Neuralstem, Inc.
Form 10-Q
August 11, 2016

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark one)

Quarterly Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934

For the Quarterly Period Ended June 30, 2016

Or

Transition Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934

Commission File Number 001-33672

NEURALSTEM, INC.

(Exact name of registrant as specified in its charter)

Delaware	**52-2007292**
State or other jurisdiction of incorporation or organization	(I.R.S. Employer Identification No.)

20271 Goldenrod Lane
Germantown, Maryland **20876**
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code **(301)-366-4841**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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.

Large accelerated filer Accelerated filer

Non-accelerated filer (Do not check if a small 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

As of July 31, 2016, there were 114,760,960 shares of common stock, $.01 par value, issued and outstanding.

Neuralstem, Inc.

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PART I

FINANCIAL INFORMATION

ITEM 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Neuralstem, Inc.

Unaudited Condensed Consolidated Balance Sheets

	June 30, 2016	December 31, 2015
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$11,128,763	$ 4,716,533
Short-term investments	-	7,517,453
Trade and other receivables	5,085	37,316
Prepaid expenses	705,840	1,159,782
Total current assets	11,839,688	13,431,084
Property and equipment, net	363,192	343,200
Patents, net	1,034,069	1,103,467
Other assets	57,916	71,797
Total assets	$13,294,865	$ 14,949,548
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$2,501,518	$ 1,455,826
Accrued bonuses	-	161,362
Current portion of long-term debt, net of fees and discount	5,905,672	4,545,180
Other current liabilities	204,464	263,104
Total current liabilities	8,611,654	6,425,472
Long-term debt, net of fees, discount and current portion	-	3,382,654
Derivative instruments	3,824,895	-
Other long-term liabilities	21,825	174,144
Total liabilities	12,458,374	9,982,270

Commitments and contingencies (Note 6)

STOCKHOLDERS' EQUITY		
Preferred stock, 7,000,000 shares authorized, zero shares issued and outstanding	-	-
Common stock, $0.01 par value; 300 million shares authorized, 114,760,960 and 92,005,705 shares outstanding in 2016 and 2015, respectively	1,147,610	920,057
Additional paid-in capital	182,101,289	176,002,832
Accumulated other comprehensive income	4,566	3,071
Accumulated deficit	(182,416,974)	(171,958,682)
Total stockholders' equity	836,491	4,967,278
Total liabilities and stockholders' equity	$13,294,865	$ 14,949,548

See accompanying notes to unaudited condensed consolidated financial statements.

Neuralstem, Inc.

Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenues	$2,500	$2,500	$5,000	$5,417
Operating expenses:				
Research and development expenses	2,474,629	3,312,841	5,540,219	6,495,664
General and administrative expenses	1,362,140	1,684,381	4,532,662	3,117,455
Total operating expenses	3,836,769	4,997,222	10,072,881	9,613,119
Operating loss	(3,834,269)	(4,994,722)	(10,067,881)	(9,607,702)
Other income (expense):				
Interest income	13,433	16,084	24,569	29,653
Interest expense	(322,407)	(459,073)	(708,913)	(912,807)
Change in fair value of derivative instruments	757,275	-	757,275	-
Fees related to issuance of derivative instrument and other expenses	(466,541)	(10,326)	(463,342)	(10,326)
Total other income (expense)	(18,240)	(453,315)	(390,411)	(893,480)
Net loss	$(3,852,509)	$(5,448,037)	$(10,458,292)	$(10,501,182)
Net loss per share - basic and diluted	$(0.04)	$(0.06)	$(0.11)	$(0.12)
Weighted average common shares outstanding - basic and diluted	105,835,578	90,791,285	98,887,421	90,004,597
Comprehensive loss:				
Net loss	$(3,852,509)	$(5,448,037)	$(10,458,292)	$(10,501,182)
Foreign currency translation adjustment	3,268	(18)	1,495	(5)
Comprehensive loss	$(3,849,241)	$(5,448,055)	$(10,456,797)	$(10,501,187)

See accompanying notes to unaudited condensed consolidated financial statements.

Neuralstem, Inc.

Unaudited Condensed Consolidated Statements of Cash Flows

	Six Months Ended June 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	$(10,458,292)	$(10,501,182)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	177,498	167,376
Share based compensation expense	2,287,953	1,315,817
Amortization of deferred financing fees and debt discount	203,825	433,596
Change in fair value of derivative instruments	(757,275)	-
Expenses related to issuance of derivative instrument	466,541	-
Changes in operating assets and liabilities:		
Trade and other receivables	32,231	206,706
Prepaid expenses	391,077	(587,344)
Other assets	13,680	1,481
Accounts payable and accrued expenses	955,159	(405,093)
Accrued bonuses	(161,362)	(156,211)
Other current liabilities	(58,640)	138,859
Other long term liabilities	(152,319)	(138,214)
Net cash used in operating activities	(7,059,924)	(9,524,209)
Cash flows from investing activities:		
Purchases of short-term investments	-	(15,032,419)
Maturity of short-term investments	7,517,453	15,007,478
Patent costs	(30,183)	(70,240)
Purchase of property and equipment	(98,088)	(96,019)
Net cash provided by (used in) investing activities	7,389,182	(191,200)
Cash flows from financing activities:		
Proceeds from issuance of common stock from warrants exercised, net	-	3,073,537
Proceeds from sale of common stock and warrants, net of issuance costs	8,308,931	2,931,924
Payment of fees for future financing	-	(42,758)
Payments of long-term debt	(2,225,987)	-
Payments of short-term notes payable	-	(117,068)
Net cash provided by financing activities	6,082,944	5,845,635
Effects of exchange rates on cash	28	(79)
Net increase (decrease) in cash and cash equivalents	6,412,230	(3,869,853)
Cash and cash equivalents, beginning of period	4,716,533	12,518,980

Cash and cash equivalents, end of period	$11,128,763	$8,649,127
Supplemental disclosure of cash flows information:		
Cash paid for interest	$718,989	$481,847
Supplemental schedule of non cash investing and financing activities:		
Issuance of common stock for cashless exercise of options, warrants and RSUs	$8,936	$360,120

See accompanying notes to unaudited condensed consolidated financial statements.

NEURALSTEM, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2016 AND 2015

Note 1. Basis of Presentation and Liquidity

In management's opinion, the accompanying condensed financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations and cash flows. The condensed consolidated balance sheet at December 31, 2015, has been derived from audited financial statements as of that date. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in the financial statements prepared in accordance with generally accepted accounting principles in the United States of America (U.S. GAAP) have been condensed or omitted pursuant to instructions, rules and regulations prescribed by the U.S. Securities and Exchange Commission (SEC). We believe that the disclosures provided herein are adequate to make the information presented not misleading when these condensed financial statements are read in conjunction with the Financial Statements and Notes included in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC, and as may be amended. Certain prior period amounts have been reclassified to conform to current year classifications.

Neuralstem, Inc. is referred to as "Neuralstem," the "Company," "us," or "we" throughout this report. Our wholly-owned and controlled subsidiary located in China is consolidated in our condensed consolidated financial statements and all intercompany activity has been eliminated.

Our operations currently do not generate significant cash. Our management does not know when or if this will change. We have spent and will continue to spend substantial funds in the research, development, clinical and pre-clinical testing of our small molecule product candidates and to a lesser extent on our stem cell product candidates with the goal of ultimately obtaining approval from the United States Food and Drug Administration (the "FDA") and its international equivalents, to market and sell our products.

No assurance can be given that (i) approval will ever be granted for us to market and sell our product candidates, or (ii) that if approval is granted, that we will ever be able to sell our products or be profitable.

Liquidity

The Company has incurred losses since its inception and has not demonstrated an ability to generate revenues from sales or services and has not yet achieved profitable operations. There can be no assurance that profitable operations will ever be achieved, or if achieved, could be sustained on a continuing basis. In addition, development activities,

clinical and pre-clinical testing, and commercialization of our products will require significant additional financing. These factors create substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustment that might be necessary if the Company is unable to continue as a going concern.

Our cash and cash equivalents balance at June 30, 2016 was approximately $11.1 million. Our ability to continue as a going concern is wholly dependent upon obtaining sufficient financing to fund our operations.

On April 20, 2016, we received a written notice from the Nasdaq Stock Market LLC that we are not in compliance with Nasdaq Listing Rule 5550(a)(2), as the minimum bid price of our common stock has been below $1.00 per share for 30 consecutive business days. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have a period of 180 calendar days, or until October 17, 2016, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must meet or exceed $1.00 per share for at least ten consecutive business days during this 180 calendar day period. In the event we do not regain compliance by October 17, 2016, we may be eligible for an additional 180 calendar day grace period if we meet the initial listing standards, with the exception of bid price, for the Nasdaq Capital Market, and provide written notice to Nasdaq of our intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. If we do not regain compliance within the allotted compliance period(s), including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that our common stock will be subject to delisting. We will then be entitled to appeal the determination to a Nasdaq Listing Qualifications Panel and request a hearing. We cannot be sure that our share price will comply with the requirements for continued listing of our shares on the Nasdaq Capital Market in the future or that we will comply with the other continued listing requirements, including the MVLS requirement as described below. If our shares lose their status on the Nasdaq Capital Market, we believe that our shares would likely be eligible to be quoted on the inter-dealer electronic quotation and trading system operated by Pink OTC Markets Inc., commonly referred to as the Pink Sheets and now known as the OTCQB market. These markets are generally considered not to be as efficient as, and not as broad as, the Nasdaq Capital Market. If our common stock is delisted, this would, among other things, substantially impair our ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for us.

On August 8, 2016, we received a written notice from the Nasdaq Stock Market LLC that we are not in compliance with Nasdaq Listing Rule 5550(b)(2), as our market value of listed securities ("MVLS") was below $35 million for the previous 30 consecutive business days. In accordance with Nasdaq Listing Rule 5810(c)(3)(C), we have a period of 180 calendar days, or until February 7, 2017, to regain compliance with the minimum MVLS requirement. To regain compliance, our MVLS must close at $35 million or more for a minimum of 10 consecutive business days during the 180 day calendar period. In the event we do not regain compliance by the allotted compliance period, Nasdaq will provide notice that our common stock will be subject to delisting. We will then be entitled to appeal the determination to a Nasdaq Hearings Panel.

In the event that we are able to comply with the $1.00 minimum bid requirements or the MVLS requirements, there can be no assurances that we will be able to comply with both. Accordingly, our failure to meet either of these requirements during the required compliance period(s) may result in having our common stock delisted from the Nasdaq Capital Market.

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On May 3, 2016, we completed a public offering of 20,000,000 shares of common stock and 20,000,000 common stock purchase warrants at a public offering price of $0.40 per each share and common stock purchase warrant. We received aggregate gross proceeds of $8.0 million and net proceeds of approximately $7,229,000 from the offering. See Note 5.

On May 12, 2016, we entered into private placement securities purchase agreements with certain accredited investors to purchase 2,700,000 of common stock and 2,700,000 common stock purchase warrants at a price of $0.40 per each share and common stock purchase warrant. We received aggregate gross proceeds of approximately $1,080,000 and net proceeds of approximately $925,000. See Note 5.

On May 20, 2016, we announced that we had committed to a cost-reduction plan in order to better utilize our resources on the implementation of our refocused clinical and corporate strategy. This cost-reduction plan includes a reduction in force across all of the Company’s departments. See Note 7.

The May offerings and cost-reduction plan have provided us with funds which we believe will be sufficient to finance operations at least through December 31, 2016. If we do not obtain additional funds by such time, we may no longer be able to continue as a going concern and will cease operation which means that our shareholders may lose their entire investment.

Note 2. Significant Accounting Policies and Recent Accounting Pronouncements

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The condensed consolidated financial statements include significant estimates for the expected economic life and value of our licensed technology, our net operating loss and related valuation allowance for tax purposes and our stock-based compensation related to employees and directors, consultants and investment banks, among other things. Because of the use of estimates inherent in the financial reporting process, actual results could differ significantly from those estimates.

Fair Value Measurements

The carrying amounts of our short-term financial instruments, which primarily include cash and cash equivalents, other short-term investments, accounts payable and accrued expenses, approximate their fair values due to their short maturities.

Foreign Currency Translation

The functional currency of our wholly owned foreign subsidiary is its local currency. Assets and liabilities of our foreign subsidiary are translated into United States dollars based on exchange rates at the end of the reporting period; income and expense items are translated at the weighted average exchange rates prevailing during the reporting period. Translation adjustments for subsidiaries that have not been sold, substantially liquidated or otherwise disposed of are accumulated in other comprehensive income or loss, a component of stockholders' equity. Transaction gains or losses are included in the determination of net loss.

Cash, Cash Equivalents, Short-Term Investments and Credit Risk

Cash equivalents consist of investments in low risk, highly liquid money market funds and certificates of deposit with original maturities of 90 days or less. Cash deposited with banks and other financial institutions may exceed the amount of insurance provided on such deposits. If the amount of a deposit at any time exceeds the federally insured amount at a bank, the uninsured portion of the deposit could be lost, in whole or in part, if the bank were to fail.

Short-term investments consist entirely of fixed income certificates of deposit (“CDs”) with original maturities of greater than 90 days and not more than one year.

Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash equivalents and short-term investments. Our investment policy, approved by our Board of Directors, limits the amount we may invest in any one type of investment issuer, thereby reducing credit risk concentrations. In addition, our certificates of deposit are typically invested through the Certificate of Deposit Account Registry Service (“CDARS”) program which reduces or eliminates our risk related to concentrations of investments above FDIC insurance levels. We attempt to limit our credit and liquidity risks through our investment policy and through regular reviews of our portfolio against our policy. To date, we have not experienced any loss or lack of access to cash in our operating accounts or to our cash equivalents and short-term investments.

Research and Development

Research and development costs are expensed as they are incurred. Research and development expenses consist primarily of costs associated with the pre-clinical development and clinical trials of our product candidates.

Income (Loss) per Common Share

Basic income (loss) per common share is computed by dividing total net income (loss) available to common shareholders by the weighted average number of common shares outstanding during the period.

For periods of net income when the effects are dilutive, diluted earnings per share is computed by dividing net income available to common shareholders by the weighted average number of shares outstanding and the dilutive impact of all dilutive potential common shares. Dilutive potential common shares consist primarily of stock options, restricted stock units and common stock purchase warrants. The dilutive impact of potential common shares resulting from common stock equivalents is determined by applying the treasury stock method. Our unvested restricted shares contain non-forfeitable rights to dividends, and therefore are considered to be participating securities; the calculation of basic and diluted income per share excludes net income attributable to the unvested restricted shares from the numerator and excludes the impact of the shares from the denominator.

For all periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive due to the net losses; accordingly, diluted loss per share is the same as basic loss per share for the three-and six-month periods ended June 30, 2016 and 2015. A total of approximately 62.6 million and 38.9 million potential dilutive shares have been excluded in the calculation of diluted net income per share for the three- and six-month periods ended June 30, 2016 and 2015, respectively, as their inclusion would be anti-dilutive.

Share-Based Compensation

We account for share-based compensation at fair value. Share-based compensation cost for stock options and warrants granted to employees and board members is generally determined at the grant date while awards granted to non-employee consultants are generally valued at the vesting date using an option pricing model that uses level 3 unobservable inputs; share-based compensation cost for restricted stock and restricted stock units is determined at the grant date based on the closing price of our common stock on that date. The value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period.

Intangible and Long-Lived Assets

We evaluate our long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. We assess this recoverability by comparing the carrying amount of the asset to the estimated undiscounted future cash flows to be generated by the asset. If an asset is deemed to be

impaired, we estimate the impairment loss by determining the excess of the asset's carrying amount over the estimated fair value. During the six months ended June 30, 2016 and 2015, no significant impairment losses were recognized.

Income Taxes

We account for income taxes using the asset and liability approach, which requires the recognition of future tax benefits or liabilities on the temporary differences between the financial reporting and tax bases of our assets and liabilities. A valuation allowance is established when necessary to reduce deferred tax assets to the amounts expected to be realized. We also recognize a tax benefit from uncertain tax positions only if it is "more likely than not" that the position is sustainable based on its technical merits. Our policy is to recognize interest and penalties on uncertain tax positions as a component of income tax expense.

Significant New Accounting Pronouncements

In April 2015, the FASB issued *ASU 2015-03 – Interest-Imputation of Interest, Simplifying the Presentation of Debt Issuance Costs*. This Change in Accounting Principle requires that deferred debt issuance costs related to a recognized debt liability be presented in the balance sheet as a deduction of the carrying amount of the debt liability (similar to debt discounts). This change is effective for fiscal years beginning after December 15, 2015 and early adoption is permitted. This change has been applied retrospectively. This new pronouncement results in our reclassifying amounts previously reflected as current and long-term assets to a contra-liability, which reduces the carrying value of the associated debt instruments. To conform to this standard, approximately $90,000 was reclassified on our December 31, 2015 balance sheet from current assets to current portion of long term debt and approximately $9,000 was reclassified from non-current assets to long term debt.

In August 2014, the FASB issued *ASU No. 2014-15, Presentation of Financial Statements – Going Concern*. This ASU requires entities to evaluate for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). The ASU will become effective for annual reporting periods after December 15, 2016. The Company is currently evaluating the impact of the adoption of this ASU on its consolidated financial statements.

In February 2016, the FASB issued *ASU 2016-02, Leases*. This ASU requires the recognition of lease assets and lease liabilities on the balance sheet and disclosure of key information about leasing arrangements. This ASU will become effective for annual periods beginning after December 15, 2018. The Company is currently evaluating the impact of the adoption of this ASU on its consolidated financial statements.

In March 2016, the FASB issued *ASU 2016-09, Improvements to Employee Share Based Payment Accounting*. This ASU address areas for simplification in several aspects of accounting for share-based payment including income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The ASU will become effective for annual reporting periods after December 15, 2016. The Company is currently evaluating the impact of the adoption of this ASU on its consolidated financial *statements.*

The Company has reviewed other recent accounting pronouncements released during the quarter and concluded that they are either not applicable to the business, or that no material effect is expected on the consolidated financial statements as a result of future adoption.

Note 3. Fair Value Measurements

Fair value is the price that would be received from the sale of an asset or paid to transfer a liability assuming an orderly transaction in the most advantageous market at the measurement date. U.S. GAAP establishes a hierarchical disclosure framework which prioritizes and ranks the level of observability of inputs used in measuring fair value. These levels are:

- *Level 1* – inputs are based upon unadjusted quoted prices for identical instruments traded in active markets.

Level 2 – inputs are based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-based valuation techniques (e.g. the Black-Scholes model) for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs including interest rate curves, foreign exchange rates, and forward and spot prices for currencies and commodities.

Level 3 – inputs are generally unobservable and typically reflect management's estimates of assumptions that market participants would use in pricing the asset or liability. The fair values are therefore determined using model-based techniques, including option pricing models and discounted cash flow models.

Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

We have segregated our financial assets and liabilities that are measured at fair value into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date.

The inputs used in measuring the fair value of cash and cash equivalents are considered to be Level 1 in accordance with the three-tier fair value hierarchy. The fair values are based on period-end statements supplied by the various banks and brokers that held the majority of our funds. The fair value of all other financial instruments (prepaid expenses, accounts payable, accrued expenses and long-term debt) approximate their carrying values because of their short-term nature.

At June 30, 2016, we had certain common stock purchase warrants issued in connection with our May 2016 capital raises (See Note 5)

that are accounted for as derivative instruments whose fair value was determined using Level 3 inputs. The following table identifies the carrying amounts of such assets and liabilities at June 30, 2016:

	Level 1	Level 2	Level 3	Total
Liabilities				
Derivative instruments - stock purchase warrants	$ -	$ -	$3,824,895	$3,824,895
Balance at June 30, 2016	$ -	$ -	$3,824,895	$3,824,895

We had no financial assets or liabilities measured at fair value using level 3 inputs on a recurring basis at December 31, 2015.

The following table presents the activity for those items measured at fair value on a recurring basis using Level 3 inputs for the six months ended June 30, 2016:

	Derivative instruments - stock purchase warrants
Balance at December 31, 2015	$-
Issuance of warrants	4,582,170
Change in fair value	(757,275)
Balance at June 30, 2016	$3,824,895

The (gains) losses resulting from the changes in the fair value of the derivative instruments are classified as the “change in the fair value of derivative instruments” in the accompanying condensed statements of operations. The fair value of the common stock purchase warrants is determined based on the Black-Scholes option pricing model for “plain vanilla” stock options and other option pricing models as appropriate, and includes the use of unobservable inputs such as the expected term, anticipated volatility and expected dividends. Changes in any of the assumptions related to the unobservable inputs identified above may change the embedded conversion options’ fair value; increases in expected term, anticipated volatility and expected dividends generally result in increases in fair value, while decreases in these unobservable inputs generally result in decreases in fair value.

Note 4. Debt

In October 2014, we entered into an agreement with the existing lender to refinance and amend the terms of our March 2013 loan and security agreement. The amended loan provided for refinancing of approximately $5.6 million of outstanding balance of the initial loan along with approximately $4.4 million of new principal for a total of $10 million in principal. The amended loan provides for a variable interest rate based on prime with a floor of 10% and matures in April 2017. The loan provides for interest only payments through September 2015; payments of principal and interest of approximately $461,000 from October 2015 through December 2016, and principal and interest of approximately $435,000 from January, 2016 through March 2017 and a final balloon payment of approximately $2.8 million in April 2017. The loan amendment generated approximately $4.3 million in net proceeds after fees and expenses. The loan amendment is accounted for as a debt extinguishment in accordance with guidance provided for in ASC 470, Debt resulting in a loss on extinguishment of approximately $446,000. In conjunction with the loan amendment we recorded a debt discount relating to the beneficial conversion feature. Such discount is being amortized as interest expense over the term of the debt using the effective interest method.

In conjunction with the loan amendment, we issued the lender a five-year common stock purchase warrant to purchase 75,188 shares of common stock at an exercise price of $2.66 per share. The warrant contains standard anti-dilution protection but does not contain any anti-dilution price protection for subsequent offerings. The value of the warrant

was accounted for in calculating the loss on extinguishment.

We also incurred expenses with various third parties in connection with the loan amendment, consisting of approximately $86,000 in cash, 28,119 shares of common stock valued at approximately $80,000, and a three-year common stock purchase warrant to purchase 58,141 shares at an exercise price of $2.66 per share. The warrant is classified as equity and has terms substantially similar to the lender warrant. These fees related to the loan amendment are recorded as a deferred financing fees netted against the carrying amount of the loan and are being amortized as interest expense over the term of the debt using the effective interest method.

At June 30, 2016, remaining principal payments due under this loan are approximately $2,344,000 and $3,766,000 payable in the remainder of 2016 and 2017, respectively.

Note 5. Stockholders' Equity

We have granted share-based compensation awards to employees, board members and service providers. Awards may consist of common stock, restricted common stock, restricted common stock units, warrants, or stock options. Our stock options and warrants have lives of up to ten years from the grant date. The stock options and warrants vest either upon the grant date or over varying periods of time. The stock options we grant provide for option exercise prices equal to or greater than the fair value of the common stock at the date of the grant. Restricted stock units grant the holder the right to receive fully paid common shares with various restrictions on the holder's ability to transfer the shares. Vesting of the restricted stock units is similar to that of stock options. As of June 30, 2016, we have approximately 67.6 million shares of common stock reserved for issuance upon the exercise of such awards.

Share-based compensation expense included in the statements of operations is as follows:

	Three Months Ended June 30,	
	2016	2015
Research and development expenses	$264,137	$294,574
General and administrative expenses	552,930	331,385
Total	$817,067	$625,959

	Six Months Ended June 30,	
	2016	2015
Research and development costs	$973,553	$572,754
General and administrative expenses	1,314,400	743,063
Total	$2,287,953	$1,315,817

Included in the general and administrative expense for the six months ended June 30, 2016 is approximately $407,000 related to the acceleration of the vesting of options for the previous CEO who left during the first quarter. In addition, approximately $42,000 and $15,000 is included in research and development and general and administrative expenses, respectively for the three- and six- month periods ended June 30, 2016 related to the modification of certain awards in conjunction with our corporate reorganization. See Note 7.

No income tax benefit was recognized in the consolidated statements of operations for stock-based compensation for the years presented due to the Company’s net loss position.

Stock Options

We have granted stock options to our employees, board members and service providers.

A summary of stock option activity during the six months ended June 30, 2016 and related information is included in the table below:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value

Outstanding at January 1, 2016	17,102,947	$ 2.08	5.0	$550,000
Granted	3,809,944	$ 0.77		
Exercised	-			$-
Forfeited	(213,976)	$ 0.86		
Outstanding at June 30, 2016	20,698,915	$ 1.85	5.2	$-
Exercisable at June 30, 2016	15,741,392	$ 2.13	4.2	$-
Vested and expected to vest	20,451,039	$ 1.86	5.2	$-

Range of Exercise Prices	Number of Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
$0.50 - $1.00	7,829,776	$ 0.84	7.4	$ -
$1.01 - $2.00	5,043,643	$ 1.17	5.5	-
$2.01 - $3.00	2,121,202	$ 2.50	3.0	-
$3.01 - $5.00	5,704,294	$ 3.60	2.9	-
	20,698,915	$ 1.85	5.2	$ -

The Company uses the Black-Scholes option pricing model for “plain vanilla” options and other pricing models as appropriate to calculate the fair value of options. Significant assumptions used in these models include:

	Six Months Ended June 30,	
	2016	2015
Annual dividend	-	-
Expected life (in years)	5.8 - 7.3	5.8 - 6.0
Risk free interest rate	1.35% - 1.75%	1.70% - 1.78%
Expected volatility	69.0% - 80.2%	69.3% - 71.8%

The options granted in the six months ended June 30, 2016 and 2015 had a weighted average grant date fair value of $0.56 and $2.26, respectively.

Unrecognized compensation cost for unvested stock option awards outstanding at June 30, 2016 was approximately $3,147,000 to be recognized over approximately 1.8 years.

RSUs

We have granted restricted stock units (RSUs) to certain employees and board members that entitle the holders to receive shares of our common stock upon vesting and subject to certain restrictions regarding the exercise of the RSUs. The fair value of RSUs granted is based upon the market price of the underlying common stock as if they were vested and issued on the date of grant.

A summary of our restricted stock unit activity for the six months ended June 30, 2016 is as follows:

	Number of RSU's	Weighted-Average Grant Date Fair Value
Outstanding at January 1, 2016	150,906	$ 2.13
Granted	-	
Exercised and converted to common shares	(55,255)	$ 1.77
Forfeited	(6,465)	$ 2.02
Outstanding at June 30, 2016	89,186	$ 2.36
Exercisable at June 30, 2016	89,186	$ 2.36

The total intrinsic value of the outstanding restricted stock units at June 30, 2016 was approximately $26,000. The total value of all restricted stock units that were converted in the six months ended June 30, 2016 was approximately $35,000.

Restricted Stock

We have granted restricted stock to certain board members.

A summary of our restricted stock activity for the six months ended June 30, 2016 is as follows:

	Shares of Restricted Stock	Weighted-Average Grant Date Fair Value
Outstanding at January 1, 2016	213,904	$ 1.87
Granted	-	
Vested	(213,904)	$ 1.87
Forfeited	-	
Outstanding at June 30, 2016	-	

All restricted stock was vested as of June 30, 2016. The total intrinsic value of all restricted stock vested in the six months ended June 30, 2016 was approximately $111,000.

Stock Purchase Warrants. In the past, we have issued Warrants to purchase common stock to certain officers, directors, stockholders and service providers as well as in conjunction with debt and equity offerings and at various times replacement warrants were issued as an inducement for warrant exercises.

In May 2016, we issued 22,700,000 stock purchase warrants in conjunction with our equity raise transactions. Such warrants are classified as derivative liabilities and are recorded at fair value each period due to the existence of non-standard anti-dilution conditions contained in the warrants. See Note 3.

A summary of warrant activity for the six months ended June 30, 2016 is as follows:

	Number of Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2016	19,652,096	$ 2.34	3.1	$309,724
Granted	22,700,000	$ 0.40		
Exercised	-			$-
Forfeited	(440,000)	$ 1.25		
Outstanding at June 30, 2016	41,912,096	$ 1.30	3.9	$-
Exercisable at June 30, 2016	41,912,096	$ 1.30	3.9	$-

Common Stock

During the six months ended June 30, 2015, we issued 812,423 shares of common stock as a result of sales under our At the Market Offering Agreement. The shares were sold at an average price of $3.77 per share and we received approximately $2,932,000 in net proceeds.

During the six months ended June 30, 2015, we issued 1,705,400 shares of common stock upon the exercise of outstanding common stock purchase warrants. The warrants were exercised at an average exercise price of $1.94. We received approximately $3,074,000 of net proceeds from the exercises.

During the six months ended June 30, 2015, we issued 52,259 shares of our common stock upon the cashless exercise of 209,000 outstanding common stock purchase warrants and stock options. The warrants and options were exercised at an average price of $1.72. We received no proceeds from the exercises.

During the six months ended June 30, 2016, we issued 55,255 shares of our common stock upon the conversion of 61,720 outstanding restricted stock units.

On May 03, 2016, we completed a public offering of 20,000,000 shares of common stock and 20,000,000 common stock purchase warrants at a public offering price of $0.40 per each share and common stock purchase warrant. We received aggregate gross proceeds of $8.0 million and net proceeds of approximately $7,229,000 from the offering. The warrants allow the holder to purchase one share of common stock, have an exercise price of $0.40 per share and a term of 5 years. The warrants contain certain non-standard anti-dilution protection and consequently, are being accounted for as derivative instruments recorded at fair value each period (See Note 3). The costs directly related to this offering were allocated between the common stock and the derivative instruments with those being allocated to the derivative instruments being expensed as incurred and those allocated to the common stock being charged directly to additional paid-in capital. This offering was made pursuant to our shelf registration statement declared effective by the SEC on June 19, 2014 (Registration No. 333-196567).

On May 12, 2016, we entered into private placement securities purchase agreements with certain accredited investors to purchase 2,700,000 of common stock and 2,700,000 common stock purchase warrants at a price of $0.40 per each share and common stock purchase warrant. We received aggregate gross proceeds of approximately $1,080,000 and net proceeds of approximately $925,000. The warrants allow the holder to purchase one share of common stock, have an exercise price of $0.40 per share and a term of 5 years. The warrants contain certain non-standard anti-dilution protection and consequently, are being accounted for as derivative instruments recorded at fair value each period (See Note 3). The costs directly related to this offering were allocated between the common stock and the derivative instruments with those being allocated to the derivative instruments being expensed as incurred and those allocated to the common stock being charged directly to additional paid-in capital. This private placement transaction was not made pursuant to any registration statement.

Note 6. Commitments and Contingencies

We currently operate three facilities located in the United States and one facility located in People’s Republic of China. Our corporate offices and primary research facilities are located in Germantown, Maryland, where we license approximately 1,500 square feet. This license provides for monthly payments of approximately $5,300 per month, expires on December 31, 2016 and can be terminated by us upon 60 days written notice.

In 2015, we entered into a lease consisting of approximately 3,100 square feet of research space in San Diego, California. This lease provides for current monthly payments of approximately $11,000 and expires on August 31, 2018. In conjunction with our recent cost-reduction exercise, we are currently exploring opportunities to sub-lease this facility.

In 2016, we entered into a license for an Incubator Laboratory Facility in Urbana, Illinois. The license provides for monthly payments of $1,800, expires on December 31, 2019 and can be terminated by us upon 90 days written notice.

We also lease a research facility in People's Republic of China. This lease expires on September 30, 2018 with lease payments of approximately $3,200 per month.

From time to time, we are parties to legal proceedings that we believe to be ordinary, routine litigation incidental to the business of present or former operations. We are currently not a party to any litigation or legal proceeding.

The Company is currently obligated under three written employment agreements and a general release agreement. The employment agreements are with our: (i) Chief Executive Officer, (ii) Chief Scientific Officer ("CSO") and (iii) Chief Financial Officer ("CFO"): Pursuant to the terms of the agreements, our CEO, CSO and CFO receive annual salaries of $410,000, $490,000 and $315,000, respectively. The agreements also provide for the payment of severance in the event one of the executives is terminated and in certain circumstances, the agreements also provide for the acceleration of vesting with regard to options.

On March 1, 2016, Neuralstem, Inc. (the "Company") entered into a General Release and Waiver of Claims ("General Release") with I. Richard Garr in connection with his resignation as the Company's chief executive officer. Pursuant to the General Release, Mr. Garr will: (i) continue to receive his monthly salary of $36,667 until March 1, 2017, (ii) receive lump sum payments of $177,000 to be paid on June 1, 2016, January 1, 2017 and March 1, 2017, (iii) receive healthcare benefits until January 1, 2017, and (iv) be entitled to the immediate vesting of any previously outstanding but unvested equity awards (collectively, the "Severance"). This General Release and Waiver of Claims was amended on June 16, 2016, whereupon Mr. Garr voluntarily agreed to forego the lump sum payments due to him on January 1, 2017 and March 1, 2017.

Note 7. Cost-Reduction Plan

On May 20, 2016 we announced that we had committed to a cost-reduction plan in order to better utilize our resources on the implementation of our refocused clinical and corporate strategy. This cost-reduction plan includes a reduction in force across all of the Company's departments. With the exception of an on-going lease obligations on our facility in San Diego, California we have completed this cost-reduction plan in the quarter ended June 30, 2016. As a result of this cost-reduction plan we incurred total costs of approximately $470,000 comprised of $413,000 for severance and other employee payments, and $57,000 of non-cash costs for modification of employee stock options. Of the total expense, $312,000 is included in research and development expense and $158,000 is included in general and administrative expense in our statement of operations for the three and six months ended June 30, 2016. At June 30, 2016, a balance of approximately $72,000 remained to be paid and such balance is reflected as an accrued expense in our unaudited condensed consolidated balance sheet.

Our facility in San Diego, California consists of 3,100 square feet of research space. This lease provides for current monthly payments of approximately $11,000 and expires on August 31, 2018. We are currently exploring opportunities to sub-lease this facility.

Note 8. Subsequent Events

On August 10, 2016, the Company entered into a reimbursement agreement with a former executive officer of the Company. Pursuant to the reimbursement agreement, the former officer agreed to repay the Company over a six-year period, approximately $670,000 in expenses that the Company determined to have been improperly paid under the Company's prior expense reimbursement policies. In addition to this reimbursement agreement, the Company has implemented and is continuing to implement enhanced policies and procedures for travel expense reimbursements and disbursements.

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

Statements in this Quarterly Report that are not strictly historical are forward-looking statements and include statements about products in development, results and analyses of pre-clinical studies, clinical trials and studies, research and development expenses, cash expenditures, and alliances and partnerships, among other matters. You can identify these forward-looking statements because they involve our expectations, intentions, beliefs, plans, projections, anticipations, or other characterizations of future events or circumstances. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that may cause actual results to differ materially from those in the forward-looking statements as a result of any number of factors. These factors include, but are not limited to, risks relating to our ability to conduct and obtain successful results from ongoing clinical trials, commercialize our technology, obtain regulatory approval for our product candidates, contract with third parties to adequately test and manufacture our proposed therapeutic products, protect our intellectual property rights and obtain additional financing to continue our development efforts. Some of these factors are more fully discussed, as are other factors, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, filed with the SEC, as well as in the section of this Quarterly Report entitled "Risk Factors" and elsewhere herein. We do not undertake to update any of these forward-looking statements or to announce the results of any revisions to these forward-looking statements except as required by law.

We urge you to read this entire Quarterly Report on Form 10-Q, including the "Risk Factors" section, the financial statements, and related notes. As used in this Quarterly Report, unless the context otherwise requires, the words "we," "us," "our," "the Company," "Neuralstem" and "Registrant" refers to Neuralstem, Inc. and its subsidiaries. Also, any reference "common shares," "common stock," or "shares" refers to our $.01 par value common stock. The information contained herein is current as of the date of this Quarterly Report (June 30, 2016), unless another date is specified. We prepare our interim financial statements in accordance with U.S. GAAP. Our financials and results of operations for the three- and six-month periods ended June 30, 2016 are not necessarily indicative of our prospective financial condition and results of operations for the pending full fiscal year ending December 31, 2016. The interim financial statements

presented in this Quarterly Report as well as other information relating to our Company contained in this Quarterly Report should be read in conjunction and together with the reports, statements and information filed by us with the United States Securities and Exchange Commission or SEC.

Our Management's Discussion and Analysis of Financial Condition and Results of Operations or MD&A, is provided in addition to the accompanying financial statements and notes to assist readers in understanding our results of operations, financial condition and cash flows. Our MD&A is organized as follows:

- *Executive Overview* — Discussion of our business and overall analysis of financial and other highlights affecting the Company in order to provide context for the remainder of MD&A.

- *Trends & Outlook* — Discussion of what we view as the overall trends affecting our business and overall strategy.

- *Critical Accounting Policies*— Accounting policies that we believe are important to understanding the assumptions and judgments incorporated in our reported financial results and forecasts.

- *Results of Operations*— Analysis of our financial results comparing the three-month and six-month periods ended June 30, 2016 to the comparable period of 2015.

- *Liquidity and Capital Resources*— An analysis of cash flows and discussion of our financial condition and future liquidity needs.

Executive Overview

We are focused on the research, development and commercialization of central nervous system therapies based on our proprietary human neural stem cells and small molecule compounds discovered from our stem cell-based screening platform. We are headquartered in Germantown, Maryland and have a wholly-owned subsidiary in China, Suzhou Neuralstem Biopharmaceutical Co. Ltd ("Neuralstem China").

Our technology base has produced three primary assets: Our NSI-189 small molecule program, our NSI-566 stem cell therapy program and our novel and proprietary new chemical entity screening platform.

Our patented technology enables the commercial-scale production of multiple types of central nervous system stem cells, which are under development for the potential treatment of central nervous system diseases and conditions. In addition, this ability to generate human neural stem cell lines provides a platform for new chemical entity screening and discovery of novel compounds that we believe may have the capacity to treat a broad array of pathologies associated with certain central nervous system (CNS) conditions. This proprietary screening platform led to our discovery of NSI-189.

We have developed and maintain what we believe is a strong portfolio of patents and patent applications that form the proprietary base for our research and development efforts. We own or exclusively license over 20 U.S. issued and pending patents and over 120 foreign issued and pending patents in the field of regenerative medicine, related to our stem cell technologies as well as our small molecule compounds.

We believe our technology base, in combination with our expertise, and collaborative projects with major research institutions, could facilitate the development and commercialization of products for use in the treatment of a wide array of central nervous system disorders including neurodegenerative conditions and regenerative repair of acute and chronic diseases.

There can be no assurances that we will ultimately produce any viable products or processes or that our screening platform will lead to the discovery of any additional product candidates. Even if we are able to produce a commercially viable product, there are strong competitors in this field and our products may not be able to successfully compete against them.

All of our research efforts to date are at the pre-clinical or clinical stage of development. We are focused on leveraging our key assets, including our intellectual property, proprietary technology, scientific team and facilities, to advance our technologies and clinical programs. In addition, we are pursuing strategic collaborations with members of academia and industry to further advance and discover additional product candidates.

Recent Clinical & Business Highlights

- In January 2016, we announced a strategic refocusing to concentrate the Company's resources on our NSI-189 small molecule program. As part of this refocusing, the Company announced that it will seek external funding to defray all, or substantially all, of the costs associated with the NSI-566 stem cell therapy program. The Company is in active conversations with a number of sources of funding to achieve this goal and minimize any delay in progressing our stem cell therapy programs.

- In February 2016, we strengthened our management team with the appointment of Richard Daly as our President and Chief Executive Officer. Additionally, in June 2016, Mr. Daly was appointed as Chairman of the Board.

- In May 2016, we completed a public offering of securities and, separately, a private placement of securities which resulted in total gross proceeds of $9.1 million and net proceeds of approximately $8.2 million from the offerings.

- In May 2016, we underwent a reduction in force to better align our organization with our refocused corporate strategy. We undertook the following cost savings measures during the second quarter of 2016:

  - The Compensation of our non-employee directors was reduced from $200,000 to $100 per annum.

  - Richard Daly, CEO and Dr. Karl Johe, CSO, voluntarily agreed to salary reductions.

  - Richard Garr, the Company's former CEO and President, voluntarily took a reduction in his severance payments, resulting in savings to the Company of approximately $354,000.

  - The Compensation Committee determined to defer all compensation under the non-employee director compensation policy for the year 2016 until such time as we are adequately funded, or the shareholders approve an amendment to one of the equity compensation plans to increase the number of shares, but in no event prior to July 1, 2017.

- In May 2016, we enrolled the first subject in our NSI-189 Phase 2 clinical trial for the treatment of Major Depressive Disorder (MDD).

- In June 2016, we announced that new in vitro data on NSI-189 which showed enhancement of long-term potentiation (LTP) in mouse models and contributed to the understanding of 189's mechanism of action.

Clinical Development Program Review

We have devoted substantially all our efforts to the pre-clinical and clinical development of our small molecule compounds and our stem cell therapeutics. Below is a description of our most advanced clinical programs, their intended indication, current stage of development and our expected future development plans:

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Clinical Pipeline:

Pipeline Summary

NSI-189 Phase 2 clinical trial for the treatment of MDD

- In May 2016, we enrolled the first subject in our NSI-189 Phase 2 clinical trial for the treatment of MDD. The Phase 2 trial will randomize 220 patients, in three cohorts (two doses plus placebo), at 12 select MDD trial sites, under the direction of principal investigator (PI) Maurizio Fava, MD, Executive Vice Chair, Department of Psychiatry and Executive Director, Clinical Trials Network and Institute, Massachusetts General Hospital. We expect to release data on this double-blind, randomized, placebo-controlled, 220 subject study in the second half of 2017.

NSI-566 Phase 1 and 2 safety trials for the treatment of Amyotrophic Lateral Sclerosis (ALS)

- In September 2015, data on 24 Subjects from the Phase 2 and combined Phase 1 and Phase 2 NSI-566 ALS trials were presented at the American Neurological Association Annual Meeting by the principal investigator, Eva Feldman, MD, PhD, Director of the A. Alfred Taubman Medical Research Institute and Director of Research of the ALS Clinic at the University of Michigan Health. The data showed that the intraspinal transplantation of the cells was safe and well tolerated.

NSI-566 Phase 1 safety trial for the treatment of chronic Spinal Cord Injury (cSCI)

- In January 2016, we reported on the interim status of the Phase 1 safety data on all four subjects with thoracic spinal cord injuries (T2-T12); the stem cell treatment demonstrated feasibility and safety. A self-reported ability to contract some muscles below the level of injury was confirmed via clinical and electrophysiological follow-up examinations in one of the four patients treated. All patients will be followed for five years. This study was completed with the collaboration of the UCSD School of Medicine, supported by the UCSD Sanford Stem Cell Clinical Center. Substantially all of the clinical costs of this study have been and will continue to be funded by grants arranged through the University of California, San Diego.

NSI-566 Phase 1 safety trial for the treatment of motor deficits in stroke

- In March, 2016, we completed dosing the third planned cohort in a Phase 1 clinical trial evaluating safety at BaYi Brain Hospital in Beijing. Patients are currently being monitored through their 24 month observational follow-up period. The trial is being conducted by Suzhou Neuralstem, a wholly owned subsidiary of Neuralstem in China, at BaYi Brain Hospital in Beijing, China.

Pre-Clinical Development Pipeline

The company has recently completed five preclinical studies supporting NSI-189's activity. In June, 2016, we announced that new in vitro data on NSI-189 provide insight into the drug's mechanism of action. In a study entitled "NSI-189, a neurogenic compound enhances short-term and long-term potentiation in C57Bl/6 mice and reverses LTP impairment in a mouse model of Angelman syndrome", Investigators determined that NSI-189 increased LTP magnitude in a time-dependent manner within hours of incubation in hippocampal slices and that NSI-189's effect is cumulative over exposure time.

The additional preclinical study data supporting the potential broad neurogenic ability of NSI-189 will be presented at future scientific conferences. These exploratory studies include irradiation – induced cognition, diabetes-related neuropathy and ischemic stroke.

Our Technologies

Stem Cells

Our technology enables the isolation and large-scale expansion of regionally specific, human neural stem cells from all areas of the developing human brain and spinal cord, thus enabling the generation of physiologically relevant human neurons of all types. We believe that our stem cell technology will assist the body in producing new cells to replace malfunctioning or dead cells as a way to treat disease and injury. Many significant and currently untreatable human diseases arise from the loss or malfunction of specific cell types in the body. Our focus is the development of effective methods to generate replacement cells from neural stem cells. We believe that replacing damaged, malfunctioning or dead neural cells with fully functional ones may be a useful therapeutic strategy in treating many diseases and conditions of the central nervous system. We own or exclusively license over 10 U.S. issued and pending patents and over 70 foreign issued and pending patents related to our stem cell and related medical device technologies.

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Small Molecule Compounds

The inhibition of adult hippocampal neurogenesis has been implicated in a number of diseases that affect cognition and/or emotion such as major depressive disorder. Utilizing our proprietary stem cell derived, screening capability, we have developed and patented a series of small molecule compounds. As part of our research, we focused on compounds that were shown to enhance the baseline level of neurogenesis in normal healthy young mice. We believe that by enhancing baseline neurogenesis and accordingly, increasing hippocampal neurogenesis, we can decrease the effects of central nervous system or CNS diseases. Additionally, we believe that a compound that stimulates in vitro neurogenesis, enhances in vivo neurogenesis, increases hippocampal volume, and exerts anti-depressive effects on animals will be well suited for treating major depressive disorder. We believe the low molecular weight organic compounds can efficiently cross the blood/brain barrier. In mice, research indicated that the small molecule compounds both stimulate neurogenesis of the hippocampus and increase its volume. Additionally, we believe that a compound that stimulates in vitro neurogenesis, enhances in vivo neurogenesis, increases hippocampal volume, and exerts anti-depressive effects on animals will be well suited for treating major depressive disorder. During our pre-clinical research, we identified NSI-189 as seeming to stimulate all four activities. Pre-clinical testing of this compound at multiple doses showed antidepressant activity at 10, 30, and 100mg/kg doses with rapid bioavailability in the brain. Histology analysis of the mouse brains suggested a bell-shaped dose-response curve, 10mg/kg and 30mg/kg being optimal for pharmacologically active concentrations and with higher doses not necessarily yielding larger biological effects. Our collaborators at Massachusetts General Hospital have presented the human data from the MDD trial which showed clinically meaningful and statistically significant improvement in depressive and cognitive scales. We believe that our small molecule compounds may assist promoting synaptogenesis or neurogenesis in the human hippocampus documented in indications such as MDD.

Our small molecule compounds are covered by 10 U.S. exclusively owned issued and pending patents and over 60 exclusively owned foreign issued and pending patents related to our small molecule compounds.

Targeted Indications

About Major Depressive Disorder (MDD)

Major depressive disorder, or MDD (also known as recurrent depressive disorder, clinical depression, major depression, unipolar depression, or unipolar disorder), is a mental disorder characterized by episodes of all-encompassing low mood accompanied by low self-esteem and loss of interest or pleasure in normally enjoyable activities. MDD affects approximately 14.8 million American adults, or about 6.7 percent of the U.S. population age 18 and older in a given year. Additionally, the incidence of first line therapy failure creates a robust market for branded molecules in second/third line therapy. These factors combine to create a significant opportunity for a differentiated therapeutic agent.

NSI-189 is being developed for the treatment of major depressive disorder and other psychiatric and/or cognitive impairment indications associated with hippocampal atrophy. NSI-189 is the lead compound in our neurogenic small molecule drug platform. We believe that NSI-189 may provide an effective treatment for patients suffering from MDD by promoting neurogenesis and an underlying molecular pathway.

About Amyotrophic Lateral Sclerosis (ALS)

Amyotrophic lateral sclerosis, or ALS, is a disease of the nerve cells in the brain and spinal cord that control voluntary muscle movement. Approximately 6,400 people in the U.S. are diagnosed with ALS each year. The incidence of ALS is two per 100,000 people, and it is estimated that more than 20,000 Americans may be living with ALS at any given time. In ALS, nerve cells (neurons) waste away or die, and can no longer send messages to muscles. This eventually leads to muscle weakening, twitching, and an inability to move the arms, legs, and body. The condition slowly gets worse. When the muscles in the chest area stop working, it becomes hard or impossible to breathe. NSI-566 is under development as a potential treatment for ALS by providing cells designed to nurture and protect the patients' remaining motor neurons; and possibly repair some motor neurons which have not yet died but which are diseased. Neuralstem received orphan designation by the FDA for NSI-566 in ALS.

About Chronic Spinal Cord Injury

A spinal cord injury, or SCI, generally refers to any injury to the spinal cord that is caused by trauma instead of disease although in some cases, it can be the result of diseases. It is estimated that there are 12,500 new cases of SCI per year and that at any given time, there are between 240,000 and 337,000 people in the United States that are living with SCI. Chronic spinal cord injury generally refers to the phase beginning 6 months after the initial injury. SCIs are most often traumatic, caused by lateral bending, dislocation, rotation, axial loading, and hyperflexion or hyperextension of the cord or cauda equina. Motor vehicle accidents are the most common cause of SCIs, while other causes include falls, work-related accidents, sports injuries, and penetrations such as stab or gunshot wounds. In certain instances, SCIs can also be of a non-traumatic origin, as in the case of cancer, infection, intervertebral disc disease, vertebral injury and spinal cord vascular disease. We believe that NSI-566 may provide an effective treatment for chronic spinal cord injury by "bridging the gap" in the spinal cord circuitry created in traumatic spinal cord injury and providing new cells to help transmit the signal from the brain to points at or below the point of injury.

About Ischemic Stroke

Ischemic strokes, the most common type of stroke, occur as a result of an obstruction within a blood vessel supplying blood to the brain. Approximately 15 million people worldwide suffer stroke of which it is estimated that 87% of all strokes are ischemic strokes. Post-stroke motor deficits include paralysis in arms and legs and can be permanent. We believe that NSI-566 may provide an effective treatment for restoring motor deficits resulting from ischemic stroke by both creating new circuitry in the area of injury and through repairing and or nurturing diseased cells to improve function in patients.

Intellectual Property

Our research and development is supported by our intellectual property. We own or exclusively license over 20 U.S. issued and pending patents and over 120 foreign issued and pending patents in the field of regenerative medicine, related to our stem cell technologies as well as our small molecule compounds. Our issued patents have expiration dates ranging from 2016 through 2034, based on appropriate Patent Expansions. In our opinion the patents expiring in 2016 and in the near term are not critical to our business.

Operating Strategy

We generally employ an outsourcing strategy where we outsource our Good Laboratory Practices, or GLP, preclinical development activities and Good Manufacturing Practices, or GMP, Good Tissue Practices, or GTP, if applicable, and clinical development activities to contract research organizations or CROs and contract manufacturing organizations or CMOs as well as all non-critical corporate functions. Manufacturing is also outsourced to organizations with approved facilities and manufacturing practices. This outsource model allows us to better manage cash on hand and minimize non-vital expenditures. It also allows for us to operate with relatively fewer employees and lower fixed costs than that required by other companies conducting similar business.

Employees

As of June 30, 2016, we had 12 full-time employees. Of these full-time employees, 8 work on research and development and clinical operations 4 in administration. We also use the services of numerous outside consultants in business and scientific matters.

Our Corporate Information

We were incorporated in Delaware in 2001. Our principal executive offices are located at 20271 Goldenrod Lane, Germantown, Maryland 20876, and our telephone number is (301) 366-4841. Our website is located at www.neuralstem.com.

In addition to announcing material financial information through our investor relations website, press releases, SEC filings and public conference calls and webcasts, we also intend to use the following social media channels as a means of disclosing information about the company, its services and other matters and for complying with our disclosure obligations under Regulation FD:

- Neuralstem's Twitter Account (https://twitter.com/Neuralstem_Inc)

- Neuralstem's LinkedIn Company Page (http://www.linkedin.com/company/neuralstem-inc-)

The information we post through these social media channels may be deemed material. Accordingly, investors should monitor these accounts and the blog, in addition to following the company's press releases, SEC filings and public conference calls and webcasts. This list may be updated from time to time.

We have not incorporated by reference into this report the information in, or that can be accessed through, our website or social media channels, and you should not consider it to be a part of this report.

Trends & Outlook

Revenue

We generated no revenues from the sale of our proposed therapies for any of the periods presented. We are mainly focused on successfully managing our current clinical trials related to our small molecule compounds and seeking potential partnerships for our stem cell product candidates. We are also pursuing pre-clinical studies on other central nervous system indications in preparation for potential future clinical trials.

During the six months ended June 30, 2016 and 2015, we recognized approximately $5,000 of revenue in each period related to ongoing fees pursuant to certain licenses of our intellectual property to third parties.

On a long-term basis, we anticipate that our revenue will be derived primarily from licensing fees and sales of our small molecule compounds and licensing fees and royalties from our cell based therapies. Because we are at such an early stage in the clinical trials process, we are not yet able to accurately predict when we will have a product ready for commercialization, if ever.

Research and Development Expenses

Our research and development expenses consist primarily of clinical trial expenses, including payments to clinical trial sites that perform our clinical trials and clinical research organizations (CROs) that help us manage our clinical trials; manufacturing of small molecule drugs and stem cells for both human clinical trials and for pre-clinical studies and research; personnel costs for research and clinical personnel; and other costs including research supplies and facilities.

We focus on the development of treatment candidates with potential uses in multiple indications, and use employee and infrastructure resources across several projects. Accordingly, many of our costs are not attributable to a specifically identified product and we do not account for internal research and development costs on a project-by-project basis.

We expect that research and development expenses, which include expenses related to our ongoing clinical trials, will increase in the future, as funding allows and we proceed with our Phase 2 trial in major depressive disorder.

We have formed a wholly owned subsidiary in the People’s Republic of China. We anticipate that this subsidiary will primarily: (i) conduct pre-clinical research with regard to proposed stem cells therapies, and (ii) oversee our approved future clinical trials in China, including the current trial to treat motor deficits due to ischemic stroke.

General and Administrative Expenses

General and administrative expenses are primarily comprised of salaries, benefits and other costs associated with our operations including, finance, human resources, information technology, public relations and costs associated with maintaining a public company listing, legal, audit and compliance fees, facilities and other external general and administrative services.

Critical Accounting Policies

Our consolidated financial statements have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. Note 2 of the Notes to Condensed Consolidated Financial Statements included elsewhere herein describes the significant accounting policies used in the preparation of the financial statements. Certain of these significant accounting policies are considered to be critical accounting policies, as defined below.

A critical accounting policy is defined as one that is both material to the presentation of our financial statements and requires management to make difficult, subjective or complex judgments that could have a material effect on our financial condition and results of operations. Specifically, critical accounting estimates have the following attributes: (1) we are required to make assumptions about matters that are highly uncertain at the time of the estimate; and (2) different estimates we could reasonably have used, or changes in the estimate that are reasonably likely to occur, would have a material effect on our financial condition or results of operations.

Estimates and assumptions about future events and their effects cannot be determined with certainty. We base our estimates on historical experience and on various other assumptions believed to be applicable and reasonable under the circumstances. These estimates may change as new events occur, as additional information is obtained and as our operating environment changes. These changes have historically been minor and have been included in the financial statements as soon as they became known. Based on a critical assessment of our accounting policies and the underlying judgments and uncertainties affecting the application of those policies, management believes that our financial statements are fairly stated in accordance with U.S. GAAP, and present a meaningful presentation of our financial condition and results of operations. We believe the following critical accounting policies reflect our more significant estimates and assumptions used in the preparation of our consolidated financial statements:

Use of Estimates - Our financial statements prepared in accordance with U.S. GAAP require us to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Specifically, we have estimated the expected economic life and value of our patent technology, our net operating loss carryforward and related valuation allowance for tax purposes and our stock -based compensation expenses related to employees, directors, consultants and investment banks. Actual results could differ from those estimates.

Long Lived Intangible Assets - Our long lived intangible assets consist of our intellectual property patents including primarily legal fees associated with the filings and in defense of our patents. The assets are amortized on a straight-line basis over the expected useful life which we define as ending on the expiration of the patent group. These assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. We assess this recoverability by comparing the carrying amount of the asset to the estimated undiscounted future cash flows to be generated by the asset. If an asset is deemed to be impaired, we estimate the impairment loss by determining the excess of the asset's carrying amount over the estimated fair value. These determinations use assumptions that are highly subjective and include a high degree of uncertainty. During the six months ended June 30, 2016 and 2015, no significant impairment losses were recognized.

Fair Value Measurements - The carrying amounts of our short-term financial instruments, which primarily include cash and cash equivalents, other short-term investments, accounts payable and accrued expenses, approximate their fair values due to their short maturities. The fair value of our long-term indebtedness is estimated based on the quoted prices for the same or similar issues or on the current rates offered to the Company for debt of the same remaining maturities. The fair values of our derivative instruments are estimated using Level 3 unobservable inputs.

Share-Based Compensation - We account for share-based compensation at fair value; accordingly we expense the estimated fair value of share-based awards over the requisite service period. Share-based compensation cost for stock options and warrants issued to employees and board members is determined at the grant date while awards granted to non-employee consultants are generally valued at the vesting date using an option pricing model. Option pricing models require us to make assumptions, including expected volatility and expected term of the options. If any of the assumptions we use in the model were to significantly change, stock based compensation expense may be materially different. Share-based compensation cost for restricted stock and restricted stock units issued to employees and board members is determined at the grant date based on the closing price of our common stock on that date. The value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period.

RESULTS OF OPERATIONS

Comparison of Three Months Ended June 30, 2016 and 2015

Revenue

During the three months ended June 30, 2016 and 2015, we recognized approximately $3,000 and $3,000 of revenue, respectively, related to ongoing fees pursuant to certain licenses of our intellectual property to third parties.

Operating Expenses

Operating expenses for the three months ended June 30, 2016 and 2015 were as follows:

	Three Months Ended June 30,		Increase (Decrease)	
	2016	2015	$	%
Operating Expenses				
Research and development expenses	$2,474,629	$3,312,841	$(838,212)	(25%)
General and administrative expenses	1,362,140	1,684,381	(322,241)	(19%)
Total operating expenses	$3,836,769	$4,997,222	$(1,160,453)	(23%)

Research and Development Expenses

The decrease of approximately $838,000 or 25% in research and development expenses for the period ended June 30, 2016 compared to the comparable period of 2015 was primarily attributable to a decrease in pre-clinical and manufacturing costs partially offset by an increase clinical trial expenses related to the initiation of our Phase MDD study and severance payments related to our cost-reduction plan.

General and Administrative Expenses

The decrease of approximately $322,000 or 19% in general and administrative expenses for the period ended June 30, 2016 compared to the comparable period of 2015 was primarily due to reversal of expenses related to an amendment of the severance agreement with our former Chief Executive Officer partially offset by an increase in non-cash stock based compensation expense resulting from grants to our new Chief Executive Officer.

Research and development and general and administrative expenses for the three months ended June 30, 2016 include approximately $312,000 and $158,000, respectively related to our May 2016 cost-reduction effort. The total $470,000 of expense is comprised of approximately $413,000 for severance and other employee payments, and $57,000 of non-cash costs for modification of employee stock options.

Other expense

Other expense, net totaled approximately $18,000 and $453,000 for the three months ended June 30, 2016 and 2015, respectively. Other expense, net in 2016 consisted of approximately $467,000 of fees related to the issuance of our derivative instruments and $322,000 of interest expense related to our long term debt, partially offset by a gain of approximately $757,000 related to the fair value adjustment of our derivative instruments.

Other expenses, net in 2015 consisted primarily of approximately $459,000 of interest expense principally related to our long-term debt partially offset by approximately $16,000 in interest income.

Comparison of Six Months Ended June 30, 2016 and 2015

Revenue

During the six months ended June 30, 2016 and 2015, we recognized approximately $5,000 and $5,000 of revenue, respectively, related to ongoing fees pursuant to certain licenses of our intellectual property to third parties.

Operating Expenses

Operating expenses for the six months ended June 30, 2016 and 2015 were as follows:

	Six Months Ended June 30,		Increase (Decrease)	
	2016	2015	$	%
Operating Expenses				
Research and development expenses	$5,540,219	$6,495,664	$(955,445)	(15%)
General and administrative expenses	4,532,662	3,117,455	1,415,207	45 %
Total operating expenses	$10,072,881	$9,613,119	$459,762	5 %

Research and Development Expenses

The decrease of approximately $955,000 or 15% in research and development expenses for the period ended June 30, 2016 compared to the comparable period of 2015 was primarily attributable to a decrease in pre-clinical and manufacturing costs partially offset by an increase clinical trial expenses related to the initiation of our Phase MDD study.

General and Administrative Expenses

The increase of approximately $1,415,000 or 45% in general and administrative expenses for the period ended June 30, 2016 compared to the comparable period of 2015 was primarily due to a severance accrual and increased non-cash stock based compensation resulting from the accelerated vesting of options, both related to the resignation of our former Chief Executive Officer coupled with non-cash stock based compensation expense resulting from grants to our new Chief Executive Officer all partially offset by a decrease in our employee bonus expense.

Research and development and general and administrative expenses for the six months ended June 30, 2016 include approximately $312,000 and $158,000, respectively related to our May 2016 cost-reduction effort. The total $470,000 of expense is comprised of approximately $413,000 for severance and other employee payments, and $57,000 of non-cash costs for modification of employee stock options.

Other expense

Other expenses, net totaled approximately $390,000 and $893,000 for the six months ended June 30, 2016 and 2015, respectively. Other expense, net in 2016 consisted of approximately $467,000 of fees related to the issuance of our derivative instruments and $709,000 of interest related to our long term debt, partially offset by a gain of approximately $757,000 related to the fair value adjustment of our derivative instruments.

Other expenses, net in 2015 consisted primarily of approximately $913,000 of interest expense principally related to our long-term debt partially offset by approximately $30,000 in interest income.

Liquidity and Capital Resources

Financial Condition

Our Cash and Cash Equivalent balances were approximately $11.1 million as of June 30, 2016. We believe these funds are only sufficient to fund operations through December 2016. We will require additional capital to continue to develop our pre-clinical and clinical development operations. We cannot assure you that we will be able to secure additional financing or that the expected income will materialize. Several factors will affect our ability to raise additional funding, including, but not limited to market conditions, interest rates and, more specifically, our progress in our exploratory, preclinical and future clinical development programs.

Since our inception, we have financed our operations through the sales of our securities, issuance of long term debt, the exercise of investor warrants, and to a lesser degree from grants and research contracts.

	Six Months Ended June 30,		Increase (Decrease)	
	2016	2015	$	%
Net cash used in operating activities	$(7,059,924)	$(9,524,209)	$2,464,285	26 %
Net cash used in investing activities	$7,389,182	$(191,200)	$7,580,382	3965%
Net cash provided by financing activities	$6,082,944	$5,845,635	$237,309	4 %

On May 3, 2016, we completed a public offering of 20,000,000 shares of common stock and 20,000,000 common stock purchase warrants at a public offering price of $0.40 per each share and common stock purchase warrant. We received aggregate gross proceeds of $8.0 million and net proceeds of approximately $7,229,000 from the offering. The warrants allow the holder to purchase one share of common stock, have an exercise price of $0.40 per share and a term of 5 years. The warrants contain certain non-standard anti-dilution protection and. Consequently, are being accounted for as derivative instruments recorded at fair value each period (See Note 3). This offering was made pursuant to our shelf registration statement declared effective by the SEC on June 19, 2014 (Registration No. 333-196567).

On May 12, 2016, we entered into private placement securities purchase agreements with certain accredited investors to purchase 2,700,000 of common stock and 2,700,000 common stock purchase warrants at a price of $0.40 per each share and common stock purchase warrant. We received aggregate gross proceeds of approximately $1,080,000 and net proceeds of approximately $925,000. The warrants allow the holder to purchase one share of common stock, have an exercise price of $0.40 per share and a term of 5 years. The warrants contain certain non-standard anti-dilution protection and. Consequently, are being accounted for as derivative instruments recorded at fair value each period (See Note 3). This private placement transaction was not made pursuant to any registration statement.

The offerings in May 2016 have provided us with sufficient funds to finance operations at least through December 31, 2016, however, we will require additional capital to conduct research and development, establish and conduct clinical and pre-clinical trials, enter into commercial-scale manufacturing arrangements and to provide for marketing and distribution of our products. We cannot assure you that we will be able to secure such additional financing or that the expected income will materialize. Several factors will affect our ability to raise additional funding, including, but not limited to market conditions, interest rates and, more specifically, our progress in our exploratory, preclinical and future clinical development programs.

Net Cash Used in Operating Activities

We used approximately $7,060,000 and $9,524,000 of cash in our operating activities for the six months ended June 30, 2016 and 2015, respectively. The decrease in our use of cash in operating activities of approximately $2,464,000 was primarily due to reduction in cash used in our daily operations and a reduction in cash invested in working capital.

Net Cash Provided by (used in) Investing Activities

We received approximately $7,389,000 and used approximately $191,000 of cash in connection with investment activities for the six months ended June 30, 2016 and 2015 respectively.

Net Cash Provided by (used in) Financing Activities

We received approximately $6,083,000 and $5,846,000 from financing activities in the six months ended June 30, 2016 and 2015, respectively. Net proceeds from our two financing in May 2016 of approximately $8,309,000 were partially offset by loan principal repayments of approximately $2,226,000. For the corresponding period in 2015, net cash provided in financing activities related substantially to proceeds from equity transactions.

Future Liquidity and Needs

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 the proceeds from the offering of our securities, exercise of outstanding warrants and grants to fund our operations.

We intend to pursue opportunities to obtain additional financing in the future through the sale of our securities and additional research grants. We currently have two shelf registration statements that are effective. On September 13, 2013, our shelf registration statement (Registration No. 333-190936) registering the sale of up to $50 million of our securities was declared effective by the SEC. To date, through June 30, 2016 we have sold or reserved for sale upon the exercise of outstanding warrants approximately $48.2 million of securities under this shelf registration statement. On June 19, 2014, our shelf registration statement registering the sale of up to $100 million of our securities was declared effective by the SEC. To date, through June 30, 2016 we have sold or reserved for sale upon exercise of outstanding warrants approximately $16.0 million of securities under this shelf registration statement.

We anticipate conducting financing in the future based on our shelf registration statement when and if financing opportunities arise.

The source, timing and availability of any future financing will depend principally upon market conditions, interest rates and, more specifically, 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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Financial instruments that potentially subject us to concentrations of credit risk consist of cash and cash equivalents which are held at highly rated United States financial institutions and at times maintain the balances of our deposits in excess of federally insured limits. We invest our cash in instruments with short-term maturities with the objective of preserving capital. Because of the short-term maturities, we do not believe that a one-half percentage point increase or decrease in interest rates would have had a material effect on our interest income.

We are subject to interest rate risk for our long-term debt which contains a floating interest rate based on Wall Street Journal published prime rate. For the full year ended December 31, 2016 a one percentage point increase in the prime rate would increase our interest expense by approximately $61,000.

Our foreign operations in China subject us to changes in foreign exchange rates. Changes in exchange rates for the year ended December 31, 2016 are not expected to have a material effect as the operations are expected to be limited. Future changes to foreign exchange rates could have a material effect on us as our clinical trial activity increases.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Based on an evaluation under the supervision and with the participation of the Company's management, the Company's principal executive officer and principal financial officer have concluded that the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act were effective as of June 30, 2016, to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms and (ii) accumulated and communicated to the Company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

Management has identified the following changes in our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) that occurred during the second quarter of 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

In conjunction with the cost-reduction plan discussed in Footnote 7, we have outsourced the majority of our accounting and finance functions to external third party consultants. These outside consultants work under the supervision of and will be supported by our Chief Financial Officer.

Inherent Limitations Over Internal Controls

The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles ("GAAP"). The Company's internal control over financial reporting includes those policies and procedures that:

(i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the Company's assets;

(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that the Company's receipts and expenditures are being made only in accordance with authorizations of the Company's management and directors; and

(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Management, including the Company's principal executive officer and principal financial officer, does not expect that the Company's internal controls will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of internal controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Also, any evaluation of the effectiveness of controls in future periods are subject to the risk that those internal controls may become inadequate because of changes in business conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PART II

OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are parties to legal proceedings that we believe to be ordinary, routine litigation incidental to the business of present or former operations. It is management's opinion, based on the advice of counsel, that the ultimate resolution of such litigation will not have a material adverse effect on our financial condition, results of operations or cash flows.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. We have described below a number of uncertainties and risks which, in addition to uncertainties and risks presented elsewhere in this Quarterly Report, may adversely affect our business, operating results and financial condition. The uncertainties and risks enumerated below as well as those presented elsewhere in this Quarterly Report, and those included in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC should be considered carefully in evaluating our company and our business and the value of our securities.

Risks Relating to Our Stage of Development and Capital Structure

We may not be able to continue as a going concern if we do not obtain additional financing by December, 2016.

The Company has incurred losses since its inception and has not demonstrated an ability to generate revenues from sales or services. These factors create substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustment that might be necessary if the Company is unable to continue as a going concern.

The ability of the Company to continue as a going concern is dependent on generating cash from the sale of its securities and/or obtaining debt financing.

Our cash and cash equivalents balance at June 30, 2016 was approximately $11.1M. Based on our current expected level of operating expenditures, we expect these funds to be only sufficient to fund our operations through December 31, 2016. Our ability to continue as a going concern is wholly dependent upon obtaining sufficient financing to fund our operations.

Despite our ability to secure capital in the past, there is no assurance that additional equity or debt financing will be available to us when needed. In the event that we are not able to secure financing, we may be forced to curtail operations, delay or stop ongoing clinical trials, cease operations altogether or file for bankruptcy.

Our auditors have expressed substantial doubt about our ability to continue as a going concern.

Our auditors' report on our December 31, 2015 financial statements expressed an opinion that our capital resources as of the date of their Audit Report were not sufficient to sustain operations or complete our planned activities for the upcoming year unless we raised additional funds. Accordingly, our current cash level raises substantial doubt about our ability to continue as a going concern past July. If we do not obtain additional funds by such time, we may no longer be able to continue as a going concern and will cease operation which means that our shareholders may lose their entire investment.

We have a history of losses.

Since inception in 1996 and through June 30, 2016, we have accumulated losses totaling approximately $182,417,000. On June 30, 2016, we had a working capital surplus of approximately $3,228,000 and stockholders' equity of approximately $836,000. Our net losses for the two most recent fiscal years have been approximately $20,904,000 and $22,629,000, for 2015 and 2014, respectively, while our loss for the six months ended June 30, 2016 was approximately $10,458,000. We have generated no significant revenue from the sales of our proposed products.

Our ability to generate revenues and achieve profitability will depend upon our ability to complete the development of our proposed products, obtain the required regulatory approvals, manufacture and market and sell our proposed products. To date, we have not generated any revenue from the commercial sale of our proposed products. No assurances can be given as to exactly when, if at all, we will be able to fully develop, commercialize, market, sell and/or derive any, let alone material, revenues from our proposed products.

We will need to raise additional capital to continue operations.

Since our inception, we have funded our operations through the sale of our securities, credit facilities, the exercise of options and warrants, and to a lesser degree, from grants and research contracts and other revenue generating activities such as licensing. As of June 30, 2016, we had cash, cash equivalents and short-term investments on hand of approximately $11.1 million. We cannot assure you that we will be able to secure additional capital through financing transactions, including issuance of debt, licensing agreements or grants. Our inability to license our intellectual property, obtain grants or secure additional financing will materially impact our ability to fund our current and planned operations.

We have spent and expect to continue spending substantial cash in the research, development, clinical and pre-clinical testing of our proposed products with the goal of ultimately obtaining FDA approval and equivalent international approvals to market such products. We will require additional capital to conduct research and development, establish and conduct clinical and pre-clinical trials, enter into commercial-scale manufacturing arrangements and to provide for marketing and distribution of our products. We cannot assure you that financing will be available if needed. If additional financing is not available, we may not be able to fund our operations, develop or enhance our technologies, take advantage of business opportunities or respond to competitive market pressures. If we exhaust our cash reserves and are unable to secure adequate additional financing, we may be unable to meet operating obligations which could result in us initiating bankruptcy proceedings or delaying, or eliminating some or all of our research and product development programs.

We will need to raise additional capital to pay our indebtedness as it comes due.

We have a substantial level of debt. As of June 30, 2016, we had approximately $6,109,000 in aggregate principal amount long-term indebtedness outstanding. Under our amended loan and security agreement, we were required to make monthly interest only payments through September 2015; and are required to make monthly interest and principal payments of approximately $435,000 per month from January 2016 through March 2017 and make a balloon payment for the remaining principal in April 2017. As security for such indebtedness, we have pledged substantially all of our assets, including our intellectual property. If we are unable to make the required payments, or if we fail to comply with the various requirements and covenants of our indebtedness, we would be in default, which would permit the holders of our indebtedness to accelerate the maturity and require immediate repayment and lead to potential foreclosure on the assets securing the debt. Any default under our indebtedness would have a material adverse effect on our business, operating results and financial condition. Additionally, our amended loan and security agreement governing this loan also contains a number of affirmative and restrictive covenants, including reporting requirements and other collateral limitations, certain limitations on liens and indebtedness, dispositions, mergers and acquisitions, restricted payments and investments, corporate changes and limitations on waivers and amendments to certain agreements, our organizational documents, and documents relating to debt that is subordinate to our obligations under the credit facility. Our failure to comply with the covenants in the amended loan and security agreement could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our debt and potential foreclosure on the assets securing the debt. If we are unable to refinance or repay our indebtedness as it becomes due, including upon an event of default, we may become insolvent and be unable to continue operations.

If we are unable to meet the continued listing requirements for the Nasdaq Capital Market, our securities will be subject to delisting.

On August 8, 2016, we received a deficiency notice from the Nasdaq Stock Market LLC that we are not in compliance with Nasdaq Listing Rule 5550(b)(2), as our market value of listed securities was below $35 million for the previous thirty (30) consecutive business days. In accordance with Nasdaq Marketplace Rule 5810(c)(3)(C), we have a period of 180 calendar days, or until February 6, 2016, to regain compliance with the minimum market value of listed securities requirement. To regain compliance, our market value of listed securities must close at $35 million or more for a minimum of ten (10) consecutive business days during the 180 calendar day compliance period. During the compliance period, our shares of common stock will continue to be listed and traded on the Nasdaq Capital Market. We intend to monitor our market value of listed securities between now and February 6, 2017, and will consider and evaluate all available options to resolve our noncompliance. There can be no assurance that the Company will be able to regain compliance with the market value of listed securities requirement or will otherwise be in compliance with other NASDAQ listing criteria.

On April 20, 2016, we received a written notice from the Nasdaq Stock Market LLC that we are not in compliance with Nasdaq Listing Rule 5550(a)(2), as the minimum bid price of our common stock has been below $1.00 per share for 30 consecutive business days. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have a period of 180 calendar days, or until October 17, 2016, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must meet or exceed $1.00 per share for at least ten consecutive business days during this 180 calendar day period. In the event we do not regain compliance by October 17, 2016, we may be eligible for an additional 180 calendar day grace period if we meet the initial listing standards, with the exception of bid price, for the Nasdaq Capital Market, and provide written notice to Nasdaq of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary.

Accordingly, we have until October 17, 2016 to regain compliance with the minimum bid price requirement of $1.00 and until February 6, 2017 to regain compliance with the market value of listed securities of $35 million requirement. Additionally, only complying with the minimum bid price requirement, or only complying with the market value of listed securities requirement will not serve to satisfy the requirements of the other. Accordingly, we will need to comply with both standards in their allotted compliance periods as discussed above.

If we do not regain compliance within the allotted compliance period(s), including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that our common stock will be subject to delisting. We will then be entitled to appeal the determination to a Nasdaq Listing Qualifications Panel and request a hearing. We cannot be sure that our share price will comply with the requirements for continued listing of our shares on the Nasdaq Capital Market in the future or that we will comply with the other continued listing requirements. If our shares lose their status on the Nasdaq Capital Market, we believe that our shares would likely be eligible to be quoted on the inter-dealer electronic quotation and trading system operated by Pink OTC Markets Inc., commonly referred to as the Pink Sheets and now known as the OTCQB market. These markets are generally considered not to be as efficient as, and not as broad as, the Nasdaq Capital Market. If our common stock is delisted, this would, among other things, substantially impair our ability to raise additional funds and could result in a loss of institutional investor interest and fewer development

opportunities for us.

Risks Relating to Our Business

Our business is dependent on the successful development of our product candidates and our ability to raise additional capital.

Our business is significantly dependent on our product candidates which are currently at different phases of pre-clinical and clinical development. The process to approve our product candidates is time-consuming, involves substantial expenditures of resources, and depends upon a number of factors, including the availability of alternative treatments, and the risks and benefits demonstrated in our clinical trials. Our success will depend on our ability to achieve scientific and technological advances and to translate such advances into FDA-approvable, commercially competitive products on a timely basis. Failure can occur at any stage of the process. If we are not successful in developing our product candidates, we will have invested substantial amounts of time and money without developing revenue-producing products. As we enter a more extensive clinical program for our product candidates, the data generated in these studies may not be as compelling as the earlier results. This, in turn, could adversely impact our ability to raise additional capital and pursue our business plan and planned research and development efforts.

Our proposed products are not likely to be commercially available for at least several years, if at all. Our development schedules for our proposed products may be affected by a variety of factors, including technological difficulties, clinical trial failures, regulatory hurdles, competitive products, intellectual property challenges and/or changes in governmental regulation, many of which will not be within our control. Any delay in the development, introduction or marketing of our product candidates could result either in such products being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long-term nature of our projects, the unproven technology involved and the other factors described elsewhere in this section, there can be no assurance that we will be able to successfully complete the development or marketing of any of our proposed product candidates.

Our business relies on technologies that we may not be able to commercially develop and we are unable to predict when or if we will be able to earn revenues.

We have allocated the majority of our resources to the development of our stem cell and small molecule technologies. Our ability to generate revenue and operate profitably will depend on being able to develop these technologies for human applications. These are emerging technologies that may have limited human application. We cannot guarantee that we will be able to develop our technologies or that if developed, our technologies will result in commercially viable products or have any commercial utility or value. We anticipate that the commercial sale of our proposed products and/or royalty/licensing fees related to our technologies, will be our primary sources of revenue. We recognized revenue of approximately $10,000 and $19,000 for the years ended December 31, 2015 and 2014, respectively, and $5,000 for the six months ended June 30, 2016, related to the licensing of certain intellectual property to third parties and certain subcontractor services that we provided. If we are unable to develop our technologies, we may never realize any significant revenue. Additionally, given the uncertainty of our technologies, product candidates and the need for government regulatory approval, we cannot predict when, or if ever, we will be

able to realize revenues related to our products. As a result, we will be primarily dependent on our ability to raise capital through the sale of our securities for the foreseeable future.

Our product development programs are based on novel technologies in an emerging field and are inherently risky.

We are subject to the risks inherent in the development of products based on new technologies. The novel nature of therapies in the field of regenerative medicine creates significant challenges in regard to product development and optimization, manufacturing, government regulation, third party reimbursement, and market acceptance. For example, the pathway to regulatory approval for cell-based therapies, including our product candidates, may be more complex and lengthy than the pathway for conventional drugs. These challenges may prevent us from developing and commercializing products on a timely or profitable basis or at all. Regenerative medicine is still an emerging field. There can be no assurances that we will ultimately produce any viable commercialized products and processes. Even if we are able to produce a commercially viable product, there may be strong competitors in this field and our products may not be able to successfully compete against them.

Our stem cell therapy programs rely on experimental surgical devices and experimental and highly invasive surgical procedures.

We are subject to the risks inherent in the use and development of experimental surgical devices and procedures. We have limited experience with medical devices and must rely on outside consultants and manufacturers to develop and seek any required approvals for the device we use in connection with our stem cell therapy program. Additionally, the surgical procedures required to administer our stem cell therapy is experimental, highly invasive and is required to be performed by highly experienced neurosurgeons who have received special training. We cannot guarantee consistent and safe performance of the device or the surgical procedure. A surgery related adverse event may result in a clinical hold and may have long-term and damaging effects on our ability to complete development of the stem cell therapy programs, including the completion of any ongoing or planned clinical trials. Even if one or more of our programs is successful and receives marketing approval from a regulatory authority, due to the specialized nature of the device and surgical procedure, there may not be sufficient train surgeons to administer our therapy.

We are unable to predict when or if we will be able to earn revenues.

Given the uncertainty of our technologies and the need for government regulatory approval, we cannot predict when, or if ever, we will be able to realize revenues related to our products.

Our proposed products are not likely to be commercially available for at least several or more years, if ever. Accordingly, we do not foresee generating any significant revenue during such time. As a result, we will be primarily dependent on our ability to raise capital through the sale of our securities to fund our operations for the foreseeable future.

Our inability to manufacture and store our stem cells in-house that are used in our products could adversely impact our business.

We currently outsource most of the manufacturing of our stem cells and small molecule pharmaceutical compounds to third party contractors and as such have limited ability to adequately control the manufacturing process and the safe storage thereof. Any manufacturing or storage irregularity, error, or failure to comply with applicable regulatory procedure would require us to find new third parties to outsource our manufacturing and storage responsibilities or our business would be impacted. Additionally, as part of our business plan, we are developing in-house manufacturing capabilities but there can be no assurance that such capabilities will be successfully developed or if developed, be sufficient to meet our demands. And delays in the development of such in-house manufacturing capabilities could adversely affect our plans.

If we are unable to complete pre-clinical and clinical testing and trials or if clinical trials of our product candidates are prolonged, delayed, suspended or terminated, our business and results of operations could be materially harmed.

We are currently in clinical trials for NSI-566 and NSI-189, two of our proposed products, with regard to multiple indications. Although we have commenced a number of trials, the ultimate outcome of the trials is uncertain. If we are unable to satisfactorily complete such trials, or if such trials yield unsatisfactory results, we may be unable to obtain regulatory approval for and commercialize our proposed products. No assurances can be given that our clinical trials will be completed or result in successful outcomes. A number of events, including any of the following, could delay the completion of our planned clinical trials and negatively impact our ability to obtain regulatory approval for, and to market and sell, a particular product candidate:

- conditions imposed on us by the FDA or any foreign regulatory authority regarding the scope or design of our clinical trials;
- delays in obtaining, or our inability to obtain, required approvals from institutional review boards, or IRBs, or other reviewing entities at clinical sites selected for participation in our clinical trials;
- insufficient supply or deficient quality of our product candidates or other materials necessary to conduct our clinical trials;
- delays in obtaining regulatory agency agreement for the conduct of our clinical trials;
- lower than anticipated enrollment and retention rate of subjects in clinical trials;
- serious and unexpected side effects experienced by patients in our clinical trials which are related to the use of our product candidates; or
- failure of our third-party contractors to meet their contractual obligations to us in a timely manner.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRBs at the sites where the IRBs are overseeing a trial, or a data safety monitoring board, or DSMB, overseeing the clinical trial at issue, or other regulatory authorities due to a number of factors. Additionally, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the cost, timing or successful completion of a clinical trial. We do not know whether our clinical trials will be conducted as planned, will need to be restructured or will be completed on schedule, if at all. Delays in our clinical trials will result in increased development costs for our drug candidates. In addition, if we experience delays in the completion of, or if we terminate, any of our clinical trials, the commercial prospects for our drug candidates may be harmed and our ability to generate product revenues will be jeopardized. Furthermore, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a drug candidate. If regulatory authorities do not approve our products or if we fail to maintain regulatory compliance, we would be unable to commercialize our proposed products, and our business and results of operations could be materially harmed.

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The results of pre-clinical studies and clinical trials may not be predictive of the results of our later-stage clinical trials and our proposed products may not have favorable results in later-stage clinical trials or receive regulatory approval.

Positive results from pre-clinical studies or our Phase 1 and Phase 2 trials should not be relied upon as evidence that our clinical trials will succeed. Even if our product candidates achieve positive results in pre-clinical studies or during our Phase 1 and Phase 2 studies, we will be required to demonstrate through further clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale. There is typically an extremely high rate of attrition from the failure of product candidates as they proceed through clinical trials. If any product candidate fails to demonstrate sufficient safety and efficacy in any clinical trial, then we may experience potentially significant delays in, or be required to abandon, development of that product candidate. Additionally, failure to demonstrate safety and efficacy results acceptable to the FDA in later stage trials could impair our development prospects and even prevent regulatory approval of our current and future product candidates. Any such delays or abandonment in our development efforts of any of our product candidates would materially impair our ability to generate revenues.

Our research and development expenses are subject to uncertainty.

Factors affecting our research and development expenses include, but are not limited to:

- competition from companies that have substantially greater assets and financial resources than we have;
- need for acceptance of our proposed products;
- ability to anticipate and adapt to a competitive market and rapid technological developments;
- amount and timing of operating costs and capital expenditures relating to outsourcing of manufacturing and management of pre-clinical and clinical trials;
- need to rely on multiple levels of outside funding due to the length of drug development cycles and governmental approved protocols associated with the pharmaceutical industry; and
- dependence upon key personnel including key independent consultants and advisors.

There can be no guarantee that our research and development expenses will be consistent from period to period. We may be required to accelerate or delay incurring certain expenses depending on the results of our studies and the availability of adequate funding.

We are subject to numerous risks inherent in conducting clinical trials.

We outsource the management of our clinical trials to third parties. Agreements with clinical investigators and medical institutions for clinical testing and with other third parties for data management services, place substantial responsibilities on these parties that, if unmet, could result in delays in, or termination of, our clinical trials. For example, if any of our clinical trial sites fail to comply with FDA-approved good clinical practices, we may be unable to use the data gathered at those sites. If these clinical investigators, medical institutions or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for, or successfully commercialize, our proposed products. Delays in recruitment, lack of clinical benefit or unacceptable side effects would delay or prevent the completion of our clinical trials.

We or our regulators may suspend or terminate our clinical trials for a number of reasons. We may voluntarily suspend or terminate our clinical trials if at any time we believe they present an unacceptable risk to the patients enrolled in our clinical trials or do not demonstrate clinical benefit. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the patients enrolled in our clinical trials.

Our clinical trial operations are subject to regulatory inspections at any time. If regulatory inspectors conclude that we or our clinical trial sites are not in compliance with applicable regulatory requirements for conducting clinical trials, we may receive reports of observations or warning letters detailing deficiencies, and we will be required to implement corrective actions. If regulatory agencies deem our responses to be inadequate, or are dissatisfied with the corrective actions we or our clinical trial sites have implemented, our clinical trials may be temporarily or permanently discontinued, we may be fined, we or our investigators may be precluded from conducting any ongoing or any future clinical trials, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, and we may be criminally prosecuted.

The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval for our proposed products, which would materially harm our business, results of operations and prospects.

There are no assurances that we will be able to submit a pre-market application or obtain FDA approval in order to market and sell our products.

There can be no assurance that even if the clinical trial of any potential product candidate is successfully initiated and completed, that we will be able to submit a Biologics License Application ("BLA") or New Drug Application ("NDA") to the FDA, or that any BLA or NDA that we submit will be approved in a timely manner, if at all. If we are unable to submit a BLA or NDA with respect to any future product, or if such application is not approved by the FDA, we will be unable to commercialize that product. The FDA can and does reject BLAs and NDAs and may require additional clinical trials, even when product candidates performed well or achieved favorable results during initial clinical trials. If we fail to commercialize our product candidates and are unable to generate sufficient revenues to attain profitability our business will be adversely effected.

The manufacturing of stem cell-based therapeutic products is novel and dependent upon specialized key materials.

The manufacturing of stem cell-based therapeutic products is a complicated and difficult process, dependent upon substantial know-how and subject to the need for continual process improvements. We depend almost exclusively on third party manufacturers to supply our cells. In addition, our suppliers' ability to scale-up manufacturing to satisfy the various requirements of our planned clinical trials is uncertain. Manufacturing irregularities or lapses in quality control could have a material adverse effect on our business. Additionally, many of the materials that we use to prepare our cell-based products are highly specialized, complex and available from only a limited number of suppliers. The loss of one or more of these sources would likely delay our ability to conduct planned clinical trials and otherwise adversely affect our business.

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

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

We may not be able to obtain necessary licenses to third-party patents and other rights.

A number of companies, universities and research institutions have filed patent applications or have received patents relating to technologies in our field. We cannot predict which, if any, of these applications will issue as patents or how many of these issued patents will be found valid and enforceable. There may also be existing issued patents on which we would infringe by the commercialization of our product candidates. If so, we may be prevented from commercializing these products unless the third party is willing to grant a license to us. We may be unable to obtain licenses to the relevant patents at a reasonable cost, if at all, and may also be unable to develop or obtain alternative non-infringing technology. If we are unable to obtain such licenses or develop non-infringing technology at a reasonable cost, our business could be significantly harmed. Also, any infringement lawsuits commenced against us may result in significant costs, divert our management's attention and result in an award against us for substantial damages, or potentially prevent us from continuing certain operations.

We may not be able to obtain government or third-party payor coverage and reimbursement.

Our ability to successfully commercialize our product candidates, if approved, depends to a significant degree on the ability of patients to be reimbursed for the costs of such products and related treatments. We cannot assure you that reimbursement in the U.S. or in foreign countries will be available for any products developed, or, if available, will not decrease in the future, or that reimbursement amounts will not reduce the demand for, or the price of, our products. There is considerable pressure to reduce the cost of therapeutic products. Government and other third party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new therapeutic products and by refusing, in some cases, to provide any coverage for uses of approved products for disease indications for which the FDA or other relevant authority has not granted marketing approval. Moreover, in some cases, government and other third party payors have refused to provide reimbursement for uses of approved products for disease indications for which the FDA or other relevant authority has granted marketing approval. Significant uncertainty exists as to the reimbursement status of newly approved health-care products or novel therapies such as ours. We cannot predict what additional regulation or legislation relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such regulation or legislation may have on our business. If additional regulations are overly onerous or expensive or if healthcare related legislation makes our business more expensive or burdensome than originally anticipated, we may be forced to significantly downsize our business plans or completely abandon the current business model.

Our products may not be profitable due to manufacturing costs and our inability to receive favorable pricing.

Our products may be significantly more expensive to manufacture than other drugs or therapies currently on the market today due to a fewer number of potential manufacturers, greater level of needed expertise and other general market conditions affecting manufacturers of our proposed products. Even if we are able to receive approval for the reimbursement of our proposed products the amount of reimbursement may be significantly less than the manufacturing costs of our products. Additionally, other market factors may limit the price which we can charge for our proposed products while still being competitive. Accordingly, even if we are successful in developing our proposed products, we may not be able to charge a high enough price for us to earn a profit.

We are dependent on the acceptance of our products by the healthcare community.

Our product candidates, if approved for marketing, may not achieve market acceptance since hospitals, physicians, patients or the medical community, in general, may decide not to accept and utilize these products. The products that we are attempting to develop represent substantial departures from established treatment methods and will compete with a number of more conventional therapies marketed by major pharmaceutical companies. If the healthcare community does not accept our products for any reason, our business will be materially harmed.

We depend on key employees and consultants for our continued operations and future success.

We are highly dependent on our chief executive officer, chief scientific officer and outside consultants. Although we have entered into employment and consulting agreements with these parties, these agreements can be terminated at any time. The loss of any of these key employees or consultants could adversely affect our opportunities and materially harm our future prospects. In addition, we anticipate growth and expansion into areas and activities requiring additional expertise, such as clinical testing, regulatory compliance, manufacturing and marketing. We anticipate the need for additional management personnel as well as the development of additional expertise by existing management personnel. There is intense competition for qualified personnel in the areas of our present and planned activities, and there can be no assurance that we will be able to attract and retain the qualified personnel necessary for the development our business.

The employment contracts of certain key employees contain significant anti-termination provisions which could make changes in management difficult or expensive.

We have entered into employment agreements with Messrs. Daly and Lloyd Jones and Dr. Johe. Each of these employment agreements require the payment of severance, in the event certain conditions are met, if these individuals are terminated. These provisions will make the replacement of these employees very costly and could cause difficulty in effecting a change in control.

If we are unable to successfully execute our new refocused business strategy or integrate our new management team, our business could be harmed.

During 2016, the strategic direction of our company and executive management team have undergone significant change. In January 2016, we announced a new strategic refocusing to concentrate our resources on the NSI-189 small molecule program. As part of this refocusing, we announced that we will seek external funding to defray all, or substantially all, of the costs associated with the NSI-566 stem cell therapy program. During 2016, we also received the resignation of our former President and Chief Executive Officer and founder. In addition, in February 2016, Richard Daly joined our company as our new President and Chief Executive Officer and was appointed to the board and, in May 2015, Jonathan Lloyd Jones joined our company as our new Chief Financial Officer. In May, 2016 we announced that we had committed to a cost-reduction plan in order to better utilize our resources on the implementation of our refocused clinical and corporate strategy. This cost-reduction plan includes a reduction in force across all of the Company's departments. In June, 2016 we announced that the executive salaries of our chief executive officer and chief scientific officer have voluntarily been reduced. Furthermore, all compensation to non-employee directors were deferred until such time that our equity compensation plans are amended to authorize additional shares or the committee determines that the company is sufficiently funded. Our success depends largely on the development and execution of our refocused business strategy by our senior management team as well as the acceptance of such refocused strategy and team by our stakeholders. The recent transitions may be disruptive to our business, and if we are unable to manage orderly transitions, our business may be adversely affected. Additionally, since our management team consists of a limited number of individuals, the loss of these members of our senior management team or key personnel would likely harm our ability to implement our business strategy and respond to the rapidly changing market conditions in which we operate. There may be a limited number of persons with the requisite skills to serve in these positions, and we cannot assure you that we would be able to identify or employ such qualified personnel on acceptable terms, if at all. We cannot assure you that we will be able to successfully execute our refocused business strategy or that management will succeed in working together as a team. In the event we are unsuccessful, our business and prospects could be harmed.

Our competition has significantly greater experience and financial resources.

The biotechnology industry is characterized by rapid technological developments and a high degree of competition. We compete against numerous companies, many of which have substantially greater resources. Several such enterprises have initiated cell therapy research programs and/or efforts to treat the same diseases which we target. Given our current stage of development and resources, it may be extremely difficult for us to compete against more developed companies.

As a result, our proposed products could become obsolete before we recoup any portion of our related research and development and commercialization expenses. Competition in the biopharmaceutical industry is based significantly on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval for testing, manufacturing and marketing. We compete with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions and governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to us.

We believe that our proposed products under development and in pre-clinical testing and clinical trials will address unmet medical needs for those indications for which we are focusing our development efforts. Our competition will be determined in part by the potential indications for which our proposed products are developed and ultimately approved by regulatory authorities. Additionally, the timing of market introduction of some of our proposed products or of competitors' products may be an important competitive factor. Accordingly, the relative speed with which we can develop our proposed products, complete preclinical testing, clinical trials and approval processes and supply commercial quantities to market is expected to be important competitive factors. We expect that competition among products approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent position.

Our outsource model depends on third parties to assist in developing and testing our proposed products.

Our strategy for the development, clinical and pre-clinical testing and commercialization of our proposed products is based in large part on an outsource model. This model requires us to engage third parties in order to further develop our technology and products as well as for the day to day operations of our business. In the event we are not able to enter into such relationships in the future, our ability to operate and develop products may be seriously hindered or we may be required to spend considerable time and resources to bring such functions in-house. Either outcome could result in our inability to develop a commercially feasible product or in the need for substantially more working capital to complete the research in-house.

The commercialization of therapeutic products exposes us to product liability claims.

Product liability claims could result in substantial litigation costs and damage awards against us. We attempt to mitigate this risk by obtaining and maintaining appropriate insurance coverage. Historically, we have obtained liability insurance that covers our clinical trials. If we begin commercializing products, we will need to increase our insurance coverage. We may not be able to obtain insurance on acceptable terms, if at all, and the policy limits on our insurance policies may be insufficient to cover our liability.

We currently rely heavily upon third party FDA-regulated manufacturers and suppliers for our products

We currently manufacture our cells both in-house and on an outsource basis. We outsource the manufacturing of our pharmaceutical compound to third party manufacturers. We manufacture cells in-house which are not required to meet stringent FDA requirements. We use these cells in our research and collaborative programs. At present, we outsource all the manufacturing and storage of our stem cells and pharmaceuticals compound to be used in pre-clinical and clinical works, and which are subject to higher FDA requirements, to Charles River Laboratories, Inc., of Wilmington, Massachusetts (stem cells) and Albany Molecular Resources, Inc. (small molecule). Failure by our contract manufacturer to achieve and maintain high manufacturing standards could result in patient injury or death, product recalls or withdrawals, delays or failures in testing or delivery, cost overruns, or other problems that could seriously hurt our business. Contract manufacturers may encounter difficulties involving production yields, quality control, and quality assurance. These manufacturers are subject to ongoing periodic and unannounced inspections by the FDA and corresponding state and foreign agencies to ensure strict compliance with cGMPs, GTPs and other applicable government regulations and corresponding foreign standards; however, we do not have control over third-party manufacturers’ compliance with these regulations and standards.

Because manufacturing facilities are subject to regulatory oversight and inspection, failure to comply with regulatory requirements could result in material manufacturing delays and product shortages, which could delay or otherwise negatively impact our clinical trials and product development. Moreover, we do not have quantity or volume commitment orders from these manufacturers and we cannot assure you that the manufacturers will be able to manufacture in the quantity we require on a timely basis or at all. In the event we are required to seek alternative third party suppliers or manufacturers, they may require us to purchase a minimum amount of materials or could require other unfavorable terms. Any such event would materially impact our business prospects and could delay the development of our products. Moreover, there can be no assurance that any manufacturer or supplier that we select will be able to supply our products in a timely or cost effective manner or in accordance with applicable regulatory requirements or our specifications. In addition, due to the novelty of our products and product development, there can be no assurances that we would be able to find other suitable third party FDA-regulated manufacturers on a timely basis and at terms reasonable to us. Even if we were to locate alternative manufacturers there may be delays before they are able to begin manufacturing. Failure to secure such third party manufacturers or suppliers would materially impact our business.

We rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing our product candidates.

We do not have the in-house capability to conduct clinical trials for our product candidates. We rely, and will rely in the future, on medical institutions, clinical investigators, contract research organizations, contract laboratories, and collaborators to perform data collection and analysis and other aspects of our clinical trials. Our reliance on these third parties for clinical development activities results in reduced control over these activities. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. Our preclinical activities or clinical trials conducted in reliance on third parties may be delayed, suspended, or terminated if:

- the third parties do not successfully carry out their contractual duties;
- the third parties fail to meet FDA and other regulatory obligations or expected deadlines;
- we replace a third party for any reason; or
- the quality or accuracy of the data obtained by third parties is compromised due to their failure to adhere to clinical protocols, regulatory requirements, or for other reasons.

Third party performance failures may increase our development costs, delay our ability to obtain regulatory approval, and delay or prevent the commercialization of our product candidates. While we believe that there are numerous alternative sources to provide these services, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without incurring delays or additional costs.

Risks Relating to Intellectual Property

We may not be able to withstand challenges to our intellectual property rights.

We rely on our intellectual property, including issued and applied-for patents, as the foundation of our business. Our intellectual property rights may come under challenge. No assurances can be given that our current and potential future patents will survive such challenges. For example, in 2005 one of our patents was challenged in the USPTO. Although we prevailed in this particular matter, these cases are complex, lengthy, expensive, and could potentially be adjudicated adversely to our interests, removing the protection afforded by an issued patent. The viability of our business would suffer if such patent protection were limited or eliminated. Moreover, the costs associated with defending or settling intellectual property claims would likely have a material adverse effect on our business and future prospects.

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

We conduct research in countries outside of the U.S., including through our subsidiary in the People's Republic of China. A number of our competitors are located in these countries and may be able to access our technology or test results. The laws protecting intellectual property in some of these countries may not adequately protect our trade secrets and intellectual property. The misappropriation of our intellectual property may materially impact our position in the market and any competitive advantages, if any, that we may have.

Risks Relating to Our Common Stock

The market price for our common shares is particularly volatile.

The market for our common shares is characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will continue to be more volatile than those of a seasoned issuer. The volatility in our share price is attributable to a number of factors. Mainly however, we are a speculative or "risky" investment due to our limited operating history, lack of significant revenues to date and the uncertainty of FDA approval. As a consequence of this enhanced risk, more risk-adverse investors may, under the fear of losing all or most of their investment in the event of negative news or lack of progress, be more inclined to sell their shares on the market more quickly and at greater discounts than would be the case with the stock of a seasoned issuer. Additionally, in the past, plaintiffs have often initiated securities class action litigation against a company following periods of volatility in the market price of its securities. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs and liabilities and could divert management's attention and resources.

The following factors may add to the volatility in the price of our common shares: actual or anticipated variations in our quarterly or annual operating results; the results of clinical trials for our product candidates; FDA's determination with respect to filings for new clinical studies, new drug applications and new indications; government regulations; announcements of significant acquisitions, strategic partnerships or joint ventures; our capital commitments; offerings of our securities and additions or departures of our key personnel. Many of these factors are beyond our control and may decrease the market price of our common shares, regardless of our operating performance. We cannot make any predictions or projections as to what the prevailing market price for our common shares will be at any time, including as to whether our common shares will sustain their current market prices, or as to what effect the sale of shares or the availability of common shares for sale at any time will have on the prevailing market price.

The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified board members.

As a public company, we incur significant legal, accounting and other expenses that we would not incur as a private company, including costs associated with public company reporting requirements. We also incur costs associated with the Sarbanes-Oxley Act of 2002, as amended, the Dodd-Frank Wall Street Reform and Consumer Protection Act and related rules implemented or to be implemented by the SEC and the Nasdaq. The expenses incurred by public companies generally for reporting, insurance and corporate governance purposes have been increasing. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. These laws and regulations could also make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our executive officers and may divert management's attention. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation.

We have never paid a cash dividend and do not intend to pay cash dividends on our common stock in the foreseeable future.

We have never paid cash dividends nor do we anticipate paying cash dividends in the foreseeable future. Accordingly, any return on your investment will be as a result of stock appreciation if any. Additionally, we are prohibited from paying any cash dividends under the terms of our loan and security agreement.

Our anti-takeover provisions may delay or prevent a change of control, which could adversely affect the price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make it difficult to remove our board of directors and management and may discourage or delay "change of control" transactions, which could adversely affect the price of our common stock. These provisions include, among others:

- our board of directors is divided into three classes, with each class serving for a staggered three-year term, which prevents stockholders from electing an entirely new board of directors at an annual meeting;
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors and propose matters to be brought before an annual meeting of our stockholders may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company; and
- our board of directors may, without stockholder approval, issue series of preferred stock, or rights to acquire preferred stock, that could dilute the interest of, or impair the voting power of, holders of our common stock or could also be used as a method of discouraging, delaying or preventing a change of control.

If securities or industry analysts do not publish research reports, or publish unfavorable research about our business, the price and trading volume of our common stock could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us and our business. We currently have limited research coverage by securities and industry analysts. In the event an analyst downgrades our securities, the price of our securities would likely decline. If analysts cease to cover us or fails to publish regular reports on us, interest in our securities could decrease, which could cause the price of our common stock and other securities and their trading volume to decline.

Our charter documents and Delaware law contain provisions that could make it difficult for us to be acquired in a transaction that might be beneficial to our stockholders.

Our board of directors has the authority to issue shares of preferred stock and to fix the rights, preferences, privileges, and restrictions of these shares without stockholder approval. Additionally, our Bylaws provide for a staggered board. These provisions in our charter documents, along with certain provisions under Delaware law, may make it more difficult for a third party to acquire us or discourage a third party from attempting to acquire us, even if the acquisition might be beneficial to our stockholders.

Our board of directors has broad discretion to issue additional securities which might dilute the net tangible book value per share of our common stock for existing stockholders.

We are entitled under our certificate of incorporation to issue up to 300,000,000 shares of common stock and 7,000,000 “blank check” shares of preferred stock. Shares of our blank check preferred stock provide our board of directors with broad authority to determine voting, dividend, conversion, and other rights. As of June 30, 2016 we have issued and outstanding 114,760,960 shares of common stock and we have 67,642,485 shares of common stock reserved for future grants under our equity compensation plans and for issuances upon the exercise or conversion of currently outstanding options, warrants and convertible securities. As of June 30, 2016, we had no shares of preferred stock issued and outstanding. Accordingly, we are entitled to issue up to 117,596,555 additional shares of common stock and 7,000,000 additional shares of “blank check” preferred stock. Our board may generally issue those common and preferred shares, or convertible securities to purchase those shares, without further approval by our shareholders. Any preferred shares we may issue will have such rights, preferences, privileges and restrictions as may be designated from time-to-time by our board, including preferential dividend rights, voting rights, conversion rights, redemption rights and liquidation provisions. It is likely that we will be required to issue a large amount of additional securities to raise capital in order to further our development and marketing plans. It is also likely that we will be required to issue a large amount of additional securities to directors, officers, employees and consultants as compensatory grants in connection with their services, both in the form of stand-alone grants or under our various stock plans. The issuance of additional securities may cause substantial dilution to our shareholders.

Risks Related to Government Regulation and Approval of our Product Candidates.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and our products may not receive regulatory approval.

The time required to obtain approval by the FDA and comparable foreign authorities is inherently unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate’s clinical

development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our drug candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA, NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We are currently undertaking clinical trials for our lead products candidates NSI-189 and NSI-566. We cannot assure you that we will successfully complete any clinical trials in connection with such INDs. Further, we cannot predict when we might first submit any product license application (NDA or BLA) for FDA approval or whether any such product license application will be granted on a timely basis, if at all. Moreover, we cannot assure you that FDA approvals for any products developed by us will be granted on a timely basis, if at all. Any delay in obtaining, or failure to obtain, such approvals could have a material adverse effect on the marketing of our products and our ability to generate product revenue.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a drug candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that drug candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our drug candidates.

Development of our product candidates is subject to extensive government regulation.

Our research and development efforts, as well as any future clinical trials, and the manufacturing and marketing of any products we may develop, will be subject to, and restricted by, extensive regulation by governmental authorities in the U.S. and other countries. The process of obtaining FDA and other necessary regulatory approvals is lengthy, expensive and uncertain. FDA and other legal and regulatory requirements applicable to our proposed products could substantially delay or prevent us from initiating additional clinical trials. We may fail to obtain the necessary approvals to commence clinical testing or to manufacture or market our potential products in reasonable time frames, if at all. In addition, the U.S. Congress and other legislative bodies may enact regulatory reforms or restrictions on the development of new therapies that could adversely affect the regulatory environment in which we operate or the development of any products we may develop.

A substantial portion of our research and development entails the use of stem cells obtained from human tissue. The U.S. federal and state governments and other jurisdictions impose restrictions on the acquisition and use of human tissue, including those incorporated in federal Good Tissue Practice, or “GTP,” regulations. These regulatory and other constraints could prevent us from obtaining cells and other components of our products in the quantity or of the quality needed for their development or commercialization. These restrictions change from time to time and may become more onerous. Additionally, we may not be able to identify or develop reliable sources for the cells necessary for our potential products — that is, sources that follow all state and federal laws and guidelines for cell procurement. Certain components used to manufacture our stem and progenitor cell product candidates will need to be manufactured in compliance with the FDA’s GMP. Accordingly, we will need to enter into supply agreements with companies that manufacture these components to GMP standards. There is no assurance that we will be able to enter into any such agreements.

Noncompliance with applicable regulatory requirements can subject us, our third party suppliers and manufacturers and our other collaborators to administrative and judicial sanctions, such as, among other things, warning letters, fines

and other monetary payments, recall or seizure of products, criminal proceedings, suspension or withdrawal of regulatory approvals, interruption or cessation of clinical trials, total or partial suspension of production or distribution, injunctions, limitations on or the elimination of claims we can make for our products, refusal of the government to enter into supply contracts or fund research, or government delay in approving or refusal to approve new drug applications.

We cannot predict if or when we will be able to commercialize our products due to regulatory constraints.

Federal, state and local governments and agencies in the U.S. (including the FDA) and governments in other countries have significant regulations in place that govern many of our activities. We are, or may become, subject to various federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances used in connection with its research and development work. The preclinical testing and clinical trials of our proposed products are subject to extensive government regulation that may prevent us from creating commercially viable products. In addition, our sale of any commercially viable product will be subject to government regulation from several standpoints, including manufacturing, advertising, marketing, promoting, selling, labeling and distributing. If, and to the extent that, we are unable to comply with these regulations, our ability to earn revenues, if any, will be materially and negatively impacted.

If our clinical trials fail to demonstrate that any of our product candidates are safe and effective for the treatment of particular diseases, the FDA may require us to conduct additional clinical trials or may not grant us marketing approval for such product candidates for those diseases.

We are not permitted to market our product candidates in the United States until we receive approval of a BLA or NDA from the FDA. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with evidence gathered in preclinical and well-controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA and, with respect to approval in other countries, similar regulatory authorities in those countries, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls used to produce the product are compliant with applicable statutory and regulatory requirements. Our failure to adequately demonstrate the safety and effectiveness of any of our product candidates for the treatment of particular diseases may delay or prevent our receipt of the FDA's approval and, ultimately, may prevent commercialization of our product candidates for those diseases. The FDA has substantial discretion in deciding whether, based on the benefits and risks in a particular disease, any of our product candidates should be granted approval for the treatment of that particular disease. Even if we believe that a clinical trial or trials has demonstrated the safety and statistically significant efficacy of any of our product candidates for the treatment of a disease, the results may not be satisfactory to the FDA. Preclinical and clinical data can be interpreted by the FDA and other regulatory authorities in different ways, which could delay, limit or prevent regulatory approval. If regulatory delays are significant or regulatory approval is limited or denied altogether, our financial results and the commercial prospects for those of our product candidates involved will be harmed, and our prospects for profitability will be significantly impaired.

Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain, and subject to unanticipated delays. Despite our efforts, our drug candidates may not:

- offer improvement over existing comparable products;
- be proven safe and effective in clinical trials; or
- meet applicable regulatory standards.

In addition, in the course of its review of a BLA or NDA or other regulatory application, the FDA or other regulatory authorities may conduct audits of the practices and procedures of a company and its suppliers and contractors concerning manufacturing, clinical study conduct, non-clinical studies and several other areas. If the FDA and/or other regulatory authorities conducts an audit relating to a BLA, NDA or other regulatory application and finds a significant deficiency in any of these or other areas, the FDA or other regulatory authorities could delay or not approve such BLA, NDA or other regulatory application. If regulatory delays are significant or regulatory approval is limited or denied altogether, our financial results and the commercial prospects for those of our products or product candidates involved will be harmed, and our prospects for profitability will be significantly impaired.

Both before and after marketing approval, our product candidates are subject to extensive and rigorous ongoing regulatory requirements and continued regulatory review, and if we fail to comply with these continuing requirements, we could be subject to a variety of sanctions.

Both before and after the approval of our product candidates, we, our product candidates, our operations, our facilities, our suppliers, and our contract manufacturers, contract research organizations, and contract testing laboratories are subject to extensive regulation by governmental authorities in the United States and other countries, with regulations differing from country to country. In the United States, the FDA regulates, among other things, the pre-clinical testing, clinical trials, manufacturing, safety, efficacy, potency, labeling, packaging, adverse event reporting, storage, record keeping, quality systems, advertising, promotion, sale and distribution of therapeutic products. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP, requirements and current good clinical practice, or cGCP, requirements for any clinical trials that we conduct post-approval. Failure to comply with applicable requirements could result in, among other things, one or more of the following actions: restrictions on the marketing of our products or their manufacturing processes, notices of violation, untitled letters, warning letters, civil penalties, fines and other monetary penalties, unanticipated expenditures, delays in approval or refusal to approve a product candidate, suspension or withdrawal of regulatory approvals, product, seizure or detention, voluntary or mandatory product recalls and related publicity requirements, interruption of manufacturing or clinical trials, operating restrictions, injunctions, import or export bans, and criminal prosecution. We or the FDA, or an institutional review board, may suspend or terminate human clinical trials at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk.

The FDA’s policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

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

Undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Even if any of our drug candidates receives marketing approval, as greater numbers of patients use a drug following its approval, an increase in the incidence of side effects or the incidence of other post-approval problems that were not seen or anticipated during pre-approval clinical trials could result in a number of potentially significant negative consequences, including:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

Even if our product candidates receive regulatory approval in the United States, we may never receive approval or commercialize our products outside of the United States.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval would impair our ability to develop foreign markets for our drug candidates.

Our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

We expect our stem cell product candidates to be regulated by the FDA as biologic products and we intend to seek approval for these products pursuant to the BLA pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated pathway for the approval of biosimilar and interchangeable biologic products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biologic products.

We believe that any of our product candidates approved as a biologic product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our drug candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

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

The following information is given with regard to unregistered securities sold from January 1, 2016 to March 31, 2016. The following securities were issued in private offerings pursuant to the exemption from registration contained in the Securities Act and the rules promulgated thereunder in reliance on Section 4(2) thereof, relating to offers of securities by an issuer not involving any public offering:

- On February 15, 2016, as an inducement to Mr. Daly's employment, we granted an inducement option to purchase 2,750,000 shares of Common Stock. The option has a term of ten (10) years, and vests as follows: (i) 687,500 options vest on the six (6) month anniversary of the grant date, (ii) 687,500 options vest on the one (1) year anniversary of the grant date and the remaining 1,375,000 options vesting quarterly over the subsequent three (3) year period such that the option will be fully vested on the four (4) year anniversary of the grant date.

- On May 12, 2016, we entered into private placement securities purchase agreements with certain accredited investors to purchase 2,700,000 of common stock and 2,700,000 common stock purchase warrants at a price of $0.40 per each share and common stock purchase warrant. We received aggregate gross proceeds of approximately $1,080,000 and net proceeds of approximately $925,000. The warrants allow the holder to purchase one share of common stock, have an exercise price of $0.40 per share and a term of 5 years. The warrants contain certain non-standard anti-dilution protection and. Consequently, are being accounted for as derivative instruments recorded at fair value each period. This private placement transaction was not made pursuant to any registration statement.

ITEM 3. DEFAULT UPON SENIOR SECURITIES

None

ITEM 4. MINE SAFETY DISCLOSURE

Not Applicable

ITEM 5. OTHER INFORMATION

- On August 6, 2016, Dr. Karl Johe informed the Company that he is resigning effective immediately as a member of board of directors. Dr. Johe's resignation from the board of directors did not result from any disagreement with the Company on any matter relating to the Company's operations, policies or practices. A copy of the resignation letter from Dr. Johe is attached to this quarterly report as Exhibit 99.01.

- On August 9, 2016, the Company's board of directors created a scientific policy committee consisting of the following employees: (i) Dr. Karl Johe, Chief Scientific Officer, (ii) Richard Daly, President and Chief Executive Officer and (iii) Dr. Thomas Hazel, Senior Vice President of Research. Dr. Karl Johe was appointed as the chairman of the committee. The committee shall oversee all of the Company's scientific development policies and will assume all prior policy making functions, duties and responsibilities of the Company's Chief Scientific Officer. Accordingly, the Company's Chief Scientific Officer will continue to report to the Chief Executive Officer and he shall no longer be considered an officer of the Company as such term is defined under Section 16 of the Securities Exchange Act of 1934, as amended.

ITEM 6. EXHIBITS

The exhibits listed in the accompanying index to exhibits are filed or incorporated by reference as part of this Form 10-Q.

SIGNATURES

In accordance with the requirements of the Securities Exchange Act of 1934, the Registrant has caused this report to be signed by the undersigned hereunto duly authorized.

NEURALSTEM, INC.

Date: August 11, 2016 /s/ Richard Daly
Chief Executive Officer

/s/ Jonathan Lloyd Jones
Chief Financial Officer
(Principal Accounting Officer)

INDEX TO EXHIBITS

Exhibit No.	Description	Filed/ Furnished Herewith	Incorporated by Reference			
			Form	Exhibit No.	File No.	Filing Date
3.01(i)	Amended and Restated Certificate of Incorporation of Neuralstem, Inc. filed on 7/9/14		10-Q	3.01(i)	001-33672	8/8/14
3.02(ii)	Amended and Restated Bylaws of Neuralstem, Inc. adopted on 11/10/2015		8-K	3.01	001-33672	11/16/15
4.01**	Amended and Restated 2005 Stock Plan adopted on 6/28/07		10-QSB	4.2(i)	333-132923	8/14/07
4.02**	Non-qualified Stock Option Agreement between Neuralstem, Inc. and Richard Garr dated 7/28/05		SB-2	4.4	333-132923	6/21/06
4.03**	Non-qualified Stock Option Agreement between Neuralstem, Inc. and Karl Johe dated 7/28/05		SB-2	4.5	333-132923	6/21/06
4.04**	Neuralstem, Inc. 2007 Stock Plan		10-QSB	4.21	333-132923	8/14/07
4.05	Form of Common Stock Purchase Warrant Issued to Karl Johe on 6/5/07		10-KSB	4.22	333-132923	3/27/08
4.06	Form of Placement Agent Warrant Issued to Midtown Partners & Company on 12/18/08		8-K	4.1	001-33672	12/18/08
4.07	Form of Consultant Common Stock Purchase Warrant issued on 1/5/09		S-3/A	10.1	333-157079	2/3/09
4.08	Form of Series D, E and F Warrants		8-K	4.01	001-33672	7/1/09
4.09	Form of Placement Agent Warrant		8-K	4.02	001-33672	7/1/09

4.10	Form of Consultant Warrant Issued 1/8/10	10-K	4.2	001-33672	3/31/10
4.11	Form of Replacement Warrant Issued 1/29/10	10-K	4.21	001-33672	3/31/10
4.12	Form of Series C Replacement Warrant Issued March of 2010 and May, June and July of 2013 (Original Ex. Price $2.13 and $1.25)	10-K	4.22	001-33672	3/31/10
4.13	Form of employee and consultant option grant pursuant to our 2007 Stock Plan and 2010 Equity Compensation Plan	10-K	4.23	001-33672	3/31/10
4.14	Form of Warrants dated 6/29/10	8-K	4.01	001-33672	6/29/10
4.15**	Amended Neuralstem 2010 Equity Compensation Plan adopted on June 21, 2013	DEF 14A	Appendix I	001-33672	4/30/13
4.16	Form of Consultant Warrant issued 10/1/09 and 10/1/10	S-3	4.07	333-169847	10/8/10
4.17**	Form of Restricted Stock Award Agreement pursuant to our 2007 Stock Plan and 2010 Equity Compensation Plan	S-8	4.06	333-172563	3/1/11
4.18**	Form of Restricted Stock Unit Agreement	S-8	4.08	333-172563	3/1/11
4.19	Form of Common Stock Purchase Warrant issued pursuant to February 2012 registered offering	8-K	4.01	001-33672	2/8/12
4.20	Form of Common Stock Purchase Warrant issued to Consultants in June of 2012 and March 19, 2013	10-Q	4.2	001-33672	8/9/12
4.21	Form of Underwriter Warrant issued to Aegis Capital Corp. on 8/20/12	8-K	4.1	001-33672	8/17/12
4.22	Form of Placement Agent Warrant issued to Aegis Capital Corp. on 9/13/12	8-K	4.1	001-33672	9/19/12

4.23	Form of Consulting Warrant issued January 2011 and March 2012	S-3	4.01	333-188859	5/24/13
	Form of Replacement Warrant issued January, February and May of 2013 (Original Ex. Prices $3.17 and $2.14)				
4.24	Form of Lender Warrant issued March 22, 2013	8-K	4.01	001-33672	3/27/03
4.25	Form of Advisor Warrant issued March 22, 2013	8-K	4.02	001-33672	3/27/13
4.26	Form of Warrant issued June of 2013 and July of 2014 to Legal Counsel	10-Q	4.26	001-33672	8/8/13
4.27	Form of Warrant issued in September 2013 in connection with Issuer's registered direct offering	8-K	4.01	011-33672	9/10/13
4.28	Form of Warrant issued to strategic advisor in August 2013	10-Q	4.28	001-33672	11/12/13
4.29	Form of Investor Warrant issued January 2014	8-K	4.01	001-33672	1/6/14
4.30	Form of Lender Warrant Issued October 28, 2014	8-K	4.01	001-33672	10/29/14
4.31**	Inducement Stock Option Plan adopted 2/15/2016	8-K	4.01	001-33672	2/19/16
4.32**	Form of Inducement Award Non-Qualified Stock Option Grant pursuant to Inducement Stock Option Plan	8-K	4.02	001-33672	2/19/16
4.33	Form of Common Stock Purchase Warrant From May 2016 Public Offering dated May 6, 2016	8-K	4.01	001-33672	5/3/16
4.34	Form of Common Stock Purchase Warrant from May 2016 Private Offering Dated May 12, 2016	8-K	4.01	001-33672	5/13/16
10.01**	Employment Agreement with I. Richard Garr dated January 1, 2007 and amended as of November 1, 2005	SB-2	10.1	333-132923	6/21/06
10.02**	Amended terms to the Employment Agreement of I Richard Garr dated January 1, 2008	10-K	10.02	001-33672	3/31/09

10.03**	Amended terms to the employment Agreement of I. Richard Garr dated March 1, 2015	8-K	10.01	001-33672	3/2/15
10.04**	Employment Agreement with Karl Johe dated January 1, 2007 and amended as of November 1, 2005	SB-2	10.2	333-132923	6/21/06
10.05**	Amended terms to the Employment Agreement of Karl Johe dated January 1, 2009	10-K	10.04	001-33672	3/31/09
10.06**	Employment Agreement with Thomas Hazel, Ph.D dated August 11, 2008	10-K/A	10.05	001-33672	10/5/10
10.07**	Employment Agreement with Richard Daly dated February 15, 2016	8-K	10.01	001-33672	2/19/16
10.08	Consulting Agreement dated January 2010 between Market Development Consulting Group and the Company and amendments No. 1 and 2.	10-K	10.07	001-33672	3/16/11
10.09**	Renewal of I. Richard Garr Employment Agreement dated 7/25/12	8-K	10.01	001-33672	7/27/12
10.10**	Renewal of Dr. Karl Johe Employment Agreement dated 7/25/12	8-K	10.02	001-33672	7/27/12
10.11**	Renewal of Dr. Tom Hazel Employment Agreement dated 7/25/12	8-K	10.03	001-33672	7/27/12
10.12	Loan and Security Agreement dated March 2013	8-K	10.01	001-33672	3/27/13
10.13	Intellectual Property and Security Agreement dated March 2013	8-K	10.02	001-33672	3/27/13
10.14	At the Market Offering Agreement entered into on October 25, 2013	8-K	10.01	001-33672	10/25/13
10.15**	Form of Amendment to Karl Johe Employment Agreement	8-K	10.01	001-33672	9/18/14
10.16	Form of Second Amendment to Loan and Security Agreement dated March of 2013 that was entered into on October 28, 2014	8-K	10.01	001-33672	10/29/14
10.17**	Offer Letter Between Neuralstem, Inc. and Jonathan Lloyd Jones	8-K	10.01	001-33672	5/11/15

10.18**	General Release and Waiver of Claims with I. Richard Garr dated 3/2/2016	8-K	10.01001-33672	3/4/16
10.19	Form of Securities Purchase Agreement from May 2016 Private Offering	8-K	10.01001-33672	5/13/16
10.20	Amendment to General Release and Waiver of Claims with I. Richard Garr dated 6/16/2016	8-K	10.01001-33672	6/16/16
31.1/31.2	Certification of the Principal Executive Officer and Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	*		
32.1/32.2	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. § 1350	*		
99.01	Resignation Letter from Dr. Karl Johe dated August 6, 2016	*		
101.INS	XBRL Instance Document	*		
101.SCH	XBRL Taxonomy Extension Schema	*		
101.CAL	XBRL Taxonomy Extension Calculation Linkbase	*		
101.DEF	XBRL Taxonomy Extension Definition Linkbase	*		
101.LAB	XBRL Taxonomy Extension Label Linkbase	*		
101.PRE	XBRL Taxonomy Extension Presentation Linkbase	*		

* Filed herein

** Management contracts or compensation plans or arrangements in which directors or executive officers are eligible to participate.