Neuralstem, Inc.
Form 10-Q
May 08, 2015
UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q
(Mark one)
x Quarterly Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934
For the Quarterly Period Ended March 31, 2015
Or
"Transition Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934
Commission File Number 000-1357459
Commission 2 no realist to value . Tex
NEURALSTEM, INC.
(Exact name of registrant as specified in its charter)

Delaware52-2007292State or other jurisdiction of<br/>incorporation or organization(I.R.S. Employer<br/>Identification No.)

20271 Goldenrod Lane Germantown, Maryland (Address of principal executive offices)	<b>20876</b> (Zip Code)
Registrant's telephone number, including	g area code (301)-366-4841
Securities Exchange Act of 1934 during	strant (1) has filed all reports required to be filed by Section 13 or 15(d) of the the preceding 12 months (or for such shorter period that the registrant was been subject to such filing requirements for the past 90 days. x Yes "No
any, every Interactive Data File required	strant has submitted electronically and posted on its corporate Web site, if to be submitted and posted pursuant to Rule 405 of Regulation S-T ceding 12 months (or for such shorter period that the registrant was required No
•	strant is a large accelerated filer, an accelerated filer, a non-accelerated filer, definitions of "large accelerated filer," "accelerated filer" and "smaller reporting e Act.
Large accelerated filer "	Accelerated filer x

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

Yes x No

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act) "

As of April 30, 2015, there were 90,336,643 shares of common stock, \$.01 par value, issued and outstanding.

# Neuralstem, Inc.

# **Table of Contents**

		Page
PART I	FINANCIAL INFORMATION	3
Item 1.	<u>Unaudited Condensed Consolidated Financial Statements</u>	3
	Unaudited Condensed Consolidated Balance Sheets as of March 31, 2015 and December 31, 2014	3
	Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss For the Three Months Ended March 31, 2015 and 2014	4
	Unaudited Condensed Consolidated Statements of Cash Flows For the Three Months Ended March 31, 2015 and 2014	5
	Notes to Unaudited Condensed Consolidated Financial Statements	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	14
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	22
Item 4.	Controls and Procedures	22
PART II -	OTHER INFORMATION	23
Item 1.	<u>Legal Proceedings</u>	23
Item 1A.	Risk Factors	23
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	36
Item 3.	Defaults Upon Senior Securities	36
Item 4.	Mine Safety Disclosure	36
Item 5.	Other Information	36
Item 6.	Exhibits	36

Signatures 36

Certificates

# **PART I**

# FINANCIAL INFORMATION

# ITEM 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Neuralstem, Inc.

# **Unaudited Condensed Consolidated Balance Sheets**

	March 31, 2015	December 31, 2014
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$13,593,461	\$12,518,980
Short-term investments	15,032,419	15,007,478
Trade and other receivables	8,173	225,524
Deferred financing fees, current portion	130,677	135,694
Prepaid expenses	388,065	274,106
Total current assets	29,152,795	28,161,782
Property and equipment, net	282,057	301,265
Patents, net	1,242,026	1,233,172
Deferred financing fees, net of current portion	62,992	89,143
Other assets	59,098	58,713
Total assets	\$30,798,968	\$29,844,075
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	\$2,129,199	\$2,504,978
Accrued bonuses	225,321	646,960
Current portion of long-term debt, net of discount	1,929,010	730,012
Other current liabilities	52,856	126,745
Total current liabilities	4,336,386	4,008,695
Long-term debt, net of discount and current portion	6,954,895	8,056,470
Other long-term liabilities	146,165	59,574
Total liabilities	11,437,446	12,124,739

# STOCKHOLDERS' EQUITY

Preferred stock, 7,000,000 shares authorized, zero shares issued and outstanding Common stock, \$0.01 par value; 300 million shares authorized, 90,336,643 and 903,366 877,897 87,789,679 shares outstanding in 2015 and 2014, respectively Additional paid-in capital 174,560,069 167,890,220 Accumulated other comprehensive income 6,013 6,000 Accumulated deficit (156,107,926) (151,054,781)Total stockholders' equity 19,361,522 17,719,336 Total liabilities and stockholders' equity \$30,798,968 \$29,844,075

See accompanying notes to unaudited condensed consolidated financial statements.

# Neuralstem, Inc.

# **Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss**

	Three Months 2015	s Ended March 31, 2014	
Revenues	\$ 2,917	\$ 4,167	
Operating expenses: Research and development expenses General and administrative expenses Total operating expenses Operating loss	3,182,823 1,433,074 4,615,897 (4,612,980	5,181,068	)
Other income (expense): Interest income Interest expense Loss from change in fair value of derivative instruments Other income Total other income (expense)	13,569 (453,734 - - (440,165	(334,133	)
Net loss	\$ (5,053,145	) \$ (5,919,057	)
Net loss per share - basic and diluted	\$ (0.06	) \$ (0.07	)
Weighted average common shares outstanding - basic and diluted	89,654,634	85,750,298	
Comprehensive loss: Net loss Foreign currency translation adjustment Comprehensive loss	\$ (5,053,145 13 \$ (5,053,132	(1,264	)

See accompanying notes to unaudited condensed consolidated financial statements.

# Neuralstem, Inc.

# **Unaudited Condensed Consolidated Statements of Cash Flows**

	Three Months 2015		ded March 31 2014	,
Cash flows from operating activities:				
Net loss	\$ (5,053,145	) 5	\$ (5,919,057	)
Adjustments to reconcile net loss to cash used in operating activities:				
Depreciation and amortization	83,773		90,488	
Share based compensation expense	689,857		2,440,999	
Amortization of deferred financing fees and debt discount	215,182		224,795	
Loss from change in fair value of derivative instruments	-		334,133	
Changes in operating assets and liabilities:				
Trade and other receivables	217,351		(1,359	)
Prepaid expenses	(71,207	)	(64,963	)
Other assets	(357	)	-	
Accounts payable and accrued expenses	(375,988	)	492,156	
Accrued bonuses	(421,639	)	(307,411	)
Other current liabilities	(3,648	)	626	
Other long term liabilities	-		(3,231	)
Net cash used in operating activities	(4,719,821	)	(2,712,824	)
Cash flows from investing activities:				
Purchases of short-term investments	(15,032,419	)	(15,000,000	)
Maturity of short-term investments	15,007,478		_	
Patent costs	(57,283	)	(112,068	)
Purchase of property and equipment	(16,052	)	(111,087	)
Net cash used in investing activities	(98,276	)	(15,223,155	)
Cash flows from financing activities:				
Proceeds from issuance of common stock from warrants exercised, net	3,073,537		1,391,466	
Proceeds from issuance of common stock from options exercised	-		113,000	
Proceeds from sale of common stock and warrants, net of issuance costs	2,931,925		19,101,034	
Payment of fees for future financing	(42,758	)	_	
Payment of taxes on stock option exercise	-	,	(426,212	)
Payments of long-term debt	-		(704,818	)
Payments of short-term notes payable	(70,241	)	(40,772	)
Net cash provided by financing activities	5,892,463	,	19,433,698	
Effects of exchange rates on cash	115		(1,035	)
Net increase in cash and cash equivalents	1,074,481		1,496,684	,
^	. ,			

Cash and cash equivalents, beginning of period	12,518,980	16,846,052
Cash and cash equivalents, end of period	\$13,593,461	\$ 18,342,736
Supplemental disclosure of cash flows information:  Cash paid for interest	\$ 238,552	\$ 214,622
Supplemental schedule of non cash investing and financing activities:  Issuance of common stock for cashless exercise of warrants and options	\$ 201,720	\$ 1,073,663

See accompanying notes to unaudited condensed consolidated financial statements.

#### **NEURALSTEM, INC.**

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2015 AND 2014

#### 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, 2014, 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, 2014, filed with the SEC, and as may be amended. Certain prior period amounts have been reclassified to conform to current year classifications. Specifically, depreciation and amortization expense is no longer shown as a separate line item; patent amortization is now included in research and development expense and fixed asset depreciation is included in general and administrative expense. Management feels that this reclassification better represents the expenses in their functional categories.

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 the our stem cell and small molecule product candidates with the goal of ultimately obtaining approval from the United States Food and Drug Administration (the "FDA"), to market and sell our products. While we believe our long-term cash position is inadequate to fund all of the costs associated with the full range of testing and clinical trials required by the FDA for our core product candidates, we anticipate that our available cash and expected income will be sufficient to finance our current activities at least through March 31, 2016.

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

# 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 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. 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 were estimated using level 3 unobservable inputs. See Note 3 for further details.

# 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 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 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 exclusively 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-month periods ended March 31, 2015 and 2014. A total of approximately 39.1 million and 39.8 million potential dilutive shares have been excluded in the calculation of diluted net income per share for the three-month periods ended March 31, 2015 and 2014, 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 three months ended March 31 2015 and 2014, 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 May 2014, the Financial Accounting Standards Board (FASB) issued *ASU 2014-09 – Revenue from Contracts with Customers*. This guidance is effective for fiscal years beginning after December 15, 2016 and early adoption is not permitted. This guidance is to be applied retrospectively. We have not yet determined the effects of this new guidance on our financial statements.

In April 2015, the FASB issued ASU 2015-03 – Interest-Imputation of Interest, Simplifying the Presentation of Debt Issuance Costs. This guidance 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 guidance is effective for fiscal years beginning after December 15, 2015 and early adoption is permitted. This guidance is to be applied retrospectively. This new pronouncement will result in our reclassifying amounts currently reflected as current and long-term assets to a contra-liability, which will reduce the carrying value of the associated debt instruments.

We have evaluated all additional Accounting Standards Updates through the date the financial statements were issued and believe the adoption of any new accounting and disclosure requirements will not have a material impact to our results of operations or financial position.

#### **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. Our Level 3 non-derivative assets

primarily comprise investments in certain corporate bonds and goodwill when it is recorded at fair value due to an impairment charge.

# 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 market values are based on period-end statements supplied by the various banks and brokers that held the majority of our funds.

We had no financial assets or liabilities measured at fair value on a recurring basis at March 31, 2015 or December 31, 2014.

The following table presents the activity for those items measured at fair value on a recurring basis using Level 3 inputs for the three months ended March 31, 2014:

Derivative
Instruments – Stock
Purchase Warrants
Balance at December 31, 2013 \$ 1,417,527
Change in fair value 334,133
Exercise of underlying warrants
Balance at March 31, 2014 \$ -

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.

# Non-Financial Assets and Liabilities Measure at Fair Value on a Recurring Basis

We have no non-financial assets or liabilities that are measured at fair value on a recurring basis.

# Non-Financial Assets and Liabilities Measured at Fair Value on a Nonrecurring Basis

We measure our long-lived assets, including property and equipment and patent assets, at fair value on a nonrecurring basis. These assets are recognized at fair value when they are deemed to be other-than-temporarily impaired. No such fair value impairment was recognized in the three-months ended March 31, 2015 or 2014.

#### Note 4. Debt

In March 2013, we entered into a loan and security agreement for an initial \$8 million term loan with an additional \$2 million of borrowing capacity if certain conditions involving new partnerships were met. The loan is collateralized by substantially all of our assets, including our intellectual property.

The loan provided for interest at a variable rate based on prime with a floor of 11% and matured in June 2016. The variable rate was 11% and did not change during the period through the loan amendment. The loan provided for interest only payments through December 2013 at which time monthly principal and interest payments of approximately \$300,000 were due through maturity. The loan resulted in net proceeds of approximately \$7,551,000 after origination and other cash fees and expenses related to the closing of the loan.

In conjunction with the loan agreement, we issued the lender a five-year common stock purchase warrant to purchase 648,809 shares of common stock at an exercise price of \$1.0789 per share. This warrant contained non-standard anti-dilution protection and, consequently, was being accounted for as a derivative instrument, recorded at fair market value each period (see Note 3). The allocation of proceeds to this warrant resulted in a debt discount which was amortized as interest expense over the term of the debt using the effective interest method. The warrant was exercised in the first quarter of 2014.

We also incurred expenses with various third parties in connection with the debt issuance, consisting of approximately \$449,000 in cash, 350,650 shares of common stock valued at approximately \$396,000, and a five-year common stock purchase warrant to purchase 648,798 shares at an exercise price of \$1.07892 per share. The warrant is classified as equity. Fees related to the debt offering are recorded as deferred financing fees and are being amortized as interest expense over the term of the debt using the effective interest method.

The loan agreement provided for a conversion feature whereby the lender or the Company could each convert up to a maximum of \$1 million in principal payments into common stock of the Company. In 2014, the lender elected to convert the maximum principal payments of \$1 million into 805,972 shares of our common stock in accordance with the terms of the loan and security agreement.

In October 2014, we entered into an agreement with the existing lender to refinance and amend the terms of our 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 March 2017 and a final balloon payment of approximately \$2.1 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 deferred financing fees and are being amortized as interest expense over the term of the debt using the effective interest method.

# 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 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 market 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 March 31, 2015, we have approximately 42.7 million shares of common stock reserved for issuance upon the exercise of such awards.

Share-based compensation expense included in the statements of operations for the three months ended March 31, 2015 and 2014 was as follows:

	Three Months Ended March 31,		
	2015	2014	
Research and development expenses General and administrative expenses Total	\$ 278,180 411,677 \$ 689,857	\$ 233,573 2,207,426 \$ 2,440,999	

Included in general and administrative expenses for the three months ended March 31, 2014 is approximately \$2.0 million related to the extension of the term of a common stock purchase warrant based on the holder achieving certain performance based milestones.

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.

<u>Stock Options</u> A summary of stock option activity during the three months ended March 31, 2015 and related information is included in the table below:

	Number of Options	A E	Veighted- verage xercise rice	Weighted- Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2015	18,986,395	\$	1.89	5.1	\$ 2,306,807
Granted	490,901	\$	3.80		
Exercised	(9,935	) \$	2.40		\$ 30,600
Forfeited	(35,065	) \$	2.40		
Outstanding at March 31, 2015	19,432,296	\$	1.94	5.0	\$ 10,661,919
Exercisable at March 31, 2015	15,268,586	\$	2.03	4.2	\$ 7,816,368
Vested and expected to vest	18,809,910	\$	1.97	4.9	\$ 10,078,814

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	7,000,000	\$ 0.80	5.3	\$ 7,700,000
\$1.01 - \$2.00	4,171,336	\$ 1.19	6.4	2,961,919
\$2.01 - \$3.00	2,123,333	\$ 2.50	4.5	-
\$3.01 - \$5.00	6,137,627	\$ 3.56	3.1	-
	19,432,296	\$ 1.94	5.0	\$ 10,661,919

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:

	Three Months Ended March 31,		
	2015	2014	
Annual dividend	-	-	
Expected life (in years)	6.0	4.0 - 8.5	
Risk free interest rate	1.70% - 1.78%	1.12% - 2.50%	
Expected volatility	69.3% - 69.4%	68.8% - 100.0%	

The options granted in the three months ended March 31, 2015 and 2014 had weighted average grant date fair values of \$2.38 and \$2.09, respectively.

Unrecognized compensation cost for unvested stock option awards outstanding at March 31, 2015 was approximately \$4,956,000 to be recognized over approximately 2.3 years.

<u>RSUs</u> We have granted restricted stock units (RSUs) to certain employees 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 three months ended March 31, 2015 is as follows:

	Number of RSU's	Weighted- Average Grant Date Fair Value
Outstanding at January 1, 2015	447,275	\$ 2.18
Granted	_	\$ -
Vested and converted to common shares	_	\$ -
Forfeited	_	\$ -
Outstanding at March 31, 2015	447,275	\$ 2.18
Exercisable at March 31, 2015	444,150	\$ 2.17

Unrecognized compensation cost for unvested RSUs outstanding at March 31, 2015 was approximately \$7,000 to be recognized over approximately 0.1 years.

<u>Stock Purchase Warrants</u> Warrants to purchase common stock were issued to certain officers, directors, stockholders and service providers. We have also issued warrants in conjunction with debt offerings and equity raises and at various times replacement warrants were issued in conjunction with warrant exercises.

A summary of warrant activity for the three months ended March 31, 2015 follows:

	Number of Warrants	Weighted- Average Exercised Price	Weighted- Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2015	21,422,346	\$ 2.30	3.8	\$15,984,739
Granted	-			
Exercised	(1,724,606)	\$ 1.94		
Forfeited	(24,794)	\$ 2.13		
Outstanding at March 31, 2015	19,672,946	\$ 2.34	3.8	\$6,618,385
Exercisable at March 31, 2015	19,635,446	\$ 2.34	3.8	\$6,618,385

The stock purchase warrants granted in the three months ended March 31, 2014 had a weighted average grant date fair value of \$2.08.

#### Common Stock

In January, 2014, we closed a registered direct offering of 6,872,859 shares of common stock at a price of \$2.91 per share. We received aggregate gross proceeds of \$20 million and net proceeds of approximately \$18,630,000 from the offering. In connection with the offering, we also issued 3,436,435 common stock purchase warrants; the warrants have an exercise price of \$3.64, a term of five years and are classified within equity. This offering was made pursuant to our \$50 million shelf registration statement declared effective by the SEC on September 13, 2013 (Registration No. 333-190936). Additionally, as a result of this transaction an advisor to the Company met certain capital raising milestones and consequently, the term of their common stock purchase warrant was extended to 5 years.

In 2014, we issued 249,163 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 \$3.55 per share and we received approximately \$838,000 in net proceeds.

In 2014, we issued a total of 1,234,428 shares of our common stock upon the exercise of outstanding common stock purchase warrants and stock options. The warrants and options were exercised at an average exercise price of \$1.44. We received approximately \$1,714,000 of net proceeds from the exercises.

In the 2014, we issued a total of 712,539 shares of our common stock upon the cashless and partial-cashless exercise of 1,194,372 outstanding common stock purchase warrants and stock options. The warrants and options were exercised at an average price of \$1.03. We received approximately \$20,000 of net proceeds from the exercises.

In 2014, we issued 568 shares of common stock upon conversion of certain outstanding RSU's. We received no proceeds from this transaction.

In 2014, we issued 805,972 shares of common stock upon the conversion by the lender of \$1 million of principal payments due under our March 2013 long-term debt in accordance with the terms of the loan and security agreement (see Note 4). We received no such proceeds from this conversion.

In October 2014, we issued 28,119 shares of common stock and common stock purchase warrants to purchase 133,329 to various parties in conjunction with our loan amendment (see Note 4).

In the three months ended March 31, 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.

In the three months ended March 31, 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.

In the three months ended March 31, 2015, we issued 29,141 shares of our common stock upon the cashless exercise of 89,000 outstanding common stock purchase warrants and stock options. The warrants and options were exercised at an average price of \$2.27. We received no proceeds from the exercises.

#### **Note 6. Commitments and Contingencies**

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.

On May 7, 2008, we filed suit against StemCells, Inc., StemCells California, Inc. (collectively "StemCells") and Neurospheres Holding Ltd. in U.S. District Court for the District of Maryland, alleging that U.S. Patent No. 7,361,505 (the "'505 patent") is invalid, not infringed, and unenforceable. See Civil Action No. 08-1173. On May 13, 2008 we filed an Amended Complaint seeking declaratory judgment that U.S. Patent No. 7,155,418 (the "'418 patent") is invalid and not infringed and that certain statements made by our CEO are not trade libel or do not constitute unfair competition. On September 11, 2008, StemCells filed its answer asserting counterclaims of infringement for the '505

patent, the '418 patent, and state law claims for trade libel and unfair competition. This case was consolidated with the 2006 litigation discussed below and it is not known when, nor on what basis, this matter will be concluded.

On July 28, 2006, StemCells, Inc., filed suit against Neuralstem, Inc. in the U.S. District Court in Maryland, alleging that Neuralstem has been infringing, contributing to the infringement of, and or inducing the infringement of four patents allegedly owned by or exclusively licensed to StemCells. See Civil Action No. 06-1877. We answered the Complaint denying infringement, asserting that the patents are invalid, asserting that we have intervening rights based on amendments made to the patents during reexamination proceedings, and further asserting that some of the patents are unenforceable due to inequitable conduct. Neuralstem has also asserted counterclaims that StemCells has engaged in anticompetitive conduct in violation of antitrust laws. On February 28, 2011, Neuralstem filed a Motion to Dismiss for lack of standing and concurrently filed a Motion for Leave to Amend its Answer and Counterclaim to allege that StemCells is not the exclusive licensee of the patents-in-suit and also that Neuralstem has obtained a non-exclusive license to the patents-in-suit. In addition, before the Court decided Neuralstem's Motion to Dismiss for lack of standing, StemCells filed a motion for summary judgment on the issue standing. Neuralstem responded to that motion and cross-moved for summary judgment on the issue of standing. The Court further issued its Markman Order (an order ruling on the scope and meaning of disputed patent claim language regarding the patents at issue) on August 12, 2011. On August 26, 2011, StemCells moved for reconsideration of two terms construed in the Markman Order and that motion remains pending. On April 6, 2012 the Court granted Neuralstem's Motion for Leave to Amend to assert lack of standing and denied Neuralstem's Motion to Dismiss and Motion for Summary Judgment without prejudice. The Court also denied StemCells' Motion for Summary Judgment with prejudice. The Court stayed all other matters pending resolution of the question of standing. The case was then reassigned to Judge Roger W. Titus.

Judge Titus held a bench trial on the issue of standing and inventorship on December 9, 11, and 12, 2014. The parties filed their post-trial briefs on January 16, 2015. Judge Titus is expected to issue an order that will either resolve the case in its entirety or will allow the case to move forward to expert discovery.

## **Note 7. Subsequent Events**

On May 5, 2015, we announced the appointment of Jonathan Lloyd Jones to the position of Chief Financial Officer, effective May 18, 2015. Mr. Lloyd Jones brings to the position more than 25 years of corporate finance and business development experience. He previously served as Chief Financial Officer at Columbia Laboratories (Juniper Pharmaceuticals), CFO and VP of Corporate Development at TetraLogic, and Senior Director, Corporate Development at Genzyme Corporation (Sanofi-Aventis). Mr. Lloyd Jones is a Chartered Accountant who holds a MBA degree from the Wharton School of the University of Pennsylvania a BS from the University of Bradford.

# ITEM 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, 2014, 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 (March 31, 2015), 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-month period ended March 31, 2015 are not necessarily indicative of our prospective financial condition and results of operations for the pending full fiscal year ending December 31, 2015. 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 periods ended March 31, 2015 to the comparable period of 2014.

*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 development and commercialization of regenerative medicine treatments based on our human neuronal stem cells and our small molecule compounds. We are headquartered in Germantown, Maryland and have a wholly-owned and consolidated subsidiary in China, Suzhou Sun-Now Biopharmaceutical Co. Ltd., or NeuralStem China.

We have developed and maintain a portfolio of patents and patent applications that form the proprietary base for our research and development efforts. We own or exclusively license ninety-six (96) U.S. and foreign issued patents and fifty-three (53) U.S. and foreign patent applications in the field of regenerative medicine, related to our stem cell technologies as well as our small molecule compounds. At times we have licensed the use of our intellectual property to third parties.

We believe our technology, in combination with our know-how, and collaborative projects with major research institutions, will facilitate the development and commercialization of products for use in the treatment of a wide array of neurodegenerative conditions and in regenerative repair of acute disease.

Regenerative medicine is still an emerging field. Regenerative medicine is the process of creating living, functional tissues to repair or replace tissue or organ function lost due to age, disease, damage, or congenital defects. 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 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, our scientific team and our facilities, to advance our technologies. In addition, we are pursuing strategic collaborations with members of academia and industry.

#### **Clinical Programs**

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

Program NSI - 566	Indication Amyotrophic Lateral Sclerosis (ALS)	Development Status Completion of Phase II clinical trial primarily evaluating safety.	Development Plan Preparation for a controlled Phase II t expected to commence in 2015.
NSI – 566	Chronic Spinal Cord Injury	Ongoing Phase I clinical trials.	The Phase I trial is ongoing.
NSI – 566	Motor deficits due to ischemic stroke	Completion of Phase I clinical trial evaluating safety.	The Phase II trial is expected to commence in 2015.
NSI – 189	Major Depressive Disorder	Phase II preparation underway.	The Phase II trial is expected to commence in mid 2015.
NSI-189	Cognitive Deficit in Schizophrenia	Phase Ib preparation.	The Phase Ib trial is expected to commence in 2015.

NSI - 566 (Stem Cells)

trial

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. 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 of the diseased motor neurons which have not yet died. Neuralstem received orphan designation by the FDA for NSI-566 in ALS which allows more imminent FDA reviews and responses.

We commenced the Phase I trial of NSI-566 in ALS at Emory University in Atlanta Georgia. The purpose of the Phase I trial was to evaluate the safety and transplantation technique of our proposed treatment and procedure specifically in the lumbar region of the spinal cord. The last cohort received both lumbar and cervical injections. The dosing of patients in the Phase I trial, as designed, was completed in August of 2012. We commenced our Phase II clinical trial for ALS in September of 2013 primarily evaluating safety of NSI-566 cells and cervical surgeries. The Phase II dose escalation trial enrolled 15 ambulatory patients in five different dosing cohorts, under an accelerated dosing and treatment schedule for a total of 18 surgeries. Each patient in the final cohort received transplantation in both the cervical and lumbar areas with 20 injections of 400,000 cells per injection; what we consider to be the maximum safe tolerated dose. The completion of the Phase II observation period of six months after the last surgery concluded in January 2015. In March, the company announced topline data concluding that the Phase II ALS clinical trial met the primary safety endpoints and established what we believe to be the maximum safe tolerated dose of 16 million cells delivered in 40 injections. Secondary efficacy endpoints such as the Amyotrophic Lateral Sclerosis Functional Rating Scale, or ALSFRS, and grip strength were evaluated at nine months post-surgery to assess the potential therapeuitic benefit of disease stabilization. The company will proceed to a larger Phase II controlled study. Although we believe the initial data from the Phase I and II trials appears promising, any future trials may ultimately be unsuccessful.

#### 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. Chronic spinal cord injury refers to the time after the initial hospitalization. Spinal cord injuries 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.

During the first quarter of 2013, we received authorization from the United States Food and Drug Administration, or FDA, to commence our proposed Phase I clinical trial to treat chronic spinal cord injury. The entire trial will take place at The University of California, San Diego. The trial commenced during the third quarter of 2014 and the first patient was treated in October 2014. We expect to complete enrollment in the first half of 2015 and data is expected in the fourth quarter of 2015.

Motor Deficits Due to 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. 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.

In September of 2012, we received authorization from the FDA to commence a human clinical trial for treatment of motor deficits due to ischemic stroke. The trial is being conducted by Neuralstem China, at BaYi Brain Hospital in Beijing, China utilizing our spinal cord stem cells. The trial authorization encompasses a combined phase I/II/III design and will test direct injections of NSI-566 into the brain, the same cell product used in our recently-completed Phase II ALS trial in the United States. The trial commenced in the fourth quarter of 2013 and is designed to enroll up to 118 patients. The first phase of the trial is structured to confirm the maximum safe tolerated dose and has been fully enrolled. We expect to begin the Phase II portion of the trial in 2015.

Acute Spinal Cord Injury

In the fourth quarter of 2013 we filed an investigatory new drug application, or IND, with the Ministry of Food and Drug Safety in Korea, or MFDS, to start a trial for treatment of acute spinal cord injury (within several weeks of the injury) in Seoul Korea. If approved as submitted, this trial will treat complete patients, who are those who have no sensory or motor function below the point of the injury and also progressively incomplete patients, who have varying degrees of each. We now anticipate this trial being authorized by MFDS in 2015.

NSI - 189 (Small Molecule Pharmaceutical Compound)

*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. 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 structurally rebuilding the hippocampus.

In February of 2011, we commenced a Phase I clinical trial (Phase Ia portion), NSI-189, at California Clinical Trials, LLC, in Glendale, California. The purpose of the Phase Ia portion of the trial was to evaluate the safety of the drug in healthy volunteers. The Phase Ia portion tested a single oral administration of NSI-189 in 24 healthy volunteers and was completed in October of 2011. In December of 2011, we received authorization from the FDA to commence the Phase Ib randomized, dose-escalating, placebo controlled clinical trial for the treatment of MDD. The primary end points of the Phase Ib portion of the clinical trial were to determine the drug safety and tolerability in three dosages in diagnosed MDD patients. Secondary endpoints included traditional depression scales tests, cognition testing and testing for both electrophysiological and traditional plasma biomarkers for Depression. The Phase Ib trial entailed patients with MDD receiving daily doses, or placebo for 28 consecutive days followed by an eight week post dose observation period. The trial was completed and data was presented at two conferences: the American Society of Clinical Psychopharmacology Annual Meeting in Hollywood, Florida and at the International College of Neuropyschopharmacology Annual Meeting in Vancouver Canada. We are currently preparing regulatory and clinical protocol for a Phase II approximately 150 patient, multi-site clinical trial that is expected to commence in 2015. Although we believe data from the Phase Ia/b appears promising, any future trials may ultimately be unsuccessful.

Cognitive Deficit in Schizophrenia

We have expanded the NSI-189 program to include a second indication for the treatment of cognitive deficit in schizophrenia. Cognitive deficit is a prominent characteristic of schizophrenia that is correlated with the occurrence of hippocampal atrophy in this patient population. We expect the Phase Ib trial to commence in 2015.

**Technology** 

Stem Cells

Our technology enables the isolation and large-scale expansion of 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 thirty-eight (38) U.S. and foreign issued patents and thirty-seven (37) U.S. and foreign patent applications related to our stem cell technologies.

We have developed and patented a series of small molecule compounds. 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. 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 the small molecule compounds may assist in reversing atrophy in the human hippocampus documented in indications such as MDD and schizophrenia.

Our small molecule compounds are covered by fifty-eight (58) exclusively owned U.S. and foreign issued patents and sixteen (16) exclusively owned U.S. and foreign patent applications related to our small molecule compounds.

#### Research

Substantial resources are devoted to our research programs in order to isolate and develop a series of neural stem cell banks that we believe can serve as a basis for our therapeutic product candidates. Our efforts are directed at developing therapies utilizing our stem cells and small molecule regenerative drug candidates. This research is conducted internally, through the use of third party laboratories and consulting companies under our direct supervision, and through collaboration with academic institutes.

#### **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.

#### **Manufacturing**

We currently manufacture our cells both in-house and on an outsourced basis. We outsource the manufacturing of our pharmaceutical compounds to third party manufacturers. We manufacture, in-house, cells that are not required to meet stringent FDA requirements. We use these cells in our research and collaborative programs. During 2015, we are beginning the process of bringing the manufacturing of our spinal cord stem cells, in-house to better assure availability of our stem cells as the number of patients in our trials increase. We will also continue to outsource manufacturing and storage of our stem cells and pharmaceuticals compound to be used in clinical and pre-clinical work studies to Charles River Laboratories, Inc., of Wilmington, Massachusetts, or Charles River, (stem cells) and Albany Molecular Resources, Inc., or AMRI, (small molecule). We believe both the Charles River and AMRI facilities have the capacity to be used for manufacturing under the FDA's cGMP and GTP standards, as applicable, in quantities sufficient for our current and anticipated pre-trial and clinical trial needs. We have no quantity or volume commitment with either Charles River Laboratories or AMRI and our cells and pharmaceutical compounds are ordered and manufactured on an as needed basis. As part of our plan to bring a portion of the manufacturing of our stem cells in house, we relocated our headquarters to a facility with GMP manufacturing capability. We anticipate the facility will be ready to commence manufacturing of our stem cells for our clinical trials by the second quarter of 2015. Such increased manufacturing will supplement our current outsource supply of both stem cells and pharmaceutical compounds. We believe such additional manufacturing capacity will be beneficial as our clinical trials expand by indication, geographic region and to larger patient populations and will allow us to begin to build the infrastructure in-house as we move towards complete internal control of our cell manufacturing needs.

## **Employees**

As of March 31, 2015, we had 21 full-time employees and four (4) full-time independent contractors. Of these full-time employees and contractors, 18 work on research and development and seven (7) 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 Facebook Page (https://www.facebook.com/Neuralstem)

Neuralstem's Company Blog (http://neuralstem.com/neuralstem-ceo-blog)

Neuralstem's Google+ Page

(https://plus.google.com/u/0/b/104875574397171789280/104875574397171789280/posts)

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

Neuralstem Asia's Tencent Weibo Account (http://t.qq.com/neuralstem)

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 stem cell technology and small molecule compounds. We are also pursuing pre-clinical studies on other central nervous system indications in preparation for potential future clinical trials.

In the first quarter of 2013 and the third quarter of 2012, we licensed the use of certain of our intellectual property to third parties. During the three-months ended March 31, 2015 and 2014, we recognized approximately \$3,000 and \$4,000 of revenue, respectively, related to ongoing fees under these licenses.

On a long-term basis, we anticipate that our revenue will be derived primarily from licensing fees and sales of our cell based therapy and small molecule compounds. 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 contractor and personnel expenses associated with clinical trials and regulatory submissions; costs associated with preclinical activities such as proof of principle for new indications; toxicology studies; costs associated with cell processing and process development; facilities-related costs and supplies. Clinical trial expenses include payments to research organizations, contract manufacturers, clinical trial sites, consultants and laboratories for testing clinical samples.

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.

For a further description of these clinical trials, see the section of this report entitled "Clinical Programs" contained in Item 2.

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 into our anticipated Phase II trials. To the extent that it is practical, we will continue to outsource much of our efforts, including product manufacture, proof of principle and pre-clinical testing, toxicology, tumorigenicity, dosing rationale, and development of clinical protocol and IND applications. This approach allows us to use the best expertise available for each task and permits staging new research projects to fit available cash resources.

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, legal 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 three months ended March 31 2015 and 2014, 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 were 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 March 31, 2015 and 2014

#### Revenue

We did not generate any revenues from the sale of our products in any of the periods presented. For the three months ended March 31, 2015 and 2014, we recognized approximately \$3,000 and \$4,000, respectively related to the licensing of certain intellectual properties to third parties.

#### **Operating Expenses**

Operating expenses for the three months ended March 31, 2015 and 2014 were as follows:

	Three Months	Ended March 31,	Increase (Decrease)		
	2015	2014	\$	<b>%</b>	
Operating Expenses					
Research and development expenses	\$ 3,182,823	\$ 1,630,365	\$1,552,458	95 %	
General and administrative expenses	1,433,074	3,550,703	(2,117,629	(60)%	
Total operating expenses	\$ 4,615,897	\$ 5,181,068	\$ (565,171	(11)%	

#### Research and Development Expenses

The increase of approximately \$1,552,000 or 95% in research and development expenses was primarily attributable to a \$1,151,000 increase in project and lab expenses, a \$274,000 increase in payroll and related expenses due to increased salaries and headcount and a \$75,000 increase in travel and related expenses. These increased expenses are related to the expansion of our pre-clinical and clinical trial efforts and are expected to continue into subsequent periods.

# General and Administrative Expenses

The decrease of approximately \$2,118,000 or 60% was primarily due to a decrease of \$1,796,000 in non-cash stock based compensation largely the result of an expense in the first quarter of 2014 related to a consultant achieving a performance based milestone coupled with a \$466,000 decrease in legal fees primarily resulting from insurance claims related to litigation expense. These decreases are partially offset by an \$86,000 increase in consulting expenses and a \$74,000 increase in payroll and related expenses due to increased salaries and headcount.

#### Other expense

Other expense totaled approximately \$440,000 and \$742,000 for the three months ended March 31, 2015 and 2014, respectively. Other expense in 2015 consisted of \$454,000 of interest expense principally related to our long-term debt partially offset by \$14,000 of interest income.

Other expense in 2014 consisted primarily of \$432,000 of interest expense principally related to our long-term debt and a \$334,000 expense related to the change in fair value of the Company's warrant liabilities partially offset by \$25,000 in interest income.

## **Liquidity and Capital Resources**

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. In January 2014, we received approximately \$20 million of gross proceeds from the sale or our securities pursuant to a registered direct offering.

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.

	Three Month	s Ended March 31,	Increase (Decrease)		
	2015	2014	\$	<b>%</b>	
Net cash used in operating activities	\$ (4,719,821	) \$ (2,712,824	) \$(2,006,997 )	(74)%	
Net cash used in investing activities	\$ (98,276	) \$ (15,223,155	) \$15,124,879	99 %	
Net cash provided by financing activities	\$ 5,892,463	\$ 19,433,698	\$(13,541,235)	(70)%	

Our cash and short-term investment balances was approximately \$28,626,000 at March 31, 2015 compared to \$27,526,000 at December 31, 2014. The increase of \$1,100,000 was primarily due to our raising \$6,005,000, net from the issuance of our common stock from warrant exercises and from the sale of our common stock largely offset by our cash used in operations.

## Net Cash Used in Operating Activities

We used approximately \$4,720,000 and \$2,713,000 of cash in our operating activities for the three months ended March 31, 2015 and 2014, respectively. The increase in our use of cash of approximately \$2,007,000 was primarily due to an increase in our net loss as adjusted for stock based compensation coupled with changes in our operating assets and liabilities.

#### Net Cash Used in Investing Activities

We used approximately \$98,000 and \$15,223,000 of cash in connection with investment activities for the three months ended March 31, 2015 and 2014, respectively. The decrease in our use of cash of approximately \$15,125,000 was primarily due to our purchase of short-term investments using the proceeds from our January 2014 registered direct offering.

## Net Cash Provided by Financing Activities

Proceeds from financing activities were approximately \$5,892,000 and \$19,434,000 in the three months ended March 31, 2015 and 2014, respectively. The decrease of \$13,541,000 was primarily the result of raising approximately \$19,101,000, net from our registered direct offering and other sales of common stock and warrants in 2014 as compared to raising \$2,932,000, net from the sales of our common stock in 2015. In addition, we raised approximately \$3,074,000 and \$1,391,000 in 2015 and 2014, respectively from the issuance of our common stock from warrant exercises. In 2014 we also made \$705,000 of payments on our long term debt compared to no principal payments being due or made in 2015.

#### 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 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, we have not sold any securities under this shelf registration statement. 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 March 31, 2015 we have sold or reserved for sale upon the exercise of outstanding warrants approximately \$48.2 million of securities under this shelf registration statement. Additionally, securities sold pursuant to our At the Market Offering Agreement (see below) are being sold pursuant to this registration statement and accordingly, we have reserved the balance of approximately \$1.8 million of securities pursuant thereto. We anticipate conducting financing in the future based on our shelf registration statement when and if financing opportunities arise.

In October 2013, we entered into an At the Market Offering Agreement with T.R. Winston & Company as our sales agent pursuant to which we can sell up to \$25 million of our common stock. The At the Market Offering Agreement was entered into pursuant to a takedown from our shelf registration statement declared effective on September 13, 2013 (Registration No. 333-190936). To date through March 31, 2015 we have sold 2,202,580 shares under such agreement at an average price per share of \$3.16 resulting in gross proceeds of approximately \$6,965,000 and net proceeds of approximately \$6,666,000. Future sales under our agreement are limited to approximately \$1.8 million which is the amount available under our shelf registration of which the At the Market Offering Agreement is part of.

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.

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, 2015 a one percentage point increase in the prime rate would increase our interest expense by approximately \$90,000.

Our foreign operations in China subject us to changes in foreign exchange rates. Changes in exchange rates for the year ended December 31, 2015 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**

Disclosure controls and procedures are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act are recorded, processed, summarized and reported, within the time period specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports filed under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer (CEO) who is also our acting Chief Financial Officer (CFO), as appropriate, to allow timely decisions regarding required disclosure.

Based on management's evaluation (with the participation of our CEO, who is also our acting CFO), as of the end of the period covered by this report, our CEO has concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)), are effective to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

#### **Changes in Internal Control over Financial Reporting**

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. 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, and therefore, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. We do not expect that our disclosure controls and procedures or our internal control over financial reporting are able to prevent with certainty all errors and all fraud.

#### **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.

On May 7, 2008, we filed suit against StemCells, Inc., StemCells California, Inc. (collectively "StemCells") and Neurospheres Holding Ltd. in U.S. District Court for the District of Maryland, alleging that U.S. Patent No. 7,361,505 (the "'505 patent") is invalid, not infringed, and unenforceable. See Civil Action No. 08-1173. On May 13, 2008 we filed an Amended Complaint seeking declaratory judgment that U.S. Patent No. 7,155,418 (the "'418 patent") is invalid and not infringed and that certain statements made by our CEO are not trade libel or do not constitute unfair competition. On September 11, 2008, StemCells filed its answer asserting counterclaims of infringement for the '505 patent, the '418 patent, and state law claims for trade libel and unfair competition. This case was consolidated with the 2006 litigation discussed below and it is not known when, nor on what basis, this matter will be concluded.

On July 28, 2006, StemCells, Inc., filed suit against Neuralstem, Inc. in the U.S. District Court in Maryland, alleging that Neuralstem has been infringing, contributing to the infringement of, and or inducing the infringement of four patents allegedly owned by or exclusively licensed to StemCells. See Civil Action No. 06-1877. We answered the Complaint denying infringement, asserting that the patents are invalid, asserting that we have intervening rights based on amendments made to the patents during reexamination proceedings, and further asserting that some of the patents are unenforceable due to inequitable conduct. Neuralstem has also asserted counterclaims that StemCells has engaged in anticompetitive conduct in violation of antitrust laws. On February 28, 2011, Neuralstem filed a Motion to Dismiss for lack of standing and concurrently filed a Motion for Leave to Amend its Answer and Counterclaim to allege that StemCells is not the exclusive licensee of the patents-in-suit and also that Neuralstem has obtained a non-exclusive license to the patents-in-suit. In addition, before the Court decided Neuralstem's Motion to Dismiss for lack of standing, StemCells filed a motion for summary judgment on the issue standing. Neuralstem responded to that motion and cross-moved for summary judgment on the issue of standing. The Court further issued its Markman Order (an order ruling on the scope and meaning of disputed patent claim language regarding the patents at issue) on August 12, 2011. On August 26, 2011, StemCells moved for reconsideration of two terms construed in the Markman Order and that motion remains pending. On April 6, 2012 the Court granted Neuralstem's Motion for Leave to Amend to assert lack of standing and denied Neuralstem's Motion to Dismiss and Motion for Summary Judgment without prejudice. The Court also denied StemCells' Motion for Summary Judgment with prejudice. The Court stayed all other matters pending resolution of the question of standing. The case was then reassigned to Judge Roger W. Titus.

Judge Titus held a bench trial on the issue of standing and inventorship on December 9, 11, and 12, 2014. The parties filed their post-trial briefs on January 16, 2015. Judge Titus is expected to issue an order that will either resolve the case in its entirety or will allow the case to move forward to expert discovery.

#### 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, 2014, 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 have a history of losses.

Since inception in 1996 and through March 31, 2015, we have accumulated losses totaling approximately \$156,108,000. On March31, 2015, we had a working capital surplus of approximately \$24,816,000 and stockholders' equity of approximately \$19,362,000. Our net losses for the two most recent fiscal years have been approximately \$22,629,000 and \$19,832,000 for 2014 and 2013, respectively while our loss for the three months ended March 31, 2015 was approximately \$5,053,000. We had no revenue from the sales of our products during the three months ended March 31, 2015 or 2014.

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 ultimately sell our proposed products. To date, none of our proposed products have been approved for sale and 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, receive regulatory approval, 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 March 31, 2015, we had cash, cash equivalents and short-term investments on hand of approximately \$28,626,000. 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 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 March 31, 2015, we had approximately \$9.5 million in aggregate principal outstanding of long-term indebtedness. Under our amended loan and security agreement, we are required to make monthly interest only payments through September 2015; interest and principal payments of approximately \$460,000 per month from October 2015 through March 2017 and 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 will be in default, which would permit the holders of our indebtedness to accelerate the maturity and require immediate repayment which could lead to the 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 our \$10 million credit facility 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.

## **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 \$19,000 and \$110,000 for the years ended December 31, 2014 and 2013, respectively related to the licensing of certain intellectual property to third parties. 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.

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.

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 I and Phase II 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 I and Phase II trials, 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. By way of example, in May of 2008, we filed a complaint against StemCells Inc., alleging that U.S. Patent No. 7,361,505 (the "'505 patent"), allegedly exclusively licensed to StemCells, Inc., is invalid, not infringed and unenforceable. On the same day, StemCells, Inc. filed a complaint alleging that we had infringed, contributed to the infringement of, and or induced the infringement of two patents allegedly exclusively licensed to StemCells. Please refer to the section of this Quarterly Report entitled "Legal Proceedings" for a further discussion of the status of such litigation.

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 Mr. Garr and Dr. Johe which expire on October 31, 2017. In the event either individual is terminated prior to the full term of their respective contracts, for any reason other than a voluntary resignation, all compensation due to such employee under the terms of the respective agreement shall become due and payable immediately. These provisions will make the replacement of either of these employees very costly and could cause difficulty in effecting a change in control. Termination prior to the full term of these contracts would cost us as much as \$1.2 million for Mr. Garr and \$2.0 million for Dr. Johe and result in the immediate vesting of all outstanding options and/or warrants held by Mr. Garr and Dr. Johe.

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. At present, there is litigation with StemCells, Inc., which is further described in this Quarterly Report in the section entitled "Legal Proceedings."

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; 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 NYSE MKT. 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 March 31, 2015 we have issued and outstanding 90,336,643 shares of common stock and we have 42,712,265 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 March 31, 2015, we had no shares of preferred stock issued and outstanding. Accordingly, we are entitled to issue up to 166,951,092 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-566 and NSI-189. 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 (BLA or NDA) 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 during the three months ended March 31, 2015. The unregistered securities were issued pursuant to section 4(2) of the Securities Act:

We issued a total of 19,206 shares of common stock upon the cashless exercise of 44,000 outstanding common stock purchase warrants. The warrants had an average exercise price of \$2.13.

# ITEM 3. DEFAULT UPON SENIOR SECURITIES

None

# ITEM 4. MINE SAFETY DISCLOSURE

**Not Applicable** 

## **ITEM 5. OTHER INFORMATION**

None.

# 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: May 8, 2015 /s/ I. Richard Garr Chief Executive Officer

> /s/ I. Richard Garr Chief Financial Officer (Principal Accounting Officer)

# INDEX TO EXHIBITS

		T21 1/	<b>Incorporated by Reference</b>			
Exhibit No.	Description	Filed/ Furnished Herewith	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 7/16/07		10-QSB	3.2(i)	333-132923	8/14/07
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	02/3/09
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

		Filed/	Incorporated by Reference			
Exhibit No.	Description	Furnished Herewith		Exhibit No.	File No.	Filing Date
4.10	Form of Consultant Warrant Issued 1/8/10		10-K	4.20	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	4.20	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

		1791 - 37	<b>Incorporated by Reference</b>			
Exhibit No.	Description	Filed/ Furnished Herewith		Exhibit No.	File No.	Filing Date
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	011-33672	3/27/13
4.25	Form of Advisor Warrant issued March 22, 2013		8-K	4.02	011-33672	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
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

τ		Filed/	Incorporated by Reference			
Exhibit No.	Description	Furnished Herewith	Form	Exhibit No.	File No.	Filing Date
10.07	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
10.08**	Renewal of I. Richard Garr Employment Agreement dated 7/25/12		8-K	10.01	001-33672	7/27/12
10.09**	Renewal of Dr. Karl Johe Employment Agreement dated 7/25/12		8-K	10.02	001-33672	7/27/12
10.10**	Renewal of Dr. Tom Hazel Employment Agreement dated 7/25/12		8-K	10.03	001-33672	7/27/12
10.11	Loan and Security Agreement dated March 2013		8-K	10.01	011-33672	3/27/13
10.12	Intellectual Property and Security Agreement dated March 2013		8-K	10.02	011-33672	3/27/13
10.13	At the Market Offering Agreement entered into on October 25, 2013		8-K	10.01	011-33672	10/25/13
10.14	Form of Outside Director Agreement		10-K	10.13	011-33672	3/10/14
10.15**	Form of Amendment to Karl Johe Employment Agreement		8-K	10.01	011-33672	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	011-33672	10/29/14
14.01	Neuralstem Code of Ethics		SB-2			