

Neuralstem, Inc.  
Form 10-Q  
November 09, 2012

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

**Washington, D.C. 20549**

**FORM 10-Q**

**(Mark one)**

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

**For the Quarterly Period Ended September 30, 2012**

**Or**

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

**Commission File Number 000-1357459**

**NEURALSTEM, INC.**

(Exact name of registrant as specified in its charter)

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

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

**9700 Great Seneca Highway**

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**Rockville, MD** **20850**  
(Address of principal executive offices) (Zip Code)

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

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

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

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

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

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

As of October 31, 2012, there were 67,989,314 shares of common stock, \$.01 par value, issued and outstanding.

**Neuralstem, Inc.**

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**PART I****FINANCIAL INFORMATION****ITEM 1. UNAUDITED CONDENSED FINANCIAL STATEMENTS****Unaudited Condensed Balance Sheets**

	September 30, 2012	December 31, 2011
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$9,873,395	\$2,352,013
Prepaid expenses	289,788	430,356
Billed and unbilled receivables	833	234,375
Total current assets	10,164,016	3,016,744
Property and equipment, net	246,017	292,193
Patent filing fees, net	772,186	701,846
Other assets	59,533	75,394
Total assets	\$11,241,752	\$4,086,177
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable and accrued expenses	\$1,501,345	\$1,843,684
Accrued bonus expense	479,368	582,675
Other current liabilities	138,987	-
Total current liabilities	2,119,700	2,426,359
Deferred rent, net of current portion	23,750	-
Total liabilities	2,143,450	2,426,359
Commitments and contingencies (Note 5)		
<b>STOCKHOLDERS' EQUITY</b>		

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Preferred stock, 7,000,000 shares authorized, zero shares issued and outstanding	-	-
Common stock, \$0.01 par value; 150 million shares authorized, 67,964,314 and 48,682,118 shares outstanding in 2012 and 2011, respectively	679,643	486,821
Additional paid-in capital	114,297,870	99,645,655
Accumulated deficit	(105,879,211)	(98,472,658 )
Total stockholders' equity	9,098,302	1,659,818
Total liabilities and stockholders' equity	\$11,241,752	\$4,086,177

See accompanying notes to unaudited condensed financial statements.

**Neuralstem, Inc.****Unaudited Condensed Statements of Operations**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Revenues	\$ 170,833	\$ 103,417	\$ 405,208	\$ 103,417
Operating expenses:				
Research and development costs	1,385,478	2,124,204	4,406,538	5,948,603
General and administrative expenses	1,280,606	1,137,995	3,264,146	4,433,703
Depreciation and amortization	87,908	64,285	164,154	149,548
Total operating expenses	2,753,992	3,326,484	7,834,838	10,531,854
Operating loss	(2,583,159 )	(3,223,067 )	(7,429,630 )	(10,428,437 )
Other income (expense):				
Litigation settlement	692	-	3,265	250,000
Interest income	5,411	11,463	21,601	54,497
Interest expense	(335 )	-	(1,789 )	-
Gain from change in fair value of warrant obligations	-	-	-	161,809
Total other income (expense)	5,768	11,463	23,077	466,306
Net loss	\$ (2,577,391 )	\$ (3,211,604 )	\$ (7,406,553 )	\$ (9,962,131 )
Net loss per share - basic and diluted	\$ (0.04 )	\$ (0.07 )	\$ (0.14 )	\$ (0.21 )
Weighted average common shares outstanding - basic and diluted	58,363,721	48,488,432	54,751,377	48,225,452

See accompanying notes to unaudited condensed financial statements.

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

	Nine Months Ended September 30,	
	2012	2011
Cash flows from operating activities:		
Net loss	\$ (7,406,553	) \$ (9,962,131
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	164,154	149,548
Share based compensation expenses	1,187,692	2,874,698
Gain from change in fair value of warrant obligations	-	(161,809
		)
Changes in operating assets and liabilities:		
Prepaid expenses	117,838	(106,422
Billed and unbilled receivables	233,542	-
Other current assets	-	322,127
Other assets	15,861	(7,778
Accounts payable and accrued expenses	(342,339	) 438,598
Accrued bonus expense	37,812	86,308
Deferred revenue	-	52,833
Deferred rent	32,557	-
Net cash used in operating activities	(5,959,436	) (6,314,028
		)
Cash flows from investing activities:		
Patent filing fees	(158,115	) (232,968
Purchase of property and equipment	(30,203	) (187,092
Net cash used in investing activities	(188,318	) (420,060
		)
Cash flows from financing activities:		
Proceeds from issuance of common stock from warrants exercised	-	1,668,326
Proceeds from sale of common stock and warrants, net of issuance costs	13,685,408	-
Payments on notes payable	(16,272	) -
Net cash provided by financing activities	13,669,136	1,668,326
Net increase (decrease) in cash and cash equivalents	7,521,382	(5,065,762
		)
Cash and cash equivalents, beginning of period	2,352,013	9,261,233
Cash and cash equivalents, end of period	\$ 9,873,395	\$ 4,195,471
Supplemental disclosure of cash flows information:		
Cash paid for interest	\$ 1,789	\$ -



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Supplemental schedule of non cash investing and financing activities:

Extinguishment of warrant obligations through exercise, expiration and modification	\$ -	\$ 1,089,030
Prepayment of services through common stock issuance	\$ 180,000	\$ 565,050
Issuance of common stock for executive bonuses	\$ 141,119	\$ 77,500
Issuance of common stock for exercise of restricted stock units	\$ 330	\$ -
Financing of insurance premiums through note payable	\$ 146,452	\$ -
Service provider return of shares upon contract amendment	\$ 27,712	\$ -

See accompanying notes to unaudited condensed financial statements.

**NEURALSTEM, INC.**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**

**SEPTEMBER 30, 2012 AND 2011**

**Note 1. Basis of Presentation and Liquidity**

In management's opinion, the accompanying condensed financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations and cash flows. The condensed balance sheet at December 31, 2011, has been derived from audited financial statements as of that date. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in the financial statements prepared in accordance with generally accepted accounting principles in the United States of America (U.S. GAAP) have been condensed or omitted pursuant to instructions, rules and regulations prescribed by the U.S. Securities and Exchange Commission (SEC). We believe that the disclosures provided herein are adequate to make the information presented not misleading when these condensed financial statements are read in conjunction with the Financial Statements and Notes included in our Annual Report on Form 10-K for the year ended December 31, 2011, filed with the SEC on March 30, 2012, and as may be amended.

Neuralstem, Inc. is referred to as "Neuralstem," the "Company," "us," or "we" throughout this report. Our investment in, and the operations of, a recently established wholly-owned and controlled subsidiary located in China were not material in any period presented.

The Company's operations currently do not generate significant cash. The Company's management does not know when this will change. The Company has spent and will continue to spend substantial funds in the research, development, clinical and pre-clinical testing of the Company's stem cell and small molecule product candidates with the goal of ultimately obtaining approval from the United States Food and Drug Administration (the "FDA"), to market and sell our products. While we believe our long-term cash position is inadequate to fund all of the costs associated with the full range of testing and clinical trials required by the FDA for our core product candidates, we anticipate that our available cash and expected income will be sufficient to finance our current activities at least through September 30, 2013, although certain activities and related personnel may need to be reduced.

No assurance can be given that (i) we will be able to expand our operations prior to FDA approval of our products, or (ii) that FDA approval will ever be granted for our product candidates.

**Note 2. Significant Accounting Policies and Recent Accounting Pronouncements**

### Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The condensed financial statements include significant estimates for the expected economic life and value of our licensed technology, our net operating loss 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.

### Financial Instruments

The carrying amounts of financial instruments including cash equivalents, receivables and accounts payable reflect approximate fair value as of September 30, 2012 and December 31, 2011, because of the relatively short-term maturity of these instruments.

### Cash, Cash Equivalents and Credit Risk

Cash equivalents consist of investments in low risk, highly liquid securities with original maturities of 90 days or less. We place most of our cash in United States banks and we invest some of our cash in interest bearing instruments issued by United States banks. Deposits with banks may exceed the amount of insurance provided on such deposits. If the amount of a deposit at any time exceeds the federally insured amount at a bank, the uninsured portion of the deposit could be lost, in whole or in part, if the bank were to fail. While we monitor the cash balances in our operating accounts and adjust the cash balances as appropriate, these cash balances could be impacted if the underlying financial institutions fail or could be subject to other adverse conditions in the financial markets. Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash equivalents. Cash equivalents currently consist solely of money market funds and certificates of deposit. Our investment policy, approved by our Board of Directors, limits the amount we may invest in any one type of investment issuer, thereby reducing credit risk concentrations. We limit our credit and liquidity risks through our investment policy and through regular reviews of our portfolio against our policy. To date, we have not experienced any loss or lack of access to cash in our operating accounts or to our cash equivalents and marketable securities in our investment portfolios.

### Revenue Recognition

Historically, our revenue has been derived primarily from (i) selling treated samples for gene expression data from stem cell experiments, (ii) providing services under various contracts and grants and (iii) licensing the use of our intellectual property to third parties. Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery of goods and services has occurred, the price is fixed and determinable, and collection is reasonably assured. In 2012, we recognized revenue of from our services as principal subcontractor pursuant to a Department of Defense contract with Loma Linda University and from licensing the use of certain intellectual property. We recognized revenue of \$234,000 related to the Department of Defense contract, using a proportional performance method over the period of performance of the contract; this contract expired pursuant to its terms in the second quarter of 2012. We also recognized revenue of \$170,000 related to up-front payments for the licensing of certain intellectual property to third parties, since our performance obligations contained in the licenses are substantially complete.

### Research and Development

Research and development costs are expensed as they are incurred. Research and development expenses consist primarily of costs associated exclusively for the development of treatments for central nervous system diseases, and the Company's clinical trials for both pharmaceutical and stem cell based treatments. These expenses represent both pre-clinical development costs and costs associated with non-clinical support activities such as quality control and regulatory processes as well as the cost of our stem cell and pharmaceutical clinical trials.

### Income (Loss) per Common Share

Basic income (loss) per common share is computed by dividing consolidated net income (loss) available to common shareholders by the weighted average number of common shares outstanding during the period. The Company's 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 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 share units and stock warrants. The dilutive impact of potential common shares resulting from common stock equivalents is determined by applying the treasury stock method.

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, 2012 and 2011. A total of approximately 35.2 million and 24.5 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, 2012 and 2011, respectively, as their

inclusion would be anti-dilutive.

### Share-Based Compensation

We account for share-based compensation at fair value; accordingly we expense the estimated fair value of share-based awards over the requisite service period. Share-based compensation cost for stock options and warrants is determined at the grant date using an option pricing model; share-based compensation cost for restricted stock and restricted stock units is determined at the grant date based on the closing price of our common stock on that date. The value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period.

### Intangible and Long-Lived Assets

We assess impairment of our long-lived assets using a "*primary asset*" approach to determine the cash flow estimation period for a group of assets and liabilities that represents the unit of accounting for a long-lived asset to be held and used. Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The carrying amount of a long-lived asset is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset. Long-lived assets to be disposed of are reported at the lower of carrying amount or fair value less cost to sell. During the three- and nine-month periods ended September 30, 2012 and 2011, no impairment losses were recognized.

### Income Taxes

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

### Significant New Accounting Pronouncements

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

**Note 3. Fair Value of Common Stock Purchase Warrants**

The Company previously had outstanding common stock purchase warrants which were classified as derivative liabilities and measured at fair value. All of these warrants were either exercised or expired during the nine months ended September 30, 2011. The following table presents the activity for those items which were measured at fair value on a recurring basis using significant unobservable inputs (Level 3):

	Nine Months Ended September 30,	
	2012	2011
Fair value of warrant obligations at beginning of period	\$ -	\$ 1,250,839
Extinguishment through warrant exercises and modifications	-	(1,089,030 )
Extinguishment through warrant expirations	-	-
Net gain for change in fair value included in the statement of operations for period	-	(161,809 )
Fair value of warrant obligations at end of period	\$ -	\$ -

The fair value of the warrant obligations was determined using the Black Scholes option pricing model with inputs which are described in Note 4.

**Note 4. Stockholders' Equity**

We have granted stock-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 or warrants vest either upon the grant date or over varying periods of time. The stock options we grant provide for option exercise prices equal to or greater than the fair market value of the common stock at the date of the grant. Restricted stock units grant the holder the right to receive fully paid common shares with various restrictions on the holder's ability to transfer the shares. Vesting of the restricted stock units is similar to that of stock options. As of September 30, 2012, we have approximately 38.8 million shares of common stock reserved for issuance of such awards.

We record share-based compensation expense on a straight-line basis over the requisite service period and recognized approximately \$1,188,000 and \$2,875,000 in total share-based compensation expense during the nine months ended September 30, 2012 and 2011, respectively. Included in general and administrative expenses for each of the nine months ended September 30, 2012 and 2011, is approximately \$180,000 related to consulting expenses where we paid the consultant in shares of common stock. Additionally, included in the expense for the nine months ended September

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30, 2012, is approximately \$141,000 related to research and development expenses that we paid for with shares of common stock.

Share-based compensation expense included in the statements of operations for the three and nine months ended September 30, 2012 and 2011 was as follows:

	Three Months Ended September 30,	
	2012	2011
Research and development costs	\$ 193,558	\$ 392,380
General and administrative expenses	293,142	275,244
Total	\$ 486,700	\$ 667,624

	Nine Months Ended September 30,	
	2012	2011
Research and development costs	\$ 462,380	\$ 1,499,140
General and administrative expenses	725,312	1,375,558
Total	\$ 1,187,692	\$ 2,874,698

Stock Options. A summary of stock option activity during the nine months ended September 30, 2012 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, 2012	9,993,195	\$ 2.46	5.5	\$ 1,128,000
Granted	4,847,504	\$ 0.99		
Exercised	-	\$ -		\$ -
Forfeited	(53,412)	) \$ 2.51		
Outstanding at September 30, 2012	14,787,287	\$ 1.98	6.3	\$ 3,097,639
Exercisable at September 30, 2012	10,253,193	\$ 2.39	4.9	\$ 1,902,556
Vested and expected to vest	14,773,802	\$ 1.98	6.3	\$ 3,097,500

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	5,400,000	\$ 0.73	6.7	\$ 2,790,000
\$1.01 - \$2.00	2,680,420	\$ 1.23	8.3	\$ 307,639
\$2.01 - \$3.00	1,903,534	\$ 2.47	6.0	\$ -
\$3.01 - \$4.00	4,803,333	\$ 3.59	5.0	\$ -
	14,787,287	\$ 1.98	6.3	\$ 3,097,639

The Company uses the Black-Scholes option pricing model to calculate the fair value of options. Significant assumptions used in this model include:

	Nine Months Ended September 30,	
	2012	2011
Annual dividend	-	-
Expected life (in years)	2.0 - 4.0	2.0 - 6.5
Risk free interest rate	0.29% - 0.65%	0.25% - 4.76%
Expected volatility	55.5% - 70.6%	59.9% - 75.4%



The 4,847,504 options granted in the first nine months of 2012 had a weighted average grant date fair value of \$0.49.

RSUs. We have granted restricted stock units (RSUs) to certain employees that entitle the holders to receive shares of our common stock upon vesting of the RSUs, and subject to certain restrictions regarding the exercise of the RSUs. The fair value of restricted stock units 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, 2012 is as follows:

	Number of RSU's	Weighted- Average Grant Date Fair Value
Outstanding at January 1, 2012	341,171	\$ 2.18
Granted	30,320	\$ 1.19
Vested and converted to common shares	-	\$ -
Forfeited	-	\$ -
Outstanding at September 30, 2012	371,491	\$ 2.10
Exercisable at September 30, 2012	228,987	\$ 2.15

Stock Purchase Warrants. Warrants to purchase common stock were issued to certain officers, directors, stockholders and service providers. A summary of warrant activity for the nine months ended September 30, 2012 follows:

	Number of Warrants	Weighted- Average Exercised Price	Weighted- Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2012	14,152,355	\$ 2.61	3.4	\$-
Granted	6,687,821	\$ 1.02	5.1	
Exercised	-	\$ -		\$-
Forfeited	(800,000 )	\$ 1.25		
Outstanding at September 30, 2012	20,040,176	\$ 2.07	3.8	\$1,905,381
Exercisable at September 30, 2012	20,040,176	\$ 2.07	3.8	\$1,905,381

The 6,687,821 stock purchase warrants granted in the first nine months of 2012 had a weighted average grant date fair value of \$0.47.

Prior to 2012, certain of our stock purchase warrants were classified as derivative liabilities due to non-standard anti-dilutions provisions contained in the warrant agreements. On February 23, 2011, all remaining common stock purchase warrants which had an exercise price reset and an anti-liquidation feature were exercised or expired, eliminating the derivative liability. In the nine months ended September 30, 2011, approximately 1.4 million common stock purchase warrants were exercised or forfeited; the expiration of these common stock purchase warrants resulted in a net gain from the change in fair value of \$161,809 for the nine months ended September 30, 2011.

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In February 2012, the Company completed a registered direct placement of 5,200,000 shares of common stock at a price of \$1.00 per share, and 5,200,000 warrants, each with an exercise price of \$1.02 per share and exercisable starting six months from the issuance date for a term of five years. The Company received aggregate gross proceeds of \$5,200,000, which will be used for general corporate purposes, including ongoing U.S. clinical trials. Net proceeds were approximately \$4,877,000. The warrants are classified within equity.

In March 2012, pursuant to the terms of the consulting agreement entered into with Market Development Consulting Group, Inc. in January of 2010 and amended May 14, 2010 and February 7, 2011, we issued: (i) 180,000 common shares; and (ii) a common stock purchase warrant entitling the holder to purchase 510,821 shares of common stock at \$0.99 per share as compensation for business advisory services. The warrant was exercisable immediately, expires on January 6, 2022, and is freely assignable in whole or in part. We also agreed to register the shares underlying the warrant with the SEC for resale. The warrants are classified within equity.

In August 2012, the Company completed an underwritten public offering of 6,900,000 shares of common stock at a price of \$0.40 per share. The Company received aggregate gross proceeds of \$2,760,000, which will be used for general corporate purposes, including ongoing clinical trials. Net proceeds were approximately \$2,441,000. In connection with the offering, the Company issued stock purchase warrants to the underwriters for the purchase of up to 300,000 shares of its common stock; the warrants have an exercise price of \$0.50 per share and are exercisable for five years. The warrants are classified within equity.

In September 2012, the Company completed a registered direct placement of 7,000,000 shares of common stock at a price of \$1.00 per share. The Company received aggregate gross proceeds of \$7,000,000, which will be used for general corporate purposes, including ongoing clinical trials. Net proceeds were approximately \$6,368,000. In connection with the offering, the Company issued stock purchase warrants to the placement agent for the purchase of up to 350,000 shares of its common stock; the warrants have an exercise price of \$1.25 per share and are exercisable for five years. The warrants are classified within equity.

## Note 5. Commitments and Contingencies

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

On May 7, 2008, we filed suit against StemCells, Inc., StemCells California, Inc. (collectively "StemCells") and Neurospheres Holding Ltd., (collectively StemCells and Neurospheres Holding Ltd are referred to as "Plaintiffs") in U.S. District Court for the District of Maryland, alleging that U.S. Patent No. 7,361,505 (the "'505 patent"), alleging that the '505 patent was exclusively licensed to the Plaintiffs, is invalid, not infringed, and unenforceable. See Civil Action No. 08-1173. On May 13, we filed an Amended Complaint seeking declaratory judgment that U.S. Patent No. 7,155,418 (the "'418 patent") is invalid and not infringed and that certain statements made by our CEO are not trade libel or do not constitute unfair competition as alleged by the Plaintiffs. On July 15, 2008, the Plaintiffs filed a Motion to Dismiss for Lack of Subject Matter Jurisdiction, Lack of Personal Jurisdiction, and Improper Venue or in the Alternative to Transfer to the Northern District of California. On August 27, 2008, Judge Alexander Williams, Jr. of the District of Maryland denied StemCells' Motion to Dismiss, but granted Neurospheres' motion to dismiss. On September 11, 2008, StemCells filed its answer asserting counterclaims of infringement for the '505 patent, the 418 patent, and state law claims for trade libel and unfair competition. This case was consolidated with the 2006 litigation discussed below and it is not known when, nor on what basis, this matter will be concluded.

On July 28, 2006, StemCells, Inc., filed suit against Neuralstem, Inc. in the U.S. District Court in Maryland, alleging that Neuralstem has been infringing, contributing to the infringement of, and or inducing the infringement of four patents allegedly owned by or exclusively licensed to StemCells relating to stem cell culture compositions, genetically modified stem cell cultures, and methods of using such cultures. See Civil Action No. 06-1877. We answered the Complaint denying infringement, asserting that the patents are invalid, asserting that we have intervening rights based on amendments made to the patents during reexamination proceedings, and further asserting that some of the patents are unenforceable due to inequitable conduct. Neuralstem has also asserted counterclaims that StemCells has engaged in anticompetitive conduct in violation of antitrust laws. On February 28, 2011, Neuralstem filed a Motion to Dismiss for lack of standing and concurrently filed a Motion for Leave to Amend its Answer and Counterclaim to allege that StemCells is not the exclusive licensee of the patents-in-suit and also that Neuralstem has obtained a non-exclusive license to the patents-in-suit. Both motions are fully briefed, apply to the patents at issue in Civil Action Nos. 08-1173 and 08-2664 and remain pending before the Court. The Court further issued its Markman Order on August 12, 2011. On August 26, 2011, StemCells moved for reconsideration of two terms construed in the Markman Order and that motion remains pending. In addition, before the Court decided Neuralstem's Motion to Dismiss for lack of standing, StemCells filed a motion for summary judgment on the issue standing. Neuralstem responded to that motion and cross-moved for summary judgment on the issue of standing. Those motions are fully briefed and remain pending. On December 1, 2011, Neuralstem filed a motion to supplement the record on its cross motion for summary judgment on standing. StemCells opposed Neuralstem's motion to supplement and also cross-moved to supplement the record. On April 6, 2012 the Court granted Neuralstem's Motion for Leave to Amend to assert lack of standing and denied Neuralstem's Motion to Dismiss and Motion for Summary Judgment without prejudice. The Court also denied StemCells' Motion for Summary Judgment with prejudice. The Court has stayed all other matters pending resolution of the question of standing and discovery on that issue is ongoing. It is not known when, nor on what basis, this matter will be concluded.

## Note 6. Subsequent Events

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

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

### FORWARD LOOKING STATEMENTS

*Statements in this quarterly report that are not strictly historical are forward-looking statements and include statements about products in development, results and analyses of clinical trials and studies, research and development expenses, cash expenditures, licensure applications and approvals, and alliances and partnerships, among other matters. You can identify these forward-looking statements because they involve our expectations, intentions, beliefs, plans, projections, anticipations, or other characterizations of future events or circumstances. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that may cause actual results to differ materially from those in the forward-looking statements as a result of any number of factors. These factors include, but are not limited to, risks relating to our ability to conduct and obtain successful results from our two Phase I clinical trials, our ability to commercialize our technology, our ability to obtain regulatory approval for our product candidates, our ability to contract with third parties to adequately manufacture stem cell-based therapeutic product, our ability to protect our intellectual property rights and our ability to obtain additional financing to continue 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, 2011 filed with the SEC on March 30, 2012, and as amended. 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. Also, any reference to "common shares" "common stock," refers to our \$.01 par value common stock. The information contained herein is current as of the date of this Quarterly Report (September 30, 2012), 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, 2012 are not necessarily indicative of our prospective financial condition and results of operations for the pending full fiscal year ending December 31, 2012. The interim financial statements presented in this Quarterly Report as well as other information relating to our company contained in this Quarterly Report should be read in conjunction and together with the reports, statements and information filed by us with the United States Securities and Exchange Commission or SEC.

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

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

*Trends & Outlook* — Discussion of what we view as the overall trends affecting our business and the strategy for 2012.

*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, 2012 to the comparable periods of 2011.

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

## **Executive Overview**

We are focused on the development and commercialization of treatments based on human neuronal stem cells and the development and commercialization of treatments using small molecule compounds. We are headquartered in Rockville, Maryland and have a wholly-owned subsidiary in China.

We have developed and maintain a portfolio of patents and patent applications that form the proprietary base for our research and development efforts in the area of neural stem cell research. We own or exclusively license twenty-seven (27) U.S. or foreign issued patents and forty-four (44) 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, including in the third quarter 2012, we have license the use of our intellectual property to third parties.

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

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

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

## *Clinical Trials*

### *Stem Cells.*

During the first nine months of 2012, we were primarily engaged in conducting the Phase I clinical trials for our proposed treatment of Amyotrophic Lateral Sclerosis (“ALS” or “Lou Gehrig’s disease”) at Emory University in Atlanta Georgia. The purpose of the Phase I clinical trial is to evaluate the safety and transplantation technique of our proposed treatment. The Phase I trial, as designed, was completed in August of 2012. During the Phase I trial, we treated eighteen (18) patients of which twelve (12) were treated by transplantation in the lumbar (lower back) region, three (3) in the cervical (upper back) region and three (3) in both the lumbar and cervical regions under our amended protocol. Although initial data from the Phase I clinical trial for our treatment of ALS appears promising, the outcome of the trial is uncertain and this trial or future trials may ultimately be unsuccessful. We anticipate commencing the Phase II clinical trials, for our proposed treatment of ALS, during the first half of 2013

On August 24, 2010, we filed our second Investigational New Drug Application or IND with the FDA for our proposed Phase I clinical trials to treat chronic spinal cord injury. In October of 2010, we were notified that our IND for spinal cord injury had been placed on clinical hold. At the time, the FDA provided us with specific comments, questions and recommendations for modifications to our trial protocol as contained in our IND application. We expect to revisit this IND with the FDA with a review of the long term human safety data from our ALS trial as well as additional long term animal safety data that was generated for the next phase of the ALS trial. We anticipate the study, if approved and commenced, will be a multi-site study in the United States. It is still too early to predict when or if the trial will be approved to move forward.

In September of 2012, we received approval to commence human clinical trials to treat motor deficits due to ischemic stroke. The trial will be conducted by our wholly owned subsidiary, Neuralstem China, and will utilize our spinal cord stem cells. The trial will be conducted at BaYi Brain Hospital in Veijing, China. The trial approval includes a combined phase I/II design and will test direct injections into the brain of NSI-566, the same cell product tested by Neuralstem in a recently-completed Phase I ALS trial in the United States. The trial is expected to begin early next year. 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. The trial is designed to enroll up to 118 patients.

### *Pharmaceutical Compounds.*

In February of 2011, we commenced Phase I clinical trials (Phase Ia portion) of our drug compound, NSI-189, at California Clinical Trials, LLC, in Glendale, California. NSI-189 is being developed for the treatment of major



depressive disorder and other psychiatric indications. NSI-189 is the lead compound in our neurogenerative small molecule drug platform. The purpose of the Phase Ia portion of the clinical trial was to evaluate the safety of the drug in healthy volunteers. The Phase Ia portion tested a single oral administration of NSI-189 in 24 healthy volunteers and was completed in October of 2011. In December of 2011, we received approval from the FDA to commence the Phase Ib portion of the trial. The purpose of the Phase Ib portion of the clinical trial is to determine the safety of the drug at several dosings in actual Major Depressive Disorder or MDD patients. The Phase Ib portion consists of patients with MDD receiving daily doses for 28 consecutive days. In June of 2012, we dosed our first patient in the Phase Ib portion of the trial. To date, we have dosed a total of eight (8) patients. We anticipate a total of 24 patients will be dosed in the Phase Ib portion. It is still too early in the trial to make any determination as to its level of success, if any.

### ***Technology***

#### *Stem Cells.*

Our technology enables the isolation and large-scale expansion of human neural stem cells from all areas of the developing human brain and spinal cord, thus enabling the generation of physiologically relevant human neurons of all types. We believe that our stem cell technology will assist the body in producing new cells to replace malfunctioning or dead cells as a way to treat disease and injury. Many significant and currently untreatable human diseases arise from the loss or malfunction of specific cell types in the body. Our focus is the development of effective methods to generate replacement cells from neural stem cells. We believe that replacing damaged or malfunctioning or dead neural cells with fully functional ones may be a useful therapeutic strategy in treating many diseases and conditions of the central nervous system or CNS, including: Alzheimer's disease, Parkinson's disease, Multiple Sclerosis, ALS, depression, and injuries to the spinal cord. We own or exclusively license 21 U.S. and foreign issued patents and 19 U.S. and foreign patent applications related to our stem cell technologies.

To date we have focused our research efforts on applications involving spinal cord stem cells. We believe we have established "proof of principle" for two important spinal cord applications: ALS, or Lou Gehrig's disease, and Ischemic Spastic Paraplegia (a painful form of spasticity that may arise as a complication of surgery to repair aortic aneurysms). Of these applications, we have completed our first Phase I trial with regard to ALS. We believe that, if successfully developed, stem cell therapeutics have the potential to provide a broad therapeutic approach comparable to traditional pharmaceuticals and genetically engineered biologics.

We intend to treat both chronic and acute spinal cord injury with the same spinal cord stem cells, utilizing the same injection devices we are using for ALS. Therefore, we add to our knowledge about the surgical route of entry for both the ALS patients and the spinal cord injury patients with each patient we treat in the ALS trial.

*Pharmaceutical Compounds.*

We have developed and patented a series of small molecule compounds (low molecular weight organic compounds which can efficiently cross the blood/brain barrier). We believe that these small molecule compounds will stimulate the growth of new neurons in the hippocampus and provide a treatment for depression, and possibly other cognitive impacting diseases. The claims covered by the patents include both structure and method claims for inducing neurogenesis and the growth of new neurons, both in-vitro and in-vivo. We own or exclusively license four (4) U.S. and foreign issued patents and 22 U.S. and foreign patent applications related to our small molecule compounds.

NSI-189 is the first in a class of compounds that we plan to develop into orally administered drugs for major depressive disorder and other psychiatric disorders which are based on our small molecule technologies. In mice, Company research indicated that NSI-189 both stimulates neurogenesis of the hippocampus and increases its volume. Additionally, Company research indicated that NSI-189 stimulates neurogenesis of human hippocampus-derived neural stem cells in vitro. Based on this research, we believe NSI-189 may reverse the human hippocampal atrophy seen in major depression and other disorders.

Our small molecule platform results from discoveries made through our ability to generate stable human neural stem cell lines suitable for screening large chemical libraries. Our small molecule platform complements our cell therapy platform, in which brain and spinal cord stem cells are transplanted directly into diseased areas to repair and/or replace diseased or dead cells.

***Department of Defense — Loma Linda Subcontract Agreement***

During 2011, we were selected as the primary subcontractor for a U.S. Department of Defense or DOD contract, awarded to Loma Linda University, to develop human neural stem cell technology for the treatment of cancerous brain tumors. The research contract, entitled "Research to Treat Cancerous Brain Tumors with Neural Stem Cells," was carried out in collaboration with Principal Investigator John Zhang, MD, PhD, Professor of Neurosurgery, Loma Linda University, in Loma Linda, CA. The DOD has three one-year options to continue the program after the first year, based upon milestones. The goal of the program is to develop a therapeutic product for the treatment of cancerous brain tumors and submit that product to the FDA by the end of the fourth year (2015). We began work on the project during August of 2011 and completed the first year in June of 2012. Due to uncertainties with the DOD budget, there can be no assurances that this program will continue beyond the initial year completed.

***Research***

We have devoted substantial resources to our research programs in order to isolate and develop a series of neural stem cell banks that we believe can serve as a basis for our therapeutic products. Our efforts to date have been directed at methods to identify, isolate and culture large varieties of stem cells of the human nervous system, and to develop therapies utilizing these stem cells. This research is conducted internally, through the use of third party laboratories and consulting companies under our direct supervision, and through collaboration with academic institutes.

### *Operating Strategy*

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

### *Manufacturing*

We currently manufacture our cells both in-house and on an outsource basis. We outsource the manufacturing of our pharmaceutical compound to third party manufacturers. We manufacture cells in-house which are not required to meet stringent FDA requirements. We use these cells in our research and collaborative programs. We outsource all the manufacturing and storage of our stem cells and pharmaceuticals compound to be used in pre-clinical works, and which are accordingly subject to higher FDA requirements, to Charles River Laboratories, Inc., of Wilmington, Massachusetts (stem cells) and Albany Molecular Resources, Inc. ("AMRI") (small molecule). Both the Charles River and AMRI facilities have the capacity to be used for manufacturing under the FDA determined GMP standards in quantities sufficient for our current and anticipated pre-trial and clinical trial needs. We have no quantity or volume commitment with either Charles River Laboratories or AMRI and our cells and pharmaceutical compounds are ordered and manufactured on an as needed basis.

### *Employees*

As of September 30, 2012, we had 15 full-time employees and one (1) full-time independent contractor. Of these full-time employees and contractor, 11 work on research and development and five (5) in administration. We also use the services of numerous outside consultants in business and scientific matters.

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

We were incorporated in Delaware. Our principal executive offices are located at 9700 Great Seneca Highway, Rockville, Maryland 20850, and our telephone number is (301) 366-4841. Our website is located at [www.neuralstem.com](http://www.neuralstem.com). We have not incorporated by reference into this report the information in, or that can be accessed through, our website, and you should not consider it to be a part of this report.

### **Trends & Outlook**

#### ***Revenue***

For the nine months ended September 30, 2012 and 2011, we generated no revenues from the sale of our proposed therapies based on our stem cell and small molecule technologies. We are mainly focused on: (i) successfully managing our clinical trials, and (ii) preparing for the initiation of clinical trials relating to Chronic Spinal Cord injury. We are also pursuing pre-clinical studies on other central nervous system indications in preparation for additional clinical trials.

In August of 2011, we were selected as the primary subcontractor for a DOD contract awarded to Loma Linda University entitled "Research to Treat Cancerous Brain Tumors with Neural Stem Cells." We received \$625,000 for our effort on this contract through its completion in the second quarter of 2012, and recognized revenue related to this contract of approximately \$234,000 and \$103,000 for the nine months ended September 30, 2012 and September 30, 2011, respectively.

During 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, 2012, we recognized revenue of approximately \$170,000 related to up-front payments received under these licenses, since our performance obligations contained in the licenses are substantially complete. The license agreements also provide for ongoing annual fees which are recognized on a straight-line basis over the annual period.

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

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

For a further description of these clinical trials, see the portion of this report entitled “Clinical Trials.”

We expect that research and development expenses, which include expenses related to our ongoing clinical trials, will increase in the future, as funding allows and we proceed into our anticipated Phase II trials. To the extent that it is practical, we will continue to outsource much of our efforts, including product manufacture, proof of principle and preclinical testing, toxicology, tumorigenicity, dosing rationale, and development of clinical protocol and IND applications. This approach allows us to use the best expertise available for each task and permits staging new research projects to fit available cash resources.

We have formed a wholly owned subsidiary in the People’s Republic of China. We anticipate that this subsidiary will primarily: (i) conduct pre-clinical research with regard to proposed stem cells therapies, and (ii) oversee our anticipated future clinical trials in China, including our proposed trial to treat motor deficits due to ischemic stroke. Through September 30, 2012, we have expensed all costs in connection with establishing this new subsidiary and its operations (which have not been material).

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

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

## Critical Accounting Policies

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

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

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

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

***Revenue Recognition***—Historically, our revenue has been derived primarily from (i) selling treated samples for gene expression data from stem cell experiments, (ii) providing services under various grants and contracts, and (iii) through the licensing of the use of our intellectual property. During the nine months ended September 30, 2012, we recognized revenue from our services as principal subcontractor pursuant to a DOD contract with Loma Linda University and from the licensing of certain of our intellectual property to third parties. Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery of goods and services has occurred, the price is fixed

and determinable, and collection is reasonably assured.

***Intangible and Long-Lived Assets***—We assess impairment of our long-lived assets using a "*primary asset*" approach to determine the cash flow estimation period for a group of assets and liabilities that represents the unit of accounting for a long-lived asset to be held and used. Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The carrying amount of a long-lived asset is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset. Long-lived assets to be disposed of are reported at the lower of carrying amount or fair value less cost to sell. During the nine month periods ended September 30, 2012 and 2011, no impairment losses were recognized.

***Research and Development Expenses*** - Research and development expenses consist of expenditures for the research and development of patents and technology, including the costs of pre-clinical and clinical trials, which are not capitalizable and charged to operations when incurred. Our research and development costs consist mainly of payroll and payroll related expenses, research supplies and costs incurred in connection with specific research grants.

***Share-Based Compensation*** - We account for share-based compensation at fair value; accordingly we expense the estimated fair value of share-based awards over the requisite service period. Share-based compensation cost for stock options and warrants is determined at the grant date using an option pricing model; share-based compensation cost for restricted stock and restricted stock units is determined at the grant date based on the closing price of our common stock on that date. The value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period.

## **RESULTS OF OPERATIONS**

### **Comparison of Three Months Ended September 30, 2012 and 2011**

#### ***Revenue***

We did not generate any revenues from the sale of our products in 2012 or 2011. For the three month periods ended September 30, 2012 and 2011, we recognized revenue of approximately \$0 and \$103,000, respectively for our services as principal subcontractor under the DOD contract; this contract was completed in the second quarter of 2012. Additionally, during the three months ended September 30, 2012 and 2011, we recognized revenue of approximately \$171,000 and \$0, respectively related to the licensing of certain intellectual properties to third parties.





*Operating Expenses*

Operating expenses totaled approximately \$2,754,000 and \$3,326,000 for the three months ended September 30, 2012 and 2011, respectively.

	Three Months Ended September 30,		Increase (Decrease)	
	2012	2011	\$	%
Operating Expenses				
Research and development costs	\$ 1,385,478	\$ 2,124,204	\$ (738,726 )	(35 )%
General and administrative expenses	1,280,606	1,137,995	142,611	13 %
Depreciation and amortization	87,908	64,285	23,623	37 %
Total operating expenses	\$ 2,753,992	\$ 3,326,484	\$ (572,492 )	(17 )%

*Research and Development Expenses*

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

Research and development expenses totaled approximately \$1,385,000 and \$2,124,000 for the three months ended September 30, 2012 and 2011, respectively. The decrease of approximately \$739,000 or 35% was primarily attributable to a \$698,000 decrease in project expenses related to studies which ended in 2011 coupled with a \$199,000 decrease in stock based compensation and partially offset by increases in personnel related expenses.

*General and Administrative Expenses*

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

General and administrative expenses totaled approximately \$1,281,000 and \$1,138,000 for the three months ended September 30, 2012 and 2011, respectively. The increase of approximately \$143,000 or 13% was primarily due to increased use of consulting services.

*Depreciation and Amortization*

Depreciation and amortization expenses totaled approximately \$88,000 and \$64,000 for the three months ended September 30, 2012 and 2011, respectively.

*Other income (expense)*

Other income (expense) totaled \$6,000 and \$11,000 for the three months ended September 30, 2012 and 2011, respectively, and consisted primarily of interest income in both periods.

**Comparison of Nine Months Ended September 30, 2012 and 2011**

*Revenue*

For the nine month periods ended September 30, 2012 and 2011, we recognized revenue of approximately \$234,000 and \$103,000, respectively, for our services as principal subcontractor under the DOD contract; this contract was completed in the second quarter of 2012. During the nine months ended September 30, 2012 and 2011, we recognized revenue of approximately \$171,000 and \$0, respectively related to the licensing of certain of our intellectual properties to third parties.

*Operating Expenses*

Operating expenses totaled approximately \$7,835,000 and \$10,532,000 for the nine months ended September 30, 2012 and 2011, respectively.

	Nine Months Ended September 30,		Increase (Decrease)	
	2012	2011	\$	%
Operating Expenses				
Research and development costs	\$ 4,406,538	\$ 5,948,603	\$ (1,542,065 )	(26 )%
General and administrative expenses	3,264,146	4,433,703	(1,169,557 )	(26 )%
Depreciation and amortization	164,154	149,548	14,606	10 %
Total operating expenses	\$ 7,834,838	\$ 10,531,854	\$ (2,697,016 )	(26 )%

#### *Research and Development Expenses*

Research and development expenses totaled approximately \$4,407,000 and \$5,949,000 for the nine months ended September 30, 2012 and 2011, respectively. The decrease of approximately \$1,542,000 or 26% was primarily attributable to a decrease of approximately \$1,037,000 in stock based compensation coupled with a decrease of approximately \$617,000 in project expenses due to studies that ended in 2011 partially offset by increases in personnel related expenses.

#### *General and Administrative Expenses*

General and administrative expenses totaled approximately \$3,264,000 and \$4,434,000 for the nine months ended September 30, 2012 and 2011, respectively. The decrease of approximately \$1,170,000 or 26% was primarily attributable to decreases of approximately \$650,000 in stock based compensation expense, \$355,000 in legal expenses related to patent litigation, \$137,000 in employee bonuses and \$107,000 in salaries due to the resignation of our CFO in April 2012.

#### *Depreciation and Amortization*

Depreciation and amortization expenses totaled approximately \$164,000 and \$150,000 for the nine months ended September 30, 2012 and 2011, respectively.

#### *Other income (expense)*

Other income (expense) totaled approximately \$23,000 and \$466,000 for the nine months ended September 30, 2012 and 2011, respectively. Other income in 2012 consisted primarily of interest income. In 2011, other income consisted

primarily of \$250,000 in connection with the settlement of a lawsuit and approximately \$162,000 related to gains from changes in the fair value of certain warrant obligations.

#### *Settlement of Lawsuit*

On February 2, 2011, we received \$250,000 from a settlement with ReNeuron, Ltd., ending litigation between the parties. In addition to the settlement, ReNeuron agreed to make future milestone payments to Neuralstem based on ReNeuron's development of certain products which were at issue in the case. The success of ReNeuron's development of these products and our future receipt of any payment milestones is uncertain.

#### *Warrant Obligations*

The gain from the change in fair value of warrant obligations of \$161,809 in the nine months ended September 30, 2011 represents the final mark to market adjustment prior to the expiration and exercise of all outstanding derivative warrant liabilities.

### **Liquidity and Capital Resources**

Since our inception, we have financed our operations through the sales of our securities, the exercise of investor warrants, and to a lesser degree from grants and research contracts. During the first nine months of 2012 the Company raised gross proceeds of approximately \$15 million from the issuance of its common shares and warrants from a registered direct placement and underwritten public offerings.

Currently, our monthly cash burn for operations is approximately \$700,000. We anticipate that our available cash, expected income and expected proceeds from the sales of our securities will be sufficient to finance our current activities at least through September 30, 2013, although certain activities and related personnel may need to be reduced. We cannot assure you that we will be able to secure such additional financing or that the expected income will materialize. Several factors will affect our ability to raise additional funding, including, but not limited to, the volatility of our common shares and general market conditions.

	Nine Months Ended September 30,		Increase (Decrease)	
	2012	2011	\$	%
Cash and cash equivalents	\$ 9,873,395	\$ 4,195,471	\$ 5,677,924	135 %
Net cash used in operating activities	\$ (5,959,436 )	\$ (6,314,028 )	\$ 354,592	6 %
Net cash used in investing activities	\$ (188,318 )	\$ (420,060 )	\$ 231,742	55 %
Net cash provided by financing activities	\$ 13,669,136	\$ 1,668,326	\$ 12,000,810	719 %

Total cash and cash equivalents was approximately \$9,873,000 at September 30, 2012, compared with \$4,195,000 at September 30, 2011. The increase in our cash and cash equivalents of approximately \$5,678,000 or 135% was primarily due to proceeds from our common stock offerings in 2012 partially offset by cash used in operations.

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

We used approximately \$5,959,000 and \$6,314,000 of cash in our operating activities for the nine months ended September 30, 2012 and 2011, respectively. The decrease in our use of cash was approximately \$355,000 or 6%. This decrease is primarily due to decreases in expenses partially offset by timing of payments.

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

We used approximately \$188,000 and \$420,000 of cash in connection with investment activities for the nine months ended September 30, 2012 and 2011, respectively. The decrease in our use of cash of approximately \$232,000 or 55% was primarily due to a greater level of purchases of property and equipment in 2011.

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

We raised approximately \$13,685,000 and \$1,668,000 in net proceeds from the issuance of our securities during the nine months ended September 30, 2012 and 2011, respectively.

#### ***Future Liquidity and Needs***

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

We intend to pursue opportunities to obtain additional financing in the future through the sale of our securities and additional research grants. On October 14, 2010, our shelf registration statement registering the sale of up to \$50 million of our securities was declared effective by the SEC. We currently have approximately \$28.8 million remaining under this shelf registration statement. We anticipate conducting financing in the future based on our shelf registration statement when and if financing opportunities arise.

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

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

We are not required to provide the information required by this items as we are considered a smaller reporting company, as defined by Rule 229.10(f)(1).

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

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

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

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

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

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

## **PART II**

### **OTHER INFORMATION**

## **ITEM 1. LEGAL PROCEEDINGS**

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

On May 7, 2008, we filed suit against StemCells, Inc., StemCells California, Inc. (collectively "StemCells") and Neurospheres Holding Ltd., (collectively StemCells and Neurospheres Holding Ltd are referred to as "Plaintiffs") in U.S. District Court for the District of Maryland, alleging that U.S. Patent No. 7,361,505 (the "'505 patent"), alleging that the '505 patent was exclusively licensed to the Plaintiffs, is invalid, not infringed, and unenforceable. See Civil Action No. 08-1173. On May 13, we filed an Amended Complaint seeking declaratory judgment that U.S. Patent No. 7,155,418 (the "'418 patent") is invalid and not infringed and that certain statements made by our CEO are not trade libel or do not constitute unfair competition as alleged by the Plaintiffs. On July 15, 2008, the Plaintiffs filed a Motion to Dismiss for Lack of Subject Matter Jurisdiction, Lack of Personal Jurisdiction, and Improper Venue or in the Alternative to Transfer to the Northern District of California. On August 27, 2008, Judge Alexander Williams, Jr. of the District of Maryland denied StemCells' Motion to Dismiss, but granted Neurospheres' motion to dismiss. On September 11, 2008, StemCells filed its answer asserting counterclaims of infringement for the '505 patent, the 418 patent, and state law claims for trade libel and unfair competition. This case was consolidated with the 2006 litigation discussed below and it is not known when, nor on what basis, this matter will be concluded.

On July 28, 2006, StemCells, Inc., filed suit against Neuralstem, Inc. in the U.S. District Court in Maryland, alleging that Neuralstem has been infringing, contributing to the infringement of, and or inducing the infringement of four patents allegedly owned by or exclusively licensed to StemCells relating to stem cell culture compositions, genetically modified stem cell cultures, and methods of using such cultures. See Civil Action No. 06-1877. We answered the Complaint denying infringement, asserting that the patents are invalid, asserting that we have intervening rights based on amendments made to the patents during reexamination proceedings, and further asserting that some of the patents are unenforceable due to inequitable conduct. Neuralstem has also asserted counterclaims that StemCells has engaged in anticompetitive conduct in violation of antitrust laws. On February 28, 2011, Neuralstem filed a Motion to Dismiss for lack of standing and concurrently filed a Motion for Leave to Amend its Answer and Counterclaim to allege that StemCells is not the exclusive licensee of the patents-in-suit and also that Neuralstem has obtained a non-exclusive license to the patents-in-suit. Both motions are fully briefed, apply to the patents at issue in Civil Action Nos. 08-1173 and 08-2664 and remain pending before the Court. The Court further issued its Markman Order on August 12, 2011. On August 26, 2011, StemCells moved for reconsideration of two terms construed in the Markman Order and that motion remains pending. In addition, before the Court decided Neuralstem's Motion to Dismiss for lack of standing, StemCells filed a motion for summary judgment on the issue standing. Neuralstem responded to that motion and cross-moved for summary judgment on the issue of standing. Those motions are fully briefed and remain pending. On December 1, 2011, Neuralstem filed a motion to supplement the record on its cross motion for summary judgment on standing. StemCells opposed Neuralstem's motion to supplement and also cross-moved to supplement the record. On April 6, 2012 the Court granted Neuralstem's Motion for Leave to Amend to assert lack of standing and denied Neuralstem's Motion to Dismiss and Motion for Summary Judgment without prejudice. The Court also denied StemCells' Motion for Summary Judgment with prejudice. The Court has stayed all other matters pending resolution of the question of standing and discovery on that issue is ongoing. It is not known when, nor on what basis, this matter will be concluded.





**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 should be considered carefully in evaluating our company and our business and the value of our securities.*

**Risks Relating to Our Stage of Development**

*We have a history of losses.*

Since inception in 1996 and through September 30, 2012, we have recorded accumulated losses totaling approximately \$105,879,000. On September 30, 2012, we had a working capital surplus of approximately \$8,044,000 and stockholders' equity of approximately \$9,098,000. Our net losses for the three most recent fiscal years have been \$12,518,527, \$18,387,300 and \$10,364,363 for 2011, 2010 and 2009, respectively. In August of 2011, we were selected as the primary subcontractor under a DOD contract to develop its human neural stem cell technology for the treatment of cancerous brain tumors. We have recognized revenue related to this contract of approximately \$234,000 and \$391,000 for nine months ended September 30, 2012 and the year ended December 31, 2011, respectively. We recognized revenue of approximately \$171,000 and \$0, in the nine months ended September 30, 2012 and 2011, respectively related to the licensing of certain of our intellectual property to third parties. We had no revenue from the sales of our products during 2012 and 2011. For the nine months ended September 30, 2012, we had a net loss of approximately \$7,407,000.

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

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

Since our inception, we have funded our operations through the sale of our securities, the exercise of investor warrants, and to a lesser degree, from grants and research contracts and other revenue generating activities such as

licensing. As of September 30, 2012, we had cash and cash equivalents on hand of approximately \$9,873,000. Currently our monthly cash burn for operations is approximately \$700,000. We anticipate that our available cash, expected income and expected proceeds from sales of our securities will be sufficient to finance our current activities at least through September 30, 2013, although certain activities and related personnel may need to be reduced. We cannot assure you that we will be able to secure additional financing or enter into licensing agreements. Our inability to accomplish either licensing or additional financing will materially impact our ability to fund our current activities which will result in our being required to substantially reduce our activities.

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

## **Risks Relating to Our Business**

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

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

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

We have concentrated the majority of our research on 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 and may have limited human applications. We cannot guarantee that we will be able to develop our technologies or that such development will result in products with any commercial utility or value. We anticipate that the commercial sale of such products and royalty/licensing fees related to the technology, will be our primary sources of revenues. We recognized revenue of approximately \$171,000 in the third quarter of 2012 related to the licensing of certain intellectual property to third parties. If we are unable to develop our technologies, we may never realize any additional revenue.

***Our product development programs are based on novel technologies and are inherently risky.***

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of therapies in the field of regenerative medicine creates significant challenges in regard to product development and optimization, manufacturing, government regulation, third party reimbursement, and market acceptance. For example, the pathway to regulatory approval for cell-based therapies, including our product candidates, may be more complex and lengthy than the pathway for conventional drugs. These challenges may prevent us from developing and commercializing products on a timely or profitable basis or at all.

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

Given the uncertainty of our technologies and the need for government regulatory approval, we cannot possibly predict when or 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.

***We are unable to accurately predict time frames for approvals relating to government contracts or time frames for our products to receive regulatory approvals.***

In 2011 we were selected as a subcontractor for a U.S. department of Defense or DOD contract awarded to Loma Linda University to develop human neural stem cell technology for treatment of cancerous brain tumors. We currently have completed our initial year under this contract. The transaction was cash neutral and did not offset any of our other operating expenses. We completed our work under the contract in June of 2012. In the event the extension option is not exercised by the DOD, we will need to either secure additional financing, or curtail the research with

regard to stem cell treatment of cancerous brain tumors. Given the uncertainty of budget allocation for the DOD and other uncontrollable factors, we cannot predict whether the DOD will exercise its option for future years under this contract.

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

We currently outsource the manufacturing of our stem cells to third party contractors and as such are unable to adequately control the manufacturing process and the safe storage of such stem cells. Any manufacturing or storage irregularity, error, or failure to comply with applicable regulatory procedure would require us to find new third parties to outsource our manufacturing and storage responsibilities. Our business would suffer in the event that there are delays in locating suitable third parties or if no suitable third parties are found.

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

We are currently undertaking one sponsored Phase I clinical trial and we anticipate commencing our first Phase II clinical trial, related to our proposed product for the treatment of ALS, during the first half of 2013. Although we have commenced our trials, the ultimate outcome of the trials is uncertain, and if we are unable to satisfactorily complete such trials, or if such trials yield unsatisfactory results, we will be unable to commercialize our proposed products. No assurances can be given that the clinical trials will be completed or result in a successful outcome. If regulatory authorities do not approve our products or if we fail to maintain regulatory compliance, we would be unable to commercialize our therapeutic products, and our business and results of operations would be materially harmed.

***Our proposed products may not have favorable results in clinical trials or receive regulatory approval.***

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

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

There can be no assurance that even if the clinical trial of any potential product candidate is successfully initiated and completed, that we will be able to submit a Biologics License Application (“BLA”) or New Drug Application (“NDA”) to the FDA or that any BLA or NDA we submit will be approved in a timely manner, if at all. If we are unable to submit a BLA or NDA with respect to any future product candidate, or if such application is not approved by the FDA, we will be unable to commercialize that product. The FDA can and does reject BLAs and NDAs and may require additional clinical trials, even when product candidates performed well or achieved favorable results in clinical trials. If we fail to commercialize our product candidate, we may be unable to generate sufficient revenues to attain profitability and our reputation in the industry and in the investment community would likely be damaged, each of which would cause our stock price to decrease.

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

The manufacturing of stem cell-based therapeutic products is a complicated and difficult process, dependent upon substantial know-how and subject to the need for continual process improvements. We depend almost exclusively on third party manufacturers to supply our cells. In addition, our suppliers’ ability to scale-up manufacturing to satisfy the various requirements of our planned clinical trials is uncertain. Manufacturing irregularities or lapses in quality control could have a material adverse effect on our reputation and business, which could cause a significant loss of stockholder value. Many of the materials that we use to prepare our cell-based products are highly specialized, complex and available from only a limited number of suppliers. At present, some of our material requirements are single sourced, and the loss of one or more of these sources may adversely affect our business.

***Our business is subject to ethical and social concerns.***

The use of stem cells for research and therapy has been the subject of debate regarding ethical, legal and social issues. Negative public attitudes toward stem cell therapy could result in greater governmental regulation of stem cell therapies, which could harm our business. For example, concerns regarding such possible regulation could impact our ability to attract collaborators and investors. Existing and potential U.S. government regulation of human tissue may lead researchers to leave the field of stem cell research or the country altogether, in order to assure that their careers will not be impeded by restrictions on their work. Similarly, these factors may induce graduate students to choose other fields less vulnerable to changes in regulatory oversight, thus exacerbating the risk that we may not be able to attract and retain the scientific personnel we need in the face of competition among pharmaceutical, biotechnology and health care companies, universities and research institutions for what may become a shrinking class of qualified individuals

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

Our business may bring us into conflict with licensees, licensors, or others with whom we have contractual or other business relationships or with our competitors or others whose interests differs from ours. If we are unable to resolve these conflicts on terms that are satisfactory to all parties, we may become involved in litigation brought by or against such parties. Any litigation is likely to be expensive and may require a significant amount of management's time and attention, at the expense of other aspects of our business. The outcome of litigation is always uncertain, and in some cases could include judgments against us which could have a materially adverse effect on our business. By way of example, in May of 2008, we filed a complaint against StemCells Inc., alleging that U.S. Patent No. 7,361,505 (the "505 patent"), allegedly exclusively licensed to StemCells, Inc., is invalid, not infringed and unenforceable. On the same day, StemCells, Inc. filed a complaint alleging that we had infringed, contributed to the infringement of, and or induced the infringement of two patents owned by or exclusively licensed to StemCells relating to stem cell culture compositions. Please refer to the section of this Quarterly Report entitled "Legal Proceedings" for a further discussion of such litigation.

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

A number of companies, universities and research institutions have filed patent applications or have received patents relating to technologies in our field. We cannot predict which, if any, of these applications will issue as patents or how many of these issued patents will be found valid and enforceable. There may also be existing issued patents on which we would be infringed 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 third-party patient reimbursement or favorable product pricing.***

Our ability to successfully commercialize our proposed products in the human therapeutic field depends to a significant degree on patient reimbursement of the costs of such products and related treatments. We cannot assure you that reimbursement in the U.S. or in foreign countries will be available for any products developed, or, if available, will not decrease in the future, or that reimbursement amounts will not reduce the demand for, or the price of, our products. 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.***

Our products may be significantly more expensive to manufacture than other drugs or therapies currently on the market today due to a fewer number of potential manufacturers, greater level of needed expertise and other general market conditions affecting manufacturers of stem cell based products. Accordingly, if developed, we may not be able to charge a high enough price for us to make a profit from the sale of our cell therapy products.

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

Our proposed products, if approved for marketing, may not achieve market acceptance since hospitals, physicians, patients or the medical community, in general, may decide not to accept and utilize these products. The products that we are attempting to develop represent substantial departures from established treatment methods and will compete with a number of more conventional drugs and therapies manufactured and marketed by major pharmaceutical companies. The degree of market acceptance will depend on a number of factors, including:

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

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

***We depend on key employees 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 and 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 continue to attract and retain the qualified personnel necessary for the development our business.

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

We have entered into employment agreements with Messrs. Garr and Johe which expire on October 31, 2017. In the event either individual is terminated prior to the full term of their respective contracts, for any reason other than a voluntary resignation, all compensation due to such employee under the terms of the respective agreement shall become due and payable immediately. These provisions will make the replacement of either of these employees very costly and could cause difficulty in effecting a change in control. Termination prior to the full term of these contracts would cost us as much as approximately \$2,200,000 per contract and the immediate vesting of all outstanding options and/or warrants held by Messrs. Garr and Johe.

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

The biotechnology industry is characterized by intense competition. We will 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. Although not necessarily direct competitors, in the event we develop a commercially feasible product, we will compete against companies such as Genzyme Corporation, Aastrom Biosciences, Inc. and Viacell, Inc., as well as others, who may have substantially greater resources and experience in our fields.

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

Our strategy for the development, clinical and preclinical testing and commercialization of our proposed products is based 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 would be required to expend considerable 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 cell-based therapeutic products exposes us to product liability claims.***

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

***We currently rely upon third-party FDA-approved manufacturers for our stem cells.***

We currently have no internal commercial manufacturing capability, and rely extensively on FDA-approved licensees, strategic partners or third party contract manufacturers or suppliers. Should we be forced to manufacture our proposed products, we cannot give you any assurance that we will be able to develop an internal manufacturing capability or procure alternative third party suppliers. Moreover, we cannot give you any assurance that any contract manufacturers or suppliers we procure will be able to supply our product in a timely or cost effective manner or in accordance with applicable regulatory requirements or our specifications.

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

We currently have no internal commercial manufacturing capability, and rely exclusively on FDA-approved licensees, strategic partners or third party contract manufacturers or suppliers for the foreseeable future. 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. We currently engage Charles River Laboratories, Inc., of Wilmington, Massachusetts (stem cells) and Albany Molecular Resources, Inc. (“AMRI”) (small molecule). In the event we are required to seek third party suppliers or alternative 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, we cannot give you any assurance that any contract manufacturers or suppliers that we select will be able to supply our products in a timely or cost effective manner or in accordance with applicable regulatory requirements or our specifications. In addition, due to the novelty of our products and product development, there can be no assurances that we would be able to find other suitable third party FDA-regulated manufacturers at terms reasonable to us. Failure to secure such third party manufacturers or suppliers would materially impact our business.

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

Although we design and manage our current preclinical studies, we do not have the in-house capability to conduct clinical trials for our product candidates. We rely, and will rely in the future, on medical institutions, clinical investigators, contract research organizations, contract laboratories, and collaborators to perform data collection and analysis and other aspects of our clinical trials. Our preclinical activities or clinical trials conducted in reliance on third parties may be delayed, suspended, or terminated if:

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

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

### **Risks Relating to Intellectual Property**

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

We rely on our intellectual property, including issued and applied-for patents, as the foundation of our business. Our intellectual property rights may come under challenge. No assurances can be given that, even though issued, our current and potential future patents will survive such challenges. For example, in 2005 our neural stem cell technology was challenged in the USPTO. Although we prevailed in this particular matter upon re-examination by the patent office, these cases are complex, lengthy, expensive, and could potentially be adjudicated adversely to our interests, removing the protection afforded by an issued patent. The viability of our business would suffer if such patent protection were limited or eliminated. Moreover, the costs associated with defending or settling intellectual property claims would likely have a material adverse effect on our business and future prospects. At present, there is litigation with StemCells, Inc., which is further described in this Quarterly Report in the section entitled “*Legal Proceedings.*”

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

We anticipate conducting 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**

*Our common shares have until recently been “thinly” traded.*

Until recently, our common shares have been “thinly” traded, meaning that the number of persons interested in purchasing our common shares at or near the asking price at any given time may be relatively small or non-existent. Recently, the trading volume and liquidity for our common shares has increased. However, there can be no assurances that this increase trading volume will persist in the future. The lack of historical liquidity in our common shares is attributable to a number of factors, including the facts that we are a small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community. Although our common shares have recently experienced an increase in liquidity, these factors still exist. We cannot give you any assurance that a broader or more active trading market for our common shares will continue, or that current trading levels will be sustained. Due to these conditions, you may not be able to sell your shares if you need money or otherwise desire to liquidate your investment.

*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 future market acceptance for our products if successfully developed. 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; 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.

***We face risks related to compliance with corporate governance laws and financial reporting standard.***

The Sarbanes-Oxley Act of 2002, as well as related rules and regulations implemented by the SEC and the Public Company Accounting Oversight Board, require changes in the corporate governance practices and financial reporting standards for public companies. These laws, rules and regulations, including compliance with Section 404 of the Sarbanes-Oxley Act of 2002 relating to internal control over financial reporting (“Section 404”), have materially increased the Company's legal and financial compliance costs and have and will continue to make some activities more time-consuming, burdensome and expensive. Any failure to comply with the requirements of the Sarbanes-Oxley Act of 2002, our ability to remediate any material weaknesses that we may identify during our compliance program, or difficulties encountered in their implementation, could harm our operating results, cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. Any such failure could also adversely affect the results of the periodic management evaluations of our internal controls and, in the case of a failure to remediate any material weaknesses that we may identify, would adversely affect the annual auditor attestation reports regarding the effectiveness of our internal control over financial reporting that are required under Section 404 of the Sarbanes-Oxley Act. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

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

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

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

We have never paid cash dividends nor do we anticipate paying cash dividends in the foreseeable future. Accordingly, any return on your investment will be as a result of stock appreciation if any.

***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 any of the analysts who cover us downgrades our securities, the price of our securities would likely decline. If one or more of these analysts ceases to cover us or fails to publish regular reports on us, interest in the purchase of our securities could decrease, which could cause the price of our common stock and other securities and their trading volume to decline.

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

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

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

We are entitled under our certificate of incorporation to issue up to 150,000,000 shares of common stock and 7,000,000 "blank check" shares of preferred stock. Shares of our blank check preferred stock provide the board of directors broad authority to determine voting, dividend, conversion, and other rights. As of September 30, 2012 we have issued and outstanding 67,964,314 shares of common stock and we have 38,764,368 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, 2012, we had no shares of preferred stock issued and outstanding. Accordingly, we are entitled to issue up to 43,271,318 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.

***Our publicly filed reports are subject to review by the SEC, and any significant changes or amendments required as a result of any such review may result in material liability to us and may have a material adverse impact on the trading price of our common stock.***

The reports of publicly traded companies are subject to review by the SEC from time to time for the purpose of assisting companies in complying with applicable disclosure requirements, and the SEC is required to undertake a comprehensive review of a company's reports at least once every three years under the Sarbanes-Oxley Act of 2002. SEC reviews may be initiated at any time. We could be required to modify, amend or reformulate information contained in prior filings as a result of an SEC review. Any modification, amendment or reformulation of information contained in such reports could be significant and result in material liability to us and have a material adverse impact on the trading price of our common stock.

***If we cannot continue to satisfy the NYSE MKT listing maintenance requirements and other rules, our securities may be delisted, which could negatively impact the price of our securities.***

Although our common stock is listed on the NYSE MKT, we may be unable to continue to satisfy the listing maintenance requirements and rules. If we are unable to satisfy the criteria for maintaining our listing on the NYSE MKT, our securities could be subject to delisting. To qualify for continued listing on the NYSE MKT, we must continue to meet specific criteria including conditions with respect to our shareholders equity as well as minimum stock price. There can be no assurance that we will continue to meet this criteria. If we fail to meet the listing requirements and the NYSE MKT makes the determination that our common stock is no longer eligible for listing and is delisted, trading in our common stock may be conducted on the over-the-counter bulletin board or on the OTC Markets. In such event, broker-dealers may be less willing or able to sell and/or make a market in our common stock. Moreover, such markets have historically been less liquid than the NYSE MKT. Accordingly, an investor would find it more difficult to dispose of his shares or to obtain accurate quotations for the price which could result in a negative impact on the price of our common shares.

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

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

The FDA and comparable government agencies in foreign countries impose substantial regulations on the manufacturing and marketing of pharmaceutical and biological products through lengthy and detailed laboratory, pre-clinical and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Satisfaction of these regulations typically takes several years or more and vary substantially based upon the type, complexity and novelty of the proposed product. We are currently undertaking two sponsored Phase I clinical

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

***Development of our technologies is subject to extensive government regulation.***

Our research and development efforts, as well as any future clinical trials, and the manufacturing and marketing of any products we may develop, will be subject to, and restricted by, extensive regulation by governmental authorities in the U.S. and other countries. The process of obtaining FDA and other necessary regulatory approvals is lengthy, expensive and uncertain. FDA and other legal and regulatory requirements applicable to the development and manufacture of the cells and cell lines required for our preclinical and clinical products could substantially delay or prevent us from producing the cells needed to initiate 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.

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

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

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

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

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

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

our financial results and the commercial prospects for those of our product candidates involved will be harmed, and our prospects for profitability will be significantly impaired.

In addition, in the course of its review of an NDA or 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 an NDA or regulatory application submitted by us and finds a significant deficiency in any of these or other areas, the FDA or other regulatory authorities could delay or not approve our NDA or regulatory application. If regulatory delays are significant or regulatory approval is limited or denied altogether, our financial results and the commercial prospects for those of our products or product candidates involved will be harmed, and our prospects for profitability will be significantly impaired.

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

Both before and after the approval of our product candidates, we, our product candidates, our operations, our facilities, our suppliers, and our contract manufacturers, contract research organizations, and contract testing laboratories are subject to extensive regulation by governmental authorities in the United States and other countries, with regulations differing from country to country. In the United States, the FDA regulates, among other things, the pre-clinical testing, clinical trials, manufacturing, safety, efficacy, potency, labeling, storage, record keeping, quality systems, advertising, promotion, sale and distribution of therapeutic products. Failure to comply with applicable requirements could result in, among other things, one or more of the following actions: notices of violation, untitled letters, warning letters, fines and other monetary penalties, unanticipated expenditures, delays in approval or refusal to approve a product candidate; product recall or seizure; interruption of manufacturing or clinical trials; operating restrictions; injunctions; and criminal prosecution. We or the FDA, or an institutional review board, may suspend or terminate human clinical trials at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Our product candidates cannot be lawfully marketed in the United States without FDA approval. Any failure to receive the marketing approvals necessary to commercialize our product candidates could harm our business.

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

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

***The results of pre-clinical studies and early-stage clinical trials, such as the results from our recent Phase I ALS trial, may not be predictive of the results of later-stage clinical trials.***

A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in Phase II and Phase III clinical trials, despite positive results from earlier-stage trials. The principal investigator of the Phase I safety trial of our human spinal cord stem cells (HSSC's) in amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease), recently presented primary and secondary endpoint data on the first 12 patients in the study. The study was designed to assess the safety of intraspinal transplantation in ALS patients and was not intended to demonstrate efficacy. While no adverse events related to the surgical procedure or our neural stem cells were reported, the small sample size, limited time frame and preliminary nature of the study make it difficult to draw any conclusions from the results of the study. No assurance can be given that the surgical procedure or our neural stem cells will be deemed safe by the FDA or that efficacy in the treatment of ALS will be demonstrated in any future studies. Failure to demonstrate safety and efficacy results acceptable to the

FDA in later stage trials could impair our development prospects and even prevent regulatory approval of our neuronal stem cells, NSI-189 or other future products.

## **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, 2012. The unregistered securities were issued pursuant to section 4(2) of the Securities Act:

In March of 2012, pursuant to the terms of the consulting agreement entered into with Market Development Consulting Group, Inc. in January of 2010 and amended May 14, 2010 and February 7, 2011, we issued: (i) 180,000 common shares; and (ii) a common stock purchase warrant entitling the holder to purchase 510,821 shares of common stock at \$0.99 per share as compensation for business advisory services. The common stock was deliverable on April 1, 2012. The warrant is exercisable immediately, expires on January 6, 2022, and is freely assignable in whole or in part. We also agreed to register the shares underlying the warrant with the SEC for resale. The form of warrant is substantially similar to the one issued on January 8, 2010.

In June of 2012, we issued warrants to purchase an aggregate of 15,000 common shares as compensation for business advisory services. The warrant has an exercise price of \$1.25 per share, a term of 5 years and provides for an adjustment to the exercise price, as well as the number of shares underlying the warrant, in the event of stock dividends and stock splits.

In September of 2012, we amended the terms of an aggregate of 468,757 warrants issued in connection with our June 29, 2010 registered direct offering as consideration for certain services provided by the warrant holders. Pursuant to the amendment, we: (i) reduced the exercise price of the warrants from \$3.25 to \$0.50; and (ii) extended the expiration date from June 29, 2013 to June 30, 2017. All other terms and conditions of the warrants remained unchanged.

In October of 2012, we entered into a consulting agreement related to the marketing of NS-189, our small molecule compound to other pharmaceutical and drug development companies. As partial consideration for the services to be rendered, we agreed to issue an aggregate of 25,000 shares of our common stock during the initial five month term of the agreement.

**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, 2012 /s/ I. Richard Garr  
Chief Executive Officer



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

## INDEX TO EXHIBITS

Exhibit No.	Description	Filed Herewith	Incorporated by Reference			
			Form	Exhibit No.	File No.	Filing Date
3.01(i)	Amended and Restated Certificate of Incorporation of Neuralstem, Inc. filed on 9/29/05		10-K	3.01(i)	001-33672	3/31/09
3.02(i)	Certificate of Amendment to Certificate of Incorporation of Neuralstem, Inc. filed on 5/29/08		DEF 14A	Appendix I	001-33672	4/24/08
3.03(ii)	Amended and Restated Bylaws of Neuralstem, Inc. adopted on 7/16/07		10-QSB	3.2(i)	333-132923	8/14/07
4.01**	Amended and Restated 2005 Stock Plan adopted on 6/28/07		10-QSB	4.2(i)	333-132923	8/14/07
4.02**	Non-qualified Stock Option Agreement between Neuralstem, Inc. and Richard Garr dated 7/28/05		SB-2	4.4	333-132923	6/21/06
4.03**	Non-qualified Stock Option Agreement between Neuralstem, Inc. and Karl Johe dated 7/28/05		SB-2	4.5	333-132923	6/21/06
4.04**	Neuralstem, Inc. 2007 Stock Plan		10-QSB	4.21	333-132923	8/14/07
4.05	Form of Common Stock Purchase Warrant Issued to Karl Johe on 6/5/07		10-KSB	4.22	333-132923	3/27/08
4.06	Form of Placement Agent Warrant Issued to Midtown Partners & Company on 12/18/08		8-K	4.1	001-33672	12/18/08
4.07	Form of Consultant Common Stock Purchase Warrant issued on 1/5/09		S-3/A	10.1	333-157079	02/3/09
4.08	Form of Series D, E and F Warrants		8-K	4.01	001-33672	7/1/09
4.09	Form of Placement Agent Warrant		8-K	4.02	001-33672	7/1/09
4.10	Form of Consultant Warrant Issued 1/8/10		10-K	4.20	001-33672	3/31/10
4.11	Form of Replacement Warrant Issued 1/29/10		10-K	4.21	001-33672	3/31/10
4.12	Form of Replacement Warrant Issued March of 2010		10-K	4.22	001-33672	3/31/10

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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
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4.14	Form of Warrants dated 6/29/10	8-K	4.01	001-33672	6/29/10
4.15**	Neuralstem 2010 Equity Compensation Plan	8-K	10.01	001-33672	7/14/10
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 June 2012	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
10.01**	Employment Agreement with I. Richard Garr dated January 1, 2007 and amended as of November 1, 2005	SB-2	10.1	333-132923	6/21/06
10.02**	Amended terms to the Employment Agreement of I Richard Garr dated January 1, 2008	10-K	10.02	001-33672	3/31/09
10.03**	Employment Agreement with Karl Johe dated January 1, 2007 and amended as of November 1, 2005	SB-2	10.2	333-132923	6/21/06
10.04**	Amended terms to the Employment Agreement of Karl Johe dated January 1, 2009	10-K	10.04	001-33672	3/31/09
10.05**	Employment Agreement with Thomas Hazel, Ph.D dated August 11, 2008	10-K/A	10.05	001-33672	10/5/10
10.06	Consulting Agreement dated January 2010 between Market Development Consulting Group and the Company and amendments No. 1 and 2.	10-K	10.07	001-33672	3/16/11
10.07**	Renewal of I. Richard Garr Employment Agreement dated 7/25/12	8-K	10.01	001-33672	7/27/12
10.08**	Renewal of Dr. Karl Johe Employment Agreement dated 7/25/12	8-K	10.02	001-33672	7/27/12



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10.09**	Renewal of Dr. Tom Hazel Employment Agreement dated 7/25/12	8-K	10.03	001-33672	7/27/12
14.01	Neuralstem Code of Ethics	SB-2	14.1	333-132923	6/21/06
14.02	Neuralstem Financial Code of Profession Conduct adopted on May 16, 2007	8-K	14.2	333-132923	6/6/07
31.1	Certification of the Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				*
31.2	Certification of the Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				*
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. § 1350				*
32.2	Certification of 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*