

Neuralstem, Inc.  
Form 10-Q  
November 09, 2015

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

**(Mark one)**

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

**For the Quarterly Period Ended September 30, 2015**

**Or**

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

**Commission File Number 001-33672**

**NEURALSTEM, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
State or other jurisdiction of  
incorporation or organization

**52-2007292**  
(I.R.S. Employer  
Identification No.)



**Neuralstem, Inc.**

Table of Contents

|                                                                                                                                                         | Page |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| PART I                                                                                                                                                  |      |
| <u>FINANCIAL INFORMATION</u>                                                                                                                            | 4    |
| -                                                                                                                                                       |      |
| Item 1. <u>Unaudited Condensed Consolidated Financial Statements</u>                                                                                    | 4    |
| <u>Unaudited Condensed Consolidated Balance Sheets as of September 30, 2015 and December 31, 2014</u>                                                   | 4    |
| <u>Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss For the Three and Nine Months Ended September 30, 2015 and 2014</u> | 5    |
| <u>Unaudited Condensed Consolidated Statements of Cash Flows For the Nine Months Ended September 30, 2015 and 2014</u>                                  | 6    |
| <u>Notes to Unaudited Condensed Consolidated Financial Statements</u>                                                                                   | 7    |
| 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>                                                                               | 23   |
| Item 4. <u>Controls and Procedures</u>                                                                                                                  | 24   |
| PART II                                                                                                                                                 |      |
| <u>OTHER INFORMATION</u>                                                                                                                                | 25   |
| -                                                                                                                                                       |      |
| Item 1. <u>Legal Proceedings</u>                                                                                                                        | 25   |
| Item 1A. <u>Risk Factors</u>                                                                                                                            | 25   |
| Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>                                                                              | 38   |
| Item 3. <u>Defaults Upon Senior Securities</u>                                                                                                          | 38   |
| Item 4. <u>Mine Safety Disclosure</u>                                                                                                                   | 38   |
| Item 5. <u>Other Information</u>                                                                                                                        | 38   |
| Item 6. <u>Exhibits</u>                                                                                                                                 | 38   |

Signatures

38

Certificates

Page 2

## INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

*This quarterly report on Form 10-Q of Neuralstem, Inc. and certain information incorporated herein by reference contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. In this Form 10-Q, we refer to Neuralstem, Inc., including its wholly owned subsidiary, as the “Company,” “we,” “our” or “us.” All statements other than statements of historical facts contained herein, including statements regarding our future results of operations and financial position, strategy and plans, and our expectations for future operations, are forward-looking statements. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect” or the negative version of these words and similar expressions are intended to identify forward-looking statements.*

*We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part II Item 1A “Risk Factors.” In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed included herein may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements.*

*Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. In addition, neither we nor any other person assumes responsibility for the accuracy and completeness of any of these forward-looking statements. New risks emerge from time to time and it is not possible for our management to predict all risks. Forward-looking statements made by us in this quarterly report on Form 10-Q speak only as of the date on which such statements are made. We disclaim any duty to update any of these forward looking statements after the date of this quarterly report on Form 10-Q to confirm these statements to actual results or revised expectations.*

*[NTD: Covered above]*

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

|                                                     | <b>September 30,<br/>2015</b> | December 31, 2014 |
|-----------------------------------------------------|-------------------------------|-------------------|
| <b>ASSETS</b>                                       |                               |                   |
| <b>CURRENT ASSETS</b>                               |                               |                   |
| Cash and cash equivalents                           | \$ 13,130,795                 | \$ 12,518,980     |
| Short-term investments                              | 5,017,453                     | 15,007,478        |
| Trade and other receivables                         | 19,159                        | 225,524           |
| Deferred financing fees, current portion            | 107,096                       | 135,694           |
| Prepaid expenses                                    | 1,289,195                     | 274,106           |
| Total current assets                                | 19,563,698                    | 28,161,782        |
| Property and equipment, net                         | 335,863                       | 301,265           |
| Patents, net                                        | 1,147,153                     | 1,233,172         |
| Deferred financing fees, net of current portion     | 22,825                        | 89,143            |
| Other assets                                        | 72,163                        | 58,713            |
| Total assets                                        | \$ 21,141,702                 | \$ 29,844,075     |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>         |                               |                   |
| <b>CURRENT LIABILITIES</b>                          |                               |                   |
| Accounts payable and accrued expenses               | \$ 2,036,769                  | \$ 2,504,978      |
| Accrued bonuses                                     | 767,989                       | 646,960           |
| Current portion of long-term debt, net of discount  | 4,457,768                     | 730,012           |
| Other current liabilities                           | 207,292                       | 126,745           |
| Total current liabilities                           | 7,469,818                     | 4,008,695         |
| Long-term debt, net of discount and current portion | 4,625,394                     | 8,056,470         |
| Other long-term liabilities                         | 143,730                       | 59,574            |
| Total liabilities                                   | 12,238,942                    | 12,124,739        |

Commitments and contingencies (Note 6)

STOCKHOLDERS' EQUITY

|                                                                                                                                            |                |                |
|--------------------------------------------------------------------------------------------------------------------------------------------|----------------|----------------|
| Preferred stock, 7,000,000 shares authorized, zero shares issued and outstanding                                                           | -              | -              |
| Common stock, \$0.01 par value; 300 million shares authorized, 91,786,290 and 87,789,679 shares outstanding in 2015 and 2014, respectively | 917,863        | 877,897        |
| Additional paid-in capital                                                                                                                 | 175,174,708    | 167,890,220    |
| Accumulated other comprehensive income                                                                                                     | 3,720          | 6,000          |
| Accumulated deficit                                                                                                                        | (167,193,531 ) | (151,054,781 ) |
| Total stockholders' equity                                                                                                                 | 8,902,760      | 17,719,336     |
| Total liabilities and stockholders' equity                                                                                                 | \$21,141,702   | \$ 29,844,075  |

See accompanying notes to unaudited condensed consolidated financial statements.

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

|                                                                | Three Months Ended September |                 | Nine Months Ended September |                  |
|----------------------------------------------------------------|------------------------------|-----------------|-----------------------------|------------------|
|                                                                | 30,                          | 2014            | 30,                         | 2014             |
|                                                                | 2015                         |                 | 2015                        |                  |
| Revenues                                                       | \$ 2,500                     | \$ 5,000        | \$ 7,917                    | \$ 14,167        |
| Operating expenses:                                            |                              |                 |                             |                  |
| Research and development expenses                              | 3,392,086                    | 2,109,880       | 9,887,750                   | 5,747,922        |
| General and administrative expenses                            | 1,807,934                    | 2,001,865       | 4,925,389                   | 7,061,129        |
| Total operating expenses                                       | 5,200,020                    | 4,111,745       | 14,813,139                  | 12,809,051       |
| Operating loss                                                 | (5,197,520 )                 | (4,106,745 )    | (14,805,222 )               | (12,794,884 )    |
| Other income (expense):                                        |                              |                 |                             |                  |
| Interest income                                                | 24,149                       | 13,127          | 53,802                      | 55,267           |
| Interest expense                                               | (464,197 )                   | (361,619 )      | (1,377,004 )                | (1,191,976 )     |
| Warrant modification expense                                   | -                            | -               | -                           | (3,109,850 )     |
| Loss from change in fair value of derivative instruments       | -                            | -               | -                           | (334,133 )       |
| Other income (expense)                                         | -                            | -               | (10,326 )                   | 250,000          |
| Total other income (expense)                                   | (440,048 )                   | (348,492 )      | (1,333,528 )                | (4,330,692 )     |
| Net loss                                                       | \$ (5,637,568 )              | \$ (4,455,237 ) | \$ (16,138,750 )            | \$ (17,125,576 ) |
| Net loss per share - basic and diluted                         | \$ (0.06 )                   | \$ (0.05 )      | \$ (0.18 )                  | \$ (0.20 )       |
| Weighted average common shares outstanding - basic and diluted | 91,569,826                   | 87,366,234      | 90,532,073                  | 86,777,197       |
| Comprehensive loss:                                            |                              |                 |                             |                  |
| Net loss                                                       | \$ (5,637,568 )              | \$ (4,455,237 ) | \$ (16,138,750 )            | \$ (17,125,576 ) |
| Foreign currency translation adjustment                        | (2,275 )                     | 3               | (2,280 )                    | (1,131 )         |
| Comprehensive loss                                             | \$ (5,639,843 )              | \$ (4,455,234 ) | \$ (16,141,030 )            | \$ (17,126,707 ) |

See accompanying notes to unaudited condensed consolidated financial statements.

**Neuralstem, Inc.****Unaudited Condensed Consolidated Statements of Cash Flows**

|                                                                         | Nine Months Ended September 30, |                  |
|-------------------------------------------------------------------------|---------------------------------|------------------|
|                                                                         | 2015                            | 2014             |
| Cash flows from operating activities:                                   |                                 |                  |
| Net loss                                                                | \$ (16,138,750 )                | \$ (17,125,576 ) |
| Adjustments to reconcile net loss to cash used in operating activities: |                                 |                  |
| Depreciation and amortization                                           | 255,398                         | 260,221          |
| Share based compensation expense                                        | 2,121,049                       | 3,638,972        |
| Amortization of deferred financing fees and debt discount               | 655,090                         | 622,244          |
| Warrant modification expense                                            | -                               | 3,109,850        |
| Loss from change in fair value of derivative instruments                | -                               | 334,133          |
| Changes in operating assets and liabilities:                            |                                 |                  |
| Trade and other receivables                                             | 206,365                         | (22,761 )        |
| Prepaid expenses                                                        | (972,371 )                      | 56,221           |
| Other assets                                                            | (14,102 )                       | 7,131            |
| Accounts payable and accrued expenses                                   | (1,269,384 )                    | 899,299          |
| Other current liabilities                                               | 318,644                         | 3,191            |
| Other long term liabilities                                             | (194,343 )                      | (9,261 )         |
| Net cash used in operating activities                                   | (15,032,404 )                   | (8,226,336 )     |
| Cash flows from investing activities:                                   |                                 |                  |
| Purchases of short-term investments                                     | (5,017,453 )                    | (25,007,478 )    |
| Maturity of short-term investments                                      | 15,007,478                      | 10,000,000       |
| Patent costs                                                            | (61,417 )                       | (308,136 )       |
| Purchase of property and equipment                                      | (128,213 )                      | (172,171 )       |
| Net cash provided by (used in) investing activities                     | 9,800,395                       | (15,487,785 )    |
| Cash flows from financing activities:                                   |                                 |                  |
| Proceeds from issuance of common stock from warrants exercised, net     | 3,073,537                       | 1,661,865        |
| Proceeds from issuance of common stock from options exercised           | -                               | 133,000          |
| Proceeds from sale of common stock and warrants, net of issuance costs  | 2,931,925                       | 19,467,859       |
| Payment of fees for future financing                                    | (42,758 )                       | -                |
| Payment of taxes on stock option exercise                               | -                               | (426,212 )       |
| Payments of long-term debt                                              | -                               | (1,917,353 )     |
| Payments of short-term notes payable                                    | (117,068 )                      | (104,957 )       |
| Net cash provided by financing activities                               | 5,845,636                       | 18,814,202       |
| Effects of exchange rates on cash                                       | (1,812 )                        | (880 )           |
| Net Change in cash and cash equivalents                                 | 611,815                         | (4,900,799 )     |

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

|                                                                        |               |               |
|------------------------------------------------------------------------|---------------|---------------|
| Cash and cash equivalents, beginning of period                         | 12,518,980    | 16,846,052    |
| Cash and cash equivalents, end of period                               | \$ 13,130,795 | \$ 11,945,253 |
| Supplemental disclosure of cash flows information:                     |               |               |
| Cash paid for interest                                                 | \$ 724,350    | \$ 573,869    |
| Supplemental schedule of non-cash investing and financing activities:  |               |               |
| Issuance of common stock for cashless exercise of warrants and options | \$ 2,736,120  | \$ 1,208,080  |

See accompanying notes to unaudited condensed consolidated financial statements.

**NEURALSTEM, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**SEPTEMBER 30, 2015 AND 2014**

**Note 1. Basis of Presentation, Estimates and Recent Accounting Pronouncements**

Basis of Presentation

In management's opinion, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations and cash flows. The condensed consolidated balance sheet at December 31, 2014, has been derived from our 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 unaudited condensed consolidated financial statements are read in conjunction with the Financial Statements and Notes included in our Annual Report on Form 10-K for the year ended December 31, 2014, filed with the SEC on March 16, 2015, and as may be amended from time to time. Certain prior period amounts have been reclassified to conform to current year classifications. Specifically, depreciation and amortization expense is no longer shown as a separate line item; patent amortization is now included in research and development expense and fixed asset depreciation is included in general and administrative expense. Management feels that this reclassification better represents the expenses in their functional categories.

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

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 unaudited condensed consolidated financial statements include significant estimates for the expected economic life and value of our owned and 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.

### Recent Accounting Pronouncements

In April 2015, the FASB issued *ASU 2015-03 – Interest-Imputation of Interest, Simplifying the Presentation of Debt Issuance Costs*. This guidance requires that deferred debt issuance costs related to a recognized debt liability be presented in the balance sheet as a deduction of the carrying amount of the debt liability (similar to debt discounts). This guidance is effective for fiscal years beginning after December 15, 2015 and early adoption is permitted. This guidance is to be applied retrospectively. This new pronouncement will result in our reclassifying amounts currently reflected as current and long-term assets to a contra-liability, which will reduce the carrying value of the associated debt instruments.

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

### **Note 2. Fair Value Measurements**

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

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

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

*Level 3* – inputs are generally unobservable and typically reflect management's estimates of assumptions that market participants would use in pricing the asset or liability. The fair values are therefore determined using model-based techniques, including option pricing models and discounted cash flow models. Our Level 3 non-derivative assets primarily comprise investments in certain corporate bonds and goodwill when it is recorded at fair value due to an impairment charge.

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

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

The inputs used in measuring the fair value of cash and cash equivalents are considered to be Level 1 in accordance with the three-tier fair value hierarchy. The fair market values are based on period-end statements supplied by the various banks and brokers that held the majority of our funds.

We had no financial assets or liabilities measured at fair value using level 3 inputs on a recurring basis at September 30, 2015 or December 31, 2014.

The following table presents the activity for those items measured at fair value on a recurring basis using Level 3 inputs for the nine months ended September 30, 2014:

|                                 | Derivative<br>Instruments – Stock<br>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 September 30, 2014   | \$ -                                                   |

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

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

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

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

We measure our long-lived assets, including property and equipment and patent assets, at fair value on a nonrecurring basis. These assets are recognized at fair value when they are deemed to be other-than-temporarily impaired. No such fair value impairment was recognized in the nine months ended September 30, 2015 or 2014.

**Note 3. Debt**

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

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

In conjunction with the loan agreement, we issued the lender a five-year common stock purchase warrant to purchase 648,809 shares of common stock at an exercise price of \$1.07892 per share. This warrant contained non-standard anti-dilution protection and, consequently, was being accounted for as a derivative instrument, recorded at fair market value each period (see Note 2). The allocation of proceeds to this warrant resulted in a debt discount which was amortized as interest expense over the term of the debt using the effective interest method. The warrant was exercised in the first quarter of 2014.

In total we 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 648,809 shares at an exercise price of \$1.07892 per share. The warrant is classified as equity. Fees related to the debt offering are recorded as deferred financing fees and are being amortized as interest expense over the term of the debt using the effective interest method.

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

In October 2014, we entered into an agreement with the existing lender to refinance and amend the terms of our loan and security agreement. The amended loan provided for refinancing of approximately \$5.6 million of outstanding balance of the initial loan along with approximately \$4.4 million of new principal for a total of \$10 million in principal. The amended loan provides for a variable interest rate based on prime with a floor of 10% and matures in April 2017. The loan provides for monthly interest only payments through September 2015, monthly payments of principal and interest of approximately \$461,000 from October 2015 through March 2017 and a final balloon payment of approximately \$2.1 million in April 2017. The loan amendment generated approximately \$4.3 million in net proceeds after fees and expenses. The loan amendment is accounted for as a debt extinguishment in accordance with guidance provided for in *ASC 470, Debt* resulting in a loss on extinguishment of approximately \$446,000. In conjunction with the loan amendment we recorded a debt discount relating to the beneficial conversion feature. Such discount is being amortized as interest expense over the term of the debt using the effective interest method.

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

We also incurred expenses with various third parties in connection with the loan amendment, consisting of approximately \$86,000 in cash, 28,119 shares of common stock valued at approximately \$80,000, and a three-year

common stock purchase warrant to purchase 58,141 shares at an exercise price of \$2.66 per share. The warrant is classified as equity and has terms substantially similar to the lender warrant. These fees related to the loan amendment are recorded as deferred financing fees and are being amortized as interest expense over the term of the debt using the effective interest method.

#### **Note 4. 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. Share-based payments are recognized at fair value. The fair value of share-based payments to employees and directors is estimated, on the date of grant. The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the option. For all time-vesting awards granted, expense is amortized using the straight-line attribution method. Share-based compensation expense recognized is based on the value of the portion of stock-based awards that is ultimately expected to vest during the period. Option valuation models, including the Black-Scholes model, require the input of highly subjective assumptions, and changes in the assumptions used can materially affect the grant-date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility and the expected life of the award.

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 September 30, 2015, we have approximately 37.3 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 and nine months ended September 30, 2015 and 2014 was as follows:

|                                     | Three Months Ended September 30, |            |
|-------------------------------------|----------------------------------|------------|
|                                     | 2015                             | 2014       |
| Research and development expenses   | \$ 385,153                       | \$ 245,000 |
| General and administrative expenses | 420,079                          | 411,947    |
| Total                               | \$ 805,232                       | \$ 656,947 |

|                                     | Nine Months Ended September 30, |              |
|-------------------------------------|---------------------------------|--------------|
|                                     | 2015                            | 2014         |
| Research and development costs      | \$ 957,907                      | \$ 723,558   |
| General and administrative expenses | 1,163,142                       | 2,915,414    |
| Total                               | \$ 2,121,049                    | \$ 3,638,972 |

Included in general and administrative expenses for the nine months ended September 30, 2014 is approximately \$2.0 million related to the extension of the term of a common stock purchase warrant based on the holder achieving certain performance based milestones.

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

Stock Options A summary of stock option activity during the nine months ended September 30, 2015 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, 2015 | 18,986,395        | \$ 1.89                         | 5.1                                                    | \$ 20,306,807             |
| Granted                        | 765,549           | \$ 3.09                         |                                                        |                           |
| Exercised                      | (1,031,774)       | ) \$ 0.54                       |                                                        | \$ 68,400                 |
| Forfeited                      | (1,233,890)       | ) \$ 0.83                       |                                                        |                           |

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

|                                   |            |         |     |              |
|-----------------------------------|------------|---------|-----|--------------|
| Outstanding at September 30, 2015 | 17,486,280 | \$ 2.10 | 5.1 | \$ 1,897,315 |
| Exercisable at September 30, 2015 | 14,240,432 | \$ 2.21 | 4.6 | \$ 1,277,927 |
| Vested and expected to vest       | 17,481,198 | \$ 2.10 | 4.8 | \$ 1,897,315 |

| 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          | 5,000,000                     | \$ 0.92                         | 6.8                                                    | \$ 1,500,000              |
| \$1.01 - \$2.00          | 4,325,984                     | \$ 1.23                         | 6.1                                                    | 397,315                   |
| \$2.01 - \$3.00          | 2,122,669                     | \$ 2.50                         | 4.0                                                    |                           |
| \$3.01 - \$5.00          | 6,037,627                     | \$ 3.57                         | 3.4                                                    |                           |
|                          | 17,486,280                    | \$ 2.10                         | 5.1                                                    | \$ 1,897,315              |

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:

|                          | Nine Months Ended September 30, |                |
|--------------------------|---------------------------------|----------------|
|                          | 2015                            | 2014           |
| Annual dividend          | -                               | -              |
| Expected life (in years) | 4.0-6.0                         | 4.0 - 8.5      |
| Risk free interest rate  | 1.39%-1.78%                     | 1.12% - 2.50%  |
| Expected volatility      | 68.6% - 71.8%                   | 68.8% - 100.0% |

The options granted in the nine months ended September 30, 2015 and 2014 had weighted average grant date fair values of \$1.89 and \$1.93, respectively.

Unrecognized compensation cost for unvested stock option awards outstanding at September 30, 2015 was approximately \$4,060,000 to be recognized over approximately 1.9 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 nine months ended September 30, 2015 is as follows:

|                                       | <b>Number of<br/>RSU's</b> | <b>Weighted-<br/>Average<br/>Grant Date<br/>Fair Value</b> |
|---------------------------------------|----------------------------|------------------------------------------------------------|
| Outstanding at January 1, 2015        | 447,275                    | \$ 2.18                                                    |
| Granted                               | -                          |                                                            |
| Vested and converted to common shares | -                          |                                                            |
| Forfeited                             | -                          |                                                            |
| Outstanding at September 30, 2015     | 447,275                    | \$ 2.18                                                    |
| Exercisable at September 30, 2015     | 447,275                    | \$ 2.18                                                    |

Restricted Stock We have granted restricted stock to certain board members based on revised board of director year and compensation policy.

Page 11

A summary of our restricted stock activity for the nine months ended September 30, 2015 is as follows:

|                                   | <b>Number of<br/>RS</b> | <b>Weighted-<br/>Average<br/>Grant Date<br/>Fair Value</b> |
|-----------------------------------|-------------------------|------------------------------------------------------------|
| Granted                           | 427,808                 |                                                            |
| Converted to common shares        | (106,952 )              |                                                            |
| Forfeited                         | -                       |                                                            |
| Outstanding at September 30, 2015 | 320,856                 | \$ 1.87                                                    |

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

A summary of warrant activity for the nine months ended September 30, 2015 follows:

|                                   | <b>Number of<br/>Warrants</b> | <b>Weighted-<br/>Average<br/>Exercised<br/>Price</b> | <b>Weighted-<br/>Average<br/>Remaining<br/>Contractual Life<br/>(in years)</b> | <b>Aggregate<br/>Intrinsic<br/>Value</b> |
|-----------------------------------|-------------------------------|------------------------------------------------------|--------------------------------------------------------------------------------|------------------------------------------|
| Outstanding at January 1, 2015    | 21,422,346                    | \$ 2.30                                              | 3.8                                                                            | \$15,984,739                             |
| Granted                           | 150,000                       | \$ 1.87                                              | 4.8                                                                            |                                          |
| Exercised                         | (1,724,606 )                  | \$ 1.94                                              |                                                                                |                                          |
| Forfeited                         | (24,794 )                     | \$ 2.13                                              |                                                                                |                                          |
| Outstanding at September 30, 2015 | 19,822,946                    | \$ 2.33                                              | 3.3                                                                            | \$1,271,994                              |
| Exercisable at September 30, 2015 | 19,710,446                    | \$ 2.33                                              | 3.3                                                                            | \$1,271,994                              |

### Common Stock

In January, 2014, we closed a registered direct offering of 6,872,859 shares of common stock at a price of \$2.91 per share. We received aggregate gross proceeds of \$20 million and net proceeds of approximately \$18,630,000 from the offering. In connection with the offering, we also issued 3,436,435 common stock purchase warrants; the warrants have an exercise price of \$3.64, a term of five years and are classified within equity. This offering was made pursuant to our \$50 million shelf registration statement declared effective by the SEC on September 13, 2013 (Registration No.

333-190936). Additionally, as a result of this transaction an advisor to the Company met certain capital raising milestones and consequently, the term of their common stock purchase warrant was extended to 5 years.

In 2014, we issued 249,163 shares of common stock as a result of sales under our At the Market Offering Agreement. The shares were sold at an average price of \$3.55 per share and we received approximately \$838,000 in net proceeds.

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

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

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

In 2014, we issued 805,972 shares of common stock upon the conversion by the lender of \$1 million of principal payments due under our March 2013 long-term debt in accordance with the terms of the loan and security agreement (see Note 3). We received no proceeds from this conversion.

In October 2014, we issued 28,119 shares of common stock and common stock purchase warrants to purchase 133,329 to various parties in conjunction with our loan amendment (see Note 3).

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

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

In the nine months ended September 30, 2015, we issued 1,050,980 shares of our common stock upon the cashless exercise of 2,209,000 outstanding common stock purchase warrants and stock options. The warrants and options were exercised at an average price of \$0.62. We received no proceeds from the exercises.

#### **Note 5. Earnings (Loss) per Share**

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

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

of basic and diluted income per share excludes net income attributable to the unvested restricted shares from the numerator and excludes the impact of the shares from the denominator.

For all periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive due to the net losses; accordingly, diluted loss per share is the same as basic loss per share for the three- and nine-month periods ended September 30, 2015 and 2014. A total of approximately 37.3 million and 40.1 million potential dilutive shares have been excluded in the calculation of diluted net income per share for the three- and nine-month periods ended September 30, 2015 and 2014, respectively, as their inclusion would be anti-dilutive.

#### **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.

##### Stem Cell Litigation

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.

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. This case was consolidated with the 2006 litigation.

On July 22, 2015, the Court issued its ruling on the issue of standing finding that a third-party who was not named as an inventor was a co-owner and co-inventor of the patents-in-suit. Thus, the Court determined that StemCells lacked standing to pursue its patent infringement claims against Neuralstem and the case was dismissed with prejudice.

On September 10 2015, the parties entered into a settlement agreement dismissing all claims and counterclaims with prejudice.

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

*Statements in this Quarterly Report that are not strictly historical are forward-looking statements and include statements about products in development, results and analyses of pre-clinical studies, clinical trials and studies, research and development expenses, cash expenditures, and alliances and partnerships, among other matters. You can identify these forward-looking statements because they involve our expectations, intentions, beliefs, plans, projections, anticipations, or other characterizations of future events or circumstances. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that may cause actual results to differ materially from those in the forward-looking statements as a result of any number of factors. These factors include, but are not limited to, risks relating to our ability to conduct and obtain successful results from ongoing clinical trials, commercialize our technology, obtain regulatory approval for our product candidates, contract with third parties to adequately test and manufacture our proposed therapeutic products, protect our intellectual property rights and obtain additional financing to continue our development efforts. Some of these factors are more fully discussed, as are other factors, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed with the SEC on March 16, 2015, as well as in the section of this Quarterly Report entitled "Risk Factors" and elsewhere herein. We do not undertake to update any of these forward-looking statements or to announce the results of any revisions to these forward-looking statements except as required by law.*

We urge you to read this entire Quarterly Report on Form 10-Q, including the "Risk Factors" section, the financial statements, and related notes. As used in this Quarterly Report, unless the context otherwise requires, the words "we," "us," "our," "the Company," "Neuralstem" and "Registrant" refers to Neuralstem, Inc. and its subsidiaries. Also, any reference "common shares," "common stock," or "shares" refers to our \$.01 par value common stock. The information contained herein is current as of the date of this Quarterly Report (September 30, 2015), unless another date is specified. We prepare our interim financial statements in accordance with U.S. GAAP. Our financials and results of operations for the three- and nine-month periods ended September 30, 2015 are not necessarily indicative of our prospective

financial condition and results of operations for the pending full fiscal year ending December 31, 2015. The interim financial statements presented in this Quarterly Report as well as other information relating to our company contained in this Quarterly Report should be read in conjunction and together with the reports, statements and information filed by us with the United States Securities and Exchange Commission or SEC.

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

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

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

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

*Results of Operations*— Analysis of our financial results comparing the three- and nine-month periods ended September 30, 2015 to the comparable periods of 2014.

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

## **Executive Overview**

We are focused on the development and commercialization of regenerative medicine treatments based on our human neuronal stem cell technology including cell therapy and traditional small molecule drugs. We are headquartered in Germantown, Maryland and have a wholly-owned and consolidated subsidiary in China, Suzhou Neuralstem Biopharmaceutical Co. Ltd., or Neuralstem China.

We have developed and maintain a portfolio of patents and patent applications that form the proprietary base for our research and development efforts. We own or exclusively license one hundred ten (110) U.S. and foreign issued patents and fifty (50) U.S. and foreign patent applications in the field of regenerative medicine, related to our stem cell technologies as well as our small molecule compounds. At times we have licensed the use of our intellectual property to third parties.

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

Regenerative medicine is still an emerging field. Regenerative medicine is the process of creating living, functional tissues to repair or replace tissue or organ function lost due to age, disease, damage, or congenital defects. There can be no assurances that we will ultimately produce any viable commercialized products and processes. Even if we are able to produce a commercially viable product, there are strong competitors in this field and our products may not be able to successfully compete against them.

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

In July 2015 our stock began trading on the NASDAQ Capital Market under the trading symbol "CUR".

## *Clinical Programs*

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

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

intended indication, current stage of development and our expected development plans:

| Program   | Indication                            | Development Status                                               | Development Plan                                                           |
|-----------|---------------------------------------|------------------------------------------------------------------|----------------------------------------------------------------------------|
| NSI – 189 | Major Depressive Disorder             | Phase II FDA protocol filed in September 2015.                   | We expect to enroll the first patient in this study in Q1 of 2016.         |
| NSI – 189 | Cognitive Deficit in Schizophrenia    | Phase Ib preparation.                                            | The Phase Ib trial is expected to commence in 2016.                        |
| NSI – 566 | Amyotrophic Lateral Sclerosis (ALS)   | Complete.                                                        | Discussions on-going with the FDA regarding a registration directed trial. |
| NSI – 566 | Chronic Spinal Cord Injury            | Phase Ib thoracic patient cohort enrollment completed July 2015. | Six month observation period ongoing.                                      |
| NSI – 566 | Motor deficits due to ischemic stroke | Phase I safety study ongoing.                                    | We expect to commence a Phase II trial in 2016.                            |

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

### *Major Depressive Disorder (MDD)*

Major depressive disorder, or MDD (also known as recurrent depressive disorder, clinical depression, major depression, unipolar depression, or unipolar disorder), is a mental disorder characterized by episodes of all-encompassing low mood accompanied by low self-esteem and loss of interest or pleasure in normally enjoyable activities. NSI-189 is being developed for the treatment of major depressive disorder and other psychiatric and/or cognitive impairment indications associated with hippocampal atrophy. NSI-189 is the lead compound in our neurogenic small molecule drug platform. We believe that NSI-189 may provide an effective treatment for patients suffering from MDD by structurally rebuilding the hippocampus.

In February of 2011, we commenced a Phase I clinical trial (Phase Ia portion) of NSI-189, at California Clinical Trials, LLC, in Glendale, California. The purpose of the Phase Ia portion of the trial was to evaluate the safety of the drug in healthy volunteers. The Phase Ia portion tested a single oral administration of NSI-189 in 24 healthy volunteers and was completed in October of 2011. In December of 2011, we received authorization from the United States Food and Drug Administration or FDA to commence the Phase Ib randomized, dose-escalating, placebo controlled clinical trial for the treatment of MDD. The primary end points of the Phase Ib portion of the clinical trial were to determine the drug safety and tolerability in three dosages in diagnosed MDD patients. Secondary endpoints included traditional depression scales tests, cognition testing and testing for both electrophysiological and traditional plasma biomarkers for Depression. The Phase Ib trial entailed patients with MDD randomized to receive daily doses, of either NSI-189 or placebo, for 28 consecutive days followed by an eight week post dose observation period. The trial was completed and data was presented at two conferences: the American Society of Clinical Psychopharmacology Annual Meeting in Hollywood, Florida and at the International College of Neuropsychopharmacology Annual Meeting in Vancouver Canada. We are currently preparing the regulatory and clinical protocol for a Phase II, multi-site clinical trial in approximately 200 patients that is expected to commence in Q1 of 2016.

### *Cognitive Deficit in Schizophrenia*

We have expanded the NSI-189 program to include a second indication for the treatment of cognitive deficit in schizophrenia. Cognitive deficit is a prominent characteristic of schizophrenia that is correlated with the occurrence of hippocampal atrophy in this patient population. We expect the Phase Ib trial to commence in 2016.

### *NSI - 566 (Stem Cells)*

*Amyotrophic Lateral Sclerosis (ALS)*

Amyotrophic lateral sclerosis or ALS is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. Motor neurons reach from the brain to the spinal cord and from the spinal cord to the muscles throughout the body. ALS is characterized by stiff muscles, muscle twitching, and gradually worsening weakness due to muscle wasting. This results in difficulty speaking, swallowing, and eventually, breathing. With voluntary muscle action progressively affected, patients in the later stages of the disease may become totally paralyzed or may die. The average survival from onset to death is three to four years. NSI-566 is under development as a potential treatment for ALS by providing cells designed to nurture and protect the patients' remaining motor neurons; and possibly repair some of the diseased motor neurons which have not yet died. Neuralstem has received orphan designation by the FDA for NSI-566 in ALS.

In January 2010, we commenced the Phase I trial of NSI-566 in ALS at Emory University in Atlanta Georgia. The purpose of the Phase I trial was to evaluate the safety and transplantation technique of our proposed treatment and procedure specifically in the lumbar region of the spinal cord. The last cohort received both lumbar and cervical injections. The dosing of patients in this Phase I trial, as designed, was completed in August, 2013. In September 2013, we commenced a Phase II clinical trial for ALS primarily evaluating safety of NSI-566 cells and cervical surgeries. The Phase II dose escalation trial enrolled 15 ambulatory patients in five different dosing cohorts, under an accelerated dosing and treatment schedule for a total of 18 surgeries. Each patient in the final cohort received transplantation in both the cervical and lumbar areas with 20 injections of 400,000 cells per injection. In March 2015, the company announced topline data concluding that the Phase II ALS clinical trial met the primary safety endpoints and established what we believe to be the maximum safe tolerated dose of 16 million cells delivered in 40 injections. Secondary efficacy endpoints such as the Amyotrophic Lateral Sclerosis Functional Rating Scale, or ALSFRS, and grip strength were evaluated at nine months post-surgery to assess the potential therapeutic benefit of disease stabilization.

In September 2015, nine-month Phase II and combined Phase I and Phase II data on the NSI-566 trial in amyotrophic lateral sclerosis (ALS) was presented at the American Neurological Association Annual Meeting by principal investigator, Eva Feldman, MD, PhD, Director of the A. Alfred Taubman Medical Research Institute and Director of Research of the ALS Clinic at the University of Michigan Health.

The Company is in discussion with the FDA for the planning of a larger registration directed, controlled trial.

### *Chronic Spinal Cord Injury*

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

During the first quarter of 2013, we received authorization from the FDA to commence a 4 patient Phase I, open-label, single-site, safety study of human spinal cord-derived neural stem cell (HSSC) transplantation for the treatment of chronic spinal cord injury. The entire trial will take place at The University of California, San Diego. The trial commenced during the third quarter of 2014 and the last patient was treated in July 2015. Each patient will be evaluated over a 6 month post-operative observation period.

### *Motor Deficits Due to Ischemic Stroke*

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

In September of 2012, we received authorization to commence a human clinical trial for treatment of motor deficits due to ischemic stroke. The trial is being conducted by Neuralstem China, at BaYi Brain Hospital in Beijing, China utilizing our spinal cord stem cells. The trial authorization encompasses a combined phase I/II/III design and will test direct injections of NSI-566 into the brain, the same cell product used in our recently-completed Phase II ALS trial in the United States. The trial commenced in the fourth quarter of 2013. The first phase of the trial is structured to confirm the maximum safe tolerated dose. We expect to begin the Phase II portion of the trial in 2016, the study is designed to enroll approximately 118 patients.

### *Acute Spinal Cord Injury*

Acute Spinal Cord Injury refers to the immediate post-injury period when there is continuing tissue damage. The acute phase is the period in which the secondary injury processes become dominant. For practical reasons, it is the SCI phase likely to be most amenable to neuroprotective interventions, as it is typically the earliest point at which patients arrive at an appropriate center to receive possible treatment. The acute phase is subdivided into early acute and subacute stages. We believe that NSI-566 may provide an effective treatment for chronic spinal cord injury by “bridging the gap” in the spinal cord circuitry created in traumatic spinal cord injury and providing new cells to help transmit the signal from the brain to points at or below the point of injury.

The Company has filed an Investigational New Drug application (IND) with the Korean FDA and expects approval to commence an acute spinal cord injury trial utilizing NSI-566 in 2016. The trial will take place at a single center in Seoul. If approved as submitted, this trial will treat complete spinal cord injury patients, who are those who have no sensory or motor function below the point of injury and also progressively incomplete patients, who have varying degrees of sensory and motor function.

## ***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 may assist the body in producing new cells to replace malfunctioning or dead cells as a way to treat disease and injury. Many significant and currently untreatable human diseases arise from the loss or malfunction of specific cell types in the body. Our focus is the development of effective methods to generate replacement cells from neural stem cells. We believe that replacing damaged, malfunctioning or dead neural cells with fully functional ones may be a useful therapeutic strategy in treating many diseases and conditions of the central nervous system. We own or exclusively license forty-nine (49) U.S. and foreign issued patents and thirty-six (36) U.S. and foreign patent applications related to our stem cell technologies.

### Small Molecule Pharmaceutical Compounds.

We have developed and patented a series of small molecule compounds. We believe these low molecular weight organic compounds can efficiently cross the blood/brain barrier. In mice, research indicated that the small molecule compounds both stimulate neurogenesis of the hippocampus and increase its volume. Human data from the MDD trial showed clinically meaningful and statistically significant improvement in depressive and cognitive scales. We believe the small molecule compounds may assist in reversing atrophy in the human hippocampus documented in indications such as MDD and schizophrenia.

Our small molecule compounds are covered by sixty-one (61) exclusively owned U.S. and foreign issued patents and Fourteen (14) exclusively owned U.S. and foreign patent applications related to our small molecule compounds.

## ***Research***

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

### ***Operating Strategy***

We generally employ an outsourcing strategy where we outsource our Good Laboratory Practices, or GLP, preclinical development activities and Good Manufacturing Practices, or GMP, Good Tissue Practices, or GTP, if applicable, and clinical development activities to contract research organizations or CROs as needed. We have also used contract manufacturing organizations or CMOs as well. Manufacturing is also outsourced to organizations with approved facilities and manufacturing practices. This outsource model has allowed us to better manage cash on hand and minimize non-vital expenditures.

### ***Manufacturing***

We currently manufacture our cells both in-house and on an outsourced basis. We outsource the manufacturing of our pharmaceutical compounds to third party manufacturers. We have manufactured, in-house, cells that are not required to meet stringent FDA requirements for use in human subjects. We use these cells in research and collaborative programs. During 2015, we began the process of bringing the manufacturing of our clinical grade spinal cord stem cells, in-house. We believe this will better assure the availability of our stem cells and to also lead to a reduction in per patient costs.

### ***Employees***

As of September 30, 2015, we had 31 full-time employees and three (3) full-time independent contractors. Of these full-time employees and contractors, 23 work on research and development and eight (8) in administration. We also use the services of numerous outside consultants in business and scientific matters.

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

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

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

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

### **Trends & Outlook**

#### ***Revenue***

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

future clinical trials.

In the first quarter of 2013 and the third quarter of 2012, we licensed the use of certain of our intellectual property to third parties. During the nine months ended September 30, 2015 and 2014, we recognized approximately \$8,000 and \$14,000 of revenue, respectively, related to ongoing fees under these licenses.

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

### ***Research and Development Expenses***

Our research and development expenses consist primarily of contractor and personnel expenses associated with clinical trials and regulatory submissions; costs associated with preclinical activities such as proof of principle for new indications; toxicology studies; costs associated with cell processing and process development; facilities-related costs and supplies. Clinical trial expenses include payments to research organizations, contract manufacturers, clinical trial sites, consultants and laboratories for testing clinical samples.

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

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

We expect that research and development expenses, which include expenses related to our ongoing clinical trials, will increase in the future, as funding allows and if we expand our clinical programs. 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 our Investigational New Drug applications or INDs. 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 current

and future clinical trials in China, including the current trial to treat motor deficits due to ischemic stroke.

### ***General and Administrative Expenses***

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

We anticipate that our general and administrative expenses will increase in the future as we expand our clinical programs.

### **Critical Accounting Policies**

Our discussion and analysis of our financial condition and results of operations is based upon our condensed consolidated financial statements prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make certain estimates and assumptions that may affect the reported amounts of assets and liabilities, the reported amounts of revenues and expenses during the reported periods and related disclosures. These estimates and assumptions, including those related to revenue recognition, inventory valuation and related reserves, research and development expenses and share-based compensation, are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on our historical experience, trends in the industry, and various other factors that are believed to be reasonable under the circumstances. Actual results may differ from our estimates under different assumptions or conditions. During the three and nine months ended September 30, 2015, there were no material changes to our critical accounting policies as reported in our Annual Report on Form 10-K for the year ended December 31, 2014, which was filed with the Securities and Exchange Commission, or SEC, on March 16, 2015.

## **RESULTS OF OPERATIONS**

### **Comparison of Three Months Ended September 30, 2015 and 2014**

#### ***Revenue***

We did not generate any revenues from the sale of our proposed products and therapies in any of the periods presented. For the three months ended September 30, 2015 and 2014, we recognized approximately \$2,500 and \$5,000, respectively, related to the licensing of certain intellectual properties to third parties.

***Operating Expenses***

Operating expenses for the three months ended September 30, 2015 and 2014 were as follows:

|                                     | Three Months Ended September 30, |              | Increase (Decrease) |        |
|-------------------------------------|----------------------------------|--------------|---------------------|--------|
|                                     | 2015                             | 2014         | \$                  | %      |
| Operating Expenses                  |                                  |              |                     |        |
| Research and development expenses   | \$ 3,392,086                     | \$ 2,109,880 | \$ 1,282,206        | 61 %   |
| General and administrative expenses | 1,807,934                        | 2,001,865    | (193,931 )          | (10 )% |
| Total operating expenses            | \$ 5,200,020                     | \$ 4,111,745 | \$ 1,088,275        | 26 %   |

***Research and Development Expenses***

The increase of approximately \$1,282,000 or 61% in research and development expenses was primarily attributable to increased project and laboratory expenses. These increased expenses are related to the expansion of our pre-clinical and clinical trial efforts and are expected to continue into subsequent periods.

***General and Administrative Expenses***

The decrease of approximately \$194,000 or 10% was primarily due to a decrease in legal fees mainly associated with litigation and a decrease in consulting expense. These decreases were partially offset by an increase in salaries and related expenses associated with increased head count.

***Other expense***

Other expenses for the three months ended September 30, 2015 and 2014 were as follows:

|                     | Three Months Ended    |             | Increase         |     |
|---------------------|-----------------------|-------------|------------------|-----|
|                     | September 30,<br>2015 | 2014        | (Decrease)<br>\$ | %   |
| Other Expense       |                       |             |                  |     |
| Interest Income     | \$24,149              | \$13,127    | \$11,022         | 84% |
| Interest Expense    | (464,197)             | (361,619)   | (102,578)        | 28% |
| Total other expense | \$(440,048)           | \$(348,492) | \$(91,556)       | 26% |

Other expense totaled approximately \$440,000 and \$348,000 for the three months ended September 30, 2015 and 2014, representing an increase of approximately \$92,000 or 26%. Other expense in 2015 primarily consisted of \$464,000 of interest expense principally related to our long-term debt partially offset by interest income of \$24,000. Other expense in 2014 consisted primarily \$362,000 of interest expense principally related to our long-term debt partially offset by \$13,000 of interest income.

**Comparison of Nine Months Ended September 30, 2015 and 2014*****Revenue***

We did not generate any revenues from the sale of our proposed products and therapies in any of the periods presented. For the nine months ended September 30, 2015 and 2014, we recognized approximately \$8,000 and \$14,000, respectively related to the licensing of certain intellectual properties to third parties.

***Operating Expenses***

Operating expenses for the nine months ended September 30, 2015 and 2014 were as follows:

|                                   | Nine Months Ended September 30, |              | Increase (Decrease) |      |
|-----------------------------------|---------------------------------|--------------|---------------------|------|
|                                   | 2015                            | 2014         | \$                  | %    |
| Operating Expenses                |                                 |              |                     |      |
| Research and development expenses | \$ 9,887,750                    | \$ 5,747,922 | \$4,139,828         | 72 % |

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

|                                     |               |               |              |        |
|-------------------------------------|---------------|---------------|--------------|--------|
| General and administrative expenses | 4,925,389     | 7,061,129     | (2,135,740 ) | (30 )% |
| Total operating expenses            | \$ 14,813,139 | \$ 12,809,051 | \$ 2,004,088 | 16 %   |

*Research and Development Expenses*

The increase of approximately \$4,140,000 or 72% in research in development expenses was primarily attributable to an increase in project and lab expenses, increase in both payroll related and stock compensation expenses due to increased salaries and headcount and an increase in rent expense. These increased expenses are related to the expansion of our pre-clinical and clinical trial efforts and are expected to continue into subsequent periods.

*General and Administrative Expenses*

The decrease of approximately \$2,136,000 or 30% was primarily due to a decrease in non-cash stock based compensation largely the result of an expense in the first quarter of 2014 related to a consultant achieving a performance based milestone. Additionally there were decreased legal fees primarily resulting from decreased litigation expenses. This decrease was partially offset by an increase in salary expense due to increased headcount and salaries and an increase in consulting expenses.

**Other Expense**

Other expenses for the nine months ended September 30, 2015 and 2014 were as follows:

|                                    | Nine Months Ended<br>September 30, |                | Increase<br>(Decrease) |        |
|------------------------------------|------------------------------------|----------------|------------------------|--------|
|                                    | 2015                               | 2014           | \$                     | %      |
| Other Expense                      |                                    |                |                        |        |
| Interest Income                    | \$53,802                           | \$55,267       | \$(1,465 )             | (3 )%  |
| Interest Expense                   | (1,377,004)                        | (1,191,976)    | (185,028 )             | 16 %   |
| Warrant Modification Expense       | -                                  | (3,109,850)    | 3,109,850              | (100)% |
| Change in fair value of derivative | -                                  | (334,133 )     | 334,133                | (100)% |
| Other Expenses                     | (10,326 )                          | 250,000        | (260,326 )             | (104)% |
| Total other expense                | \$ (1,333,528)                     | \$ (4,330,692) | \$ 2,997,164           | (69 )% |

Other expense totaled approximately \$1,334,000 and \$4,331,000 for the nine months ended September 30, 2015 and 2014, representing a decrease of approximately \$2,997,000 or 69%. Other expense in 2015 consisted primarily of \$1,377,000 of interest expense principally related to our long-term debt partially offset by interest income. Other expense in 2014 consisted primarily of \$3,110,000 related to our extension of certain common stock purchase warrants and interest expense partially offset by interest income.

**Liquidity and Capital Resources**

We have incurred cumulative operating losses and negative operating cash flow since inception in 1996, and as of September 30, 2015, we had an accumulated deficit of \$167,193,531. 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.

|                                                     | Nine Months Ended September 30, |                  | Increase (Decrease) |        |
|-----------------------------------------------------|---------------------------------|------------------|---------------------|--------|
|                                                     | 2015                            | 2014             | \$                  | %      |
| Net cash used in operating activities               | \$ (15,032,404 )                | \$ (8,226,336 )  | \$(6,806,068 )      | (83 )% |
| Net cash provided by (used) in investing activities | \$ 9,800,395                    | \$ (15,487,785 ) | \$ 25,288,180       | 163 %  |
| Net cash provided by financing activities           | \$ 5,845,636                    | \$ 18,814,202    | \$(12,968,566)      | (69 )% |

Our cash and short-term investment balances was approximately \$18,148,000 at September 30, 2015 compared to \$27,526,000 at December 31, 2014. The decrease of approximately \$9,378,000 was primarily due to our cash used in operations partially offset by our raising \$6,005,000, net from the issuance of our common stock from warrant exercises and from the sale of our common stock.

*Net Cash Used in Operating Activities*

We used approximately \$15,032,000 and \$8,226,000 of cash in our operating activities for the nine months ended September 30, 2015 and 2014, respectively. The increase in our use of cash of approximately \$6,806,000 was primarily due to an increase in our net loss related to increased spending in research and development as adjusted for stock based compensation and changes in our operating assets and liabilities.

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

We generated approximately \$9,800,000 and used approximately \$(15,487,000) of cash in connection with investment activities for the nine months ended September 30, 2015 and 2014, respectively. The decrease in our use of cash of approximately \$25,288,000 was primarily due to the maturity in 2015, of short-term investments purchased in 2014 using the proceeds from our January 2014 registered direct offering.

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

Proceeds from financing activities were approximately \$5,846,000 and \$18,814,000 in the nine months ended September 30, 2015 and 2014, respectively. The decrease of \$12,968,000 was primarily the result of receiving \$2,932,000 in net proceeds from the sales of our common stock in 2015 compared to receiving approximately \$19,468,000 in net proceeds from our registered direct offering and other sales of common stock and warrants in 2014. In addition, we received approximately \$3,074,000 and \$1,662,000 in 2015 and 2014, respectively, from the exercise of outstanding warrants. In 2014 we also made \$1,917,000 of payments on our long term debt compared to no principal payments being due or made to date in 2015.

***Future Liquidity and Needs***

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

We intend to pursue opportunities to obtain additional financing in the future through the sale of our securities and additional research grants. We currently have two shelf registration statements that are effective. On June 19, 2014, our shelf registration statement registering the sale of up to \$100 million of our securities was declared effective by the SEC. To date, we have not sold any securities under this shelf registration statement. On September 13, 2013, our shelf registration statement (Registration No. 333-190936) registering the sale of up to \$50 million of our securities was declared effective by the SEC. As of September 30, 2015 we have sold or reserved for sale upon the exercise of outstanding warrants approximately \$48.2 million of securities under this shelf registration statement. Additionally, securities sold pursuant to our At the Market Offering Agreement (see below) are being sold pursuant to this registration statement and accordingly, we have reserved the balance of approximately \$1.8 million of securities pursuant thereto. We anticipate conducting offerings in the future, based on our shelf registration statements, when and if financing opportunities arise.

In October 2013, we entered into an At the Market Offering Agreement with T.R. Winston & Company as our sales agent pursuant to which we can sell up to \$25 million of our common stock. The At the Market Offering is being conducted pursuant to our shelf registration statement declared effective on September 13, 2013 (Registration No. 333-190936). As of September 30, 2015 we have sold 2,202,580 shares under such agreement at an average price per share of \$3.16 resulting in gross proceeds of approximately \$6,965,000 and net proceeds of approximately \$6,666,000. Future sales under our agreement are limited to approximately \$1.8 million which is the amount available under our shelf registration statement pursuant to which the At the Market Offering is being conducted.

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

Our foreign operations in China subject us to changes in foreign exchange rates. Changes in exchange rates for the year ended December 31, 2015 are not expected to have a material effect as the operations are expected to be limited. Future changes to foreign exchange rates could have a material effect on us as our clinical trial activity increases.

#### **ITEM 4. CONTROLS AND PROCEDURES**

##### *Evaluation of Disclosure Controls and Procedures*

We maintain “disclosure controls and procedures,” as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the “Exchange Act”), that are designed to ensure 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 Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and no design provides absolute assurance that it will succeed in achieving its stated goals under all potential future conditions. With respect to the quarterly period ending September 30, 2015, under the supervision and with the participation of our management, we evaluated the design and operation of our disclosure controls and procedures. Based upon this evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective as of September 30, 2015 at the reasonable assurance level.

We disclosed in the Form 10-Q for the period ended June 30, 2015 that we had identified deficiencies with regard to the operation of our disclosure controls. We are committed to improving our financial oversight. As part of this commitment, we have taken the following steps:

· We hired a full-time Chief Financial Officer in May 2015

· We hired a full-time Corporate Controller in September 2015

· We have enhanced our whistleblower protocols

· We have implemented and are continuing to implement enhanced policies and processes for travel, expense reimbursements and disbursements

· We have implemented and are continuing to implement enhanced oversight by our Audit Committee of expense reimbursements

Management is continuing to review the operation of its controls with regard to expense reimbursements and disbursement

Except as noted above, there were no changes in our internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)) during the quarter ended September 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II**

### **OTHER INFORMATION**

#### **ITEM 1. LEGAL PROCEEDINGS**

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 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.

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. This case was consolidated with the 2006 litigation.

On July 22, 2015, the Court issued its ruling on the issue of standing finding that a third-party who was not named as an inventor was a co-owner and co-inventor of the patents-in-suit. Thus, the Court determined that StemCells lacked standing to pursue its patent infringement claims against Neuralstem and the case was dismissed with prejudice.

On September 10,, 2015, the parties entered into a settlement agreement dismissing all claims and counterclaims with prejudice.

#### **ITEM 1A. RISK FACTORS**

*Investing in our common stock involves a high degree of risk. We have described below a number of uncertainties and risks which, in addition to uncertainties and risks presented elsewhere in this Quarterly Report, may adversely affect our business, operating results and financial condition. The uncertainties and risks enumerated below as well as those presented elsewhere in this Quarterly Report, and those included in our Annual Report on Form 10-K for the year ended December 31, 2014, filed with the SEC should be considered carefully in evaluating our*

*company and our business and the value of our securities.*

## **Risks Relating to Our Stage of Development and Capital Structure**

*We have a history of losses.*

Since inception in 1996 and through September 30, 2015, we have accumulated losses totaling approximately \$167,194,000. At September 30, 2015, we had a working capital surplus of approximately \$12,094,000 and stockholders' equity of approximately \$8,902,000. Our net losses for the two most recent fiscal years have been approximately \$22,629,000 and \$19,832,000 for 2014 and 2013, respectively while our loss for the nine months ended September 30, 2015 was approximately \$16,139,000. We had no revenue from the sales of our products during the nine months ended September 30, 2015 or 2014.

Our ability to generate revenues and achieve profitability will depend upon our ability to complete the development of our proposed products, obtain the required regulatory approvals, manufacture and market and ultimately sell our proposed products. To date, none of our proposed products have been approved for sale and we have not generated any revenue from the commercial sale of our proposed products. No assurances can be given as to exactly when, if ever, we will be able to fully develop, receive regulatory approval, commercialize, market, sell and/or derive any, let alone material, revenues from our proposed products.

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

Since our inception, we have funded our operations through the sale of our securities, credit facilities, the exercise of options and warrants, and to a lesser degree, from grants and research contracts and other revenue generating activities such as licensing. As of September 30, 2015, we had cash, cash equivalents and short-term investments on hand of approximately \$18,148,000. We cannot assure you that we will be able to secure additional capital through financing transactions, including issuance of debt, licensing agreements or grants. Our inability to license our intellectual property, obtain grants or secure additional financing will materially impact our ability to fund our current and planned operations.

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

additional financing, we may be unable to meet operating obligations which could result in us initiating bankruptcy proceedings or delaying, or eliminating some or all of our research and product development programs.

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

We have a substantial level of debt. As of September 30, 2015, we had approximately \$9.5 million in aggregate principal outstanding of long-term secured indebtedness. Under our amended loan and security agreement, we are required to make monthly interest only payments through September 2015; interest and principal payments of approximately \$461,000 per month from October 2015 through March 2017 and a balloon payment for the remaining principal in April 2017. As security for such indebtedness, we have pledged substantially all of our assets, including our intellectual property. If we are unable to make the required payments, or if we fail to comply with the various requirements and covenants of our indebtedness, we will be in default, which would permit the holders of our indebtedness to accelerate the maturity and require immediate repayment which could lead to the potential foreclosure on the assets securing the debt. Any default under our indebtedness would have a material adverse effect on our business, operating results and financial condition. Additionally, our amended loan and security agreement governing our \$10 million credit facility also contains a number of affirmative and restrictive covenants, including reporting requirements and other collateral limitations, certain limitations on liens and indebtedness, dispositions, mergers and acquisitions, restricted payments and investments, corporate changes and limitations on waivers and amendments to certain agreements, our organizational documents, and documents relating to debt that is subordinate to our obligations under the credit facility. Our failure to comply with the covenants in the amended loan and security agreement could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our debt and potential foreclosure on the assets securing the debt. If we are unable to refinance or repay our indebtedness as it becomes due, including upon an event of default, we may become insolvent and be unable to continue operations.

## **Risks Relating to Our Business**

*Our business is dependent on the successful development of our product candidates.*

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

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

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

We have allocated the majority of our resources to the development of our stem cell and small molecule technologies. Our ability to generate revenue and operate profitably will depend on being able to develop these technologies for human applications. These are emerging technologies that may have limited human application. We cannot guarantee that we will be able to develop our technologies or that if developed, our technologies will result in commercially viable products or have any commercial utility or value. We anticipate that the commercial sale of our proposed products and/or royalty/licensing fees related to our technologies, will be our primary sources of revenue. If we are unable to develop our technologies, we may never realize any significant revenue. Additionally, given the uncertainty of our technologies, product candidates and the need for government regulatory approval, we cannot predict when, or if ever, we will be able to realize revenues related to our products. As a result, we will be primarily dependent on our ability to raise capital through the sale of our securities for the foreseeable future.

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

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

***Our stem cell therapy programs rely on an experimental surgical device and procedure and highly invasive surgical operations.***

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

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

Given the uncertainty of our technologies and the need for government regulatory approval, we cannot predict when, or if ever, we will be able to realize revenues related to our products. Our proposed products are not likely to be commercially available for at least several or more years, if ever. Accordingly, we do not foresee generating any significant revenue during such time. As a result, we will be primarily dependent on our ability to raise capital through the sale of our securities to fund our operations for the foreseeable future.

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

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

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

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

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

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

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

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

***The results of pre-clinical studies and clinical trials may not be predictive of the results of our later-stage clinical trials and our proposed products may not have favorable results in later-stage clinical trials nor receive regulatory approval.***

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

would materially impair our ability to generate revenues.

*Our research and development expenses are subject to uncertainty.*

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

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

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

***We are subject to numerous risks inherent in conducting clinical trials using third parties.***

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

regulation or legislation may have on our business. If additional regulations are overly onerous or expensive or if healthcare related legislation makes our business more expensive or burdensome than originally anticipated, we may be forced to significantly downsize our business plans or completely abandon the current business model.

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

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

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

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

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

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

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

We have entered into employment agreements with Mr. Garr and Dr. Johe which expire on October 31, 2017. In the event either individual is terminated prior to the full term of their respective contracts, for any reason other than a voluntary resignation, all compensation due to such employee under the terms of the respective agreement shall become due and payable immediately. These provisions will make the replacement of either of these employees very costly and could cause difficulty in effecting a change in control. Termination prior to the full term of these contracts would cost us as much as \$1.0 million for Mr. Garr and \$1.7 million for Dr. Johe and result in the immediate vesting of all outstanding options and/or warrants held by Mr. Garr and Dr. Johe.

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

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

As a result, our proposed products could become obsolete before we recoup any portion of our related research and development and commercialization expenses. Competition in the biopharmaceutical industry is based significantly on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval

for testing, manufacturing and marketing. We compete with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions and governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to us.

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

***Our outsource model is highly dependent on the use of third parties to assist in the development and testing of our proposed products.***

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

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

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

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

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

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

## **Risks Relating to Intellectual Property**

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

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

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

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

## **Risks Relating to Our Common Stock**

*The market price for our common shares is particularly volatile.*

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

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

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

As a public company, we incur significant legal, accounting and other expenses that we would not incur as a private company, including costs associated with public company reporting requirements. We also incur costs associated with the Sarbanes-Oxley Act of 2002, as amended, the Dodd-Frank Wall Street Reform and Consumer Protection Act and related rules implemented or to be implemented by the SEC and the NASDAQ Stock Market. 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.

***Breakdowns in our internal controls or our disclosure controls and procedures may have an adverse effect on our business.***

We maintain a system of internal controls over financial reporting that is reviewed and monitored by our management and overseen by our audit committee. We also maintain disclosures controls and procedures, which are controls and procedures that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934 are recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management to allow timely decisions regarding required disclosure. For the quarter ended June 30, 2015, our management concluded that our disclosure controls and procedures were not effective. We have taken remedial measures to correct the deficiencies that led to the conclusion that our disclosure controls and procedures were not effective. We cannot, however, be certain that these measures will ensure that our controls are adequate in the future or that the controls will be effective in preventing fraud or material misstatement. If we fail to maintain an effective system of internal control over financial reporting or disclosure controls and procedures, we may not be able to accurately report our financial results and fraud may be easier to perpetrate on us, both of which would have an adverse effect on our business.

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

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

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

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

our board of directors is divided into three classes, with each class serving for a staggered three-year term, which prevents stockholders from electing an entirely new board of directors at an annual meeting;



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

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

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

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

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

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

We are entitled under our certificate of incorporation to issue up to 300,000,000 shares of common stock and 7,000,000 "blank check" shares of preferred stock. Shares of our blank check preferred stock provide our board of directors with broad authority to determine voting, dividend, conversion, and other rights. As of September 30, 2015 we have issued and outstanding 91,786,290 shares of common stock and we have 40,311,339 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 September 30, 2015, we had no shares of preferred stock issued and outstanding. Accordingly, we are entitled to issue up to 167,902,371 additional shares of

common stock and 7,000,000 additional shares of “blank check” preferred stock. Our board may generally issue those common and preferred shares, or convertible securities to purchase those shares, without further approval by our shareholders. Any preferred shares we may issue will have such rights, preferences, privileges and restrictions as may be designated from time-to-time by our board, including preferential dividend rights, voting rights, conversion rights, redemption rights and liquidation provisions. It is likely that we will be required to issue a large amount of additional securities to raise capital in order to further our development and marketing plans. It is also likely that we will be required to issue a large amount of additional securities to directors, officers, employees and consultants as compensatory grants in connection with their services, both in the form of stand-alone grants or under our various stock plans. The issuance of additional securities may cause substantial dilution to our shareholders.

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

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

The time required to obtain approval by the FDA and comparable foreign authorities is inherently unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate’s clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

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

the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;

we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;

the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;

we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA, NDA or other submission or to obtain regulatory approval in the United States or elsewhere;

the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; or

the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

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

Noncompliance with applicable regulatory requirements can subject us, our third party suppliers and manufacturers and our other collaborators to administrative and judicial sanctions, such as, among other things, warning letters, fines and other monetary payments, recall or seizure of products, criminal proceedings, suspension or withdrawal of regulatory approvals, interruption or cessation of clinical trials, total or partial suspension of production or distribution, injunctions, limitations on or the elimination of claims we can make for our products, refusal of the government to enter into supply contracts or fund research, or government delay in approving or refusal to approve new drug applications.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to

obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval would impair our ability to develop foreign markets for our drug candidates.

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

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

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

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

The following information is given with regard to unregistered securities sold during the nine months ended September 30, 2015. The unregistered securities were issued pursuant to section 4(2) of the Securities Act:

In February of 2015, we issued a total of 19,206 shares of common stock upon the cashless exercise of 44,000 outstanding common stock purchase warrants. The warrants had an average exercise price of \$2.13.

In July 2015, we issued one of our legal advisors a common stock purchase warrant to purchase 150,000 shares of our common stock at an exercise price of \$1.87 per share in exchange for certain legal work. The warrant vests monthly over one year from the grant date, has a term of 5 years and will expire on June 30, 2020. Any vested portion of the warrant can be exercised after 6 months from the issuance date on a cashless basis at any time that the shares underlying the warrant are not subject to a registration statement. The warrant provides for an adjustment to the purchase price and number of shares underlying the warrant upon stock dividends and splits. The warrant does not contain any price protection provisions with regard to subsequent financings.

## **ITEM 3. DEFAULT UPON SENIOR SECURITIES**

**None**

## **ITEM 4. MINE SAFETY DISCLOSURE**

**Not Applicable**

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

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

**SIGNATURES**

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

**NEURALSTEM, INC.**

Date: November 9, 2015 /s/ I. Richard Garr  
Chief Executive Officer

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

## INDEX TO EXHIBITS

| Exhibit No. | Description                                                                                  | Incorporated by Reference       |        |                |            |             |
|-------------|----------------------------------------------------------------------------------------------|---------------------------------|--------|----------------|------------|-------------|
|             |                                                                                              | Filed/<br>Furnished<br>Herewith | Form   | Exhibit<br>No. | File No.   | Filing Date |
| 3.01(i)     | Amended and Restated Certificate of Incorporation of Neuralstem, Inc. filed on 7/9/14        |                                 | 10-Q   | 3.01(i)        | 001-33672  | 8/8/14      |
| 3.02(ii)    | Amended and Restated Bylaws of Neuralstem, Inc. adopted on 7/16/07                           |                                 | 10-QSB | 3.2(i)         | 333-132923 | 8/14/07     |
| 4.01**      | Amended and Restated 2005 Stock Plan adopted on 6/28/07                                      |                                 | 10-QSB | 4.2(i)         | 333-132923 | 8/14/07     |
| 4.02**      | Non-qualified Stock Option Agreement between Neuralstem, Inc. and Richard Garr dated 7/28/05 |                                 | SB-2   | 4.4            | 333-132923 | 6/21/06     |
| 4.03**      | Non-qualified Stock Option Agreement between Neuralstem, Inc. and Karl Johe dated 7/28/05    |                                 | SB-2   | 4.5            | 333-132923 | 6/21/06     |
| 4.04**      | Neuralstem, Inc. 2007 Stock Plan                                                             |                                 | 10-QSB | 4.21           | 333-132923 | 8/14/07     |
| 4.05        | Form of Common Stock Purchase Warrant Issued to Karl Johe on 6/5/07                          |                                 | 10-KSB | 4.22           | 333-132923 | 3/27/08     |
| 4.06        | Form of Placement Agent Warrant Issued to Midtown Partners & Company on 12/18/08             |                                 | 8-K    | 4.1            | 001-33672  | 12/18/08    |
| 4.07        | Form of Consultant Common Stock Purchase Warrant issued on 1/5/09                            |                                 | S-3/A  | 10.1           | 333-157079 | 02/3/09     |
| 4.08        | Form of Series D, E and F Warrants                                                           |                                 | 8-K    | 4.01           | 001-33672  | 7/1/09      |

|        |                                                                                                                                 |         |            |            |         |
|--------|---------------------------------------------------------------------------------------------------------------------------------|---------|------------|------------|---------|
| 4.09   | Form of Placement Agent Warrant                                                                                                 | 8-K     | 4.02       | 001-33672  | 7/1/09  |
| 4.10   | Form of Consultant Warrant Issued 1/8/10                                                                                        | 10-K    | 4.20       | 001-33672  | 3/31/10 |
| 4.11   | Form of Replacement Warrant Issued 1/29/10                                                                                      | 10-K    | 4.21       | 001-33672  | 3/31/10 |
| 4.12   | Form of Series C Replacement Warrant Issued March of 2010 and May, June and July of 2013 (Original Ex. Price \$2.13 and \$1.25) | 10-K    | 4.22       | 001-33672  | 3/31/10 |
| 4.13   | Form of employee and consultant option grant pursuant to our 2007 Stock Plan and 2010 Equity Compensation Plan                  | 10-K    | 4.23       | 001-33672  | 3/31/10 |
| 4.14   | Form of Warrants dated 6/29/10                                                                                                  | 8-K     | 4.01       | 001-33672  | 6/29/10 |
| 4.15** | Amended Neuralstem 2010 Equity Compensation Plan adopted on June 21, 2013                                                       | DEF 14A | Appendix I | 001-33672  | 4/30/13 |
| 4.16   | Form of Consultant Warrant issued 10/1/09 and 10/1/10                                                                           | S-3     | 4.07       | 333-169847 | 10/8/10 |
| 4.17** | Form of Restricted Stock Award Agreement pursuant to our 2007 Stock Plan and 2010 Equity Compensation Plan                      | S-8     | 4.06       | 333-172563 | 3/1/11  |
| 4.18** | Form of Restricted Stock Unit Agreement                                                                                         | S-8     | 4.08       | 333-172563 | 3/1/11  |
| 4.19   | Form of Common Stock Purchase Warrant issued pursuant to February 2012 registered offering                                      | 8-K     | 4.01       | 001-33672  | 2/8/12  |
| 4.20   | Form of Common Stock Purchase Warrant issued to Consultants in June of 2012 and March 19, 2013                                  | 10-Q    | 4.20       | 001-33672  | 8/9/12  |
| 4.21   | Form of Underwriter Warrant issued to Aegis Capital Corp. on 8/20/12                                                            | 8-K     | 4.1        | 001-33672  | 8/17/12 |
| 4.22   | Form of Placement Agent Warrant issued to Aegis Capital Corp. on 9/13/12                                                        | 8-K     | 4.1        | 001-33672  | 9/19/12 |

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

|         |                                                                                                                 |        |       |            |          |
|---------|-----------------------------------------------------------------------------------------------------------------|--------|-------|------------|----------|
| 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<br>(Original Ex. Prices \$3.17 and \$2.14) |        |       |            |          |
| 4.24    | Form of Lender Warrant issued March 22, 2013                                                                    | 8-K    | 4.01  | 011-33672  | 3/27/13  |
| 4.25    | Form of Advisor Warrant issued March 22, 2013                                                                   | 8-K    | 4.02  | 011-33672  | 3/27/13  |
| 4.26    | Form of Warrant issued June of 2013 and July of 2014 to Legal Counsel                                           | 10-Q   | 4.26  | 001-33672  | 8/8/13   |
| 4.27    | Form of Warrant issued in September 2013 in connection with Issuer's<br>registered direct offering              | 8-K    | 4.01  | 011-33672  | 9/10/13  |
| 4.28    | Form of Warrant issued to strategic advisor in August 2013                                                      | 10-Q   | 4.28  | 001-33672  | 11/12/13 |
| 4.29    | Form of Investor Warrant issued January 2014                                                                    | 8-K    | 4.01  | 001-33672  | 1/6/14   |
| 4.30    | Form of Lender Warrant Issued October 28, 2014                                                                  | 8-K    | 4.01  | 001-33672  | 10/29/14 |
| 10.01** | Employment Agreement with I. Richard Garr dated January 1, 2007<br>and amended as of November 1, 2005           | SB-2   | 10.1  | 333-132923 | 6/21/06  |
| 10.02** | Amended terms to the Employment Agreement of I Richard Garr<br>dated January 1, 2008                            | 10-K   | 10.02 | 001-33672  | 3/31/09  |
| 10.03** | Amended terms to the employment Agreement of I. Richard Garr<br>dated March 1, 2015                             | 8-K    | 10.01 | 001-33672  | 3/2/15   |
| 10.04** | Employment Agreement with Karl Johe dated January 1, 2007 and<br>amended as of November 1, 2005                 | SB-2   | 10.2  | 333-132923 | 6/21/06  |
| 10.05** | Amended terms to the Employment Agreement of Karl Johe dated<br>January 1, 2009                                 | 10-K   | 10.04 | 001-33672  | 3/31/09  |
| 10.06** | Employment Agreement with Thomas Hazel, Ph.D dated August<br>11, 2008                                           | 10-K/A | 10.05 | 001-33672  | 10/5/10  |

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

|         |                                                                                                                                            |      |       |           |          |
|---------|--------------------------------------------------------------------------------------------------------------------------------------------|------|-------|-----------|----------|
| 10.07   | Consulting Agreement dated January 2010 between Market Development Consulting Group and the Company and amendments No. 1 and 2.            | 10-K | 10.07 | 001-33672 | 3/16/11  |
| 10.08** | Renewal of I. Richard Garr Employment Agreement dated 7/25/12                                                                              | 8-K  | 10.01 | 001-33672 | 7/27/12  |
| 10.09** | Renewal of Dr. Karl Johe Employment Agreement dated 7/25/12                                                                                | 8-K  | 10.02 | 001-33672 | 7/27/12  |
| 10.10** | Renewal of Dr. Tom Hazel Employment Agreement dated 7/25/12                                                                                | 8-K  | 10.03 | 001-33672 | 7/27/12  |
| 10.11   | Loan and Security Agreement dated March 2013                                                                                               | 8-K  | 10.01 | 011-33672 | 3/27/13  |
| 10.12   | Intellectual Property and Security Agreement dated March 2013                                                                              | 8-K  | 10.02 | 011-33672 | 3/27/13  |
| 10.13   | At the Market Offering Agreement entered into on October 25, 2013                                                                          | 8-K  | 10.01 | 011-33672 | 10/25/13 |
| 10.14   | Form of Outside Director Agreement                                                                                                         | 10-K | 10.13 | 011-33672 | 3/10/14  |
| 10.15** | Form of Amendment to Karl Johe Employment Agreement                                                                                        | 8-K  | 10.01 | 011-33672 | 9/18/14  |
| 10.16   | Form of Second Amendment to Loan and Security Agreement dated March of 2013 that was entered into on October 28, 2014                      | 8-K  | 10.01 | 011-33672 | 10/29/14 |
| 10.17** | Offer Letter Between Neuralstem, Inc. and Jonathan Lloyd Jones                                                                             | 8-K  | 10.01 | 001-33672 | 5/11/15  |
| 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*