

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

Neuralstem, Inc.
Form 10-Q
August 16, 2010

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 June 30, 2010

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
Rockville, MD
(Address of principal executive offices)

20850
(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
Non-accelerated filer (Do not check if a small reporting company)

Accelerated filer
Smaller reporting company

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

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

As of July 21, 2010 there were 46,008,024 shares of common stock, \$.01 par value, issued and outstanding.

Neuralstem, Inc.

Table of Contents

	Page
PART I - FINANCIAL INFORMATION	
Item 1. Financial Statements	3
Balance Sheets as of June 30, 2010 (Unaudited) and December 31, 2009	3
Statements of Operations (Unaudited) Three and six months ended June 30, 2010 and 2009	4
Statements of Cash Flows (Unaudited) For the six months ended June 30, 2010 and 2009	5
Statements of Changes in Stockholders' (Deficit) Equity (Unaudited) For the period from January 1, 2010 through June 30, 2010	6
Notes to Financial Statements (Unaudited)	7
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	12
Item 3. Quantitative and Qualitative Disclosures about Market Risk	23
Item 4. Controls and Procedures	23
PART II - OTHER INFORMATION	
Item 1. Legal Proceedings	24
Item 1A. Risk Factors	24
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	31
Item 3. Defaults Upon Senior Securities	32
Item 4. (Removed and Reserved).	32
Item 5. Other Information	32
Item 6. Exhibits	32

PART I
FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Neuralstem, Inc.

Balance Sheets

ASSETS	June 30, 2010 (Unaudited)	December 31, 2009
CURRENT ASSETS		
Cash and cash equivalents	\$ 14,025,745	\$ 2,309,774
Prepaid expenses	272,613	143,600
Total current assets	14,298,358	2,453,374
Property and equipment, net	187,113	196,755
Intangible assets, net	370,421	301,560
Other assets	49,409	55,716
Total assets	\$ 14,905,301	\$ 3,007,405
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	\$ 1,144,916	\$ 791,607
Accrued bonus expense	588,338	769,215
Fair value of warrant obligations	2,189,064	-
Total current liabilities	3,922,318	1,560,822
LONG-TERM LIABILITIES		
Fair value of warrant obligations	-	6,462,039
Total liabilities	3,922,318	8,022,861
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred stock, 7,000,000 shares authorized, zero shares issued and outstanding	-	-
Common stock, \$0.01 par value; 150 million shares authorized, 46,008,024 and 35,743,831 shares outstanding in 2010 and 2009 respectively	460,080	357,438

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

Additional paid-in capital	89,808,035	62,193,937
Accumulated deficit	(79,285,132)	(67,566,831)
Total stockholders' equity (deficit)	10,982,983	(5,015,456)
Total liabilities and stockholders' equity (deficit)	\$ 14,905,301	\$ 3,007,405

See accompanying notes.

3

Neuralstem, Inc.

Statements of Operations
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Revenues	\$ -	\$ -	\$ -	\$ -
Operating expenses:				
Research and development costs	2,613,676	1,452,793	4,513,640	2,886,802
General, selling and administrative expenses	1,550,814	1,249,947	3,238,649	2,707,186
Depreciation and amortization	30,601	21,424	59,663	42,220
	4,195,091	2,724,164	7,811,952	5,636,208
Operating loss	(4,195,091)	(2,724,164)	(7,811,952)	(5,636,208)
Nonoperating (expense) income:				
Interest income	9,653	8,516	15,463	10,780
Interest expense	(1,462)	-	(2,120)	-
Warrant issuance and modification expense	-	-	(1,906,800)	-
(Loss) gain from change in fair value of warrant obligations	(764,440)	(473,799)	(2,012,892)	3,341,659
	(756,249)	(465,283)	(3,906,349)	3,352,439
Net loss attributable to common shareholders	\$ (4,951,340)	\$ (3,189,447)	\$ (11,718,301)	\$ (2,283,769)
Net loss per share – basic and diluted	\$ (0.12)	\$ (0.09)	\$ (0.29)	\$ (0.07)
Weighted average common shares outstanding – basic	42,450,338	33,760,091	40,505,586	33,755,720

See accompanying notes.

Neuralstem, Inc.

Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30,	
	2010	2009
Cash flows from operating activities:		
Net loss	\$ (11,718,301)	\$ (2,283,769)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	59,663	42,220
Share based compensation expenses	2,630,742	2,348,656
Warrant issuance and modification expense	1,906,800	-
Loss/(gain) from change in fair value of warrant obligations	2,012,893	(3,341,659)
Changes in operating assets and liabilities:		
Prepaid expenses	50,988	75,475
Other assets	6,307	(5,500)
Accounts payable and accrued expenses	353,055	258,993
Accrued bonus expenses	(180,877)	377,308
Net cash used in operating activities	(4,878,730)	(2,528,276)
Cash flows from investing activities:		
Acquisition of intangible assets	(92,493)	(51,692)
Purchase of property and equipment	(26,391)	(8,380)
Net cash used in investing activities	(118,884)	(60,072)
Cash flows From financing activities:		
Issuance of common stock from warrants exercised	7,442,066	903,391
Issuance of common stock from private placement	9,271,519	-
Net cash provided by financing activities	16,713,585	903,391
Net increase (decrease) in cash and cash equivalents	11,715,971	(1,684,958)
Cash and cash equivalents, beginning of period	2,309,774	4,903,279
Cash and cash equivalents, end of period	\$ 14,025,745	\$ 3,218,321
Supplemental disclosure of cash flows information:		
Cash paid for interest	\$ 1,462	\$ -
Cash paid for income taxes	-	-
Supplemental schedule of non cash investing and financing activities:		
Extinguishment of warrant obligations through exercise, expiration and modification of common stock warrants	(6,285,613)	-
Payment of services through common stock issuance	(240,000)	-

See accompanying notes.

Neuralstem, Inc.

STATEMENT OF CHANGES IN STOCKHOLDERS'(DEFICIT)EQUITY

For the period from January 1, 2010 through June 30, 2010

(Unaudited)

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity
Balance at January 1, 2010	35,743,831	\$ 357,438	\$ 62,193,937	\$ (67,566,831)	\$ (5,015,456)
Share based payments			2,570,742		2,570,742
Issuance of common stock through Private Placement (\$2.80 per share), net of financing costs of \$728,501.	3,571,436	35,714	9,235,805		9,271,519
Issuance of common stock for prepaid consulting services.	140,000	1,400	238,600		240,000
Issuance of common stock from warrants exercised (\$1.25 and \$1.10 per share), net of issuance costs of \$631,575.	6,552,757	65,528	7,376,538		7,442,066
Warrant issuances and modifications			8,167,742		8,167,742
Extinguishment of fair value of warrant obligations from warrant expiration			24,671		24,671
Net loss				(11,718,301)	(11,718,301)
Balance at June 30, 2010	46,008,024	\$ 460,080	\$ 89,808,035	\$ (79,285,132)	\$ 10,982,983

See accompanying notes.

Note 1. Basis of Presentation

The accompanying unaudited financial statements of Neuralstem, Inc. (the "Company") have been prepared in accordance with generally accepted accounting principles in the United States and the rules and regulations of the Securities and Exchange Commission (the "SEC"), for interim financial information. Therefore, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements and should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2009.

The interim financial statements are unaudited, but in the opinion of management all adjustments, consisting only of normal recurring accruals, considered necessary to present fairly the results of these interim periods have been included. The results of the Company's operations for any interim period are not necessarily indicative of results that may be expected for any other interim period or for the full year.

Note 2. Significant Accounting Policies and Recent Accounting Pronouncements

Use of Estimates

The preparation of financial statements in accordance with generally accepted accounting principles 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. Because of the use of estimates inherent in the financial reporting process, actual results could differ significantly from those estimates.

The Company's business currently does not generate cash. The Company's management does not know when this will change. The Company has expended and will continue to expend substantial funds in the research, development and clinical and pre-clinical testing of the Company's stem cell technologies and products with the goal of ultimately obtaining approval from the United States Food and Drug Administration ("FDA") to market and sell our products. 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 products. Based on our current operating levels, we believe that we have sufficient levels of cash and cash equivalents to fund operations into the third quarter of 2011.

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 products.

Revenue Recognition

Our revenue recognition policies are in accordance with guidance issued by the SEC and Financial Accounting Standards Board (FASB). Historically, our revenue has been derived primarily from providing treated samples for gene expression data from stem cell experiments, from providing services under various grant programs and through the licensing of the use of our intellectual property. Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery of goods and services has occurred, the price is fixed and determinable, and collection is reasonably assured.

Research and Development

Research and development expenses consist primarily of costs associated with basic and pre-clinical research, exclusively in the field of human neural stem cell therapies and regenerative medicine, related to our clinical cell therapy candidates. These expenses represent both pre-clinical development costs and costs associated with non-clinical support activities such as quality control and regulatory processes. Research and development costs are

expensed as they are incurred.

Loss per Common Share

Basic and diluted loss per common share is calculated by dividing the net loss by the weighted average number of common shares outstanding during the period.

	For The Six Months Ended June 30,	
	2010	2009
Net loss attributable to common shareholders	\$ (11,718,301)	\$ (2,283,769)
Weighted average common shares outstanding	40,505,586	33,755,720
Basic and diluted loss per common share	\$ (0.29)	\$ (0.07)

7

Share Based Payments

We have granted stock-based compensation awards to employees, board members and service providers. Awards may consist of common stock, warrants, or stock options. Our stock options and warrants have lives of up to ten years. 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.

We granted 145,000 options during the six months ended June 30, 2010. We granted 246,000 options in the similar period ended June 30, 2009. We recorded related compensation expenses as our options vest in accordance with guidance issued by the FASB related to share based payments. We recognized \$2,630,742 and \$2,348,656 in share-based compensation expense during the six months ended June 30, 2010 and 2009, respectively. Included in the expense for the six months ended June 30, 2010, is \$60,000 in expense related to the amortization of prepaid consulting expense paid with the issuance of \$240,000 in common stock.

A summary of stock option activity during the six months ended June 30, 2010 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, 2010	9,070,659	\$ 2.52	7.0	\$ -
Granted	145,000	2.40	5.9	\$ 14,500
Exercised	-	-	-	-
Forfeited	-	-	-	-
Outstanding at June 30, 2010	9,215,659	\$ 2.52	6.7	\$ 5,437,800
Exercisable at June 30, 2010	6,983,992	\$ 2.28	6.5	\$ 5,328,350

Share-based compensation expense included in the statements of operations for the three months and six months ended June 30, 2010 and 2009 was as follows:

	Three Months Ended June 30,	
	2010	2009
Research and development costs	\$ 703,299	\$ 740,201
General, selling and administrative expenses	626,559	409,751
Total	\$ 1,329,858	\$ 1,149,952
	Six Months Ended June 30,	
	2010	2009
Research and development costs	\$ 1,539,495	\$ 1,480,402
General, selling and administrative expenses	1,091,247	868,254

Total	\$ 2,630,742	\$ 2,348,656
-------	--------------	--------------

8

Warrants to purchase common stock were issued to certain officers, directors, stockholders and service providers.

	Number of Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2010	15,295,257	\$ 1.82	2.0	-
Granted	7,509,983	2.55	4.2	1,969,120
Exercised	(6,552,757)	1.23	-	-
Forfeited	(25,355)	1.25	-	-
Outstanding at June 30, 2010	16,227,128	\$ 2.40	3.5	4,634,720
Exercisable at June 30, 2010	12,977,127	\$ 2.24	2.9	4,634,720

Effective January 1, 2009 we adopted the provisions of recent accounting guidance, described below. As a result of adopting this guidance, 8,547,762 of our issued and outstanding common stock purchase warrants previously treated as equity pursuant to the derivative treatment exemption were no longer afforded equity treatment. These warrants have the following characteristics:

	Strike Price	Date of Issue	Date of Expiration	Warrants Outstanding
Series A & B Warrants	\$ 1.25	February-06	February-11	4,359,605
Series A & B Warrants, Placement Agent	\$ 1.10	February-06	February-11	782,005
Series C Warrants	\$ 1.25	October-07	October-12	1,227,000
Series C Warrants, Placement Agent	\$ 1.25	March-07	March-12	294,480
Series C Warrants, anti-dilution awards	\$ 1.25	December-08	October-12	1,472,400
Series C Warrants, Placement Agent, anti-dilution awards	\$ 1.25	December-08	March-12	412,272

Total warrants no longer accounted for as equity at January 1, 2009	8,547,762
---	-----------

As such, effective January 1, 2009 we reclassified the fair value of the common stock purchase warrants, which were outstanding at January 1, 2009, and which have exercise price reset and anti-liquidation features, from equity to liability status as if these warrants were treated as a derivative liability since their date of issue. On January 1, 2009, we reduced additional paid-in capital by \$6.9 million and decreased the beginning retained deficit by \$.3 million as a cumulative effect to establish a long-term warrant liability of \$6.6 million to recognize the fair value of such warrants. In the first six months of 2010, 6,484,864 of the common stock purchase warrants were exercised or forfeited. The fair value of the remaining warrants increased, due to a higher stock price, resulting in a \$2,102,892 expense for the six months ended June 30, 2010.

These common stock purchase warrants were initially issued in connection with placement of the Company's common stock. The common stock purchase warrants were not issued with the intent of effectively hedging any future cash flow, fair value of any asset, liability or any net investment in a foreign operation. The warrants do not qualify for hedge accounting, and as such, all future changes in the fair value of these warrants will be recognized currently in

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

earnings until such time as the warrants are exercised or expire. These common stock purchase warrants do not trade in an active securities market, and as such, we estimate the fair value of these warrants using the Black-Scholes option pricing model using the following assumptions:

	June 30, 2010	June 30, 2009
Annual dividend yield	-	-
Expected life (years)	0.33	.75-2.25
Risk free interest rate	0.18%	0.56-1.11%
Expected volatility	61%	82-115%

9

Expected volatility is based primarily on historical volatility. Historical volatility was computed using daily pricing observations for a group of similar companies for recent periods that correspond to the expected life of the warrants. We believe this method produces an estimate that is representative of our expectations of future volatility over the expected term of these warrants. We currently have no reason to believe future volatility over the expected remaining life of these warrants is likely to differ materially from historical volatility. The expected life is estimated by management based on the remaining term of the warrants. The risk-free interest rate is based on the rate for U.S. Treasury securities over the expected life.

Warrant Issuance and Modification Expense

In February 2010 we extended the lives of warrants for 706,752 shares of common stock with a strike price of \$1.25 for two years. The warrants had been issued earlier in exchange for extinguishment of debt. The warrants were due to expire in March 2012. As a result of the term change, we recorded a Warrant Issuance Modification Expense charge of \$171,531 for the six months ended June 30, 2010. In addition, as a fulfillment of agreements with certain vendors, 3,881,005 warrants were reissued in January and March 2010 to replace warrants that had been exercised during the period. As a result of the reissue of these warrants, the Company recognized a Warrant Modification Expense charge of \$1,735,269. The total expense for the six months ended June 30, 2010 was \$1,906,800.

Significant New Accounting Pronouncements

The following accounting pronouncements, if implemented, would have no effect on the financial statements of the company.

ASU 2010-01, "Equity (Topic 505) – Accounting for Distributions to Shareholders with Components of Stock and Cash." ASU 2010-01 was issued January 2010 and clarifies that the stock portion of a distribution to shareholders that allows them to elect to receive cash or stock with a potential limitation on the total amount of cash that all shareholders can elect to receive in the aggregate is considered a share issuance that is reflected in earnings per share prospectively and is not a stock dividend. ASU 2010-01 is effective for interim and annual periods ending on or after December 15, 2009, and should be applied on a retrospective basis. ASU 2010-01 had no impact on our financial statements.

ASU 2010-06, "Improving Disclosure about Fair Value Measurements," was issued January 2010 and requires additional disclosures regarding fair value measurements, amends disclosures about post-retirement benefit plan assets and provides clarification regarding the level of disaggregation of fair value disclosures by investment class. The ASU is effective for interim and annual reporting periods beginning after December 15, 2009, except for certain Level 3 activity disclosure requirements that will be effective for reporting periods beginning after December 15, 2010. Adoption of ASU 2010-06 had no impact on our financial statements.

Note 3. Fair Value

In September 2006, the FASB issued accounting guidance related to fair value measurements and related disclosures. This guidance establishes a standard framework for measuring fair value in generally accepted accounting principles, clarifies the definition of "fair value" within that framework, and expands disclosures about the use of fair value measurements.

Fair value is defined as the price at which an asset could be exchanged or a liability transferred (an exit price) in an orderly transaction between knowledgeable, willing parties in the principal or most advantageous market for the asset or liability. Where available, fair value is based on observable market prices or parameters or derived from such prices or parameters. Where observable prices or inputs are not available, valuation models are applied.

Financial assets recorded at fair value in the accompanying financial statements are categorized based upon the level of judgment associated with the inputs used to measure their fair value. Hierarchical levels, as defined by the new guidance related to fair value measurements and disclosures, and directly related to the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities, are as follows:

Level 1 – Inputs are unadjusted, quoted prices in active markets for identical assets at the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

The fair valued assets we hold that are generally included in this category are money market securities where fair value is based on publicly quoted prices and included in cash equivalents.

Level 2 – Inputs are other than quoted prices included in Level 1, which are either directly or indirectly observable for the asset or liability through correlation with market data at the reporting date and for the duration of the instrument's anticipated life.

We carry no investments classified as Level 2.

Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities and which reflect management's best estimate of what market participants would use in pricing the asset or liability at the reporting date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model. Our warranty obligations are considered Level 3 items.

Financial assets and liabilities measured at fair value on a recurring basis are summarized below:

	June 30, 2010	Fair value measurements at June 30, 2010 using		
		Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash and cash equivalents	\$ 14,025,745	\$ 14,025,745	\$ -	\$ -
Liabilities:				
Fair value of warrant obligations	2,189,064	-	-	2,189,064
		Three months ended June 30, 2010	Six months ended June 30, 2010	

Fair value of warrant obligations at beginning of period	\$	1,497,863	\$	6,462,039
Extinguishment through warrant exercises and modifications		(73,239)		(6,285,613)
Extinguishment through warrant expirations				(254)
Net loss (gain) for change in fair value included in the statement of operations for period		764,440		2,012,892
Fair value of warrant obligations at end of period	\$	2,189,064	\$	2,189,064

The fair value of the warrant obligations was determined using the Black Scholes option pricing model with inputs which are described in Note 2.

Note 4. Stockholders' Equity (Deficit)

During the first six months ended June 30, 2010, various warrant holders exercised 6,552,757 warrants at \$1.25 and \$1.10 per warrant increasing equity by approximately \$7.44 million, net of \$631,575 in related financing costs. The exercise of these warrants reduced the Company's derivative liability and increased equity by \$5,537,237.

The Company also completed a private placement of 3,571,436 common shares at \$2.80 per share increasing equity in the amount of \$10,000,020, at June 30, 2010, less \$728,501 in related placement and closing costs.

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

ADVISEMENT

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 (June 30, 2010), unless another date is specified.

We prepare our interim financial statements in accordance with United States generally accepted accounting principles. Our financials and results of operations for the three and six month periods ended June 30, 2010 are not necessarily indicative of our prospective financial condition and results of operations for the pending full fiscal year ending December 31, 2010. 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 ("SEC").

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These forward-looking statements include, but are not limited to, statements about:

- the success of our research and development activities, the development of a viable commercial product, and the speed with which regulatory authorizations and product launches may be achieved;
- whether or not a market for our product develops, and, if a market develops, the rate at which it develops;
- our ability to successfully sell or license our products if a market develops;
- our ability to attract and retain qualified personnel to implement our business plan and corporate growth strategies;
- our ability to develop sales, marketing, and distribution capabilities;
- our ability to obtain reimbursement from third party payers for our proposed products if they are developed;
- the accuracy of our estimates and projections;

- our ability to secure additional financing to fund our short-term and long-term financial needs;
- changes in our business plan and corporate strategies; and
- other risks and uncertainties discussed in greater detail in the section captioned “Risk Factors.”

These statements are often, but not always, made through the use of words or phrases such as “anticipate,” “estimate,” “plan,” “project,” “continuing,” “ongoing,” “expect,” “believe,” “intend” and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Discussions containing these forward-looking statements may be found throughout this Form 10-Q, including Part I, the section entitled “Item 2: Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These forward-looking statements involve risks and uncertainties, including the risks discussed in Part II, Item 1A of this Report, under the caption “Risk Factors”, that could cause our actual results to differ materially from those in the forward-looking statements. We undertake no obligation to publicly release any revisions to the forward-looking statements or reflect events or circumstances after the date of this document. The risks discussed in this report should be considered in evaluating our prospects and future financial performance.

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

Our Management’s Discussion and Analysis of Financial Condition and Results of Operations (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:

- 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 2010.
- 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 six months ended June 30, 2010 to the comparable periods of 2009.
- Liquidity and Capital Resources-- An analysis of changes in our balance sheet and cash flows and discussion of our financial condition and future liquidity needs.

The various sections of this MD&A contain a number of forward-looking statements. Words such as “expects,” “goals,” “plans,” “believes,” “continues,” “may,” and variations of such words and similar expressions are intended to identify such forward-looking statements. In addition, any statements that refer to projections of our future financial performance, our anticipated growth and trends in our businesses, and other characterizations of future events or circumstances are forward-looking statements. Such statements are based on our current expectations and could be affected by the uncertainties and risk factors described throughout this filing and particularly in the “Overview” and “Trends & Outlook” section (see also “Risk Factors” in Part II, Item 1A of this Quarterly Report). Our actual results may differ materially.

Overview

We are focused on the development and commercialization of treatments based on transplanting human neural stem cells and small molecule compounds.

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 four (4) issued patents and twelve (12) patent pending applications in the field of regenerative medicine and related technologies. 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. We are headquartered in Rockville, Maryland.

In addition to our core tissue based technology, we have begun developing neurogenic and neuroprotective Small-Molecule compounds. The patent, covering what we believe to be a new class of drug, was issued on June 10, 2009.

Clinical Trial

On December 18, 2008 we filed our first Investigational New Drug Application (“IND”) with the U.S. Food and Drug Administration (“FDA”) to begin a clinical trial to treat Amyotrophic Lateral Sclerosis (“ALS” or “Lou Gehrig’s disease”). On September 21, 2009, the FDA approved our IND. The first patient in our study was dosed on January 21, 2010 at Emory University in Atlanta Georgia. In May we announced that, after reviewing the safety data from the first cohort of three patients, the Safety Monitoring Board has approved moving to the next cohort and transplantation of the fourth patient. The first cohort of patients received five injections of the Company's spinal cord stem cells on one side of the spinal cord. The second cohort of three patients will receive ten injections, five on each side of the cord.

The trial will ultimately consist of up to 18 ALS patients, who will be examined at regular intervals post-surgery, with final review of the data to come six months after the last patient is treated. To date, we have begun the treatment of 5 patients. It is still too early in the trials 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. Our two issued core patents entitled: (i) Isolation, Propagation, and Directed Differentiation of Stem Cells from Embryonic and Adult Central Nervous System of Mammals; and (ii) In Vitro Generation of Differentiated Neurons from Cultures of Mammalian Multipotential CNS Stem Cell contain claims which cover the process of deriving the cells as well as the cells created from this process.

What differentiates our stem cell technology from others is that our patented processes do not require us to direct our cells towards a certain fate by adding specific growth factors. Our cells actually “become” the type of cell they are fated to be. This process and the resulting cells comprise a technology platform that allows for the efficient isolation and production, in commercially reasonable quantities, of neural stem cells from the human brain and spinal cord.

To date we have focused our 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 commenced Phase I trials with regard to ALS.

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. The treatment for spinal cord injury will, however, likely only involve a few injections as opposed to the fifteen injection dosage that is ultimately planned for the ALS trial. We, therefore, 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. We expect to file an Investigational New Drug application with the FDA this year to begin a Phase I clinical trial for Chronic Spinal Cord Injury, in what will most likely be a multi-site study in the U.S.

Small-molecule Compounds

We have performed tests on cultured neural stem cells as well as in animal models in order to validate the performance of small molecule compounds for hippocampal neurogenesis. As a result of those tests, we feel that our small molecule compound may have an application with regard to the treatment of depression. We expect to file an IND to commence human safety trials of our lead small molecule compound to treat major depression in early 2011. In anticipation of filing the IND, we have contracted for a production run of our compound using Good Manufacturing Practice (“GMP”) methods which will be large enough to complete safety testing and Phase I clinical trials.

In June of 2009, we received a notice of allowance from the U.S. Patent and Trademark Office (“USPTO”) for a patent covering these compounds. Patent application 12/049,922, entitled “Use of Fused Nicotinamides to Promote Neurogenesis,” claims four chemical entities and any pharmaceutical composition including them.

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 employ an outsourcing strategy where we outsource all of our Good Laboratory Practices (“GLP”) preclinical development activities and GMP manufacturing and clinical development activities to contract research organizations (“CRO”) and contract manufacturing organizations (“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 eliminates non-vital expenditures. It also allows for us to operate with relatively fewer employees and lower fixed costs than that required by our competitors.

Employees

As of June 30, 2010, we had 9 full-time employees and 11 full time independent contractors. Of these employees, 4 work on research and development and 5 in administration. We also use the services of numerous outside consultants in business and scientific matters.

Trends & Outlook

Revenue

We had no revenue for the year ended December 31, 2009 and three and six month periods ended June 30, 2010. Our focus is now on initiating and successfully managing the clinical trial for ALS commenced earlier this year. We are also pursuing pre-clinical studies on other central nervous system indications in preparation for additional clinical trials. We are not focused at this time on generating revenues.

Long-term, we anticipate 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 & Development Expenses

Our research and development costs consist of expenses incurred in identifying, developing and testing treatments for central nervous system diseases. These expenses consist primarily of salaries and related expenses for personnel, fees paid to professional service providers and academic collaborators for research, testing, contract manufacturing, costs of facilities, and the preparation of regulatory applications and reports.

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

We expect that research and development expenses will increase in the future, as funding allows. 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 also begun the process of forming a wholly owned subsidiary in the People's Republic of China. We anticipate the formation will be complete during the third quarter of 2010. This subsidiary will primarily conduct research with regard to stem cells.

Stem Cells

Our top development priority is our ongoing clinical trial for ALS at Emory University in Atlanta. We estimate that the Phase I trial for ALS will require 12 to 18 patients at an estimated cost of \$130,000 per patient. The per patient cost includes the costs of the operation to administer our spinal cord cells, post operation treatment for the patient, Emory University's charges for running the trial and third party trial monitoring and data collection. Our spending on an individual patient will be spread over the life of the trial as the majority of our costs are incurred after the patient has been operated on. We expect trial spending to gradually decrease to \$100,000 per month after a number of patients have been treated. To date, we have enrolled and begun treatment on 5 patients.

In addition to our Phase I trials, we will continue working on proof of principle testing, dosing rationale, and the development of clinical protocols for our most promising indications. We intend to submit IND applications to the FDA for our most promising treatment candidates. We expect to submit an IND application for the treatment of Spinal Cord Injury in 2010. It is still too early to determine the costs and expenses associated with such trial in the event our IND is approved by the FDA.

Small Molecule Compounds

We believe we have successfully demonstrated proof of principle to support advancement of our lead small molecule compound for the treatment of depression. We have completed planning for toxicology, tumorigenicity, dosing rationale, and development of the clinical protocol. If the remaining preclinical testing results are successful, we will file an IND. We hope to begin clinical trials for this indication in early 2011. It is still too early to determine the costs and expenses associated with such trial in the event our IND is approved by the FDA.

General and Administrative Expenses

Our general and administrative ("G&A") expenses consist of the general costs, expenses and salaries for the operation and maintenance of our business. We anticipate that general and administrative expenses will increase as we progress from a pre-clinical to clinical phase of development.

We anticipate that as a result of our outsource model, our G&A expenses related to our core business will increase at a slower rate than that of similar companies.

Critical Accounting Policies

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. 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 Financial Statements 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 accounting principles generally accepted in the United States, 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 financial statements:

Use of Estimates—Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States and, accordingly, require management 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, our management has estimated the expected economic life and value of our licensed technology, our net operating loss for tax purposes and our stock option and warrant expenses related to compensation to employees and directors, consultants and investment banks. Actual results could differ from those estimates.

Revenue Recognition—We had no revenues for the year ended December 31, 2009 and the three and six months ended June 30, 2010 and 2009. Our revenues, to date, have been derived primarily from providing treated samples for gene expression data from stem cell experiments and from providing services as a subcontractor under federal grant programs. 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 follow FASB guidelines related to the accounting for impairment of long-lived assets, which established 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 six months ended June 30, 2010 and 2009, no impairment losses were recognized.

Accounting for Warrants – We have adopted FASB guidance related to determining whether an instrument or embedded feature is indexed to an entity's own stock. This guidance applies to any freestanding financial instruments or embedded features that have the characteristics of a derivative, as defined by the FASB, and to any freestanding financial instruments that are potentially settled in an entity's own common stock. As a result, certain of our warrants are considered to be derivatives and must be valued using various assumptions as they are recorded as liabilities.

Research and Development Costs—Research and development costs consist of expenditures for the research and development of patents and technology, 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.

Stock Based Compensation—The Company accounts for equity instruments issued to non-employees in accordance with guidance issued by FASB. Accordingly, the estimated fair value of the equity instrument is recorded on the earlier of the performance commitment date or the date the services required are completed.

We adopted the guidance issued by the FASB related to share based payments. This guidance requires compensation costs related to share-based payment transactions to be recognized in the financial statements.

RESULTS OF OPERATIONS

Second Quarter of 2010 Compared to the Second Quarter of 2009

	Three Months Ended June 30,	
	2010	2009
Revenues	\$ -	\$ -
Operating expenses	4,195,091	2,724,164
Operating loss	(4,195,091)	(2,724,164)
Non-operating (expense)	(756,249)	(465,283)
Net loss	\$ (4,951,340)	\$ (3,189,447)

For the second quarter of 2010, the Company reported a net loss of \$4,951,340, or \$0.12 per share, compared to a net loss of \$3,189,447, or \$0.09 per share, for the three month period ended June 30, 2010 and 2009, respectively. The increase in net loss from year to year was due to increases in non cash stock-based compensation expense, and increases in R&D and legal fees.

Our results of operations have varied significantly from year to year and quarter to quarter and may vary significantly in the future.

Revenue

We did not have revenues for the three months ended June 30, 2010 and 2009. We do not anticipate any revenues for 2010.

Operating Expenses

Operating expenses totaled \$4,195,091 and \$2,724,164 for the three months ended June 30, 2010 and 2009, respectively.

	Three Months Ended June 30,	
	2010	2009
Operating Expenses:		
Research & development	\$ 2,613,676	\$ 1,452,793
General, selling & administrative expense	1,550,814	1,249,947
Depreciation and amortization	30,601	21,424
Total expense	\$ 4,195,091	\$ 2,724,164

Research and Development Expenses

Research and development expenses totaled \$2,613,676 and \$1,452,793 for the three months ended June 30, 2010 and 2009, respectively. The increase of \$1,160,883 or 80% for the three months ended June 30, 2010 compared to the same period in 2009 was primarily attributable to costs associated with the continuing ALS clinical trials initiated in

January of 2010.

General and Administrative Expenses

G&A expenses totaled \$1,550,814 and \$1,249,947 for the three months ended June 30, 2010 and 2009, respectively. The increase of \$300,867 or 24% for the three months ended June 30, 2010 compared to the same period in 2009, was primarily attributable to increased legal expenses and increased share based expenses.

Depreciation and Amortization

Depreciation and amortization expenses totaled \$30,601 and \$21,424 for the three months ended June 30, 2010 and 2009, respectively. The increase of \$9,177 or 43% for the three months ended June 30, 2010 compared to the same period in 2009 was primarily attributable to fixed asset and patent filing fee additions over the quarter.

18

Nonoperating (expense) income

Nonoperating expense totaled \$756,249 and \$465,283 for the three months ended June 30, 2010 and 2009, respectively. The increase in nonoperating expense was due to expenses associated with the Company's warrant accounting.

	Three Months Ended June 30,	
	2010	2009
Nonoperating (expense) income:		
Interest income	\$ 9,653	\$ 8,516
Interest expense	(1,462)	-
Warrant issuance and modification expense	-	-
Loss on change in fair value of warrant obligations	(764,440)	(473,799)
Total nonoperating (expense)	\$ (756,249)	\$ (465,283)

Interest income totaled \$9,653 and \$8,516 for the three months ended June 30, 2010 and 2009 respectively. The increase for the three months ended June 30, 2010 compared to the same period in 2009 was attributable to higher cash balances and slightly higher interest rates.

(Loss) gain from change in fair value of warrant obligations

On January 1, 2009 we reclassified the fair value of common stock purchase warrants, which have exercise price reset and anti-liquidation features, from equity to liability status as if these warrants were treated as a derivative liability since their date of issue. We established a long-term warrant liability of \$6.6 million to recognize the fair value of such warrants. In the three months ended June 30, 2009, the fair value of these common stock purchase warrants decreased/increased because of a decrease/increase in the stock price, resulting in a gain for the quarter. In the second quarter of 2010, ended June 30, 2010, we redeemed 45,713 of the warrants outstanding at the beginning of the period which had price protection features. These changes removed the price protection features. These changes reduced our derivative liability by \$73,239 at June 30, 2010. An increase in stock price resulted in an expense for the three month period of \$764,440 on the remaining outstanding warrants, and a liability of \$2,189,064 for the Company at June 30, 2010.

First Half of 2010 Compared to the First Half Quarter of 2009

	Six Months Ended June 30,	
	2010	2009
Revenues	\$ -	\$ -
Operating expenses	7,811,952	5,636,208
Operating loss	(7,811,952)	(5,636,208)
Non-operating income (expense)	(3,906,349)	3,352,439
Net income (loss)	\$ (11,718,301)	\$ (2,283,769)

For the first six months of 2010, the company reported a net loss of \$11,718,301 or \$0.29 per share, compared to a net loss of \$2,283,769, or \$0.07 per share, for the six months ended June 30, 2009. The increase in net loss from year to year was due to increases in non cash stock-based compensation expense, and increases in R&D and legal fees offset by a non-cash gain related to our warrant accounting for the first quarter 2009.

Our results of operations have varied significantly from year to year and quarter to quarter and may vary significantly in the future.

Revenue

We did not have revenues for the six months ended June 30, 2010 and 2009. We do not anticipate any revenues for 2010.

Operating Expenses

Operating expenses totaled \$7,811,952 and \$5,636,208 for the six months ended June 30, 2010 and 2009, respectively.

	Six Months Ended June 30,	
	2010	2009
Operating Expenses		
Research & development	\$ 4,513,640	\$ 2,886,802
General, selling & administrative expense	3,238,649	2,707,186
Depreciation and amortization	59,663	42,220
Total expense	\$ 7,811,952	\$ 5,636,208

Research and Development Expenses

Research and development expenses totaled \$4,513,640 and \$2,886,802 for the six months ended June 30, 2010 and 2009, respectively. The increase of \$1,626,838 or 56% for the six months ended June 30, 2010 compared to the same period in 2009 was primarily attributable to costs associated with the continuing ALS clinical trials initiated in January of 2010.

General and Administrative Expenses

G&A expenses totaled \$3,238,649 and \$2,707,186 for the six months ended June 30, 2010 and 2009, respectively. The increase of \$531,463 or 20% for the six months ended June 30, 2010 compared to the same period in 2009, was primarily attributable to increased legal expenses and share based compensation.

Depreciation and Amortization

Depreciation and amortization expenses totaled \$59,663 and \$42,220 for the six months ended June 30, 2010 and 2009, respectively. The increase of \$17,443 or 41% for the six months ended June 30, 2010 compared to the same period in 2009 was primarily attributable to fixed asset and patent filing fee additions over the period.

Nonoperating (expense) income

Nonoperating (expense) income totaled (\$3,906,349) and \$3,352,439 for the six months ended June 30, 2010 and 2009, respectively. The increase in nonoperating expense was due to expenses associated with the Company's warrant accounting.

	Six Months Ended June 30,	
	2010	2009
Nonoperating (expense) income:		
Interest income	\$ 15,463	\$ 10,780
Interest expense	(2,120)	-
Warrant issuance and modification expense	(1,906,800)	-
(Loss) Gain on change in fair value of warrant obligations	(2,012,892)	3,341,659
Total nonoperating (expense) income	\$ (3,906,349)	\$ 3,352,439

Interest income totaled \$15,463 and \$10,780 for the six months ended June 30, 2010 and 2009 respectively. The increase for the six months ended June 30, 2010 compared to the same period in 2009 was attributable to higher cash balances and slightly higher interest rates.

(Loss) gain from change in fair value of warrant obligations

On January 1, 2009 we reclassified the fair value of common stock purchase warrants, which have exercise price reset and anti-liquidation features, from equity to liability status as if these warrants were treated as a derivative liability since their date of issue. We established a long-term warrant liability of \$6.6 million to recognize the fair value of such warrants. In the six months ended June 30, 2009, the fair value of these common stock purchase warrants decreased. In the first half of 2010, ended June 30, 2010, we converted, redeemed or modified more than 80% of the warrants outstanding at the beginning of the year which had price protection features. These changes removed the price protection features. These changes reduced the Company's derivative liability from \$6,462,039 at December 31, 2009 to \$2,189,064 at June 30, 2010. An increase in the Company's stock price resulted in an expense for the period of \$2,012,892 on the remaining outstanding warrants.

Liquidity and Capital Resources

Since our inception, we have financed our operations through the sale of our securities, the exercise of investor warrants, and to a lesser degree from grants. Our currently monthly cash burn rate is \$900,000. We estimate that we will have sufficient cash and cash equivalents to finance our current operations, pre-clinical and clinical work for at least 12 months from June 30, 2010. We cannot assure you that public or private financing or grants will be available on acceptable terms, if at all. 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.

Six Months Ended
June 30,

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

	2010	2009
Cash and cash equivalents	\$ 14,025,745	\$ 3,218,321
Net cash used in operating activities	\$ (4,878,730)	\$ (2,528,277)
Net cash used in investing activities	\$ (118,884)	\$ (60,072)
Net cash provided by financing activities	\$ 16,713,585	\$ 903,391

21

Total cash and cash equivalents was \$14,025,745 and \$3,218,321 on June 30, 2010 and 2009 respectively. The increase in our cash and cash equivalents of \$10,807,424 or 336% for the six months ended June 30, 2010 compared to the same period in 2009 was primarily attributable to the exercise of outstanding warrants and the registered offering of our securities during the six months ending June 30, 2010 resulting in net proceeds to us of approximately \$16.7 million.

Net Cash Used in Operating Activities

We used \$4,878,730 and \$2,528,276 of cash in our operating activities for the six months ended June 30, 2010 and 2009, respectively. The increase in our cash used of \$2,350,453 or 93% for the six months ended June 30, 2010 compared to the same period in 2009 was primarily attributed to the initiation of our clinical trials and increase in legal expenses.

Net Cash Used in Investing Activities

We used \$118,884 and \$60,072 of cash in connection with investment activities for the six months ended June 30, 2010 and 2009, respectively. The increase in our use of cash of \$58,812 or 98% for the six months ended June 30, 2010 compared to the same period in 2009 was primarily attributed to the purchase of equipment in the first half of the year, as well as additional patents work.

Net Cash Provided by Financing Activities

We raised \$16,713,585 and \$903,391 in net proceeds from the issuance of our securities during the six months ended June 30, 2010 and 2009.

Listed below are key financing transactions entered into by us during the first half of 2010:

- On January 29, 2010, we received gross proceeds of \$1,000,000 as a result of the exercise of 800,000 \$1.25 Series D warrant exercises. We issued the holder of the D warrants 400,000 additional warrants with an exercise price of \$1.85 in conjunction with the exercise. The new warrants have a life of one year.
 - In February of 2010, we called our \$1.25 Series B Warrants. Gross exercise proceeds totaled \$2,492,345.
- In the period January through March 2010, several Series A warrant holders exercised 231,763 warrants to purchase our common stock for \$1.25 per share. Total gross proceeds were \$289,704.
- In March of 2010, holders of 2,699,400 Series C warrants exercised their option to purchase our common stock for 1.25 per share. Gross proceeds totaled \$3,374,250. We issued the holders of the exercised C Warrants 2,699,400 additional warrants with an exercise price of \$2.13 and a life of 5 years in conjunction with the exercise.
- The holder of 782,005 \$1.10 placement agent warrants exercised them in March of 2010. Gross consideration totaled \$860,205. We issued the holder of the exercised placement agent warrants 782,005 additional warrants with an exercise price of \$2.13 and a life of 5 years in conjunction with the exercise.
- In June of 2010, we sold approximately 3,571,436 units, through a registered direct offering. Each unit consists of one common share and 0.75 common share purchase warrant. Each unit was sold for \$2.80. Each warrant has an exercise price of \$3.25 per share, and is exercisable for a period of three years. As a result of the offering, we received gross proceeds of approximately \$10 million.
-

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

In the period April through June 2010, several Series A warrant holders exercised 45,713 warrants to purchase our common stock for \$1.25 per share. Total gross proceeds were \$57,141.

Call of Series B Warrants

During the first quarter of 2006, we issued an aggregate of 2,019,231 Series B warrants in connection with a private placement of our securities. The Series B warrants contained a call provision allowing us to redeem the warrants for \$.01 per warrant share, upon 30 days notice, provided the following two conditions were met: (a) we receive approval of our IND, and (b) a registration statement covering the resale of the warrant shares shall be effective. In September of 2009, we met the conditions of the call and as a result, we elected to exercise the call feature in February of 2010. As a result, Series B warrant holders exercised their respective warrants which resulted in us issuing 1,993,876 common shares and receiving gross proceeds in the amount of \$2,492,345.

Future Liquidity & 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. As a result of our June 2010 registered direct offering, we have exhausted our availability under our shelf registration statement which was declared effective on September 29, 2008. Accordingly, we anticipate filing another shelf registration statement in the future in order to take advantage of financing opportunities if and when they 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 and CFO), as of the end of the period covered by this report, our CEO and CFO have 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 were no changes to our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II
OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

As of the date of this 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 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. Discovery has commenced and 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 limited operating history and have significantly shifted our operations and strategies since inception.

Since inception in 1996 and through June 30, 2010, we have raised \$89,808,035 of capital and recorded accumulated losses totaling \$79,285,132. On June 30, 2010, we had a working capital surplus of \$10,376,040 and stockholders’ equity of \$10,982,983. Our net losses for the two most recent fiscal years have been \$10,364,363 and \$11,830,798 for 2009 and 2008 respectively. We had no revenues for the twelve months ended December 31, 2009 or the six months

ended June 30, 2010.

Our ability to generate revenues and achieve profitability will depend upon our ability to complete the development of our proposed stem cell products, obtain the required regulatory approvals, manufacture, and market and sell our proposed products. In part because of our past operating results, no assurances can be given that we will be able to accomplish any of these goals.

Although we have generated some revenue in prior years, we have not generated any revenue from the commercial sale of our proposed stem cell products. Since inception, we have engaged in several related lines of business and have discontinued operations in certain areas. For example, in 2002, we lost a material contract with the Department of Defense and were forced to close our principal facility and lay off almost all of our employees in an attempt to focus our development strategy on stem cell technologies. This limited and changing history may not be adequate to enable you to fully assess our future prospects. 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 material revenues from our proposed products

24

We will need to raise additional capital to continue operations.

Since inception, we have relied almost entirely on external financing to fund operations. Such financing has come primarily from the sale of our securities and the exercise of investor warrants. As of June 30, 2010, we had cash and cash equivalents on hand of \$14,025,745. Presently, we have a monthly cash burn rate of approximately \$900,000. We will need to raise additional capital to fund anticipated operating expenses and future expansion. Among other things, external financing will be required to further develop our technologies and products, as well as to pay general operating costs. On January 21, 2010 we dosed our first patient in our Phase I clinical trials for ALS. As a result of these trials, we may need additional capital in order to pay for expenses associated with our clinical trials.

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.

Additional financing requirements could result in dilution to existing stockholders.

We are not able to finance our operations by generating revenue. Accordingly, we will be required to issue our securities in order to secure additional financing. The issuance of additional securities may be dilutive to current shareholders. We are authorized to issue 150,000,000 shares of common stock and 7,000,000 shares of preferred stock. Such securities may generally be issued without the approval or consent of our stockholders. The issuance of such securities may result in substantial dilution.

Risks Relating to Our Business

Our business is dependent on a single product candidate.

At present our ability to progress as a company is significantly dependent on a single product candidate for ALS which is 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 cellular technologies. Moreover, any material adverse occurrence in our first clinical trials could substantially impair our ability to initiate clinical trials to test our stem cell therapies 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 stem cell technologies that we may not be able to commercially develop.

We have concentrated the majority of our research on stem cell 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 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. If we are unable to develop our technologies, we may never realize any 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 these therapies 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.

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

On September 21, 2009, we received approval from the FDA for our first IND application. We commenced the trials on January 21, 2010, with the dosing of our first patient. As of June 30, 2010, we have dosed 5 patients. Although we have commenced the trials, the 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 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, we will be required to demonstrate through 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 sufficient revenues to become profitable, and our operations could be materially harmed.

There are no assurances that we will be able to submit or obtain FDA approval of a biologics license application.

There can be no assurance that even if the clinical trials of any potential product candidate are successfully initiated and completed, that we will be able to submit a Biologics License Application (“BLA”) to the FDA or that any BLA we submit will be approved in a timely manner, if at all. If we are unable to submit a BLA with respect to any future product candidate, or if any BLA we submit is not approved by the FDA, we will be unable to commercialize that product. The FDA can and does reject BLAs and requires 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 it. 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. At present, the litigation is in its initial stages and any likely outcome is difficult to predict.

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 United States or 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 health care 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, 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 health care 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 health care 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 anytime. The loss of any of these key employee or consultant 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 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 November 1, 2012. In the event either individual is terminated prior to the full term of their respective contracts, for any reason other than a voluntary resignation, all compensation due to such employee under the terms of the respective agreement shall become due and payable immediately. These provisions will make the replacement of either of these employees very costly and could cause difficulty in effecting a change in control. Termination prior to the full term of these contracts would cost us as much as \$1,000,000 per contract and the immediate vesting of all outstanding options and/or warrants held by Messrs. Garr and Johe.

Our competition has significantly greater experience and financial resources.

The biotechnology industry is characterized by intense competition. We compete against numerous companies, many of which have substantially greater resources. Several such enterprises have initiated cell therapy research programs and/or efforts to treat the same diseases which we target. Although not necessarily direct competitors, companies such as Geron Corporation, Genzyme Corporation, StemCells, Inc., Advanced Cell Technology, Inc., Aastrom Biosciences, Inc. and Viacell, Inc., as well as others, may have substantially greater resources and experience in our fields which put us at a competitive disadvantage.

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 development, manufacturing and commercialization of cell-based therapeutic products expose us to product liability claims.

By developing and, ultimately, commercializing medical products, we are exposed to the risk of product liability claims. Product liability claims against us could result in substantial litigation costs and damage awards against us. We have obtained liability insurance that covers our clinical trials. If and when 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 intend to rely upon third-party FDA-approved manufacturers for our stem cells.

We currently have no internal manufacturing capability, and will rely extensively on FDA-approved licensees, strategic partners or third party contract manufacturers or suppliers. Should we be forced to manufacture our stem cells, 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.

Risks Relating to Our Common Stock

Our common shares are sporadically or “thinly” traded.

Our common shares have historically been sporadically or “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. This situation 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. Even if we came to the attention of such persons, they tend to be risk-adverse and would be reluctant to follow an unproven development stage company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without a material reduction in share price. We cannot give you any assurance that a broader or more active trading market for our common shares will develop or be sustained, or that current trading levels will be sustained. Due to these conditions, we can give you no assurance that you will 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. First, there is limited liquidity in the market for our common shares. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by our shareholders may disproportionately influence the price of those shares in either direction. The price for our shares could, for example, decline precipitously in the event that a large number of our common shares are sold on the market without commensurate demand. Secondly, 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-averse investors may, under the fear of losing all or most of their investment in the event of negative news or lack of progress, be more inclined to sell their shares on the market more quickly and at greater discounts than would be the case with the stock of a seasoned issuer. Additionally, in the past, plaintiffs have often initiated securities class action litigation against a company following periods of volatility in the market price of its securities. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs and liabilities and could divert management’s attention and resources.

The following factors may add to the volatility in the price of our common shares: actual or anticipated variations in our quarterly or annual operating results; government regulations; announcements of significant acquisitions, strategic partnerships or joint ventures; our capital commitments; 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 new 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 new 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”), will materially increase the Company’s legal and financial compliance costs and make some activities more time-consuming, burdensome and expensive. Since the enactment the Sarbanes-Oxley Act, we have been classified as a smaller reporting company and as a result, we have been exempt from Section 404(b). As of June 30, 2010, the market value of our securities exceeded the threshold for a smaller reporting company. As a result, commencing in 2011, we will be subject to Section 404(b). We anticipate this will further increase the costs associated with our compliance with the Sarbanes-Oxley Act of 2002.

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.

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.

Issuance of additional securities could dilute your proportionate ownership and voting rights.

We are entitled under our amended and restated certificate of incorporation to issue up to 150,000,000 common and 7,000,000 “blank check” preferred shares. As of June 30, 2010, we have issued and outstanding 46,008,024 common shares, 25,442,787 common shares reserved for issuance upon the exercise of current outstanding options, warrants and convertible securities, 319,341 common shares reserved for issuance of additional grants under our 2005 incentive stock plan, 534,525 shares reserved for issuance of grants under our 2007 stock plan, and 7,000,000 shares reserved for issuance of grants under our 2010 stock plan. Accordingly, we will be entitled to issue up to 70,695,323 additional common shares and 7,000,000 additional preferred shares. Our board may generally issue those common and preferred shares, or options or warrants to purchase those shares, or securities convertible into those shares, without further approval by our shareholders based upon such factors as our board of directors may deem relevant at that time. Any preferred shares we may issue shall 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 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 option plans, in order to attract and retain qualified personnel. In the event of issuance, your proportionate ownership and voting rights may be significantly decreased and the value of your investment impacted.

Risks Relating to Intellectual Property and Government Regulation

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 in its initial stages and any likely outcome is difficult to predict.

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 United States including through our subsidiary, currently being formed, in the Peoples 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.

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 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. On January 21, 2010 we commenced our Phase I clinical trials for ALS with the dosing of our first patient. As of June 30, 2010, we have dosed 5 patients in the study. We cannot assure you that we will

successfully complete any clinical trials in connection with such IND. Further, we cannot predict when we might first submit any product license application 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 United States 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 United States (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.

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

The following information is given with regard to unregistered securities sold during the period covered by this report. The unregistered securities were issued pursuant to section 4(2) of the Securities Act:

- On January 8, 2010, pursuant to a consulting agreement for investor relations and business development services, we issued Market Development Consulting Group, Inc.: (i) 140,000 common shares; and (ii) a common stock purchase warrant entitling the holder to purchase 400,000 shares of common stock at \$1.70 per share. The warrant is exercisable immediately, shall expire on December 31, 2019, and is freely assignable in whole or in part. We also agreed to register the shares underlying the warrant for resale.
- On January 15, 2010, we issued a consultant options to purchase an aggregate of 45,000 common shares at \$2.40 per share. The options vest as follows: (i) 25,000 upon grant; and (ii) 20,000 on December 31, 2010. The options have a term of 5 years.
-

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

On January 15, 2010, we issued a consultant options to purchase an aggregate of 100,000 common shares at \$2.40 per share. The options are 100% vested upon grant and have a term of 7 years.

- On January 29, 2010, as an inducement to exercise 800,000 Series D Warrants, we issued Vicis Capital Master Fund a replacement warrant. As a result of the exercise, we received gross proceeds in the amount of \$1,000,000. The replacement warrant entitles the holder to purchase 400,000 common shares at price of \$1.85 per share. The warrant has a term of 1 year.
- In March of 2010, in connection with the exercise of 2,699,400 Series C Warrants, we issued the prior warrant holders an aggregate of 2,699,400 replacement warrants. As a result of the exercise, we received gross proceeds in the amount of \$3,374,250. The replacement warrant is substantially the same as the prior Series C warrants except that: (i) the exercise price is \$2.13; (ii) the replacement warrants expire 5 years from the date they were issued; (iii) is callable by the company in the event our common stock trades above \$5.00 and certain other conditions are met, and (iv) the replacement warrants do not provide for any anti-dilution rights.

- In March of 2010, in connection with the exercise of 782,005 placement agent warrants, we issued T.R. Winston & Company, LLC, a replacement warrant to purchase 782,005. As a result of the exercise, we received gross proceeds in the amount of \$860,205. The replacement warrant is substantially the same as the prior warrants issued to our Series C Warrant holders except that: (i) the exercise price is \$2.13; (ii) the replacement warrants expire 5 years from the date they were issued; and (iii) the replacement warrants do not provide for any anti-dilution rights.
- In March of 2010, we amended 706,752 placement agent warrants held by TR Winston & Company, LLC. Pursuant to the amendment, we agreed to extend the expiration date of the placement agent warrants from March 15, 2012 to March 15, 2014 in exchange for the removal of the anti-dilution provisions from said warrants. We did not receive any additional consideration in connection with the amendment.
- In June of 2010, we issued Noble International Investment, Inc., D/B/A Noble Financial Capital Markets a warrant to purchase 250,001 common shares. The warrant was issued as compensation for placement agent services which Noble International Investments, Inc., performed in connection with our \$10 million registered direct offering of units. The warrant is substantially the same as the investor warrant issued in the offering and has: (i) an exercise price of \$3.25, and (ii) a term of three years.

ITEM 3. DEFAULT UPON SENIOR SECURITIES

None

ITEM 4. (REMOVED AND RESERVED)

None

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.

32

SIGNATURES

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

NEURALSTEM, INC.

Date: August 16, 2010

/s/ I. Richard Garr
Chief Executive Officer

/s/ John Conron
Chief Financial Officer
(Principal Accounting Officer)

INDEX TO EXHIBITS

Exhibit No.	Description	Filed		Incorporated by Reference		Filing Date
		Herewith	Form	Exhibit No.	File No.	
1.01	Form of Placement Agent Agreement dated June 28, 2010		8-K	1.01	001-33672	6/29/10
1.02	Form of Amendment to Placement Agent Agreement dated June 28, 2010		8-K	1.02	001-33672	6/29/10
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 July 16, 2007		10-QSB	3.2(i)	333-132923	8/14/07
4.01**	Amended and Restated 2005 Stock Plan adopted on June 28, 2007		10-QSB	4.2(i)	333-132923	8/14/07
4.02**	Non-qualified Stock Option Agreement between Neuralstem, Inc. and Richard Garr dated July 28, 2005		SB-2	4.4	333-132923	6/21/06
4.03**	Non-qualified Stock Option Agreement between Neuralstem, Inc. and Karl Johe dated July 28, 2005		SB-2	4.5	333-132923	6/21/06
4.04	Private Placement Memorandum for March 2006 offering		SB-2	4.12	333-132923	6/21/06
4.05	Form of Placement Agent Warrant issued in connection with the March 2006 offering		SB-2	4.13	333-132923	6/21/06
4.06	Form of Series A Warrant (\$1.50) issued in connection		SB-2	4.14	333-132923	6/21/06

with the March 2006 offering

4.07	Form of Series B Warrant (\$2.00) issued in connection with the March 2006 offering	SB-2	4.15	333-132923	6/21/06
4.08	Form of Subscription Agreement for March 2006 offering	SB-2	4.16	333-132923	7/26/06
4.09	Form of Securities Purchase Agreement dated March 15, 2007	8-K	4.1	333-132923	3/16/07
4.10	Form of Common Stock Purchase Warrant dated March 15, 2007 (Series C)	8-K	4.2	333-132923	3/16/07

34

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

4.11	Form of Registration Rights Agreement dated March 15, 2007	8-K	4.3	333-132923	3/16/07
4.12**	Neuralstem, Inc. 2007 Stock Plan	10-QSB	4.21	333-132923	8/14/07
4.13	Form of Common Stock Purchase Warrant Issued to Karl Johe on June 5, 2007	10-KSB	4.22	333-132923	3/27/08
4.14	Form of Registration Rights Agreement entered into on February 19, 2008 between the Company and CJ CheilJedang Corporation	8-K	10.20	001-33672	2/25/08
4.15	Form of Placement Agent Warrant Issued to Midtown Partners & Company on December 18, 2008	8-K	4.1	001-33672	12/18/08
4.16	Form of Consultant Common Stock Purchase Warrant issued on January 5, 2009	S-3/A	10.1	333-157079	02/3/09
4.17	Form of Series D, E and F Warrants	8-K	4.01	001-33672	7/1/09
4.18	Form of Placement Agent Warrant	8-K	4.02	001-33672	7/1/09
4.19	Form of December 29, 2009 Securities Purchase Agreement	10-K	4.19	001-33672	3/31/10
4.20	Form of Consultant Warrant Issued January 8, 2010	10-K	4.20	001-33672	3/31/10
4.21	Form of Replacement Warrant Issued January 29, 2010	10-K	4.21	001-33672	3/31/10
4.22	Form of Replacement Warrant Issued March of 2010	10-K	4.22	001-33672	3/31/10
4.23	Form of employee and consultant option grant	10-K	4.23	001-33672	3/31/10
4.24	Form of Warrants dated June 29, 2010	8-K	4.01	001-33672	6/29/10
4.25**	Neuralstem 2010 Equity Compensation Plan	8-K	10.01	001-33672	7/14/10
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

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

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	10.1	333-132923	6/21/06

35

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

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	Form of Securities Purchase Agreement dated June 29, 2010	8-K	10.01	001-33672	6/29/10
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				*

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