

Neuralstem, Inc.  
Form 10-Q  
May 12, 2014

---

**U.S. SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

---

**FORM 10-Q**

(Mark one)

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

**For the Quarterly Period Ended March 31, 2014**

**Or**

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

**Commission File Number 000-1357459**

**NEURALSTEM, INC.**

(Exact name of registrant as specified in its charter)

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

<b>20271 Goldenrod Lane</b>	<b>20876</b>
<b>Germantown, Maryland</b>	<b>(Zip Code)</b>
(Address of principal executive offices)	

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

**9700 Great Seneca Highway, Rockville, Maryland 20850**  
(Former Address of principal executive offices)

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

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

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

Large accelerated filer

Accelerated filer

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

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

As of April 30, 2014, there were 86,762,455 shares of common stock, \$.01 par value, issued and outstanding.

**Neuralstem, Inc.**

Table of Contents

	Page
<b>PART I - <u>FINANCIAL INFORMATION</u></b>	<b>3</b>
Item 1. <u>Unaudited Condensed Consolidated Financial Statements</u>	3
<u>Unaudited Condensed Consolidated Balance Sheets as of March 31, 2014 and December 31, 2013</u>	3
<u>Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss For the three months ended March 31, 2014 and 2013</u>	4
<u>Unaudited Condensed Consolidated Statements of Cash Flows For the three months ended March 31, 2014 and 2013</u>	5
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	22
Item 4. <u>Controls and Procedures</u>	23
<b>PART II <u>OTHER INFORMATION</u></b>	<b>23</b>
-	
Item 1. <u>Legal Proceedings</u>	23
Item 1A. <u>Risk Factors</u>	24
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	33
Item 3. <u>Defaults Upon Senior Securities</u>	33
Item 4. <u>Mine Safety Disclosure</u>	33
Item 5. <u>Other Information</u>	33
Item 6. <u>Exhibits</u>	33
<u>Signatures</u>	34

Certificates

2

**PART I****FINANCIAL INFORMATION****ITEM 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****Neuralstem, Inc.****Unaudited Condensed Consolidated Balance Sheets**

	March 31, 2014	December 31, 2013
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 18,342,736	\$ 16,846,052
Short-term investments	15,000,000	-
Billed and unbilled receivables	11,359	10,000
Deferred financing fees, current portion	435,547	507,334
Prepaid expenses	319,616	255,733
Total current assets	34,109,258	17,619,119
Property and equipment, net	310,375	230,971
Patents, net	1,190,625	1,137,701
Deferred financing fees, net of current portion	248,688	360,848
Other assets	64,850	64,897
Total assets	\$ 35,923,796	\$ 19,413,536
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable and accrued expenses	\$ 1,771,111	\$ 1,662,058
Current portion of long term debt, net of discount	2,849,812	2,763,121
Derivative instruments	-	1,417,527
Other current liabilities	53,280	93,426
Total current liabilities	4,674,203	5,936,132
Long term debt, net of discount and current portion	4,192,538	4,934,210
Other long term liabilities	160,338	124,995
Total liabilities	9,027,079	10,995,337
Commitments and contingencies (Note 6)		

STOCKHOLDERS' EQUITY

Preferred stock, 7,000,000 shares authorized, zero shares issued and outstanding	-	-
Common stock, \$0.01 par value; 150 million shares authorized, 86,688,613 and 77,886,031 shares outstanding in 2014 and 2013, respectively	866,886	778,860
Additional paid-in capital	160,368,948	136,058,135
Accumulated other comprehensive income	5,977	7,241
Accumulated deficit	(134,345,094)	(128,426,037)
Total stockholders' equity	26,896,717	8,418,199
Total liabilities and stockholders' equity	\$35,923,796	\$19,413,536

See accompanying notes to unaudited condensed consolidated financial statements.

**Neuralstem, Inc.****Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss**

	Three Months Ended March 31,	
	2014	2013
Revenues	\$ 4,167	\$ 102,500
Operating expenses:		
Research and development expenses	1,571,221	1,748,347
General and administrative expenses	3,519,359	1,195,840
Depreciation and amortization	90,488	50,093
Total operating expenses	5,181,068	2,994,280
Operating loss	(5,176,901 )	(2,891,780 )
Other income (expense):		
Interest income	24,718	9,925
Interest expense	(432,741 )	(48,257 )
Warrant modification expense	-	(666,736 )
Gain (loss) from change in fair value of derivative instruments	(334,133 )	6,518
Other income	-	243
Total other income (expense)	(742,156 )	(698,307 )
Net loss	\$ (5,919,057 )	\$ (3,590,087 )
Net loss per share - basic and diluted	\$ (0.07 )	\$ (0.05 )
Weighted average common shares outstanding - basic and diluted	85,750,298	68,700,709
Comprehensive loss:		
Net loss	\$ (5,919,057 )	\$ (3,590,087 )
Foreign currency translation adjustment	(1,264 )	-
Comprehensive loss	\$ (5,920,321 )	\$ (3,590,087 )

See accompanying notes to unaudited condensed consolidated financial statements.

**Unaudited Condensed Consolidated Statements of Cash Flows**

	Three Months Ended March 31,	
	2014	2013
Cash flows from operating activities:		
Net loss	\$ (5,919,057 )	\$ (3,590,087 )
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	90,488	50,093
Share based compensation expense	2,440,999	476,711
Amortization of deferred financing fees and debt discount	224,795	22,903
Warrant modification expense	-	666,736
(Gain) Loss from change in fair value of derivative instruments	334,133	(6,518 )
Changes in operating assets and liabilities:		
Billed and unbilled receivables	(1,359 )	(100,922 )
Prepaid expenses	(64,963 )	(18,325 )
Accounts payable and accrued expenses	184,745	(11,321 )
Other current liabilities	626	607
Other long term liabilities	(3,231 )	(2,605 )
Net cash used in operating activities	(2,712,824 )	(2,512,728 )
Cash flows from investing activities:		
Purchases of short-term investments	(15,000,000 )	-
Patent costs	(112,068 )	(95,161 )
Purchase of property and equipment	(111,087 )	(1,656 )
Net cash used in investing activities	(15,223,155 )	(96,817 )
Cash flows from financing activities:		
Proceeds from issuance of common stock from warrants exercised	1,391,466	322,500
Proceeds from issuance of common stock from options exercised	113,000	-
Proceeds from sale of common stock and warrants, net of issuance costs	19,101,034	-
Proceeds from long term debt, net of issuance costs	-	7,551,329
Payment of taxes on stock option exercise	(426,212 )	-
Payments of long term debt	(704,818 )	-
Payments of short term notes payable	(40,772 )	(48,817 )
Net cash provided by financing activities	19,433,698	7,825,012
Effects of exchange rates on cash	(1,035 )	-
Net increase in cash and cash equivalents	1,496,684	5,215,467
Cash and cash equivalents, beginning of period	16,846,052	7,443,773
Cash and cash equivalents, end of period	\$ 18,342,736	\$ 12,659,240
Supplemental disclosure of cash flows information:		
Cash paid for interest	\$ 214,622	\$ 910



Edgar Filing: Neuralstem, Inc. - Form 10-Q

Supplemental schedule of non cash investing and financing activities:

Prepayment of services through warrant issuance	\$ -	\$ 6,478
Issuance of common stock for cashless exercise of warrants	\$ 819,463	\$ -
Issuance of common stock for cashless exercise of options	\$ 254,200	\$ -
Issuance of common stock for fees related to debt issuance	\$ -	\$ 396,234
Issuance of warrants for fees related to debt issuance	\$ -	\$ 452,187

See accompanying notes to unaudited condensed consolidated financial statements.

**NEURALSTEM, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**MARCH 31, 2014 AND 2013**

**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, 2013, 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, 2013, filed with the SEC on March 10, 2014, and as may be amended.

Neuralstem, Inc. is referred to as "Neuralstem," the "Company," "us," or "we" throughout this report. Beginning in the quarter ended September 30, 2013, our investment in, and the operations of, our wholly-owned and controlled subsidiary located in China are consolidated in our condensed consolidated financial statements; previously, all investments in China were expensed as incurred. The impact of this change was not material in any period presented.

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, 2015.

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 are 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. The Company did not have any short-term investments at December 31, 2013.

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.

#### Revenue Recognition

Historically, our revenue has been derived primarily from (i) selling treated samples for gene expression data from stem cell experiments, (ii) providing services under various contracts and grants and (iii) licensing the use of our intellectual property to third parties. Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery of goods and services has occurred, the price is fixed and determinable, and collection is reasonably assured.

#### 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, 2014 and 2013. A total of approximately 39.8 million and 37.4 million potential dilutive shares have been excluded in the calculation of diluted net income per share for the three-month periods ended March 31, 2014 and 2013, 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 is determined at the grant 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 assess impairment of our long-lived assets using a "*primary asset*" approach to determine the cash flow estimation period for a group of assets and liabilities that represents the unit of accounting for a long-lived asset to be held and used. Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The carrying amount of a long-lived asset is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset. During the three month periods ended March 31, 2014 and 2013, no 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. Our income tax returns for the past three years are subject to examination by tax authorities and may change upon examination.

### Significant New Accounting Pronouncements

We have evaluated all 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. The fair value of other short-term financial instruments (primarily accounts receivable, short-term investments, inventory, prepaid expenses and other current assets, and accounts payable and accrued expenses) approximate their carrying values because of their short-term nature. The fair value of our long-term indebtedness approximates its carrying value.

At December 31, 2013, we had common stock purchase warrants issued in conjunction with our March 2013 debt offering (see Note 5) that are accounted for as derivative instruments whose fair market value is determined using Level 3 inputs. These warrants were exercised in their entirety in the first quarter of 2014.

The following table identifies the carrying amounts of such assets and liabilities at December 31, 2013:

	Level 1	Level 2	Level 3	Total
<u>Liabilities</u>				
Derivative instruments - stock purchase warrants	\$ -	\$ -	\$1,417,527	\$1,417,527
	\$ -	\$ -	\$1,417,527	\$1,417,527

We had no financial assets or liabilities measured at fair value on a recurring basis at March 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, 2013 and 2014:

	Derivative Instruments - Stock Purchase Warrants
Balance at December 31, 2012	\$ -
Issuance	452,198
Change in fair value	(6,518 )
Balance at March 31, 2013	\$ 445,680

	Derivative Instruments - Stock Purchase Warrants
Balance at December 31, 2013	\$ 1,417,527
Change in fair value	334,133
Exercise of underlying warrants	(1,751,660 )
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 increased 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 and 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 filing fees, 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, 2014 or 2013.

#### **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 are met. The loan is collateralized by substantially all of our assets, including our intellectual property.



The loan provides for interest at a variable rate based on prime with a floor of 11% and matures in June 2016. Our weighted average interest on outstanding borrowings was 11% for the year ended December 31, 2013. The loan calls for interest only payments through December 2013 at which time monthly principal and interest payments of approximately \$300,000 begin 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. Remaining principal payments due under this loan are approximately \$2,225,000, \$3,273,000 and \$1,797,000 in 2014, 2015 and 2016, respectively.

In conjunction with the loan agreement, the Company issued to 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 contains non-standard anti-dilution protection and, consequently, is being accounted for as a derivative instrument and is recorded at fair market value each period (see Note 3). The allocation of proceeds to this warrant resulted in a debt discount which is being 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.

**Note 5. Stockholders' Equity**

We have granted share-based compensation awards to employees, board members and service providers. Awards may consist of common stock, restricted common stock, restricted common stock units, warrants, or stock options. Our stock options and warrants have lives of up to ten years from the grant date. The stock options and warrants vest either upon the grant date or over varying periods of time. The stock options we grant provide for option exercise prices equal to or greater than the fair 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, 2014, we have approximately 44.5 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, 2014 and 2013 was as follows:

	Three Months Ended March 31,	
	2014	2013
Research and development expenses	\$ 233,573	\$ 206,480
General and administrative expenses	2,207,426	270,231
Total	\$ 2,440,999	\$ 476,711

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.

Stock Options A summary of stock option activity during the three months ended March 31, 2014 and related information is included in the table below:

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2014	18,577,207	\$ 1.79	5.8	\$ 24,000,710
Granted	408,482	\$ 3.22		
Exercised	(304,097 )	\$ 1.44		\$ 1,247,250
Forfeited	(220,903 )	\$ 0.62		
Outstanding at March 31, 2014	18,460,689	\$ 1.85	5.8	\$ 43,269,029

Edgar Filing: Neuralstem, Inc. - Form 10-Q

Exercisable at March 31, 2014	12,895,445	\$ 2.13	4.6	\$ 26,589,447
Vested and expected to vest	18,460,689	\$ 1.85	5.8	\$ 43,269,029

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	6.3	\$ 23,730,000
\$1.01 - \$2.00	4,281,837	\$ 1.19	7.4	12,846,782
\$2.01 - \$3.00	2,067,037	\$ 2.48	5.2	3,527,937
\$3.01 - \$4.00	5,111,815	\$ 3.57	4.0	3,164,310
	18,460,689	\$ 1.85	5.8	\$ 43,269,029

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:

	<b>Three Months Ended March 31,</b>	
	2014	2013
Annual dividend	-	-
Expected life (in years)	4.0 - 8.5	3.0 - 6.0
Risk free interest rate	1.12% - 2.50%	0.51% - 1.01%
Expected volatility	68.8% - 100.0%	65.1% - 75.2%

The options granted in the three months ended March 31, 2014 and 2013 had a weighted average grant date fair values of \$2.09 and \$0.69, respectively.

Unrecognized compensation cost for unvested stock option awards outstanding at March 31, 2014 was approximately \$4,857,000 to be recognized over approximately 2.7 years.

RSUs 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, 2014 is as follows:

	Number of RSU's	Weighted- Average Grant Date Fair Value
Outstanding at January 1, 2014	401,625	\$ 2.03
Granted	25,000	\$ 3.33
Vested and converted to common shares	-	\$ -
Forfeited	-	\$ -
Outstanding at March 31, 2014	426,625	\$ 2.11
Exercisable at March 31, 2014	404,397	\$ 2.09

Unrecognized compensation cost for unvested RSUs outstanding at March 31, 2014 was approximately \$45,000 to be recognized over approximately 0.8 years.

Stock Purchase Warrants Warrants to purchase common stock were issued to certain stockholders and service providers. In addition, warrants were issued in conjunction with the March 2013 debt transaction. A summary of warrant activity for the three months ended March 31, 2014 follows:

	Number of Warrants	Weighted-Average Exercised Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2014	19,586,819	\$ 1.96	3.4	\$21,146,495
Granted	3,436,435	\$ 3.64	4.8	
Exercised	(1,486,573 )	\$ 1.30		
Forfeited	(231,664 )	\$ 1.19		
Outstanding at March 31, 2014	21,305,017	\$ 2.29	3.5	\$41,358,464
Exercisable at March 31, 2014	21,305,017	\$ 2.29	3.5	\$41,358,464

The stock purchase warrants granted in the three months ended March 31, 2014 and 2013 had a weighted average grant date fair value of \$2.08 and \$0.73, respectively.

### Common Stock

In January and February 2013, we issued 258,000 shares of common stock upon the exercise of outstanding warrants. The shares were issued at \$1.25 per share and we received approximately \$323,000 in net proceeds from the exercises. In conjunction with the exercises we modified the warrants to reduce the exercise price to \$1.25 and issued 258,000 replacement warrants. The replacement warrants have an exercise price of \$1.25 and expire in March 2020. We recognized an expense for the value of the replacement warrants and the reduction of the exercise price on the original warrants. Such expense is classified as warrant modification expense. The warrants are classified within equity.

In March 2013, we issued 350,650 shares of common stock and 1,297,607 common stock purchase warrants to various parties in conjunction with our debt transaction (see Note 4).

In May 2013, we issued 440,000 shares of common stock upon the exercise of outstanding warrants. The shares were issued at \$1.07 per share and we received approximately \$433,000 in net proceeds from the exercises. In conjunction with the exercise we modified the warrants to reduce the exercise price to \$1.07 and issued 440,000 replacement warrants. The replacement warrants have an exercise price of \$1.25 and expire in May 2016. We recognized expense for the value of the replacement warrants and the reduction of the exercise price on the original warrants; such expense is classified as warrant modification expense. The warrants are classified within equity.

In May 2013, we issued 689,675 shares of common stock upon the exercise of outstanding warrants. The shares were issued at \$1.25 per share and we received approximately \$844,000 in net proceeds from the exercises. In conjunction with the exercises we modified the warrants to reduce the exercise price to \$1.25 and issued 689,675 replacement

warrants. The replacement warrants have an exercise price of \$1.25 and expire in March 2020. We recognized an expense for the value of the replacement warrants and the reduction of the exercise price on the original warrants; such expense is classified as warrant modification expense. The warrants are classified within equity.

In May and June 2013, we issued 378,809 shares of common stock upon the exercise of outstanding warrants. The shares were issued at \$1.25 per share and we received approximately \$474,000 in net proceeds from the exercises. In conjunction with the exercise we issued 378,809 replacement warrants. The replacement warrants have an exercise price of \$1.25 and expire in March 2020. We recognized an expense for the value of the replacement warrants; such expense is classified as warrant modification expense. The warrants are classified within equity.

In May and June 2013, we issued 300,000 shares of common stock upon the exercise of outstanding warrants. The shares were issued at \$1.02 and we received approximately \$306,000 in net proceeds from the exercises.

In July 2013, we issued 942,520 shares of our common stock upon the exercise of outstanding warrants. The shares were issued at \$1.25 per share and we received approximately \$1,178,000 in net proceeds from the exercises. In conjunction with the exercises we modified 782,005 of the warrants to reduce the exercise price to \$1.25 and issued 942,520 replacement warrants. The replacement warrants have an exercise price of \$1.25 and expire in March 2020. We recognized an expense for the value of the replacement warrants and the reduction of the exercise price on the original warrants; such expense is classified as warrant modification expense. The warrants are classified within equity.

In July 2013, we issued 100,000 shares of common stock upon the exercise of outstanding warrants. The shares were issued at \$1.02 and we received approximately \$102,000 in net proceeds from the exercise.

In September 2013, we issued 1,448,798 shares of common stock upon the exercise of outstanding warrants. The shares were issued at \$1.25 per share (800,000 shares) and \$1.08 per share (648,798 shares) and we received approximately \$1,700,000 in net proceeds from the exercises. In conjunction with the exercise we issued an additional 72,440 shares of our common stock as a commission for exercise. We recognized an expense for the value of the additional common stock; such expense is classified as warrant modification expense.

In September and December 2013, we issued 344,000 shares of common stock upon the exercise of outstanding warrants. 340,000 shares of stock were issued at \$2.13 while 4,000 shares of stock were issued at \$1.56. We received approximately \$730,000 net proceeds from the exercises.

In September 2013, we issued 401,133 shares of our common stock as a result of the cashless exercise of 650,000 outstanding common stock purchase warrants with an average strike price of \$0.90. Such exercises resulted in 248,867 warrants being forfeited and we received no proceeds.

In September 2013, we completed a registered direct offering of 2,847,500 shares of common stock at a price of \$1.60 per share. We received aggregate gross proceeds of \$4,556,000 and net proceeds were approximately \$4,242,000 from the offering. In connection with the offering, we issued common stock purchase warrants to purchase 1,423,750 shares of our common stock; the warrants have an exercise price of \$2.00 and a term of five years. Additionally, we issued a common stock purchase warrant to the placement agent to purchase up to 170,850 shares; the warrant has an exercise price of \$2.00 per share and term of 19 months. The warrants are classified within equity.

In November and December 2013, we issued 1,140,994 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 \$2.64 per share and generated approximately \$2,895,000 in net proceeds.

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 were approximately \$18,675,000 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, for a term of five years and are classified within equity. This offering was pursuant to our \$50 million shelf registration statement declared effective by the SEC on September 13, 2013. 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 February 2014, we issued 139,053 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 \$3.15 per share and we received approximately \$426,000 in net proceeds.

At certain times in the quarter ended March 31, 2014, we issued a total of 1,004,428 shares of our common stock upon the exercise of outstanding common stock purchase warrants. The warrants had an average exercise price of \$1.39. We received approximately \$1,392,000 of net proceeds from the exercises.

At certain times in the quarter ended March 31, 2014, we issued a total of 482,145 shares of our common stock upon the cashless exercise of 713,808 outstanding common stock purchase warrants. Such warrants were exercised at an average price of \$1.15 and resulted in no proceeds to the Company.

At certain times in the quarter ended March 31, 2014, we issued a total of 204,097 shares of our common stock upon the cashless exercise of 425,000 outstanding stock options. The options had an average exercise price of \$0.60. We received no proceeds from the exercise.

At certain times in the quarter ended March 31, 2014, we issued a total of 100,000 shares of our common stock upon the exercise of certain outstanding stock options. The options had an average exercise price of \$1.13 and we received approximately \$113,000 of net 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, 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 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.

On October 3, 2013, the Court ordered the parties to submit a joint status report regarding the status of the standing discovery. Following the submission the joint status report, the Court set a briefing schedule to resolve the standing issue. Before Neuralstem filed its opening brief on whether StemCells has standing, the case was reassigned to Judge Roger W. Titus from Judge Alexander Williams Jr.

Neuralstem filed its opening brief in support of the standing issue on December 19, 2013. StemCells responded on January 21, 2014. Finally, Neuralstem filed its reply brief on February 4, 2014. The standing issue is currently set for a hearing on May 19, 2014. It is expected that a ruling on whether StemCells has standing to pursue its patent infringement case will issue shortly thereafter and will either resolve the case in its entirety or will allow the case to move forward to expert discovery.

## **Note 7. Subsequent Events**

The Company has performed an evaluation of subsequent events through the date the accompanying financial statements were issued and did not identify any material subsequent transactions that require disclosure.

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

### **FORWARD LOOKING STATEMENTS**

*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 clinical trials and studies, research and development expenses, cash expenditures, licensure applications and approvals, 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 manufacture stem cell-based therapeutic product, 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, 2013 filed with the SEC on March 10, 2014, as amended, as well as in the section of this Quarterly Report entitled "Risk Factors". 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 to “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, 2014), 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, 2014 is not necessarily indicative of our prospective financial condition and results of operations for the pending full fiscal year ending December 31, 2014. 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 the strategy for 2014.

*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 period ended March 31, 2014 to the comparable period of 2013.

*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 treatments based on human neuronal stem cells and our small molecule compounds. We are headquartered in Germantown, Maryland and have a wholly-owned subsidiary in 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 fifty-one (51) U.S. or foreign issued patents and fifty-nine (59) 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 base, 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 a young and 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 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 in order 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 four most advanced clinical programs, their intended indication, current stage of development and our expected future development plans.

Program	Indication	Development Status	Future Development Plan
NSI - 566	Amyotrophic Lateral Sclerosis (ALS)	Ongoing Phase II clinical trials	Anticipated to complete patient dosing in our Phase II clinical trials near the end of the second quarter of 2014.
NSI - 566	Chronic Spinal Cord Injury	Approved to commence Phase I clinical trials.	Phase I Trial expected to commence during the second quarter of 2014.
NSI - 566	Motor deficits due to ischemic stroke	Ongoing combined Phase I/II clinical trials in China.	Dosing commenced during the fourth quarter of 2013. Phase I expected to be completed in the first quarter of 2015.
NSI - 189	Major Depressive Disorder	Completed Phase Ia, Phase Ib trials.	Phase II trial investigational new drug application or IND expected to be filed in the third quarter of 2014 with the trial commencing in late 2014 or early 2015.

*NSI - 566 (Stem Cells).*

#### 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. We believe that NSI-566 may provide an effective treatment for ALS by providing cells which nurture and protect the patients' remaining motor neurons; and possibly repair some motor neurons which were not dead, but diseased.

We commenced the Phase I trial for our proposed treatment of 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. The dosing of patients in the Phase I trial, as designed, was completed in August of 2012. We commenced Phase II clinical trial in September of 2013. The Phase II dose escalation trial is designed to treat up to 15 ambulatory patients in six different dosing cohorts, under an accelerated dosing and treatment schedule. To date, we have treated the first four cohorts. We anticipate completing the Phase II dosing near the end of the second quarter of 2014. Although initial data from the Phase I trial appears promising, the outcome of the trial is uncertain and this trial or 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 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 approval 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 California, San Diego. We anticipate the trial will commence during the second quarter of 2014.

## 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 approval to commence human clinical trials to treat motor deficits due to ischemic stroke. The trial will be conducted by our wholly owned subsidiary, Neuralstem China, at BaYi Brain Hospital in Beijing, China and will utilize our spinal cord stem cells. The trial approval includes 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 I 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 we anticipate that that will be concluded in the first quarter of 2015.

## *NSI - 189 (Small Molecule Pharmaceutical Compound).*

### Major Depression Disorder

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. NSI-189 is the lead compound in our neurogenerative 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 the 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 approval from the FDA to commence the Phase Ib portion of the trial. The purpose of the Phase Ib portion of the clinical trial is to determine the safety of the drug at several dosings in actual MDD patients. The Phase Ib portion consists of patients with MDD receiving daily doses for 28 consecutive days. In June of 2012, we dosed our first patient in the Phase Ib portion of the trial. To date, we have completed dosing all cohorts of patients in the Phase Ib portion of the trial and the data is being



reviewed. While the final data analysis will not be completed until late May, the early look at the unblended data was encouraging enough that the Company has committed to conducting a phase two trial. We expect to file the IND for the phase two in the third or fourth quarter of 2014 and expect that the Phase II trial would start before the end of the first quarter of 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 or CNS, including: Alzheimer's disease, Parkinson's disease, Multiple Sclerosis, Lou Gehrig's disease or ALS, depression, and injuries to the spinal cord. We own or exclusively license thirty-three (33) U.S. and foreign issued patents and thirty-nine (39) U.S. and foreign patent applications related to our stem cell technologies.

To date we have focused our research efforts on applications involving spinal cord stem cells. We believe we have established "proof of principle" in animal models for important spinal cord cell applications: ALS and Traumatic spinal cord injury. Of these applications, we have completed our first Phase I trial with regard to ALS and commenced initial Phase II trials in the third quarter of 2013. We have also received approval from the FDA to commence a Phase I trial in Chronic Spinal Cord Injury (patients one to two years out from their injury) in complete (no sensory or motor function from the site of the injury down) thoracic patients. We expect this trial to start during the second quarter of 2014. We believe that, if successfully developed, stem cell therapeutics have the potential to provide a broad therapeutic approach comparable to traditional pharmaceuticals and genetically engineered biologics. In the fourth quarter of 2013 we filed an IND to start a trial to treat 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. Also, if approved as submitted, this trial will treat cervical area injuries. We expect this trial to start in the second half of 2014.

*Small Molecule Pharmaceutical Compounds.*

We have developed and patented a series of small molecule compounds (low molecular weight organic compounds which can efficiently cross the blood/brain barrier). We believe that these small molecule compounds will stimulate the growth of new neurons in the hippocampus and provide a treatment for depression, and possibly other cognitive impacting diseases. In mice, our research indicated that our small molecule compounds both stimulate neurogenesis of the hippocampus and increase its volume. Additionally, our research also indicates that our small molecule compounds stimulate neurogenesis of human hippocampus-derived neural stem cells in vitro. Based on this research, we believe that our small molecule compounds may assist in reversing atrophy in the human hippocampus. Such atrophy has been seen in major depression and other disorders.

Our small molecule compounds are covered by eighteen (18) exclusively owned U.S. and foreign issued patents and twenty-one (21) exclusively owned U.S. and foreign patent applications related to our small molecule compounds.

***Research***

We have devoted substantial resources 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 products. Our efforts are directed at developing therapies utilizing our stem cells and small molecule regenerative drugs. 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 manufacturing 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 outsource basis. We outsource the manufacturing of our pharmaceutical compounds 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. We outsource all the manufacturing and storage of our stem cells and pharmaceuticals compound to be used in clinical and pre-clinical works, and which are accordingly subject to higher FDA requirements, to Charles River Laboratories, Inc., of Wilmington, Massachusetts (stem cells) and Albany Molecular Resources, Inc. (“AMRI”) (small molecule). Both the Charles River and AMRI facilities have the capacity to be used for manufacturing under the FDA determined GMP standards 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. Additionally, during the first quarter of 2014, we relocated our headquarters to a facility with GMP manufacturing capability. We anticipate the facility will be ready to commencing 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.

### ***Employees***

As of March 31, 2014, we had 15 full-time employees and one (1) full-time independent contractor. Of these full-time employees and contractor, 11 work on research and development and five (5) in administration. We also use the services of numerous outside consultants in business and scientific matters.

### ***Our Corporate Information***

We were incorporated in Delaware. 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](http://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](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 Weibo Account (<http://www.weibo.com/u/3516708787>)
- Neuralstem Asia's Tencent Weibo Account (<http://t.qq.com/neuralstem>)
- Neuralstem Asia's Facebook Page (<https://www.facebook.com/NeuralstemAsia>)
- Neuralstem Asia's Twitter Account ([https://twitter.com/Neuralste\\_Asia](https://twitter.com/Neuralste_Asia))

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, and you should not consider it to be a part of this report.

## **Trends & Outlook**

### ***Revenue***

For the three months ended March 31, 2014 and 2013, we generated no revenues from the sale of our proposed therapies based on our stem cell and small molecule technologies. We are mainly focused on: (i) successfully managing our clinical trials, and (ii) preparing for the initiation of clinical trials relating to Chronic Spinal Cord injury. We are also pursuing pre-clinical studies on other central nervous system indications in preparation for additional clinical trials.

In prior years, we have licensed the use of certain of our intellectual property to third parties. In the three months ended March 31, 2014 and 2013, we recognized approximately \$4,000 and \$103,000 of revenue related to up-front

payments and 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 portion of this report entitled “Clinical Programs.”

We expect that research and development expenses, which include expenses related to our ongoing clinical trials, will increase in the future, as funding allows and we proceed with our current and 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. Through March 31, 2014 this subsidiary has incurred expenses of approximately \$340,000.

### ***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 condensed 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 Unaudited Condensed 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 condensed 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 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.

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

***Long Lived Intangible Assets***— Our long lived intangible assets consist 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, 2014 and 2013 no impairment losses were recognized.

***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 is determined at the grant 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 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, 2014 and 2013***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, 2014 and 2013, we recognized approximately \$4,000 and \$103,000, respectively related to the licensing of certain intellectual properties to third parties. The revenue recognized in 2013 includes an up-front fee related to such a license, while the revenue in 2014 includes ongoing fees only.

*Operating Expenses*

Operating expenses for the three months ended March 31, 2014 and 2013 were as follows:

	Three Months Ended March 31,		Increase (Decrease)	
	2014	2013	\$	%
Operating Expenses				
Research and development expenses	\$ 1,571,221	\$ 1,748,347	\$ (177,126 )	(10 )%
General and administrative expenses	3,519,359	1,195,840	2,323,519	194 %
Depreciation and amortization	90,488	50,093	40,395	81 %
Total operating expenses	\$ 5,181,068	\$ 2,994,280	\$ 2,186,788	73 %

*Research and Development Expenses*

Our research and development expenses consist primarily of contractors charges 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, laboratories for testing clinical samples and consultants.

The decrease of approximately \$177,000 or 10% in research and development expenses was primarily attributable to a \$233,000 decrease in project and lab expenses related to certain projects not continuing into the first quarter of 2014 and the cost of certain studies in 2014 being subsidized by third parties. This was partially offset by increases of \$27,000 in stock based compensation and \$24,000 in consultant expenses.



*General and Administrative Expenses*

General and administrative expenses are primarily comprised of salaries, benefits and other costs associated with, finance, legal, human resources, information technology, public relations, facilities and other external general and administrative services.

The increase of approximately \$2,324,000 or 194% was primarily due to a \$2,018,000 stock based compensation expense related to a consultant achieving a performance based milestone which resulted in a term extension of certain common stock purchase warrants. This is coupled with a \$227,000 increase in legal and professional fees.

*Depreciation and Amortization*

The increase of approximately \$40,000 or 81% is was due primarily to increased amortization related to additions to our patent assets.

*Other expense*

Other income (expense) totaled approximately (\$742,000) and (\$698,000) for the three months ended March 31, 2014 and 2013, respectively. 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. Other expense in 2013 consisted primarily of a \$667,000 expense related to the modification of certain stock purchase warrants and \$48,000 of interest expense primarily related to our long term debt entered into in March 2013.

**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 of our securities pursuant to a registered direct offering.

	Three Months Ended March 31,		Increase (Decrease)	
	2014	2013	\$	%
Net cash used in operating activities	\$ (2,712,824 )	\$ (2,512,728 )	\$ (200,096 )	(8 )%
Net cash used in investing activities	\$ (15,223,155 )	\$ (96,817 )	\$ (15,126,338 )	(15624)%
Net cash provided by financing activities	\$ 19,433,698	\$ 7,825,012	\$ 11,608,686	148 %

Our cash balance was approximately \$18,343,000 at March 31, 2014 compared to \$16,846,000 at December 31, 2013. The increase of \$1,497,000 was primarily due to raising \$18,767,000, net in our January 2014 registered direct offering primarily offset by our purchase of short-term investments and our cash used in operations.

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

We used approximately \$2,713,000 and \$2,513,000 of cash in our operating activities for the three months ended March 31, 2014 and 2013, respectively. The increase in our use of cash of approximately \$200,000 was primarily due to a slight increase in payments related to general expenses including payout of certain employee bonuses in 2014.

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

We used approximately \$15,223,000 and \$97,000 of cash in connection with investment activities for the three months ended March 31, 2014 and 2013, respectively. The increase in our use of cash of approximately \$15,126,000 was primarily due to our purchase of short term investments using the proceeds from our January 2014 registered direct offering coupled with \$111,000 worth of equipment purchases in 2014.

#### ***Net Cash Provided by Financing Activities***

Proceeds from financing activities were approximately \$19,434,000 and \$7,825,000 in the three months ended March 31, 2014 and 2013, respectively. The increase of \$11,609,000 was primarily the result of raising approximately \$18,675,000, net from our registered direct offering in January 2014 as compared to raising approximately \$7,551,000, net from our debt offering in 2013. In addition, in 2014 we raised approximately \$1,504,000 from the issuance of common stock from warrant and option exercises compared to \$323,000 in 2013. In 2014 we also made \$705,000 of payments on our long term debt.

#### ***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. On September 13, 2013, our shelf registration statement registering the sale of up to \$50 million of our securities was declared effective by the SEC. We currently have approximately \$14.0 million remaining under this shelf registration statement. We anticipate conducting financing in the future based on our shelf registration statement when and if financing opportunities arise.

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

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

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

We are subject to interest rate risk for our long-term debt which contains a floating interest rate based on Wall Street Journal published prime rate. For the full year ended December 31, 2014 a one percentage point increase in the prime rate would increase our interest expense by approximately \$70,000.

Our foreign operations in China subject us to changes in foreign exchange rates. Changes in exchange rates for the year ended December 31, 2014 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**

As of the date of this Quarterly Report, there are no material pending legal or governmental proceedings relating to our company or properties to which we are a party, and to our knowledge there are no material proceedings to which any of our directors, executive officers or affiliates are a party adverse to us or which have a material interest adverse to us, other than the following:

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, 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 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.



On October 3, 2013, the Court ordered the parties to submit a joint status report regarding the status of the standing discovery. Following the submission the joint status report, the Court set a briefing schedule to resolve the standing issue. Before Neuralstem filed its opening brief on whether StemCells has standing, the case was reassigned to Judge Roger W. Titus from Judge Alexander Williams Jr.

Neuralstem filed its opening brief in support of the standing issue on December 19, 2013. StemCells responded on January 21, 2014. Finally, Neuralstem filed its reply brief on February 4, 2014. The standing issue is currently set for a hearing on May 19, 2014. It is expected that a ruling on whether StemCells has standing to pursue its patent infringement case will issue shortly thereafter and 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 securities 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 should be considered carefully in evaluating our company and our business and the value of our securities.*

### **Risks Relating to Our Stage of Development**

*We have a history of losses.*

Since inception in 1996 and through March 31, 2014, we have recorded accumulated losses totaling approximately \$134,345,000. On March 31, 2014, we had a working capital surplus of approximately \$29,435,000 and stockholders' equity of approximately \$26,897,000. Our net losses for the two most recent fiscal years have been approximately \$19,832,000 and \$10,122,000 for 2013 and 2012, respectively. We have recognized revenue of approximately \$4,000 and \$103,000 in the three months ended March 31, 2014 and 2013, respectively related to the licensing of certain intellectual property to third parties. We had no revenue from the sales of our products during the three months ended March 31, 2014 or 2013. For the three months ended March 31, 2014 we had a net loss of approximately \$5,919,000.

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, market and sell our proposed products. To date, we have not generated any revenue from the commercial sale of our proposed products. No assurances can be given as to exactly when, if at all, we will be able to fully develop, commercialize, market, sell and/or derive any, let

alone material, revenues from our proposed products.

***We will need to raise additional capital to continue operations.***

Since our inception, we have funded our operations through the sale of our securities, 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, 2014, we had cash and cash equivalents on hand of approximately \$18,343,000 and \$15,000,000 of short-term investments. We cannot assure you that we will be able to secure additional capital through financing transactions, 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.

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 operations and planned growth, 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.



***Our debt obligations expose us to risks that could adversely affect our business, operating results and financial condition. 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, 2014, we had approximately \$7.3 million in aggregate principal amount of indebtedness outstanding. Under our loan and security agreement we are required to make interest and principal payments on such indebtedness in the amount of approximately \$300,000 per month. As security for such indebtedness, we have pledged substantially all of our assets, including our intellectual property. We will need to raise additional capital to pay our indebtedness as it comes due. If we are unable to obtain funds necessary to make required payments, or if we fail to comply with the various requirements and covenants of our indebtedness, we would be in default, which would permit the holders of our indebtedness to accelerate the maturity and require immediate repayment. Any default under our indebtedness would have a material adverse effect on our business, operating results and financial condition. Additionally, our loan and security agreement governing our \$10 million credit facility 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 loan and security agreement governing the credit facility 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 or 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.***

Our business is significantly dependent on our two product candidates currently at different phases of clinical trials. Any clinical, regulatory or other development that significantly delays or prevents us from completing any of our trials, any material safety issue or adverse side effect to any study participant in these trials, or the failure of these trials to show the results expected, would likely depress our stock price significantly and could prevent us from raising the additional capital we will need to develop our technologies. Moreover, any adverse occurrence in our clinical trials could substantially impair our ability to initiate clinical trials to test our product candidates in other potential indications. This, in turn, could adversely impact our ability to raise additional capital and pursue our planned research and development efforts.

***Our business relies on technologies that we may not be able to commercially develop.***

We have concentrated the majority of our resources on the development of 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 such development will result in products with any commercial utility or value. We anticipate that the commercial sale of such products and/or royalty/licensing fees related to our technologies, will be our primary sources of revenue. We recognized revenue of approximately \$110,000 and \$173,000 for the years ended December 31, 2013 and December 31, 2012, 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.

***Our product development programs are based on novel technologies 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.

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

We currently outsource 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. Our business would suffer in the event that there are delays in locating suitable third parties or if no suitable third parties are found.

***Our inability to complete pre-clinical and clinical testing and trials will impair our viability.***

We are currently in clinical trials for NSI-566 and NSI-189, two of our proposed products, with regard to multiple indications. We commenced our first Phase II clinical trial of NSI-566 related to ALS, during the third quarter of 2013. Additionally, we commenced Phase I clinical trials of NSI-566 related to motor deficit due to ischemic stroke during the fourth quarter of 2013 and anticipate commencing the Phase I clinical trial of NSI-566 related to chronic spinal cord injury during the second quarter of 2014. Moreover, we have completed Phase I clinical trials of NSI-189, our small molecule compound, related to major depressive disorder and are actively looking to partner further development. 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 will be unable to commercialize our proposed products. No assurances can be given that our clinical trials will be completed or result in successful outcomes. 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.

***Our proposed products may not have favorable results in 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 studies, we will be required to demonstrate through further clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale. There is typically an extremely high rate of attrition from the failure of product candidates as they proceed through clinical trials. If any product candidate fails to demonstrate sufficient safety and efficacy in any clinical trial, then we would experience potentially significant delays in, or be required to abandon, development of that product candidate. If we delay or abandon the development efforts of any of our product candidates, we may not be able to generate revenues.

***The results of pre-clinical studies and early-stage clinical trials, may not be predictive of the results of later-stage clinical trials.***

A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in Phase II and Phase III clinical trials, despite positive results from earlier-stage trials. The principal investigator of the Phase I safety trial of our human spinal cord stem cells (HSSC's) in amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease), recently presented data on the patients in the study. The study was designed to assess the safety of intraspinal transplantation in ALS patients and was not intended to demonstrate efficacy. While no adverse events related to the surgical procedure or our neural stem cells were reported, the small sample size, limited time frame and preliminary nature of the study make it difficult to draw any conclusions from the results of the study. No assurance can be given that the surgical procedure or our neural stem cells will be deemed safe by the FDA or that efficacy in the treatment of ALS will be demonstrated in any future studies. 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 neuronal stem cells, NSI-189 or other future products.

***There are no assurances that we will be able to submit 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 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, we may be unable to generate sufficient revenues to attain profitability and our reputation in the industry and in the investment community would likely be damaged, each of which would have a materially adverse effect on our business.

***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 reputation and business, which could cause a significant loss of stockholder value. 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. At present, some of our material requirements are single sourced, and the loss of one or more of these sources may 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 patient reimbursement.***

Our ability to successfully commercialize our proposed products, if developed, in the human therapeutic field depends to a significant degree on patient reimbursement of 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 stem cell based 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 proposed products, 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 drugs and therapies manufactured and marketed by major pharmaceutical companies. The degree of market acceptance will depend on a number of factors, including:

the clinical efficacy and safety of our proposed products;  
the superiority of our products to alternatives currently on the market;  
the potential advantages of our products over alternative treatment methods; and  
the reimbursement policies of government and third-party payors.

If the healthcare community does not accept our products for any reason, our business will be materially harmed.

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

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

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

We have entered into employment agreements with Messrs. Garr and 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 approximately \$1,600,000 per contract and the immediate vesting of all outstanding options and/or warrants held by Messrs. Garr and Johe.

***Our competition has significantly greater experience and financial resources.***

The biotechnology industry is characterized by intense 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.

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

Our strategy for the development, clinical and preclinical 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 almost exclusively 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). 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. 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 at terms reasonable to us. 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 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 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, even though issued, 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 and future market acceptance for our products if successfully developed. As a consequence of this enhanced risk, more risk-averse 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 credit 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 corporate 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 corporate 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 150,000,000 shares of common stock and 7,000,000 “blank check” shares of preferred stock. Shares of our blank check preferred stock provide the board of directors broad authority to determine voting, dividend, conversion, and other rights. As of March 31, 2014 we have issued and outstanding 86,688,613 shares of common stock and we have 44,462,359 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, 2014, we had no shares of preferred stock issued and outstanding. Accordingly, we are entitled to issue up to 18,849,028 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**

***Our products may not receive regulatory approval.***

The FDA and comparable government agencies in foreign countries impose substantial regulations on the manufacturing and marketing of pharmaceutical and biological products through lengthy and detailed laboratory, pre-clinical and clinical testing procedures, sampling activities and other costly and time-consuming procedures.

Satisfaction of these regulations typically takes several years or more and vary substantially based upon the type, complexity and novelty of the proposed product. 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.

***Development of our technologies 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 requirements both before and after approval, if any, 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 permitted 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 to the FDA 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 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.

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.

***We are subject to extensive and rigorous governmental regulation, including the requirement of FDA or other regulatory approval before our product candidates may be lawfully marketed.***

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, storage, record keeping, quality systems, advertising, promotion, sale and distribution of therapeutic products. Failure to comply with applicable requirements could result in, among other things, one or more of the following actions: notices of violation, untitled letters, warning letters, fines and other monetary penalties, unanticipated expenditures, delays in approval or refusal to approve a product candidate; product recall or seizure; interruption of manufacturing or clinical trials; operating restrictions; injunctions; 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. Our product candidates cannot be lawfully marketed in the United States without FDA approval. Any failure to receive the marketing approvals necessary to commercialize our product candidates could harm our business.

The regulatory review and approval process of governmental authorities, which includes the need to conduct nonclinical studies and clinical trials of each product candidate, is lengthy, expensive and uncertain, and regulatory standards may change during the development of a particular product candidate. We are not permitted to market our product candidates in the United States or other countries until we have received requisite regulatory approvals. For example, securing FDA approval requires the submission of an NDA to the FDA. The approval application must include extensive nonclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each indication. The approval application must also include significant information regarding the chemistry, manufacturing and controls for the product. The FDA review process typically takes significant time to complete and approval is never guaranteed. If a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling, impose restricted distribution programs, require expedited reporting of certain adverse events, or require costly ongoing requirements for post-marketing clinical studies and surveillance or other risk management measures to monitor the safety or efficacy of the product. Markets outside of the United States also have requirements for approval of drug candidates with which we must comply prior to commencing marketing of our products in those markets. Obtaining regulatory approval for marketing of a product candidate in one country does not ensure we will be able to obtain regulatory approval in other countries, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. Also, any regulatory approval of any of our product candidates, once obtained, may be withdrawn.

In addition, we, our suppliers, our operations, our facilities, and our contract manufacturers, our contract research organizations, and our contract testing laboratories are required to comply with extensive FDA requirements both before and after approval of our products. For example, we are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain requirements concerning advertising and promotion for our product candidates and our products. Also, quality control and manufacturing procedures must continue to conform to current Good Manufacturing Practices, or cGMP, regulations after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control. In addition, discovery of safety issues may result in changes in labeling or restrictions on a product manufacturer or NDA holder, including removal of the product from the market.

## **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, 2014. The unregistered securities were issued pursuant to section 4(2) of the Securities Act:

At certain times from January through April 2014, we issued a total of 490,022 shares of common stock upon the cashless exercise of 725,808 outstanding common stock purchase warrants. Such warrants had an average exercise price of \$1.15.

In April 2014, we issued a total of 50,000 shares of common stock upon the exercise of certain outstanding common stock purchase warrants. The warrants had an exercise price of \$2.00. We received \$100,000 of gross proceeds from the exercise.

**ITEM 3. DEFAULT UPON SENIOR SECURITIES**

**None**

**ITEM 4. MINE SAFETY DISCLOSURE**

**Not Applicable**

**ITEM 5. OTHER INFORMATION**

**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 12, 2014 /s/ I. Richard Garr  
Chief Executive Officer

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

## INDEX TO EXHIBITS

Exhibit No.	Description	Incorporated by Reference				
		Filed/ Furnished Herewith	Form	Exhibit No.	File No.	Filing Date
3.01(i)	Amended and Restated Certificate of Incorporation of Neuralstem, Inc. filed on 9/29/05		10-K	3.01(i)	001-33672	3/31/09
3.02(i)	Certificate of Amendment to Certificate of Incorporation of Neuralstem, Inc. filed on 5/29/08		DEF 14A	Appendix I	001-33672	4/24/08
3.03(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
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			10-K	4.22	001-33672	3/31/10

Edgar Filing: Neuralstem, Inc. - Form 10-Q

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)

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

35

Edgar Filing: Neuralstem, Inc. - Form 10-Q

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
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 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
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**		10-K	10.02	001-33672	3/31/09



Edgar Filing: Neuralstem, Inc. - Form 10-Q

Amended terms to the Employment Agreement of I Richard Garr  
dated January 1, 2008

10.03**	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
10.04**	Amended terms to the Employment Agreement of Karl Johe dated January 1, 2009	10-K	10.04	001-33672	3/31/09
10.05**	Employment Agreement with Thomas Hazel, Ph.D dated August 11, 2008	10-K/A	10.05	001-33672	10/5/10

Edgar Filing: Neuralstem, Inc. - Form 10-Q

10.06	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
10.07**	Renewal of I. Richard Garr Employment Agreement dated 7/25/12	8-K	10.01	001-33672	7/27/12
10.08**	Renewal of Dr. Karl Johe Employment Agreement dated 7/25/12	8-K	10.02	001-33672	7/27/12
10.09**	Renewal of Dr. Tom Hazel Employment Agreement dated 7/25/12	8-K	10.03	001-33672	7/27/12
10.10	Loan and Security Agreement dated March 2013	8-K	10.01	011-33672	3/27/13
10.11	Intellectual Property and Security Agreement dated March 2013	8-K	10.02	011-33672	3/27/13
10.12	At the Market Offering Agreement entered into on October 25, 2013	8-K	10.01	011-33672	10/25/13
10.13	Form of Outside Director Agreement	10-K	10.13	011-33672	3/10/14
14.01	Neuralstem Code of Ethics	SB-2	14.1	333-132923	6/21/06
14.02	Neuralstem Financial Code of Profession Conduct adopted on May 16, 2007	8-K	14.2	333-132923	6/6/07
31.1	Certification of the Principal Executive Officer and Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 *				
32.1	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. § 1350				*
101.INS	XBRL Instance Document				***
101.SCH	XBRL Taxonomy Extension Schema				***
101.CAL	XBRL Taxonomy Extension Calculation Linkbase				***
101.DEF	XBRL Taxonomy Extension Definition Linkbase				***
101.LAB	XBRL Taxonomy Extension Label Linkbase				***
101.PRE	XBRL Taxonomy Extension Presentation Linkbase				***

\* Filed herein

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

*\*\*\* Furnished herein*