these companies could substantially strengthen their competitive position through strategic alliances or collaborative arrangements with large pharmaceutical or biotechnology companies.

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 are aware of ongoing clinical trials and preclinical development efforts directed to cell therapies as well as small molecules and biologics for treating many of the same indications for which we pursue treatments. In the case of macular degeneration, these include antibody therapies, small molecules, gene therapies and cell therapies. Some of these third party drug development programs have already reached phase3 in clinical trials, some with positive results for patients treated in phase 1 or 2 of those trials. 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 stimulative 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.

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.

General Risks Relating to Our Business

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.

For example, in mid-April of 2014 we received a notice of default from CAMOFI Master LDC and CAMHZN 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.

A significant adverse determination in any claim against us could adversely affect our operating results or financial condition. The amount we may be required to pay, in cash or in stock, in connection with any Claim 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.

Form 4 filing delays by our former Chief Executive Officer have given rise to an investigation by the Securities and Exchange Commission into the delays and our Section 16 compliance procedures, and this investigation resulted in penalties and sanctions against us.

As previously disclosed by us, in April 2013, it was determined that Gary Rabin, our then-Chief Executive Officer, failed to report 27 transactions in which Mr. Rabin sold shares of our common stock that took place between February

7, 2011 and January 10, 2013. Mr. Rabin filed a Form 4 under Section 16 of the Exchange Act on April 15, 2013 reporting the previously unreported sale transactions and correcting the total number of shares of our common stock that Mr. Rabin owned as of the date of filing of the Form 4. Our board of directors initiated an investigation into this matter upon becoming aware of it. In September 2014, we settled the SEC action arising from the SEC's investigation. Under the terms of the settlement accepted by the SEC, we consented to the entry of order under which we neither admit nor deny liability and has agreed to pay a civil penalty of $375,000, which has been previously accrued for, by July 2015. In addition, the settlement requires us to engage an independent Section 16 compliance consultant, provide Section 16(a) training to each Section 16(a) reporting person, and provide a certification of compliance that each of the preceding requirements were completed. The settlement also requires us to cease and desist from committing or causing any violations and any future violations of Section 17(a)(2) of the Securities Act, Sections 13(a) and 14(a) of the Exchange Act, and Rules 12b-20, 13a-1, and 14a-9 thereunder. The terms of this settlement require us to allocate financial and management resources to complying with the settlement's terms, which may have adverse effect on our business. Also, if the SEC deems us to not have complied with any portion of the settlement, it may issue additional fines or sanctions against us which may limit our ability to issue securities or otherwise conduct our business as currently conducted.

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.

We may not be able to obtain third-party payor reimbursement or favorable product pricing, which would reduce our ability to operate profitably.

Our ability to successfully commercialize some of our proposed products in the human therapeutic field may depend on a significant degree on obtaining coverage and adequate reimbursement of the costs of such products and related treatments at acceptable levels from government authorities, private health insurers and other third-party payors. We cannot assure you that coverage and adequate reimbursement in the United States or foreign countries will be available for any products we may develop or, if available, will not be decreased in the future, or that reimbursement amounts will not reduce the demand for, or the price of, our products with a consequent harm to our business. We cannot predict what additional regulation or legislation relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such regulation or legislation may have on our business. If additional regulations are overly onerous or expensive, or if health care related legislation makes our business more expensive or burdensome than originally anticipated, we may be forced to significantly downsize our business plans

or completely abandon our business model.

Our products are likely to be expensive to manufacture, and they may not be profitable if we are unable to control the costs to manufacture them.

Our products are likely to be significantly more expensive to manufacture than most other biologics currently on the market today. Our present manufacturing processes produce modest quantities of product intended for use in our ongoing research activities, and we have not developed processes, procedures and capability to produce commercial volumes of product. We hope to substantially reduce manufacturing costs through process improvements, development of new science, increases in manufacturing scale and outsourcing to experienced manufacturers. If we are not able to make these or other improvements, and depending on the pricing of the product, our profit margins may be significantly less than that of most biologics on the market today. In addition, we may not be able to charge a high enough price for any cell therapy product we develop, even if they are safe and effective, to make a profit. If we are unable to realize significant profits from our potential product candidates, our business would be materially harmed.

Our current source of revenues depends on the stability and performance of our sub-licensees.

Our ability to collect royalties on product sales from our sub-licensees will depend on the financial and operational success of the companies operating under a sublicense. Revenues from those licensees will depend upon the financial and operational success of those third parties. We cannot assure you that these licensees will be successful in obtaining requisite financing or in developing and successfully marketing their products. These licensees may experience unanticipated obstacles including regulatory hurdles, and scientific or technical challenges, which could have the effect of reducing their ability to generate revenues and pay us royalties.

We depend on key personnel for our continued operations and future success, and a loss of certain key personnel could significantly hinder our ability to move forward with our business plan.

Because of the specialized nature of our business, we are highly dependent on our ability to identify, hire, train and retain highly qualified scientific and technical personnel for the research and development activities we conduct or sponsor. The loss of one or more certain key executive officers, or scientific officers, would be significantly detrimental to us. In addition, recruiting and retaining qualified scientific personnel to perform research and development work is critical to our success. Our anticipated growth and expansion into areas and activities requiring additional expertise, such as clinical testing, regulatory compliance, manufacturing and marketing, will require the addition of new management personnel and the development of additional expertise by existing management personnel. There is intense competition for qualified personnel in the areas of our present and planned activities, and there can be no assurance that we will be able to continue to attract and retain the qualified personnel necessary for the development of our business. The failure to attract and retain such personnel or to develop such expertise would adversely affect our business.

Our insurance policies may be inadequate and potentially expose us to unrecoverable risks.

Any significant insurance claims would have a material adverse effect on our business, financial condition and results of operations. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify, however, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur. We have observed rapidly changing conditions in the insurance markets relating to nearly all areas of traditional corporate insurance. Such conditions have resulted in higher premium costs, higher policy deductibles, and lower coverage limits. For some risks, we may not have or maintain insurance coverage because of cost or availability.

We have limited product liability insurance, which may leave us vulnerable to future claims we will be unable to satisfy.

The testing, manufacturing, marketing and sale of human therapeutic products entail an inherent risk of product liability claims, and we cannot assure you that substantial product liability claims will not be asserted against us. We have limited product liability insurance. In the event we are forced to expend significant funds on defending product liability actions, and in the event those funds come from operating capital, we will be required to reduce our business activities, which could lead to significant losses. We cannot assure you that adequate insurance coverage will be available in the future on acceptable terms, if at all, or that, if available, we will be able to maintain any such insurance at sufficient levels of coverage or that any such insurance will provide adequate protection against potential liabilities. Whether or not a product liability insurance policy is maintained in the future, any product liability claim could harm our business or financial condition.

Risks Relating to Our Common Stock

Stock prices for biotechnology companies have historically tended to be very volatile.

Stock prices and trading volumes for many biotechnology companies fluctuate widely for a number of reasons, including but not limited to the following factors (some of which may be unrelated to their businesses or results of operations):

- clinical trial results;
- the amount of cash resources and ability to obtain additional funding;
- announcements of research activities, business developments, technological innovations or new products by companies or their competitors;
- entering into or terminating strategic relationships;
- changes in government regulation;
- disputes concerning patents or proprietary rights;
- changes in revenues or expense levels;
- public concern regarding the safety, efficacy or other aspects of the products or methodologies being developed,
- reports by securities analysts;
- activities of various interest groups or organizations;
- media coverage; and
- status of the investment markets.

This market volatility, as well as general domestic or international economic, market and political conditions, could materially and adversely affect the market price of our common stock and the return on your investment.

A significant number of shares of our common stock have become available for sale and their sale could depress the price of our common stock.

Substantially all of our common stock is freely tradable in the equity markets.

We may also sell a substantial number of additional shares of our common stock in connection with a private placement or public offering of shares of our common stock (or other series or class of capital stock to be designated in the future). The terms of any such transactions would likely require us to register the resale of any shares of capital stock issued or issuable in the transaction. For example, we currently have the ability to issue $20,001,254 worth of our common stock to Lincoln Park under the 2014 Purchase Agreement, which amount would equal 2,886,184 shares of our common stock based on the closing price of our common stock of $6.93 as of October 31, 2014.

Sales of a substantial number of shares of our common stock under any of the circumstances described above could adversely affect the market price for our common stock and make it more difficult for you to sell shares of our common stock at times and prices that you feel are appropriate.

We do not intend to pay cash dividends on our common stock in the foreseeable future.

Any payment of cash dividends will depend upon our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. We do not anticipate paying cash dividends on our common stock in the foreseeable future. Furthermore, we may incur additional indebtedness that may severely restrict or prohibit the payment of dividends.

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

On September 30, 2014, we issued 7,500 shares of common stock, valued at $55,575, to various board members 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
3.1	Certificate of Amendment to Certificate of Incorporation dated August 27, 2014 (incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on August 27, 2014, File No. 000-50295)).
10.1	Amended and Restated Executive Employment Agreement, dated as of October 1, 2014 by and between the Company and Robert Lanza*
10.2	Executive Employment Agreement, dated as of October 14, 2014 by and between the Company and H. LeRoux Jooste*
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 pursuant to 18 U.S.C. Section 1350.*
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350.*
101.INS	XBRL Instance Document
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/ Paul Wotton
Paul Wotton
President and Chief Executive Officer
Dated: November 10, 2014 (Principal Executive Officer)

ADVANCED CELL TECHNOLOGY, INC.

By: /s/ Edward Myles
Edward Myles
Chief Operating Officer and Chief Financial Officer
Dated: November 10, 2014 (Principal Financial Officer and Principal Accounting Officer)

62