

STEMCELLS INC  
Form 10-Q  
May 10, 2016  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

**FORM 10-Q**

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

**For the quarter ended: March 31, 2016**

**Commission File Number: 0-19871**

**STEMCELLS, INC.**

**(Exact name of registrant as specified in its charter)**

**DELAWARE**  
**(State or other jurisdiction of**  
**incorporation or organization)**

**94-3078125**  
**(I.R.S. Employer**  
**identification No)**

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**7707 Gateway Blvd**

**Newark, CA 94560**

**(Address of principal executive offices including zip code)**

**(510) 456-4000**

**(Registrant's telephone number, including area code)**

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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

At May 9, 2016, there were 11,703,642 shares of Common Stock, \$.01 par value, issued and outstanding.

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STEMCELLS, INC.

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Throughout this Form 10-Q, the words "we," "us," "our," and "StemCells" refer to StemCells, Inc., including our directly and indirectly wholly-owned subsidiaries. "Common stock" refers to the common stock, \$.01 par value, of StemCells, Inc.

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STEMCELLS, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

	<b>March 31, 2016</b>	<b>December 31, 2015</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 8,674,395	\$ 12,110,565
Restricted cash	2,422,500	2,422,500
Other receivables	30,671	53,405
Prepaid assets	555,445	625,296
Deferred financing costs, current		1,224
Total current assets	11,683,011	15,212,990
Property, plant and equipment, net	4,950,360	5,217,929
Intangible assets, net	42,322	45,816
Other assets, non-current	742,729	742,729
Total assets	\$ 17,418,422	\$ 21,219,464
<b>LIABILITIES AND STOCKHOLDERS DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 1,925,435	\$ 2,512,045
Accrued expenses and other current liabilities	4,742,743	5,731,596
Loan payable net of discount, current	358,318	1,417,388
Deferred revenue, current	16,826	16,826
Capital lease obligation, current	16,175	20,032
Deferred rent, current	141,344	132,338
Total current liabilities	7,200,841	9,830,225
Capital lease obligations, non-current	13,146	15,878
Loan payable net of discount, non-current	8,916,641	8,916,641
Fair value of warrant liability	6,159,671	770,964
Deferred rent, non-current	1,586,346	1,621,338
Deferred revenue, non-current	25,052	29,258
Other long-term liabilities	369,370	369,370
Total liabilities	24,271,067	21,553,674

Commitments and contingencies (Note 8)		
Stockholders' deficit:		
Common stock, \$0.01 par value; 200,000,000 shares authorized; issued and outstanding 11,601,880 at March 31, 2016 and 9,279,021 at December 31, 2015*	116,019	92,791
Additional paid-in capital	459,232,462	456,212,274
Accumulated deficit	(466,248,039)	(456,686,634)
Accumulated other comprehensive income	46,913	47,359
Total stockholders' deficit	(6,852,645)	(334,210)
Total liabilities and stockholders' deficit	\$ 17,418,422	\$ 21,219,464

See Notes to Condensed Consolidated Financial Statements.

\* Adjusted for the 1-for-12 reverse stock split as discussed in Note 1.

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STEMCELLS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

	<b>Three months ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
<b>Revenue:</b>		
Revenue from licensing agreements	\$ 23,164	\$ 20,997
<b>Operating expenses:</b>		
Research and development	5,208,705	6,292,191
General and administrative	4,628,334	2,689,196
Total operating expenses	9,837,039	8,981,387
Loss from operations	(9,813,875)	(8,960,390)
<b>Other income (expense):</b>		
Change in fair value of warrant liability	278,228	(347,330)
Interest income	4,243	1,394
Interest expense	(27,901)	(185,356)
Other income (expense), net	(2,100)	140,981
Total other income (expense), net	252,470	(390,311)
Net loss	\$ (9,561,405)	\$ (9,350,701)
Basic and diluted net loss per share*	\$ (0.98)	\$ (1.62)
Weighted average number of common shares outstanding, basic and diluted*	9,805,478	5,768,331
See Notes to Condensed Consolidated Financial Statements.		

\* Adjusted for the 1-for-12 reverse stock split as discussed in Note 1.

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STEMCELLS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(unaudited)

	<b>Three months ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
Net Loss	\$ (9,561,405)	\$ (9,350,701)
Other comprehensive income (loss)		
Foreign currency translation adjustments	(446)	(32,442)
Other comprehensive loss	(446)	(32,442)
Comprehensive loss	\$ (9,561,851)	\$ (9,383,143)

See Notes to Condensed Consolidated Financial Statements.

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STEMCELLS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	<b>Three months ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (9,561,405)	\$ (9,350,701)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	276,997	269,604
Stock-based compensation	1,852,426	1,308,894
Amortization of debt discount and issuance costs	6,331	42,206
Gain on disposal of fixed assets		(148,713)
Change in fair value of warrant liability	(278,228)	347,330
<b>Changes in operating assets and liabilities:</b>		
Trade receivables		138,071
Accrued interest and other receivables	22,581	85,317
Prepaid and other current assets	46,850	46,312
Accounts payable and accrued expenses	(1,571,391)	(1,630,659)
Deferred revenue	(4,206)	(4,206)
Deferred rent	(25,986)	(10,670)
<b>Net cash used in operating activities</b>	<b>(9,236,031)</b>	<b>(8,907,215)</b>
<b>Cash flows from investing activities:</b>		
Purchases of property, plant and equipment	(5,934)	(221,782)
Proceeds from sale of property, plant and equipment		148,713
<b>Net cash used in investing activities</b>	<b>(5,934)</b>	<b>(73,069)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from the issuance of common stock, net of issuance costs	7,102,225	
Payments related to net share issuance of stock based awards	(225,311)	(142,683)
Repayment of capital lease obligations	(6,590)	(5,573)
Repayment of loan payable	(1,064,177)	(1,681,664)
<b>Net cash provided by (used in) financing activities</b>	<b>5,806,147</b>	<b>(1,829,920)</b>
<b>Decrease in cash and cash equivalents</b>	<b>(3,435,818)</b>	<b>(10,810,204)</b>
Effects of foreign exchange rate changes on cash	(352)	(31,498)
<b>Cash and cash equivalents, beginning of period</b>	<b>12,110,565</b>	<b>24,987,603</b>
<b>Cash and cash equivalents, end of period</b>	<b>\$ 8,674,395</b>	<b>\$ 14,145,901</b>
<b>Supplemental disclosure of cash flow information:</b>		



Interest paid	\$	16,598	\$	78,508
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See Notes to Condensed Consolidated Financial Statements.

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**Notes to Condensed Consolidated Financial Statements (Unaudited)**

**March 31, 2016 and 2015**

**Note 1. Summary of Significant Accounting Policies**

**Nature of Business.**

StemCells, Inc., a Delaware corporation, is a biopharmaceutical company that operates in one segment, the research, development, and commercialization of stem cell therapeutics and related technologies.

The accompanying financial data as of March 31, 2016 and for the three months ended March 31, 2016 and 2015 have been prepared by us, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) have been condensed or omitted pursuant to these rules and regulations. The December 31, 2015 condensed consolidated balance sheet was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP. However, we believe that the disclosures are adequate to make the information presented not misleading. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and the notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

We have incurred significant operating losses since inception. We expect to incur additional operating losses over the foreseeable future. We have very limited liquidity and capital resources and must obtain significant additional capital and other resources in order to provide funding for our product development efforts, the acquisition of technologies, businesses and intellectual property rights, preclinical and clinical testing of our products, pursuit of regulatory approvals, acquisition of capital equipment, laboratory and office facilities, establishment of production capabilities, general and administrative expenses and other working capital requirements. We rely on our cash reserves, proceeds from equity and debt offerings, credit facilities, proceeds from the transfer or sale of intellectual property rights, equipment, facilities or investments, government grants and funding from collaborative arrangements, to fund our operations. If we exhaust our cash reserves and are unable to obtain adequate financing, we may be unable to meet our operating obligations and we may be required to initiate bankruptcy proceedings. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

**Reverse Stock Split**

We effected a one-for-twelve reverse stock split on May 6, 2016. As a result of the reverse stock split, each twelve shares of the Company's common stock automatically combined into and became one share of Company common stock. Any fractional shares which would otherwise be due as a result of the reverse split were rounded up to the nearest whole share. Concurrent with the reverse stock split, we reduced the authorized number of common shares from 225 million to 200 million. The reverse stock split will automatically and proportionately adjust, based on the one-for-twelve split ratio, all issued and outstanding shares of our common stock, as well as common stock underlying stock options, warrants and other derivative securities outstanding at the time of the effectiveness of the reverse stock split. The exercise price on outstanding equity based-grants will proportionately increase, while the number of shares available under our equity-based plans will also be proportionately reduced. Share and per share data (except par value) for the periods presented reflect the effects of this reverse stock split. References to numbers of shares of common stock and per share data in the accompanying financial statements and notes thereto have been adjusted to reflect the reverse stock split on a retroactive basis.

## **Principles of Consolidation**

The condensed consolidated financial statements include the accounts of StemCells, Inc., and our wholly-owned subsidiaries, including StemCells California, Inc., Stem Cell Sciences Holdings Ltd, and Stem Cell Sciences (UK) Ltd (SCS). All significant intercompany accounts and transactions have been eliminated.

## **Use of Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires management to make judgments, assumptions and estimates that affect the amounts reported in our condensed consolidated financial statements and accompanying notes. Actual results could differ materially from these estimates.

Significant estimates include the following:

the grant date fair value of stock-based awards recognized as compensation expense (see Note 6, **Stock-Based Compensation** );

the fair value of warrants recorded as a liability (see Note 9, **Warrant Liability** ).

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Cash equivalents are money market accounts, money market funds and investments with maturities of 90 days or less from the date of purchase.

*Receivables*

Our receivables generally consist of interest income on our financial instruments and royalties due from licensing agreements.

*Warrant Liability*

We account for our warrants in accordance with U.S. GAAP which defines how freestanding contracts that are indexed to and potentially settled in a company's own stock should be measured and classified. Authoritative accounting guidance prescribes that only warrants issued by us under contracts that cannot be net-cash settled, and are both indexed to and settled in our common stock, can be classified as equity.

As part of our December 2011 financing, we issued Series A Warrants with a five year term to purchase 666,667 shares at \$16.80 per share and Series B Warrants with a ninety trading day term to purchase 666,667 units at \$15.00 per unit. Each unit underlying the Series B Warrants consisted of one share of our common stock and one Series A Warrant. In the first and second quarter of 2012, an aggregate of 225,000 Series B Warrants were exercised. For the exercise of these warrants, we issued 225,000 shares of our common stock and 225,000 Series A Warrants. The remaining 441,667 Series B Warrants expired unexercised by their terms on May 2, 2012. The Series A Warrants contain full ratchet anti-dilution price protection so that, in most situations, upon the issuance of any common stock or securities convertible into common stock at a price below the then-existing exercise price of the Series A Warrants, the Series A exercise price will be reset to the lower common stock sales price. As a result of our April 2015 financing, the exercise price of the outstanding Series A warrants were reduced from \$16.80 per share to \$8.40 per share. Subsequently, as a result of our sale of shares of our common stock under a sales agreement entered into in 2009 and amended in 2012, the exercise price of the outstanding Series A warrants was reduced from \$8.40 per share to \$6.24 per share and as a result of our March 2016 financing, the exercise price of these warrants was reduced to approximately \$3.60 per share. As terms of the Series A Warrants do not meet the specific conditions for equity classification, we are required to classify the fair value of these warrants as a liability, with subsequent changes in fair value to be recorded as income (loss) due to change in fair value of warrant liability. The fair value of the Series A Warrants is determined using a Monte Carlo simulation model (see Note 9, Warrant Liability). The fair value is affected by changes in inputs to these models including our stock price, expected stock price volatility, the contractual term, and the risk-free interest rate. The use of a Monte Carlo simulation model requires input of additional assumptions including the progress of our research and development (R&D) programs and its effect on potential future financings. We will continue to classify the fair value of the warrants as a liability until the warrants are exercised, expire or are amended in a way that would no longer require these warrants to be classified as a liability. The estimated fair value of our 2011 Series A warrant liability at March 31, 2016, was approximately \$512,000.

In March 2016, we raised gross proceeds of approximately \$8,000,000 through an underwritten public offering of 2,222,250 units, at a price of \$3.60 per unit, before deducting underwriting discounts and other offering expenses. Each unit consists of a fixed combination of one share of our common stock, a Series A Warrant to purchase 0.50 of a share of our common stock, and a Series B Warrant to purchase 0.75 of a share of our common stock. Each Series A Warrant has an exercise price of \$3.60 per share, is immediately exercisable, and will expire two years from the date

of issuance. Each Series B Warrant has an exercise price of \$5.04 per share, will become exercisable upon stockholder approval of an increase in our authorized capital and the one-year anniversary of the issuance date, whichever is later, and will expire on the fifth anniversary of the date they become exercisable. In connection with the offering, we granted the underwriters a 45-day option to purchase up to an additional 333,338 shares of our common stock and/or warrants to purchase up to an additional 416,672 shares of our common stock to cover over-allotments, if any. The option was exercised in part and we issued an additional 166,473 of Series A warrants and 249,709 of Series B Warrants. The Series A and Series B Warrants contain full ratchet anti-dilution price protection for two years so that, in most situations, upon the issuance of any common stock or securities convertible into common stock at a price below the then-existing exercise price of the respective warrants, the exercise price of these warrants will be reset to the lower common stock sales price. The initial shares and warrants were offered under our effective shelf registration statement previously filed with the SEC. We intend to file a subsequent registration statement to register the common shares issuable when the Series B Warrants become exercisable. As terms of the Series A and Series B Warrants do not meet the specific conditions for equity classification, we are required to classify the fair value of these warrants as a liability, with subsequent changes in fair value to be recorded as income (loss) due to change in fair value of warrant liability. The fair value of the Series A and Series B Warrants is determined using a Monte Carlo simulation model (see Note 9, Warrant Liability ). The fair

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value is affected by changes in inputs to these models including our stock price, expected stock price volatility, the contractual term, and the risk-free interest rate. The use of a Monte Carlo simulation model requires input of additional assumptions including the progress of our R&D programs and its effect on potential future financings. We will continue to classify the fair value of the warrants as a liability until the warrants are exercised, expire or are amended in a way that would no longer require these warrants to be classified as a liability. The estimated fair value of our warrant liability for the 2016 Series A and 2016 Series B warrants at March 31, 2016, was approximately \$1,761,000 and \$3,887,000 respectively.

**Intangible Assets (Patent and License Costs)**

Other intangible assets, net were approximately \$42,000 at March 31, 2016. Intangible assets with finite useful lives are amortized generally on a straight-line basis over the periods benefited. Intangible assets deemed to have indefinite lives are not amortized but are subject to annual impairment tests. Intangible assets are also reviewed for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Prior to fiscal year 2001, we capitalized certain patent costs, which are being amortized over the estimated life of the patent and would be expensed at the time such patents are deemed to have no continuing value. Since 2001, all patent costs are expensed as incurred. License costs are capitalized and amortized over the estimated life of the license agreement.

**Revenue Recognition**

We currently recognize revenue resulting from the licensing and use of our technology and intellectual property. Licensing agreements may contain multiple elements, such as upfront fees, payments related to the achievement of particular milestones and royalties. Revenue from upfront fees for licensing agreements that contain multiple elements are generally deferred and recognized on a straight-line basis over the term of the agreement. Fees associated with substantive at risk performance-based milestones are recognized as revenue upon completion of the scientific or regulatory event specified in the agreement, and royalties received are recognized as earned. Revenue from licensing agreements is recognized net of a fixed percentage due to licensors as royalties.

**Stock-Based Compensation**

U.S. GAAP requires us to recognize expense related to the fair value of our stock-based payment awards, including employee stock options and restricted stock units. Under the provisions of U.S. GAAP, the fair value of our employee stock-based payment awards is estimated at the date of grant using the Black-Scholes-Merton (Black-Scholes) option-pricing model and is recognized as expense ratably over the requisite service period. The requisite service period is the period over which the awards vest. Stock-based awards may vest over a period of time from the date of grant or upon the attainment of certain established performance milestones. For awards with performance milestones, the expense is recorded over the service period when the achievement of the milestone is probable. The Black-Scholes option-pricing model requires the use of certain assumptions, the most significant of which are our estimates of the expected volatility of the market price of our stock and the expected term of the award. Our estimate of the expected volatility is based on historical volatility. The expected term represents our estimated period during which our stock-based awards remain outstanding. We estimate the expected term based on historical experience of similar awards, giving consideration to the contractual terms of the awards, vesting requirements, and expectation of future employee behavior, including post-vesting terminations. See Note 6, **Stock-Based Compensation** for further information.

**Per Share Data**

Basic net income or loss per share is computed by dividing net income or loss by the weighted average number of shares of common stock outstanding during the period. Diluted net income or loss per share is computed based on the weighted average number of shares of common stock and other dilutive securities. To the extent these securities are anti-dilutive, they are excluded from the calculation of diluted earnings per share.

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The following is a reconciliation of the numerators and denominators of the basic and diluted net loss per share computations:

	2016	2015
Net loss	\$ (9,561,405)	\$ (9,350,701)
Weighted average shares outstanding used to compute basic and diluted net income or loss per share	9,805,478	5,768,331
Basic and diluted net loss per share	\$ (0.98)	\$ (1.62)

The following outstanding potentially dilutive securities were excluded from the computation of diluted net income or loss per share because the effect would have been anti-dilutive as of March 31:

	2016	2015
Options	155,831	23,020
Restricted stock units	810,946	832,044
Warrants	6,883,814	1,956,516
Total	7,850,591	2,811,580

**Comprehensive Income (Loss)**

Comprehensive income (loss) is comprised of net income or loss and other comprehensive income or loss (OCL). OCL includes certain changes in stockholders' equity that are excluded from net income or loss. Specifically, when applicable, we include in OCL changes in unrealized gains and losses on foreign currency translations. Accumulated other comprehensive income was \$46,913 as of March 31, 2016, and accumulated other comprehensive income was \$47,359, as of December 31, 2015.

**Recent Accounting Pronouncements**

In June 2014, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update ( ASU ) 2014-12, *Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period* . The ASU requires that a performance target that affects vesting, and that could be achieved after the requisite service period, be treated as a performance condition. A reporting entity should apply existing guidance in Topic 718 as it relates to awards with performance conditions that affect vesting to account for such awards. In July 2015, the FASB voted to defer the effective date of this ASU for one year, revising the effective date for interim and annual periods beginning after December 15, 2016. Early adoption is permitted. We do not anticipate the adoption of this ASU will have a material impact on our consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* , which provides guidance on determining when and how reporting entities must disclose going-concern uncertainties in their financial statements. The ASU requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date of issuance of the entity's financial statements (or within one year after the date on which the financial statements are available to be issued, when applicable). Further, an entity must provide certain disclosures if there is substantial doubt about the



entity's ability to continue as a going concern. This ASU is effective for annual periods ending after December 15, 2017, and interim periods thereafter; early adoption is permitted.

In January 2016, the FASB issued ASU 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*. The amendments in this Update require all equity investments to be measured at fair value with changes in the fair value recognized through net income (other than those accounted for under equity method of accounting or those that result in consolidation of the investee). The amendments in this ASU also require an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments. In addition the amendments in this ASU requires disclosure of the methods and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet. This ASU is effective for fiscal years beginning after December 15, 2017. The adoption of the ASU will not have a material impact on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases*. The amendments in this Update create Topic 842, *Leases*, and supersede the leases requirements in Topic 840, *Leases*. Topic 842 specifies the accounting for leases. The objective of Topic 842 is to establish the principles that lessees and lessors shall apply to report useful information to users of financial statements about

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the amount, timing, and uncertainty of cash flows arising from a lease by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. Topic 842 affects any entity that enters into a lease with some specified scope exemptions. The amendments in this Update are effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. We are currently evaluating the provisions of ASU 2016-02 and its impact on our consolidated financial statements and related disclosures.

**Note 2. Financial Instruments**

The following table summarizes the fair value of our cash and cash equivalents held in our current investment portfolio:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized (Losses)	Fair Value
<b>March 31, 2016</b>				
Cash	\$ 690,078	\$	\$	\$ 690,078
Cash equivalents (money market accounts)	7,984,317			7,984,317
Restricted cash (money market accounts)	2,422,500			2,422,500
Total cash, cash equivalents and restricted cash	\$ 11,096,895	\$	\$	\$ 11,096,895

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized (Losses)	Fair Value
<b>December 31, 2015</b>				
Cash	\$ 830,190	\$	\$	\$ 830,190
Cash equivalents ( money market accounts)	11,280,375			11,280,375
Restricted cash ( money market accounts)	2,422,500			2,422,500
Total cash, cash equivalents and restricted cash	\$ 14,533,065	\$	\$	\$ 14,533,065

At March 31, 2016, our investments in money market accounts are through a money market fund that invests in high quality, short-term money market instruments which are classified as cash equivalents in the accompanying Condensed Consolidated Balance Sheet due to their short maturities. The investment seeks to provide the highest possible level of current income while still maintaining liquidity and preserving capital. From time to time, we carry cash balances in excess of federally insured limits. We do not hold any investments that were in a material unrealized loss position as of March 31, 2016.

**Note 3. Fair Value Measurement**

Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement

that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering such assumptions, we are required to apply a three-tier value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value. The three levels of the fair value hierarchy are:

*Level 1* Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

*Level 2* Directly or indirectly observable inputs other than in Level 1, that include quoted prices for similar assets or liabilities in active markets or quoted prices for identical or similar assets or liabilities in markets that are not active.

*Level 3* Unobservable inputs which are supported by little or no market activity that reflects the reporting entity's own assumptions about the assumptions that market participants would use in pricing the asset or liability.

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The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Assets measured at fair value are classified below based on the three fair value hierarchy tiers described above.

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Our cash equivalents are classified as Level 1 because they are valued primarily using quoted market prices.

We estimated the fair value of our loan payable using the net present value of the payments discounted at an effective interest rate. We believe the estimates used to measure the fair value of our loan payable constitute Level 3 inputs.

Our liability for warrants issued in our 2011 and 2016 financing are classified as Level 3 as the liability is valued using a Monte Carlo simulation model. Some of the significant inputs used to calculate the fair value of warrant liability include our stock price on the valuation date, expected volatility of our common stock as traded on NASDAQ, and risk-free interest rates that are derived from the yield on U.S. Treasury debt securities, all of which are observable from active markets. However, the use of a Monte Carlo simulation model requires the input of additional subjective assumptions including management's assumptions regarding the likelihood of a re-pricing of these warrants pursuant to anti-dilution provisions and the progress of our R&D programs and its affect on potential future financings.

The following table presents financial assets and liabilities measured at fair value as of March 31, 2016:

	<b>Fair Value Measurement at Report Date Using Quoted Prices Significant in Active Markets Other for Observable</b>		<b>Unobservable Inputs (Level 3)</b>	<b>As of March 31, 2016</b>
	<b>Identical Assets (Level 1)</b>	<b>Inputs (Level 2)</b>		
<b>Financial assets:</b>				
Cash equivalents:				
Money market funds	\$ 3,244,966	\$	\$	\$ 3,244,966
U.S. Treasury debt obligations	7,161,851			7,161,851
<b>Total financial assets</b>	<b>\$ 10,406,817</b>	<b>\$</b>	<b>\$</b>	<b>\$ 10,406,817</b>
<b>Financial liabilities:</b>				
Loan payable net of discounts	\$	\$	\$ 9,274,959	\$ 9,274,959
Warrant liabilities			6,159,671	6,159,671
<b>Total financial liabilities</b>	<b>\$</b>	<b>\$</b>	<b>\$ 15,434,630</b>	<b>\$ 15,434,630</b>

**Level 3 Reconciliation**

The following table presents a roll forward for liabilities measured at fair value using significant unobservable inputs (Level 3) for 2016:

	<b>Warrant liabilities</b>
Balance at December 31, 2015	\$ 770,964
Add fair value of warrants issued	5,666,935
Less change in fair value of warrants	(278,228)
Balance at March 31, 2016	\$ 6,159,671

	<b>Loan payable net of discounts</b>	
Balance at December 31, 2015	\$	10,334,029
Add amortization of discount		5,107
Less repayments of principal		(1,064,177)
Balance at March 31, 2016	\$	9,274,959
Current portion		358,318
Non-current portion		8,916,641
Balance at March 31, 2016	\$	9,274,959

**Table of Contents****Note 4. Property, Plant and Equipment**

Property, plant and equipment balances at March 31, 2016 and December 31, 2015 are summarized below:

	<b>March 31, 2016</b>	<b>December 31, 2015</b>
Building and improvements	\$ 3,608,588	\$ 3,608,588
Machinery and equipment	8,536,138	8,530,203
Furniture and fixtures	338,259	338,259
	12,482,985	12,477,050
Less accumulated depreciation	(7,532,625)	(7,259,121)
Property, plant and equipment, net	\$ 4,950,360	\$ 5,217,929

Depreciation expense was approximately \$274,000 for the three month period ended March 31, 2016 and approximately \$249,000 for the similar period in 2015.

**Note 5. Intangible Assets**

The components of our intangible assets at March 31, 2016 are summarized below:

<b>Intangible Asset Class</b>	<b>Cost</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Amount</b>	<b>Weighted Average Amortization Period</b>
Patents	\$ 160,436	\$ (118,114)	\$ 42,322	17 years

Amortization expense was approximately \$3,500 in the first quarter of 2016 and approximately \$21,000 for the similar period in 2015. Expected amortization expense for the year ended December 31, 2016 is approximately \$14,000.

The expected future annual amortization expense for each of the next five years based on current balances of our intangible assets is approximately as follows:

**For the year ending December 31:**

2016	\$ 13,978
2017	\$ 8,306
2018	\$ 8,306
2019	\$ 8,306
2020	\$ 6,922

**Note 6. Stock-Based Compensation**

We currently grant stock-based compensation under two equity incentive plans (2006 and 2013 Equity Incentive Plans) approved by the Company's stockholders and one plan adopted in 2012 pursuant to NASDAQ Listing Rule 5635(c)(4) concerning inducement grants for new employees (our 2012 Commencement Incentive Plan). As of March 31, 2016, we had 1,016,949 shares available to grant under the above mentioned plans. At our annual stockholders' meeting held on June 12, 2007, our stockholders approved an amendment to our 2006 Equity Incentive Plan to provide for an annual increase in the number of shares of common stock available for issuance under the plan each January 1 (beginning January 1, 2008) equal to 4% of the outstanding common shares as of that date. The amendment further provided an aggregate limit of 250,000 shares issuable pursuant to incentive stock option awards under the plan. At our annual stockholders' meeting held on December 20, 2013, our stockholders approved our 2013 Equity Incentive Plan to grant stock-based compensation of up to an initial 500,000 shares, plus an increase of 4% per year of the outstanding number of shares of our common stock beginning in January 1, 2015. Under the three stockholder-approved plans we may grant incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, 401(k) Plan employer



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match in form of shares and performance-based shares to our employees, directors and consultants, at prices determined by our Board of Directors. Incentive stock options may only be granted to employees under these plans with a grant price not less than the fair market value on the date of grant. Under our 2012 Commencement Inducement Plan, we may only award options, restricted stock units and other equity awards to newly hired employees and newly engaged directors, in each case as allowed by NASDAQ listing requirements.

Generally, stock options and restricted stock units granted to employees have a maximum term of ten years. Stock based awards may vest over a period of time from the date of grant or upon the attainment of certain performance goals established by the Compensation Committee or the Single Member Committee established under our 2006 Equity Incentive Plan and our 2013 Equity Incentive Plan. Upon employee termination of service, any unexercised vested option will be forfeited three months following termination or the expiration of the option, whichever is earlier.

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Our stock-based compensation expense for the three months ended March 31 was as follows:

	<b>Three months ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
Research and development expense	\$ 313,378	\$ 583,669
General and administrative expense	1,539,048	725,225
<b>Total stock-based compensation</b>	<b>\$ 1,852,426</b>	<b>\$ 1,308,894</b>

Effect on basic and diluted net loss per share	\$ (0.19)	\$ (0.23)
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As of March 31, 2016, we had approximately \$4,355,000 of total unrecognized compensation expense related to unvested awards of stock options and restricted stock units granted under our various equity incentive plans that we expect to recognize over a weighted-average vesting period of 1.5 years.

*Stock Options*

A summary of our stock option activity for the three months ended March 31, 2016 is as follows:

	<b>Number of options</b>	<b>Weighted-average exercise price (\$) per share</b>
Outstanding options at December 31, 2015	173,261	34.80
Granted	10,000	3.60
Exercised		
Cancelled	(27,430)	34.20
<b>Outstanding options at March 31, 2016</b>	<b>155,831</b>	<b>32.76</b>

The following is a summary of changes in unvested options:

	<b>Weighted Average Grant Date</b>	
<b>Unvested Options</b>	<b>Number of Options</b>	<b>Fair Value</b>
Unvested options at December 31, 2015	140,000	\$ 8.28
Granted(1)	10,000	\$ 3.60
Vested		\$ 145.68
Cancelled	(25,417)	\$ 8.52
	<b>124,583</b>	<b>\$ 7.92</b>

Unvested options at March 31,  
2016

- (1) The 10,000 options granted are performance based and vest on achievement of predefined milestones.

**Table of Contents***Restricted Stock Units*

We have granted restricted stock units (RSUs) to certain employees and members of the Board of Directors which entitle the holders to receive shares of our common stock upon vesting of the RSUs. The fair value of restricted stock units granted is based upon the market price of the underlying common stock as if it were vested and issued on the date of grant.

A summary of changes in our unvested restricted stock units for the three months ended March 31, 2016 is as follows:

	<b>Number of RSUs</b>	<b>Weighted Average Grant Date Fair Value (\$)</b>
Outstanding at December 31, 2015	687,613	14.52
Granted(1)	277,210	3.84
Vested and exercised	(217,919)	14.52
Cancelled	(34,875)	13.68
Outstanding at March 31, 2016	712,029	10.44

- (1) Of the 277,210 restricted stock units issued, 73,171 restricted stock units vest and convert into shares of our common stock after one year from the date of grant. 204,039 restricted stock units are performance based and vest on achievement of predefined milestones.

*Stock Appreciation Rights*

In July 2006, we granted cash-settled Stock Appreciation Rights (SARs) to certain employees that give the holder the right, upon exercise, to the difference between the price per share of our common stock at the time of exercise and the exercise price of the SARs.

The SARs have a maximum term of ten years with an exercise price of \$240.00, which is equal to the market price of our common stock at the date of grant. The SARs vest 25% on the first anniversary of the grant date and 75% vest monthly over the remaining three-year service period. At March 31, 2016 and 2015, there were 9,217 SARs outstanding. All of the outstanding SARs as of March 31, 2016 are fully vested. There were no SARs granted, exercised or forfeited during the three months ended March 31, 2016. Compensation expense is based on the fair value of SARs which is calculated using the Black-Scholes option pricing model.

The stock-based compensation expense and liability are re-measured at each reporting date through the earlier of date of settlement or forfeiture of the SARs. For the three months ended March 31, 2016 and 2015, the re-measured liability and expense for the respective periods related to the SARs were not significant.

The compensation expense related to the SARs recognized for the three months ended March 31, 2016 may not be representative of compensation expense for future periods and its resulting effect on net loss and net loss per share attributable to common stockholders, due to changes in the fair value calculation which is dependent on the stock price, volatility, interest and forfeiture rates, additional grants and subsequent periods of vesting. We will continue to recognize compensation cost each period, which will be the change in fair value from the previous period through the

earlier date of settlement or forfeiture of the SARs.

**Table of Contents****Note 7. Loan Payable***Loan Agreement with Silicon Valley Bank*

In April 2013, we entered into a Loan Agreement with Silicon Valley Bank (SVB) and received loan proceeds of \$9,900,000, net of a \$100,000 cash discount. The loan proceeds will be used for research and development and general corporate purposes. The loan has a three-year term and bears interest at an annual rate of 6%. The loan obligations are secured by a first priority security interest on substantially all of our assets excluding intellectual property. For the first six months, payments will be interest only followed by repayment of principal and interest over a period of 30 months. There is also a final \$1,000,000 fee payable at the end of the term which is being expensed over the term of the loan using the effective interest method. In conjunction with the Loan Agreement, we issued to SVB a ten year warrant to acquire 24,461 shares of common stock at an exercise price of \$20.4408 per share. The warrant is immediately exercisable and expires in April 2023. We estimated the fair value of the warrant to be approximately \$388,000 using the Black-Scholes option pricing model with the following assumptions:

Expected life (years)	10
Risk-free interest rate	1.9%
Expected volatility	88.1%
Expected dividend yield	0%

We applied the relative fair value method to allocate the \$9,900,000 net proceeds between the loan and warrant. The approximately \$388,000 fair value allocated to the warrant was recorded as an increase to additional paid-in capital and as a discount to loan payable. Approximately \$9,512,000 was assigned to the loan and was recorded as the initial carrying amount of the loan payable, net of discount. The approximately \$388,000 fair value of the warrant and the \$100,000 cash discount are both being amortized as additional interest expense over the term of the loan using the effective interest rate method.

We also incurred loan issuance costs of approximately \$117,000, which are recorded as deferred financing costs on the accompanying consolidated balance sheet and are being amortized to interest expense over the term of the Loan Agreement using the effective interest rate method.

The effective interest rate used to amortize the deferred financing costs and the discount (including the fair value of the warrant and the cash discount), and for the accretion of the final payment, is 9.0%.

We were required to maintain certain financial and other covenants set forth in the Loan Agreement. In December 2015, to remain in compliance with the terms of the agreement, we entered into an amendment to the Loan Agreement that required us to maintain with SVB a restricted money market account with a minimum aggregate balance of \$2,422,500. As part of the amendment, we pledged to SVB a security interest in the restricted money market account. In April 2016, we repaid the outstanding principal, interest and fees to SVB and the aggregate balance of \$2,422,500 was transferred from our restricted money market account to our unrestricted money market account.

The following table is a summary of the changes in the carrying value of our loan payable for the three months ended March 31, 2016:

	<b>Silicon Valley Bank Loan</b>
Carrying value of loan payable, current at December 31, 2015	\$ 1,417,388
Repayment of principal	(1,064,177)
Accretion of discount	5,107
Carrying value of loan payable, current at March 31, 2016	\$ 358,318

**Note 8. Commitments and Contingencies***Operating leases*

We lease various real properties under operating leases that generally require us to pay taxes, insurance, maintenance, and minimum lease payments. Some of our leases have options to renew.

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**Table of Contents***Operating Leases California*

In December 2010, we entered into a commercial lease agreement with BMR-Gateway Boulevard LLC (BMR), as landlord, for office and research space at BMR's Pacific Research Center in Newark, California. The initial term of the lease is approximately eleven and one-half years and includes escalating rent payments which we recognize as lease operating expense on a straight-line basis. We will pay approximately \$17,869,000 in aggregate as rent over the term of the lease to BMR. Deferred rent for this facility was approximately \$1,349,000 as of March 31, 2016, and approximately \$1,372,000 as of December 31, 2015.

In March 2013, we entered into a commercial lease agreement with Prologis, L.P. (Prologis), as landlord, for office and research space in Sunnyvale, California. The facility is for operations that support our clinical development activities. The initial term of the lease is ten years and includes escalating rent payments which we recognize as lease operating expense on a straight-line basis. We will pay approximately \$3,497,000 in aggregate rent over the term of the lease. As part of the lease, Prologis has agreed to provide us financial allowances to build initial tenant improvements, subject to customary terms and conditions relating to landlord-funded tenant improvements. The tenant improvements are recorded as leasehold improvement assets and amortized over the term of the lease. The financial allowances are treated as a lease incentive and recorded as deferred rent which is amortized as reductions to lease expense over the lease term. Deferred rent for this facility was approximately \$379,000 as of March 31, 2016, and approximately \$382,000 as of December 31, 2015.

With the exception of the operating leases discussed above, we have not entered into any significant off balance sheet financial arrangements and have not established any special purpose entities. We have not guaranteed any debts or commitments of other entities or entered into any options on non-financial assets.

**Note 9. Warrant Liability**

In December 2011, we raised gross proceeds of \$10,000,000 through a public offering of 666,667 units and 666,667 Series B Warrants. The combination of units and Series B Warrants were sold at a public offering price of \$15.00 per unit. Each Series B Warrant gave the holder the right to purchase one unit at an exercise price of \$15.00 per unit and was exercisable until May 2, 2012, the 90th trading day after the date of issuance. Each unit consists of one share of our common stock and one Series A Warrant. Each Series A Warrant gives the holder the right to purchase one share of our common stock at an initial exercise price of \$16.80 per share. The Series A Warrants are immediately exercisable upon issuance and will expire in December 2016. In 2012, an aggregate of 225,000 Series B Warrants were exercised. For the exercise of these warrants, we issued 225,000 shares of our common stock and 225,000 Series A Warrants. The remaining 441,667 Series B Warrants expired unexercised by their terms on May 2, 2012. In 2012, 2013 and 2014, an aggregate of 183,215, 32,045 and 98,335 Series A Warrants were exercised, respectively. For the exercise of these warrants, in 2012, 2013 and 2014, we issued 183,215, 32,045 and 98,335 shares of our common stock and received gross proceeds of approximately \$3,078,000, \$538,000 and \$1,652,000, respectively. The shares were offered under our shelf registration statement previously filed with previously filed with, and declared effective by, the SEC. The Series A Warrants contain full ratchet anti-dilution price protection so that, in most situations upon the issuance of any common stock or securities convertible into common stock at a price below the then-existing exercise price of the outstanding Series A Warrants, the Series A exercise price will be reset to the lower common stock sales price. As a result of our April 2015 financing, the exercise price of the outstanding Series A warrants was reduced from \$16.80 per share to \$8.40 per share. Subsequently, as a result of our sale of shares of our common stock under a sales agreement entered into in 2009 and amended in 2012, the exercise price of the outstanding Series A warrants was reduced from \$8.40 per share to \$6.24 per share and as a result of our March 2016 financing, the exercise price of these warrants were further reduced to approximately \$3.60 per share. The fair value of the warrant liability will be revalued at the end of each reporting period, with the change in fair value of the warrant liability



recorded as a gain or loss in our condensed consolidated statements of operations. The fair value of the warrants will continue to be classified as a liability until such time as the warrants are exercised, expire or an amendment of the warrant agreement renders these warrants to be no longer classified as a liability.

In March 2016, we raised gross proceeds of approximately \$8.0 million through an underwritten public offering of 2,222,250 units, at a price of \$3.60 per unit, before deducting underwriting discounts and other offering expenses. Each unit consists of a fixed combination of one share of our common stock, a Series A Warrant to purchase 0.50 of a share of our common stock, and a Series B Warrant to purchase 0.75 of a share of our common stock. Each Series A Warrant has an exercise price of \$3.60 per share, is immediately exercisable, and will expire two years from the date of issuance. Each Series B Warrant has an exercise price of \$5.04 per share, will become exercisable upon stockholder approval of an increase in our authorized capital and the one-year anniversary of the issuance date, whichever is later, and will expire on the fifth anniversary of the date they become exercisable. In connection with the offering, we granted the underwriters a 45-day option to purchase up to an additional 333,338 shares of our common stock and/or warrants to purchase up to an additional 416,672 shares of our common stock to cover over-allotments, if any. The option was exercised in part and we issued an additional 166,473 of Series A warrants and 249,709 of Series B Warrants. The Series A and Series B Warrants contain full ratchet anti-dilution price protection for two years so that, in most situations, upon the issuance of any common stock or securities convertible into common stock at a price below the then-existing exercise price of the respective warrants,

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the exercise price of these warrants will be reset to the lower common stock sales price. The initial shares and warrants were offered under our effective shelf registration statement previously filed with the SEC. We intend to file a subsequent registration statement to register the common shares issuable upon the time the Series B Warrants become exercisable. As terms of the Series A and Series B Warrants do not meet the specific conditions for equity classification, we are required to classify the fair value of these warrants as a liability, with subsequent changes in fair value to be recorded as income (loss) due to change in fair value of warrant liability.

We use the Monte Carlo simulation model, to estimate fair value of these warrants issued in our 2011 and 2016 financing transactions. In using this model, we make certain assumptions about risk-free interest rates, dividend yields, volatility, expected term of the warrants and other assumptions. Risk-free interest rates are derived from the yield on U.S. Treasury debt securities. Dividend yields are based on our historical dividend payments, which have been zero to date. Volatility is estimated from the historical volatility of our common stock as traded on NASDAQ. The expected term of the warrants is based on the time to expiration of the warrants from the date of measurement.

The assumptions used for the Monte Carlo simulation model to value the outstanding Series A Warrants at March 31, 2016 are as follows:

	Series A (2011)	Series A (2016)	Series B (2016)
Risk-free interest rate per year	0.48%	0.72%	1.4%
Expected volatility per year	85.7%	76.9%	77.5%
Expected dividend yield	0%	0%	0%
Expected life (years)	0.7	2	6

The use of the Monte Carlo simulation model requires the input of additional subjective assumptions including the progress of our R&D programs and its affect on potential future financings.

The following table is a summary of the changes in fair value of warrant liability in 2016:

	Series A (2011)	Series A (2016)	Series B (2016)	Total
Balance at December 31, 2015	\$ 770,964	\$	\$	\$ 770,964
New Issues		\$ 1,770,596	\$ 3,896,339	5,666,935
Changes in fair value	(259,370)	(9,659)	(9,199)	(278,228)
Balance at March 31, 2016	\$ 511,594	\$ 1,760,937	\$ 3,887,140	\$ 6,159,671

The following table is a summary of our warrant liability as of March 31, 2016:

Warrants	Number Outstanding	Exercise Price (\$ per share	Fair Value
Series A (2011)	578,074	3.60	\$ 511,594

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Series A (2016)	1,277,598	3.60	1,760,937
Series B (2016)	1,916,396	5.04	3,887,140
	3,772,068		\$ 6,159,671

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The fair value of the warrant liability is revalued at the end of each reporting period, with the change in fair value of the warrant liability recorded as a gain or loss in our condensed consolidated statements of operations. The fair value of the warrants will continue to be classified as a liability until such time as the warrants are exercised, expire or an amendment of the warrant agreement renders these warrants to be no longer classified as a liability.

### **Note 10. Equity Financing**

In March 2016, we raised gross proceeds of approximately \$8,000,000 through an underwritten public offering of 2,222,250 units, at a price of \$3.60 per unit, before deducting underwriting discounts and other offering expenses. Each unit consists of a fixed combination of one share of our common stock, a Series A Warrant to purchase 0.50 of a share of our common stock, and a Series B Warrant to purchase 0.75 of a share of our common stock. Each Series A Warrant has an exercise price of \$3.60 per share, is immediately exercisable, and will expire two years from the date of issuance. Each Series B Warrant has an exercise price of \$5.04 per share, will become exercisable upon stockholder approval of an increase in our authorized capital and the one year anniversary of the issuance date, whichever is later, and will expire on the fifth anniversary of the date they become exercisable. In connection with the offering, we granted the underwriters a 45 day option to purchase up to an additional 333,338 shares of our common stock and/or warrants to purchase up to an additional 416,672 shares of our common stock to cover over-allotments, if any. The option was exercised in part and we issued an additional 166,473 of Series A warrants and 249,709 of Series B Warrants. We received net proceeds (net of offering expenses underwriting discounts and commissions), of approximately \$7,100,000. The initial shares and warrants were offered under our effective shelf registration statement previously filed with the SEC. We intend to file a subsequent registration statement to register the common shares issuable when the Series B Warrants become exercisable.

### **Note 11. Subsequent Events**

In connections with our March 2016 financing transaction, we granted the underwriters a 45 day option to purchase up to an additional 333,338 shares of our common stock and/or warrants to purchase up to an additional 416,672 shares of our common stock to cover over-allotments, if any. In April 2016, the underwriters partially exercised their option to cover over-allotments and purchased an additional 41,667 shares of our common stock at an exercise price of \$3.60 per share. We received gross proceeds of approximately \$150,000 and issued 41,667 shares of our common stock.

On May 6, 2016, in keeping with stockholder approval obtained at our 2016 annual stockholder meeting, we filed with the state of Delaware a certificate of amendment to our certificate of incorporation to complete a one-for-twelve split of the Company's issued and outstanding common stock. Concurrent with the reverse stock split, we reduced the authorized number of common shares from 225 million to 200 million.

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**Table of Contents****ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

This report contains forward looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act that involve substantial risks and uncertainties. Such statements include, without limitation, all statements as to expectation or belief and statements as to our future results of operations; the progress of our research, product development and clinical programs; the need for, and timing of, additional capital and capital expenditures; partnering prospects; costs of manufacture of products; the protection of, and the need for, additional intellectual property rights; effects of regulations; the need for additional facilities; and potential market opportunities. Our actual results may vary materially from those contained in such forward-looking statements because of risks to which we are subject, including the fact that additional trials will be required to confirm the safety and demonstrate the efficacy of our HuCNS-SC cells for the treatment of any disease or disorder; uncertainty as to whether the U.S. Food and Drug Administration (FDA) or other regulatory authorities will permit us to proceed with clinical testing of proposed products despite the novel and unproven nature of our technologies; the risk that our clinical trials or studies could be substantially delayed beyond their expected dates or cause us to incur substantial unanticipated costs; uncertainties in our ability to obtain the capital resources needed to continue our current research and development operations and to conduct the research, preclinical development and clinical trials necessary for regulatory approvals; the uncertainty regarding our ability to obtain a corporate partner or partners, if needed, to support the development and commercialization of our potential cell-based therapeutics products; the uncertainty regarding the outcome of our clinical trials or studies we may conduct in the future; the uncertainty regarding the validity and enforceability of our issued patents; the risk that we may not be able to manufacture additional master and working cell banks when needed; the uncertainty whether any products that may be generated in our cell-based therapeutics programs will prove clinically safe and effective; the uncertainty whether we will achieve significant revenue from product sales or become profitable; obsolescence of our technologies; competition from third parties; intellectual property rights of third parties; litigation risks; and other risks to which we are subject. All forward-looking statements attributable to us or to persons acting on our behalf are expressly qualified in their entirety by the cautionary statements and risk factors set forth in Risk Factors in Part I, Item 1A of our Form 10-K for the year ended December 31, 2015.

***Overview******The Company***

We are engaged in researching, developing, and commercializing cell-based therapeutics. Our research and development (R&D) programs are primarily focused on identifying and developing potential cell-based therapeutics which can either restore or support organ function. In particular, since we relocated our operations to California in 1999, our R&D efforts have been directed at refining our methods for identifying, isolating, culturing, and purifying the human neural stem cell and developing this cell as potential cell-based therapeutics for the central nervous system (CNS). Our HuCNS-SC<sup>®</sup> cells (purified human neural stem cells) are currently in clinical development for several indications, with a primary focus on chronic spinal cord injury.

In May 2014, we completed the enrollment and dosing of twelve subjects in a Phase I/II clinical trial of our HuCNS-SC cells for the treatment of thoracic spinal cord injury which represents the first time that neural stem cells have been transplanted as a potential therapeutic agent for spinal cord injury. The Phase I/II trial evaluated both safety and preliminary efficacy of our proprietary HuCNS-SC human neural stem cells as a treatment for chronic thoracic spinal cord injury. To accelerate patient enrollment, we expanded this trial from a single-site, single-country study to a multi-site, multi-country program. Under this trial, a total of twelve patients that included both complete and incomplete injuries as classified by the American Spinal Injury Association Impairment Scale (AIS) were enrolled and transplanted with our HuCNS-SC cells; seven patients with complete injury (AIS A) and five patients with an

incomplete injury (AIS B). We reported the results from twelve-month data that revealed sustained improvements in sensory function that emerged consistently around three months after transplantation and persisted until the end of the study. The patterns of sensory gains were confirmed to involve multiple sensory pathways and were observed more frequently in the patients with less severe injury; three of the seven AIS A patients and four of the five AIS B patients showed signs of positive sensory gains confirming the previously reported interim results. In addition, two patients progressed during the study from the most severe classification, AIS A, to the lesser degree of injury grade, AIS B.

In October 2014, we initiated a Phase II proof of concept clinical trial to further investigate our HuCNS-SC cells as a treatment for spinal cord injury. The Phase II Pathway Study, is the first clinical trial designed to evaluate both the safety and efficacy of transplanting human neural stem cells into patients with cervical spinal cord injury. Traumatic injuries to the cervical (neck) region of the spinal cord, also known as tetraplegia or quadriplegia, impair sensation and motor function of the hands, arms, legs, and trunk. The trial will be conducted as a randomized, controlled, single-blind study and efficacy will be primarily measured by assessing motor function according to the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI). The primary efficacy outcome will focus on change in upper extremity strength as measured in the hands, arms, and shoulders. The trial will follow the participants for one year and will enroll up to fifty-two subjects. The trial has three cohorts; the first cohort is an open-label dose escalation arm involving six patients to determine the cell dose to be used for the second and third cohort of the study; the second

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cohort will enroll forty patients and forms the single blinded controlled arm of the Phase II study with the primary efficacy outcome being tested is the change in motor strength of the various muscle groups in the upper extremities innervated by the cervical spinal cord; the third cohort is an optional open label cohort targeted to enroll six patients to assess safety and preliminary efficacy in patients with less severe injuries (AIS C). We transplanted our first subject in this Phase II trial in December 2014 and completed transplanting the six patients comprising the first cohort of this trial in April 2015. The six-month results for the first cohort showed that muscle strength had improved in five of the six patients with four of these five patients also demonstrating improved performance on functional tasks assessing dexterity and fine motor skills. In addition, four of the six patients showed improvement in the level of spinal cord injury as defined and measured by the ISNCSCI assessment of at least one level. Consistent with the prior study, changes in muscle strength and function were observed and we expect to release detailed final twelve-month results on the first cohort by the end of the second quarter of 2016. We commenced enrollment of the second cohort in the Pathway Study in June 2015 and currently have thirteen sites in the United States and Canada that are actively recruiting patients. We expect to complete enrollment of Cohort II by the end of the third quarter of 2016, and expect to have final results of this trial before year-end 2017.

We conducted a Phase I/II clinical trial in dry AMD at five trial sites in the United States, and in June 2014, based on positive interim results, we closed enrollment for this trial in order to focus our efforts on initiating a follow-on Phase II randomized, controlled proof-of-concept study in 2015. The phase I/II trial was designed to evaluate the safety and preliminary efficacy of sub-retinal HuCNS-SC cell transplantation in geographic atrophy (GA), the most advanced form of dry AMD. Multiple safety and efficacy assessments were incorporated into the study, including various assessments of visual function and measurements of disease status by direct retinal examination. The tests in the study included best-corrected visual acuity (BCVA), contrast sensitivity (CS), microperimetry for analysis of visual function, optical coherence tomography (OCT), and fundus autofluorescence (FAF) to measure the extent of the underlying geographic atrophy. Initial assessment of data from the Phase I/II trial indicate that the BCVA and CS measurements for the majority of the patients in the study either improved or remained stable in the treated eye. OCT analysis showed increases in central subfield thickness and in macular volume in the treated eye relative to the untreated eye. For those patients enrolled in the study with lesions sizes consistent with the eligibility criteria for enrollment in our Phase II efficacy study, the study showed GA growth rates in the study eye that were lower than those seen in the control eye.

In July 2015, we transplanted our first subject in our Radiant Study. This Phase II randomized, controlled proof-of-concept study was designed to evaluate both the safety and efficacy of our proprietary HuCNS-SC cells for the treatment of GA. The study was designed to enroll sixty-three patients between 50-90 years of age with bi-lateral GA-AMD (geographic atrophy associated with age related macular degeneration in both eyes). Designed as a fellow eye controlled study, all subjects were to receive subretinal transplantation of HuCNS-SC cells via a single injection into the eye with the inferior best-corrected visual acuity; the untreated eye would serve as a control. The objective of the trial was to demonstrate a reduction in the rate of GA disease progression in the treated eye versus the control eye. In December 2015, however, we initiated a strategic realignment plan to fully focus our resources on our proprietary HuCNS-SC cells for the treatment of chronic spinal cord injury. A key elements of the plan included the immediate suspension of further patient enrollment into our Phase II Radiant Study in GA-AMD as well as the modification of certain service agreements related to the AMD program while we seek a partner to fund continued development of the CNS-SC cells as a potential treatment of retinal disorders.

We previously completed a Phase I clinical trial in infantile and late infantile neuronal ceroid lipofuscinosis (NCL), which showed that our HuCNS-SC cells were well tolerated and non-tumorigenic, and that there was evidence of engraftment and long-term survival of the transplanted HuCNS-SC cells. In October 2013, the results of a four-year, long-term follow up study of the patients from the initial Phase I study showed there were no long-term safety or tolerability issues associated with the cells up to five years post-transplantation.

In October 2012, we published in *Science Translational Medicine*, a peer-reviewed journal, the data from our four-patient Phase I clinical trial in Pelizeaus Merzbacher disease (PMD), which is a myelination disorder in the brain. The data showed preliminary evidence of durable and progressive donor-derived myelination in all four patients. In addition, there were measurable gains in neurological function in three of the four patients, with the fourth patient clinically stable.

In April 2013, we entered into an agreement with the California Institute for Regenerative Medicine (CIRM) under which CIRM would have provided up to approximately \$19.3 million as a forgivable loan, in accordance with mutually agreed upon terms and conditions and CIRM regulations. The CIRM loan helped fund preclinical development of our HuCNS-SC cells for Alzheimer's disease. Between July 2013 and August 2014, we received in aggregate, approximately \$9.6 million as disbursements of the loan provided under the CIRM Loan Agreement. However, in December 2014, as findings under this preclinical study in Alzheimer's disease did not meet certain pre-determined criteria for continued funding of this program by CIRM, the parties terminated the loan agreement and we wound down this preclinical study which had been funded in part by the CIRM loan agreement. In February 2015, we repaid CIRM approximately \$679,000 of the aggregate loan proceeds received. Under the terms of the CIRM loan agreement, principal amount of approximately \$8,917,000 and accrued interest of approximately \$243,000 were forgiven. However, authoritative accounting guidance requires certain conditions (which includes a legal release from the creditor) to be met before a liability can be extinguished and derecognized.



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We have not derived any revenue or cash flows from the sale or commercialization of any products except for license revenue for certain of our patented technologies and sales of products for use in stem cell research. As a result, we have incurred annual operating losses since inception and expect to incur substantial operating losses in the future. Therefore, we are dependent upon external financing, such as from equity and debt offerings, to finance our operations. Before we can derive revenue or cash inflows from the commercialization of any of our therapeutic product candidates, we will need to: (i) conduct substantial *in vitro* testing and characterization of our proprietary cell types, (ii) undertake preclinical and clinical testing for specific disease indications; (iii) develop, validate and scale-up manufacturing processes to produce these cell-based therapeutics, and (iv) obtain required regulatory approvals. These steps are risky, expensive and time consuming.

Overall, we expect our R&D expenses to be substantial and to increase for the foreseeable future as we continue the development and clinical investigation of our current and future product candidates. However, expenditures on R&D programs are subject to many uncertainties, including whether we develop our product candidates with a partner or independently. We cannot forecast with any degree of certainty which of our current product candidates will be subject to future collaboration, when such collaboration agreements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. In addition, there are numerous factors associated with the successful commercialization of any of our cell-based therapeutics, including future trial design and regulatory requirements, many of which cannot be determined with accuracy at this time given the stage of our development and the novel nature of stem cell technologies. The regulatory pathways, both in the United States and internationally, are complex and fluid given the novel and, in general, clinically unproven nature of stem cell technologies. At this time, due to such uncertainties and inherent risks, we cannot estimate in a meaningful way the duration of, or the costs to complete, our R&D programs or whether, when or to what extent we will generate revenues or cash inflows from the commercialization and sale of any of our therapeutic product candidates. While we are currently focused on advancing each of our product development programs, our future R&D expenses will depend on the determinations we make as to the scientific and clinical prospects of each product candidate, as well as our ongoing assessment of the regulatory requirements and each product candidate's commercial potential.

Given the early stage of development of our therapeutic product candidates, any estimates of when we may be able to commercialize one or more of these products would not be meaningful. Moreover, any estimate of the time and investment required to develop potential products based upon our proprietary HuCNS-SC technologies will change depending on the ultimate approach or approaches we take to pursue them, the results of preclinical and clinical studies, and the content and timing of decisions made by the FDA and other regulatory authorities. There can be no assurance that we will be able to develop any product successfully, or that we will be able to recover our development costs, whether upon commercialization of a developed product or otherwise. We cannot provide assurance that any of these programs will result in products that can be marketed or marketed profitably. If certain of our development-stage programs do not result in commercially viable products, our results of operations could be materially adversely affected.

***Reverse Stock Split***

On May 6, 2016, we effected a one-for-twelve reverse stock split. References to numbers of shares of common stock and per share data have been adjusted to reflect the reverse stock split on a retroactive basis. See Note 1 – Summary of Significant Accounting Policies in the notes to condensed consolidated financial statements of Part I, Item 1 of this Form 10-Q for further information.

***Recent Significant Events***

In January 2016, Dr. Ian Massey who joined our executive team as President and Chief Operating Officer in March 2015, was appointed by the Board of Directors to succeed Martin McGlynn, as the Company's Chief Executive Officer, and elected to the Board.

In March 2016, we sold a total of 2,222,250 shares of common stock, Series A warrants to purchase up to 1,111,125 shares of the Company's common stock, and Series B warrants to purchase up to 1,666,688 shares of our common stock, at a public offering price of approximately \$8,000,000. In addition, pursuant to the underwriters' over-allotment option, we issued additional Series A warrants to purchase up to an additional 166,473 shares of our common stock and additional Series B warrants to purchase up to an additional 249,709 shares of our common stock. We received net proceeds (net of offering expenses, underwriting discounts and commissions), of approximately \$7,100,000 million. The Series A warrants have an initial exercise price of \$3.60 per share, are exercisable immediately, and will expire two years from the date of issuance. The Series B warrants have an initial exercise price of \$5.04 per share, are exercisable 12 months from the date of issuance, provided that the Company has sufficient authorized capital to allow all of the Series B Warrants to be exercised in full by the holders, and will expire on the fifth anniversary of the date they become exercisable.

In April 2016, we provided an update for the six patients enrolled in open label Cohort I from the Pathway Study. The six-month results from Cohort I showed that muscle strength had improved in five of the six patients with four of these five patients also demonstrating improved performance on functional tasks assessing dexterity and fine motor skills. In addition, four of the six patients had improvement in the level of cord injury as measured by ISNCSCI (International Standards for Neurological Classification of Spinal Cord Injury) assessment. We expect to release detailed final twelve-month results on this first open-label cohort by the end of the second quarter of 2016. We currently have thirteen sites in the United States and Canada that are actively recruiting patients. We expect to complete enrollment by the end of the third quarter of 2016, and expect to have final results of this trial before year-end 2017.

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**Table of Contents****Critical Accounting Policies and the Use of Estimates**

The accompanying discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements and the related disclosures, which have been prepared in accordance with U.S. GAAP. The preparation of these condensed consolidated financial statements requires management to make estimates, assumptions, and judgments that affect the reported amounts in our condensed consolidated financial statements and accompanying notes. These estimates form the basis for making judgments about the carrying values of assets and liabilities. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, and we have established internal controls related to the preparation of these estimates. Actual results and the timing of the results could differ materially from these estimates.

***Stock-Based Compensation***

U.S. GAAP requires us to recognize expense related to the fair value of our stock-based payment awards, including employee stock options and restricted stock units. Under the provisions of U.S. GAAP, the fair value of our employee stock-based payment awards is estimated at the date of grant using the Black-Scholes-Merton (Black-Scholes) option-pricing model and is recognized as expense ratably over the requisite service period. The requisite service period is the period over which the awards vest. Stock-based awards may vest over a period of time from the date of grant or upon the attainment of certain established performance milestones. For awards with performance milestones, the expense is recorded over the service period when the achievement of the milestone is probable. The Black-Scholes option-pricing model requires the use of certain assumptions, the most significant of which are our estimates of the expected volatility of the market price of our stock and the expected term of the award. Our estimate of the expected volatility is based on historical volatility. The expected term represents our estimated period during which our stock-based awards remain outstanding. We estimate the expected term based on historical experience of similar awards, giving consideration to the contractual terms of the awards, vesting requirements, and expectation of future employee behavior, including post-vesting terminations.

We review our valuation assumptions at each grant date and, as a result, our assumptions in future periods may change. As of March 31, 2016, we expect to recognize approximately \$4,355,000 of compensation expense related to unvested stock-based awards over a weighted-average period of 1.5 years. See also Note 6, *Stock-Based Compensation*, in the notes to condensed consolidated financial statements of Part I, Item 1 of this Form 10-Q for further information.

***Warrant Liability***

We account for our warrants in accordance with U.S. GAAP which defines how freestanding contracts that are indexed to and potentially settled in a company's own stock should be measured and classified. Authoritative accounting guidance prescribes that only warrants issued by us under contracts that cannot be net-cash settled, and are both indexed to and settled in our common stock, can be classified as equity.

As part of our December 2011 financing, we issued Series A Warrants with a five year term to purchase 666,667 shares at \$16.80 per share and Series B Warrants with a ninety trading day term to purchase 666,667 units at \$15.00 per unit. Each unit underlying the Series B Warrants consisted of one share of our common stock and one Series A Warrant. In the first and second quarter of 2012, an aggregate of 225,000 Series B Warrants were exercised. For the exercise of these warrants, we issued 225,000 shares of our common stock and 225,000 Series A Warrants. The remaining 441,667 Series B Warrants expired unexercised by their terms on May 2, 2012. The Series A Warrants contain full ratchet anti-dilution price protection so that, in most situations, upon the issuance of any common stock or

securities convertible into common stock at a price below the then-existing exercise price of the Series A Warrants, the Series A exercise price will be reset to the lower common stock sales price. As a result of our April 2015 financing, the exercise price of the outstanding Series A warrants were reduced from \$16.80 per share to \$8.40 per share. Subsequently, as a result of our sale of shares of our common stock under a sales agreement entered into in 2009 and amended in 2012, the exercise price of the outstanding Series A warrants were reduced from \$8.40 per share to \$6.24 per share and as a result of our March 2016 financing, the exercise price of these warrants were reduced to approximately \$3.60 per share. As terms of the Series A Warrants do not meet the specific conditions for equity classification, we are required to classify the fair value of these warrants as a liability, with subsequent changes in fair value to be recorded as income (loss) due to change in fair value of warrant liability. The fair value of the Series A Warrants is determined using a Monte Carlo simulation model (see Note 9, Warrant Liability ). The fair value is affected by changes in inputs to these models including our stock price, expected stock price volatility, the contractual term, and the risk-free interest rate. The use of a Monte Carlo simulation model requires input of additional assumptions including the progress of our R&D programs and its effect on potential future financings. We will continue to classify the fair value of the warrants as a liability until the warrants are exercised, expire or are amended in a way that would no longer require these warrants to be classified as a liability. The estimated fair value of our warrant liability at March 31, 2016, was approximately \$512,000.

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In March 2016, we raised gross proceeds of approximately \$8,000,000 through an underwritten public offering of 2,222,250 units, at a price of \$3.60 per unit, before deducting underwriting discounts and other offering expenses. Each unit consists of a fixed combination of one share of our common stock, a Series A Warrant to purchase 0.50 of a share of our common stock, and a Series B Warrant to purchase 0.75 of a share of our common stock. Each Series A Warrant has an exercise price of \$3.60 per share, is immediately exercisable, and will expire two years from the date of issuance. Each Series B Warrant has an exercise price of \$5.04 per share, will become exercisable upon stockholder approval of an increase in our authorized capital and the one year anniversary of the issuance date, whichever is later, and will expire on the fifth anniversary of the date they become exercisable. In connection with the offering, we granted the underwriters a 45 day option to purchase up to an additional 333,338 shares of our common stock and/or warrants to purchase up to an additional 416,672 shares of our common stock to cover over-allotments, if any. The option was exercised in part and we issued an additional 166,473 of Series A warrants and 249,709 of Series B Warrants. The Series A and Series B Warrants contain full ratchet anti-dilution price protection for two years so that, in most situations, upon the issuance of any common stock or securities convertible into common stock at a price below the then-existing exercise price of the Warrants, the exercise price of these warrants will be reset to the lower common stock sales price. The initial shares and warrants were offered under our effective shelf registration statement previously filed with the SEC. We intend to file a subsequent registration statement to register the common shares issuable when the Series B Warrants become exercisable. As terms of the Series A and Series B Warrants do not meet the specific conditions for equity classification, we are required to classify the fair value of these warrants as a liability, with subsequent changes in fair value to be recorded as income (loss) due to change in fair value of warrant liability. The fair value of the Series A and Series B Warrants is determined using a Monte Carlo simulation model (see Note 9, *Warrant Liability* ). The fair value is affected by changes in inputs to these models including our stock price, expected stock price volatility, the contractual term, and the risk-free interest rate. The use of a Monte Carlo simulation model requires input of additional assumptions including the progress of our R&D programs and its effect on potential future financings. We will continue to classify the fair value of the warrants as a liability until the warrants are exercised, expire or are amended in a way that would no longer require these warrants to be classified as a liability. The estimated fair value of our warrant liability for the Series A and Series B warrants at March 31, 2016, was approximately \$1,761,000 and \$3,887,000 respectively.

***Revenue Recognition***

We currently recognize revenue resulting from the licensing and use of our technology and intellectual property. Licensing agreements may contain multiple elements, such as upfront fees, payments related to the achievement of particular milestones and royalties. Revenue from upfront fees for licensing agreements that contain multiple elements are generally deferred and recognized on a straight-line basis over the term of the agreement. Fees associated with substantive at risk performance-based milestones are recognized as revenue upon completion of the scientific or regulatory event specified in the agreement, and royalties received are recognized as earned. Revenue from licensing agreements is recognized net of a fixed percentage due to licensors as royalties.

**Results of Operations**

Our results of operations have varied significantly from year to year and quarter to quarter and may vary significantly in the future due to the occurrence of material recurring and nonrecurring events, including without limitation the receipt and payment of recurring and nonrecurring licensing payments, the initiation or termination of clinical studies, research collaborations and development programs for both cell-based therapeutic products and research tools, unpredictable or unanticipated manufacturing and supply costs, unanticipated capital expenditures necessary to support our business, developments in on-going patent prosecution and litigation, the on-going expenses to maintain our facilities.



**Table of Contents****Revenue**

Revenue for the three-month period ended March 31, 2016, as compared with the same period in 2015, is summarized in the table below:

	Three months ended, March 31		Change in 2016 versus 2015	
	2016	2015	\$	%
Revenue:				
Licensing agreements	\$ 23,164	\$ 20,997	\$ 2,167	10%

*First quarter ended March 31, 2016 versus First quarter ended March 31, 2015.* Total revenue in the first quarter of 2016 was approximately \$23,000 compared to approximately \$21,000 for the first quarter of 2015. Revenue for both years were from licensing agreements.

**Operating Expenses**

Operating expenses for the three-month period ended March 31, 2016, as compared with the same period in 2015, is summarized in the table below:

	Three months ended, March 31		Change in 2016 versus 2015	
	2016	2015	\$	%
Operating expenses:				
Research & development	\$ 5,208,705	\$ 6,292,191	\$ (1,083,486)	(17)%
General & administrative	4,628,334	2,689,196	1,939,138	72%
Total operating expenses	\$ 9,837,039	\$ 8,981,387	\$ 855,652	10%

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**Table of Contents***Research and Development Expenses*

Our R&D expenses consist primarily of salaries and related personnel expenses, costs associated with clinical trials and regulatory submissions, costs associated with preclinical activities such as toxicology studies, costs associated with cell processing and process development, certain patent-related costs such as licensing, facilities related costs such as allocated rent and operating expenses, depreciation, lab equipment and supplies. Clinical trial expenses include payments to vendors such as clinical research organizations, contract manufacturers, clinical trial sites, laboratories for testing clinical samples and consultants. Cumulative R&D costs incurred since we refocused our activities on developing cell-based therapeutics (fiscal years 2000 through the three months ended March 31, 2016) were approximately \$242 million. Over this period, the majority of these cumulative costs were related to: (i) characterization of our proprietary HuCNS-SC cells, (ii) expenditures for toxicology and other preclinical studies, preparation and submission of applications to regulatory agencies to conduct clinical trials and obtaining regulatory clearance to initiate such trials, all with respect to our proprietary HuCNS-SC cells, (iii) preclinical studies and development of our human liver engrafting cells, (iv) costs associated with cell processing and process development, and (v) costs associated with our clinical studies.

We use and manage our R&D resources, including our employees and facilities, across various projects rather than on a project-by-project basis for the following reasons. The allocations of time and resources change as the needs and priorities of individual projects and programs change, and many of our researchers are assigned to more than one project at any given time. Furthermore, we are exploring multiple possible uses for our proprietary HuCNS-SC cells, so much of our R&D effort is complementary to and supportive of each of these projects. Lastly, much of our R&D effort is focused on manufacturing processes, which can result in process improvements useful across cell types. We also use external service providers to assist in the conduct of our clinical trials, to manufacture certain of our product candidates and to provide various other R&D related products and services. Many of these costs and expenses are complementary to and supportive of each of our programs. Because we do not have a development collaborator for any of our product programs, we are currently responsible for all costs incurred with respect to our product candidates.

*First quarter ended March 31, 2016 versus first quarter ended March 31, 2015.* R&D expenses totaled approximately \$5,209,000 in the first quarter of 2016 compared with \$6,292,000 in the first quarter of 2015. The decrease of approximately \$1,083,000, or 17%, in 2016 compared to 2015, was primarily attributable to (i) a decrease in personnel costs of approximately \$659,000 due to a reduction in workforce that was part of a strategic realignment committed to in December 2015, (ii) a reduction in external services of approximately \$379,000 related to preclinical studies of our proprietary HuCNS-SC cells, and (iii) a decrease in other operating expenses of approximately \$45,000.

*General and Administrative Expenses*

General and administrative (G&A) expenses are primarily comprised of salaries, benefits and other staff related costs associated with sales and marketing, finance, legal, human resources, information technology, and other administrative personnel, allocated facilities and overhead costs, external legal and other external general and administrative services.

*First quarter ended March 31, 2016 versus first quarter ended March 31, 2015.* G&A expenses totaled approximately \$4,628,000 in the first quarter of 2016 compared with approximately \$2,689,000 in the same period of 2015. The increase of approximately \$1,939,000, or 72%, in 2016 compared to 2015, was primarily attributable to a net increase of approximately \$1,972,000 in payroll expenses primarily attributable to a separation and consulting agreement with our previous Chief Executive Officer who resigned in January 2016. The separation agreement included expenses of approximately \$1,257,000 in salary and benefits, and approximately \$920,000 in stock based compensation expense for accelerated vesting of his outstanding equity awards (net of cancellations). Excluding expenses related to the



separation agreement, payroll expenses would have decreased by approximately \$205,000 in the first quarter of 2016 compared to the similar period in 2015 primarily due to a reduction in workforce that was part of a strategic realignment committed to in December 2015. The net increase in payroll expenses was partially offset by a net decrease in other expenses of approximately \$33,000.

**Table of Contents****Other Income (Expense)**

Other income totaled approximately \$252,000 in the first quarter of 2016 compared with other expense of approximately \$390,000 in the same period of 2015.

	<b>Three months ended March 31, Change in 2016 versus 2015</b>			
	<b>2016</b>	<b>2015</b>	<b>\$</b>	<b>%</b>
<b>Other income (expense):</b>				
Change in fair value of warrant liability	\$ 278,228	\$ (347,330)	\$ 625,558	(180)%
Interest income	4,243	1,394	2,849	204%
Interest expense	(27,901)	(185,356)	157,455	(85)%
Other income (expense), net	(2,100)	140,981	(143,081)	(101)%
 Total other expense, net	 \$ 252,470	 \$ (390,311)	 \$ 642,781	 (165)%

*Change in Fair Value of Warrant Liability*

We record changes in fair value of warrant liability as income or loss in our condensed consolidated statements of operations. The fair value of the outstanding 2011 Series A warrants and the outstanding 2016 Series A and B warrants are determined using the Monte Carlo simulation model, and is affected by changes in inputs to the model, including our stock price, expected stock price volatility, the contractual term and the risk-free interest rate. The use of a Monte Carlo simulation model requires input of subjective assumptions including the progress of our R&D programs and its affect on potential future financings. The fair value of the warrant liability is revalued at the end of each reporting period. See Note 9 Warrant Liability in the notes to our condensed consolidated financial statements of Part I, Item 1 of this Form 10-Q for further information.

*Interest Income*

Interest income in three-month period ended March 31, 2016 and 2015 were not significant and is from the investment of our cash balances in money market accounts and short-term money market instruments that are highly liquid and that preserves capital.

*Interest Expense*

Interest expense was approximately \$28,000 in the first quarter of 2016 compared with approximately \$185,000 for the first quarter of 2015. Interest expense is primarily attributable to interest due under a Loan Agreement with SVB. See Note 7 Loan Payable, in the notes to condensed consolidated financial statements of Part I, Item 1 of this Form 10-Q for further information.

*Other income (expense), net*

Other expense of approximately \$2,000 for the first quarter of 2016, is primarily related to state franchise taxes. Other income of approximately \$141,000 for the similar period in 2015 was primarily attributable to the gain on sale of our Rhode Island property offset by state franchise taxes paid.

**Liquidity and Capital Resources**

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Since our inception, we have financed our operations through the sale of common and preferred stock, the issuance of long-term debt and capitalized lease obligations, credit facilities, revenue from collaborative agreements, research grants, license fees, and interest income.

	<b>March 31, 2016</b>	<b>December 31, 2015</b>	<b>Change</b>	
			<b>\$</b>	<b>%</b>
Cash , cash equivalents and restricted cash	\$ 11,096,895	\$ 14,533,065	\$ (3,436,170)	(24)%

In summary, our cash flows were:

	<b>Three months ended</b>		<b>Change in 2016 versus 2015</b>	
	<b>March 31, 2016</b>	<b>2015</b>	<b>\$</b>	<b>%</b>
Net cash used in operating activities	\$ (9,236,032)	\$ (8,907,215)	\$ (328,817)	4%
Net cash used in investing activities	\$ (5,934)	\$ (73,069)	\$ 67,135	(92)%
Net cash provided by (used in) financing activities	\$ 5,806,147	\$ (1,829,920)	\$ 7,636,067	417%

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***Net Cash Used in Operating Activities***

Net cash used in operating activities in the three-month period ended March 31, 2016 increased by approximately \$329,000, or 4%, when compared to the same period of 2015. Cash used in operating activities is primarily driven by our net loss as adjusted for non-cash charges and differences in the timing of operating cash flows.

***Net Cash Used in Investing Activities***

Net cash used in investing activities of approximately \$6,000 in the first quarter of 2016 was primarily related to the purchase of lab equipment. In comparison, net cash used in investing activities of approximately \$73,000 in the first quarter of 2015 was primarily related to the purchase of lab equipment for approximately \$222,000, offset by receipts of approximately \$149,000 from the sale of our property in Rhode Island.

***Net Cash Provided by (Used in) Financing Activities***

Net cash of approximately \$5,806,000 provided by financing activities in the first quarter of 2016 was primarily attributable to net proceeds (net of offering expenses underwriting discounts and commissions) of approximately \$7,100,000 received from a financing transaction in March 2016, offset by repayment of loan, lease and other obligations. In comparison, net cash of approximately \$1,830,000 used in financing activities in the three-month period ended March 31, 2015 was primarily attributable to the repayment of loan, lease and other obligations.

We have incurred significant operating losses and negative cash flows since inception. We have not achieved profitability and may not be able to realize sufficient revenue to achieve or sustain profitability in the future. We do not expect to be profitable in the next several years, but rather expect to incur additional operating losses. We have limited liquidity and capital resources and must obtain significant additional capital resources in order to sustain our product development efforts, for acquisition of technologies and intellectual property rights, for preclinical and clinical testing of our anticipated products, pursuit of regulatory approvals, acquisition of capital equipment, laboratory and office facilities, establishment of production capabilities, for general and administrative expenses and other working capital requirements. We rely on cash balances and proceeds from equity and debt offerings, proceeds from the transfer or sale of our intellectual property rights, equipment, facilities or investments, and government grants and funding from collaborative arrangements, if obtainable, to fund our operations.

We intend to pursue opportunities to obtain additional financing in the future through equity and debt financings, grants and collaborative research arrangements. In December 2013, we filed with the SEC, and the SEC declared effective, a universal shelf registration statement which permits us to issue up to \$100 million worth of registered debt and equity securities. Under this effective shelf registration, we have the flexibility to issue registered securities, from time to time, in one or more separate offerings or other transactions with the size, price and terms to be determined at the time of issuance. Registered securities issued using this shelf may be used to raise additional capital to fund our working capital and other corporate needs, for future acquisitions of assets, programs or businesses, and for other corporate purposes. As of April 30, 2016, we had approximately \$3 million under this universal shelf registration statement available for issuing debt or equity securities.

The source, timing and availability of any future financing will depend principally upon market conditions, interest rates and, more specifically, on our progress in our exploratory, preclinical and future clinical development programs. Funding may not be available when needed at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate some or all of our research and product development programs, planned clinical trials, and/or our capital expenditures or to license our potential products or technologies to third parties. In addition, a decline in economic activity, together with the deterioration of the credit and capital

markets, could have an adverse impact on potential sources of future financing.

***Commitments***

See Note 8, *Commitments and Contingencies* in the notes to condensed consolidated financial statements of Part I, Item 1 of this Form 10-Q for further information.

***Off-Balance Sheet Arrangements***

We have certain contractual arrangements that create potential risk for us and are not recognized in our Consolidated Balance Sheets. Discussed below are those off-balance sheet arrangements that have or are reasonably likely to have a material current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources.

**Table of Contents***Operating Leases*

We lease various real properties under operating leases that generally require us to pay taxes, insurance, maintenance, and minimum lease payments. Some of our leases have options to renew.

*Operating Leases - California*

In December 2010, we entered into a commercial lease agreement with BMR-Gateway Boulevard LLC (BMR), as landlord, for office and research space at BMR's Pacific Research Center in Newark, California. The initial term of the lease is approximately eleven and one-half years and includes escalating rent payments which we recognize as lease operating expense on a straight-line basis. We will pay approximately \$17,869,000 in aggregate as rent over the term of the lease to BMR. Deferred rent for this facility was approximately \$1,349,000 as of March 31, 2016, and approximately \$1,372,000 as of December 31, 2015.

In March 2013, we entered into a commercial lease agreement with Prologis, L.P. (Prologis), as landlord, for office and research space in Sunnyvale, California. The facility is for operations that support our clinical development activities. The initial term of the lease is ten years and includes escalating rent payments which we recognize as lease operating expense on a straight-line basis. We will pay approximately \$3,497,000 in aggregate rent over the term of the lease. As part of the lease, Prologis has agreed to provide us financial allowances to build initial tenant improvements, subject to customary terms and conditions relating to landlord-funded tenant improvements. The tenant improvements are recorded as leasehold improvement assets and amortized over the term of the lease. The financial allowances are treated as a lease incentive and recorded as deferred rent which is amortized as reductions to lease expense over the lease term. Deferred rent for this facility was approximately \$379,000 as of March 31, 2016, and approximately \$382,000 as of December 31, 2015.

With the exception of the operating leases discussed above, we have not entered into any significant off balance sheet financial arrangements and have not established any special purpose entities. We have not guaranteed any debts or commitments of other entities or entered into any options on non-financial assets.

*Contractual Obligations*

In the table below, we set forth our legally binding and enforceable contractual cash obligations at March 31, 2016:

	<b>Total Obligations</b>						<b>Payable in</b>
	<b>at</b>	<b>Payable in (April to</b>		<b>Payable in</b>	<b>Payable in</b>	<b>Payable in</b>	<b>2021</b>
	<b>March 31,</b>	<b>December)</b>	<b>Payable in</b>	<b>Payable in</b>	<b>Payable in</b>	<b>Payable in</b>	<b>and</b>
	<b>2016</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>	<b>2020</b>	<b>beyond</b>
Operating lease payments (1)	\$ 13,754,097	\$ 1,481,221	\$ 2,014,706	\$ 2,061,260	\$ 2,108,130	\$ 2,155,325	\$ 3,933,455
Capital lease payment (equipment)	29,933	13,818	11,202	4,913			
Loan payable (principal & interest) (2)	360,169	360,169					

Total contractual  
 cash obligations \$ 14,144,199 \$ 1,855,208 \$ 2,025,908 \$ 2,066,173 \$ 2,108,130 \$ 2,155,325 \$ 3,933,455

- (1) See Note 8, Commitments and Contingencies in the notes to condensed consolidated financial statements of Part I, Item 1 of this Form 10-Q for further information.
- (2) See Note 7, Loan Payable in the notes to condensed consolidated financial statements of Part I, Item 1 of this Form 10-Q for further information.

We periodically enter into licensing agreements with third parties to obtain exclusive or non-exclusive licenses for certain technologies. The terms of certain of these agreements require us to pay future milestone payments based upon achievement of certain developmental, regulatory or commercial milestones. We do not anticipate making any milestone payments under any of our licensing agreements for 2016. Milestone payments beyond fiscal year 2016 cannot be predicted or estimated, due to the uncertainty of achieving the required developmental, regulatory or commercial milestones.

We do not have any material unconditional purchase obligations or commercial commitments related to capital expenditures, clinical development, clinical manufacturing, or other external services contracts at March 31, 2016.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks at March 31, 2016 have not changed materially from those discussed in Item 7A of our Form 10-K for the year ended December 31, 2015 on file with the U.S. Securities and Exchange Commission.

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See also Note 2, Financial Assets, in the notes to condensed consolidated financial statements in Part I, Item 1 of this Form 10-Q.

**ITEM 4. CONTROLS AND PROCEDURES**

In response to the requirement of the Sarbanes-Oxley Act of 2002, as of the end of the period covered by this report, our chief executive officer and chief financial officer, along with other members of management, reviewed the effectiveness of the design and operation of our disclosure controls and procedures. Such controls and procedures are designed to ensure that information required to be disclosed in the Company's Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including the chief executive officer and the chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. Based on this evaluation, the chief executive officer and chief financial officer have concluded that the Company's disclosure controls and procedures are effective.

During the most recent quarter, there were no changes in internal controls over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, these controls of the Company.

**PART II-OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

None.

**ITEM 1A. RISK FACTORS**

There have been no material change from the risk factors disclosed in Part I, Item 1A, of our Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

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

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. MINE SAFETY DISCLOSURES**

None.



ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

- Exhibit 10.1** Letter agreement, dated January 10, 2016, between the Registrant and Martin McGlynn.
- Exhibit 31.1** Certification of Ian J. Massey, Ph.D. under Section 302 of the Sarbanes-Oxley Act of 2002
- Exhibit 31.2** Certification of Gregory Schiffman under Section 302 of the Sarbanes-Oxley Act of 2002
- Exhibit 32.1** Certification of Ian J. Massey, Ph.D. Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- Exhibit 32.2** Certification of Gregory Schiffman Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- Exhibit 101.1** The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 are formatted in XBRL (eXtensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Comprehensive Income, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements.

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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, thereunto duly authorized.

STEMCELLS, INC.

(name of Registrant)

May 10, 2016

/s/ Gregory Schiffman  
Gregory Schiffman  
Chief Financial Officer

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Exhibit Index

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