

Neuralstem, Inc.
Form 10-Q
November 16, 2009

U.S. SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark one)

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

For the Quarterly Period Ended September 30, 2009

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,

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

or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

As of October 5, 2009 there were 34,829,234 shares of common stock, \$.01 par value, issued and outstanding.

Neuralstem, Inc.

Table of Contents

	Page
PART FINANCIAL INFORMATION	4
I -	
Item 1. Financial Statements	4
Balance Sheets as of September 30, 2009 (Unaudited) and December 31, 2008	4
Statements of Operations (Unaudited) Three months ended September 30, 2009 and 2008 and nine months ended September 30, 2009 and 2008	5
Statements of Cash Flows (Unaudited) nine months ended September 30, 2009 and 2008	6
Statements of Changes in Stockholders' Equity (Deficit) (Unaudited) For the period from January 1, 2009 through September 30, 2009	7
Notes to Unaudited Financial Statements	8
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	14
Item 3. Quantitative and Qualitative Disclosures about Market Risk	21
Item 4. Controls and Procedures	21
PART OTHER INFORMATION	22
II	
Item 1. Legal Proceedings	22
Item 1A. Risk Factors	22
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	31
Item 3. Defaults Upon Senior Securities	31
Item 4. Submission of Matters to a Vote of Security Holders.	31
Item 5. Other Information	31

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" refer to Neuralstem, Inc. Also, any reference to "common shares" or "common stock" refers to our \$.01 par value common stock. The information contained herein is current as of the date of this Quarterly Report (September 30, 2009), unless another date is specified.

We prepare our interim financial statements in accordance with United States generally accepted accounting principles ("GAAP"). Our financials and results of operation for the three and nine month period ended September 30, 2009 are not necessarily indicative of our prospective financial condition and results of operations for the pending full fiscal year ending December 31, 2009. 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").

FORWARD LOOKING STATEMENTS

In this Quarterly Report we make a number of statements, referred to as "forward-looking statements," within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"), which are intended to convey our expectations or predictions regarding the occurrence of possible future events or the existence of trends and factors that may impact our future plans and operating results. These forward-looking statements are derived, in part, from various assumptions and analyses we have made in the context of our current business plan and information currently available to use and in light of our experience and perceptions of historical trends, current conditions and expected future developments and other factors we believe are appropriate in the circumstances. You can generally identify forward looking statements through words and phrases such as "believe," "expect," "seek," "estimate," "anticipate," "intend," "plan," "budget," "project," "may likely result," "may be," "may" or other similar expressions.

When reading any forward-looking statement you should remain mindful that actual results or developments may vary substantially from those expected as expressed in or implied by such statement for a number of reasons or factors, including but not limited to:

- the success of our research and development activities, the development of a viable commercial production, and the speed with which regulatory authorizations and product launches may be achieved;
- whether or not a market for our proposed product develops and, if a market develops, the rate at which it develops;
- our ability to successfully sell our products once developed;
- our ability to attract and retain qualified personnel to implement our business plan and corporate strategies;
- our ability to develop sales, marketing, and distribution capabilities;
- our ability to obtain reimbursement from third party payers for the products that we intend to sell;
- our ability to fund our short-term and long-term financing needs;
- changes in our business plan and corporate strategies; and

- other risks and uncertainties discussed in greater detail in the section of this report captioned “Risk Factors”

Each forward-looking statement should be read in context with, and in understanding of, the various other disclosures concerning our company and our business made elsewhere in this report as well as our public filings with the SEC. You should not place undue reliance on any forward-looking statement as a prediction of actual results or developments. We are not obligated to update or revise any forward-looking statements contained in this report or any other filing to reflect new events or circumstances unless and to the extent required by applicable law.

PART I
FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Neuralstem, Inc.
Balance Sheets

	September 30, 2009 (Unaudited)	December 31, 2008
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 2,420,715	\$ 4,903,279
Prepaid expenses	160,204	136,287
Total current assets	2,580,919	5,039,566
Property and equipment, net	136,086	163,930
Intangible assets, net	264,342	212,265
Other assets	70,525	52,972
Total assets	\$ 3,051,872	\$ 5,468,733
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
CURRENT LIABILITIES		
Accounts payable, accrued expenses and salaries	\$ 2,353,257	\$ 1,265,488
LONG-TERM LIABILITIES		
Fair value of warrant obligations	5,622,339	-
Total liabilities	7,975,596	1,265,488
STOCKHOLDERS' (DEFICIT) EQUITY		
Preferred stock, 7,000,000 shares authorized, zero shares issued and outstanding	-	-
Common stock, \$0.01 par value; 150 million shares authorized, 34,829,234 and 33,751,300 shares outstanding in 2009 and 2008 respectively	348,292	337,513
Additional paid-in capital	59,311,203	61,352,527
Accumulated deficit	(64,583,219)	(57,486,795)
Total stockholders' (deficit) equity	(4,923,724)	4,203,245
Total liabilities and stockholders' (deficit) equity	\$ 3,051,872	\$ 5,468,733

Neuralstem, Inc.
Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Revenues	\$ -	\$ -	\$ -	\$ -
Operating expenses:				
Research and development costs	1,308,565	1,766,040	4,195,366	4,598,611
General, selling and administrative expenses	1,191,480	1,400,795	3,898,666	3,802,673
Depreciation and amortization	22,537	17,223	64,757	46,760
	2,522,582	3,184,058	8,158,789	8,448,044
Operating loss	(2,522,582)	(3,184,058)	(8,158,789)	(8,448,044)
Nonoperating (expense) income:				
Interest income	6,274	6,101	17,054	37,963
Interest expense	(194)	-	(194)	-
(Loss) gain from change in fair value of warrant obligations	(2,580,481)	-	761,178	-
	(2,574,401)	6,101	778,038	37,963
Net loss attributable to common shareholders	\$ (5,096,983)	\$ (3,177,957)	\$ (7,380,751)	\$ (8,410,081)
Net loss per share, basic and diluted	\$ (0.15)	\$ (0.10)	\$ (0.22)	\$ (0.26)
Weighted average common shares outstanding, basic and diluted	34,562,322	32,151,300	34,027,542	32,008,533

Neuralstem, Inc.
Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,	
	2009	2008
Cash flows from operating activities:		
Net loss	\$ (7,380,751)	\$ (8,410,081)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	64,757	46,760
Share based compensation expenses	3,417,790	3,469,992
Gain from change in fair value of warrant obligations	(761,178)	0
Changes in operating assets and liabilities:		
Prepaid expenses	(23,917)	(81,047)
Other assets	(17,553)	(11,175)
Accounts payable and accrued expenses	1,087,768	254,109
Net cash used in operating activities	(3,613,084)	(4,731,442)
Cash flows from investing activities:		
Acquisition of intangible assets	(75,576)	(62,247)
Purchase of property and equipment	(13,413)	(71,454)
Net cash used in investing activities	(88,989)	(133,701)
Cash flows From financing activities:		
Issuance of common stock	1,219,509	2,711,211
Net cash provided by financing activities	1,219,509	2,711,211
Net decrease in cash	(2,482,564)	(2,153,932)
Cash and cash equivalents, beginning of period	4,903,279	7,403,737
Cash and cash equivalents, end of period	\$ 2,420,715	\$ 5,249,805
Cash paid for interest	\$ 194	\$ 0

Neuralstem, Inc.
 STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
 For the period from January 1, 2009 through September 30, 2009
 (Unaudited)

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance at January 1, 2009	33,751,300	\$ 337,513	\$ 61,352,527	\$ (57,486,795)	\$ 4,203,245
Cumulative effect of reclassification of warrants to liabilities			(6,862,620)	284,327	(6,578,293)
Balance, January 1, 2009, as adjusted	33,751,300	\$ 337,513	54,489,907	(57,202,468)	(2,375,048)
Share based payment - employee compensation			3,417,790		3,417,790
Issuance of common stock through Private Placement (\$1.25 per share), net of financing costs of \$96,608.	800,000	8,000	895,391		903,391
Issuance of common stock from warrants exercised (\$1.25 per share), net of financing costs of \$31,300.	277,934	2,779	508,115		510,894
Net loss				(7,380,751)	(7,380,751)
Balance at September 30, 2009	34,829,234	\$ 348,292	\$ 59,311,203	\$ (64,583,219)	\$ (4,923,724)

NEURALSTEM, INC.
NOTES TO UNAUDITED FINANCIAL STATEMENTS

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, 2008. Further, in connection with preparation of the financial statements, the Company evaluated subsequent events after the balance sheet date through November 16, 2009. See note 6 for a discussion of subsequent events.

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 first quarter of 2010.

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 loss per common share is calculated by dividing the net loss by the weighted average number of common shares outstanding during the period. Diluted loss per common share adjusts basic loss per share for the potentially dilutive effects of shares issuable under our stock option plan, using the treasury stock method. All of the Company's options and warrants, which are common stock equivalents, have been excluded from the calculation of diluted loss per share, as their effect would have been anti-dilutive.

Share Based Payments

We have granted stock-based compensation awards to employees and board members. Awards may consist of common stock, warrants, or stock options. Our stock options and warrants have up to a ten year life. 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.

During the nine months ended September 30, 2009, we granted 366,000 options, and in the similar period ended September 30, 2008, we granted 5,600,000 options. We recorded related compensation expenses as our options vest in accordance with guidance issued by the FASB related to share based payments. We recognized \$1,069,134 and \$1,309,092 in share-based compensation expense during the three months ended September 30, 2009 and 2008, respectively, from the vesting of stock options or warrants. We recognized \$3,417,790 and \$3,469,992 in share-based compensation expense during the nine months ended June 30, 2009 and 2008, respectively, from the vesting of stock options or warrants.

A summary of stock option activity during the nine months ended September 30, 2009 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, 2009	8,750,659	\$ 2.55	8.2	\$
Granted	366,000	1.31	7.4	\$ 102,720
Exercised	-			
Forfeited	-			
Outstanding at September 30, 2009	9,116,659	\$ 2.51	7.4	\$ 2,700,720
Exercisable at September 30, 2009	5,071,159	\$ 1.88	6.9	\$ 2,631,360

Share-based compensation expense included in the statements of operations for the three months and nine months ended September 30, 2009 and 2008 was as follows:

	Three Months Ended Sept. 30,	
	2009	2008
Research and development costs	\$ 703,300	\$ 817,171
General, selling and administrative expenses	365,834	491,921
Total	\$ 1,069,134	\$ 1,309,092
	Nine Months Ended Sept. 30,	
	2009	2008

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

Research and development costs	\$ 2,183,702	\$ 2,265,846
General, selling and administrative expenses	1,234,088	1,204,146
Total	\$ 3,417,790	\$ 3,469,992

9

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

	Number of Warrants	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2009	13,079,762	\$ 2.27	2.0	-
Granted	2,440,000	1.26	2.8	
Exercised	(277,934)	1.25	-	
Forfeited	-			
Outstanding at September 30, 2009	15,241,828	\$ 2.12	2.0	-
Exercisable at September 30, 2009	12,241,828	\$ 1.91	2.0	-

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				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. During the three months ended September 30, 2009, 277,934 warrants were exercised. The fair value of the common stock purchase warrants which remained declined to \$5.6 million as of September 30, 2009, and we recognized a \$0.76 million gain from the change in fair value of these warrants for the nine months ended September 30, 2009, and a \$2.6 million loss for the three months ended September 30, 2009,

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

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

hedge accounting, and as such, all future changes in the fair value of these warrants will be recognized currently in 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:

	September 30, 2009	January 1, 2009
Annual dividend yield	-	-
Expected life (years)	0.75-2.00	1-2.5
Risk free interest rate	0.18%-0.95%	0.40%
Expected volatility	85%-97%	86%

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.

Significant New Accounting Pronouncements

In June 2008, the FASB ratified consensus reached on determining whether an instrument is indexed to an entity's own stock. The FASB provides guidance for determining whether an equity-linked financial instrument (or embedded feature) is indexed to an entity's own stock. The guidance applies to any freestanding financial instrument or embedded feature that has all the characteristics of a derivative, as defined by the FASB. The guidance also applies to any freestanding financial instrument that is potentially settled in an entity's own stock, regardless of whether the instrument has all the characteristics of a derivative, for purposes of determining whether the instrument is subject to accounting guidance for instruments that are indexed to, and potentially settled in, the issuer's own stock. This guidance is effective for fiscal years beginning after December 15, 2008. See Note 5 for a discussion of the effect of this standard that was adopted on January 1, 2009.

In May 2009, the FASB issued new accounting guidance related to the accounting and disclosures of subsequent events. This guidance incorporates the subsequent events guidance contained in the auditing standards literature into authoritative accounting literature. It also requires the disclosure of the date through which a company has evaluated subsequent events occurring after the balance sheet date of the financial statements and whether this date is the date the financial statements were issued or the date the financial statements were available to be issued. This guidance is effective for financial statements issued for interim or annual periods ending after June 15, 2009. We adopted this guidance upon its issuance and it had no material impact on our financial statements. The Company has evaluated subsequent events for potential recognition and/or disclosure through November 16, 2009, the date the consolidated financial statements included in this Quarterly Report on Form 10-Q were issued.

In June 2009, the FASB issued new accounting guidance to improve financial reporting by companies involved with variable interest entities and to provide more relevant and reliable information to users of financial statements. This guidance is effective as of the beginning of each reporting entity's first annual reporting period that begins after November 15, 2009, for interim periods within that first annual reporting period, and for interim and annual reporting periods thereafter. Earlier application is prohibited. We adopted this guidance upon its issuance and it had no material impact on the Company's financial statements.

In June 2009, the FASB issued SFAS 168 the FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles "a replacement of FASB Statement No. 162" ("SFAS 168"). SFAS 168 will become the source of authoritative U.S. generally accepted accounting principles (GAAP) recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the Securities and Exchange Commission (SEC) under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. On the effective date of SFAS 168, the Codification will supersede all then-existing non-SEC accounting and reporting standards. All other nongrandfathered non-SEC accounting literature not included in the Codification will become nonauthoritative. SFAS 168 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. Once the Codification is in effect, all of its content will carry the same level of authority, effectively superseding SFAS 162.

3. Fair Value

In September 2006, the FASB issued new accounting guidance related to fair value measurements and related disclosures. This new 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. We adopted this new guidance in the first quarter of 2008 with regard to all financial assets and liabilities in our financial statements going forward. However, the FASB deferred the effective date of this new guidance for one year as it relates to fair value measurement requirements for nonfinancial assets and nonfinancial liabilities that are not recognized or disclosed at fair value on a recurring basis. We adopted these remaining provisions on January 1, 2009. The adoption of this accounting guidance had no material impact on our financial statements.

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.

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

	Fair value measurements at September 30, 2009 using			
	Fair Value on Balance Sheet	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	\$ 2,420,715	\$ 2,420,715	\$ -	\$ -
Liabilities:				
Fair value of warrant obligations	5,622,339	-	-	5,622,339

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

	Three months ended September 30, 2009	Nine months ended September 30, 2009
--	---	--

Fair value of warrant obligations at beginning of period	\$ 3,236,634	\$ -
Cumulative effect of reclassification of warrants to liabilities at beginning period	-	6,578,293
Net loss (gain) for change in fair value included in the statement of operations for period	2,580,481	(761,178)
Decrease in value from warrant exercises	(194,776)	(194,776)
Fair value of warrant obligations at end of period	\$ 5,622,339	\$ 5,622,339

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' (Deficit) Equity

The Company completed a private placement of 800,000 common shares at \$1.25 per share increasing equity by approximately \$1,000,000 in June 2009, less approximately \$97,000 in related placement and closing costs. In September 2009, several warrant holders exercised 277,934 warrants at \$1.25 per warrant increasing equity by approximately \$347,000, less \$31,300 in related financing costs.

Note 5. Change in Accounting Principle: Recharacterization of Warrants

In June 2008, the FASB ratified the consensus reached on whether an instrument or embedded feature is indexed to an entity's own stock. FASB guidance clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity's own stock, which would qualify as a scope exception.

We adopted the FASB guidance as of January 1, 2009. As is discussed in Note 1 above, as of that date we had 8,547,762 warrants which were reassessed under the new guidance. Because of certain price adjustment provisions contained in the warrants, they were no longer deemed to be indexed to our stock and therefore, no longer meet the scope exception. Hence, these warrants were determined to be derivatives and were reclassified from equity to liabilities. As a result of this change in accounting principle, on January 1, 2009 we recorded these liabilities at their value of \$6,578,293. At that date we also recorded a cumulative catch up adjustment of \$284,327 to reduce the accumulated deficit and a \$6,862,620 decrease to additional paid-in capital. The adjustment to the accumulated deficit (the cumulative income effect of the accounting change) was calculated for the decrease in the fair value of the warrants from the date of their issuance through January 1, 2009.

These warrant liabilities will be marked to fair value from January 1, 2009 going forward resulting in the recognition of gain or loss in our statement of operations for changes in their fair value. In the nine months ended September 30, 2009 we recognized a gain from the change in the fair value of these warrant obligations of \$761,178.

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

Our Management’s Discussion and Analysis of Financial Condition and Results of Operations (MD&A) is provided in addition to the accompanying consolidated financial statements and notes to assist readers in understanding our results of operations, financial condition, and cash flows. The MD&A section 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.
- 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: (i) the third quarter of 2009 to 2008; (ii) the nine month period ended September 30, 2009 and 2008.
- Liquidity and Capital Resources - An analysis of changes in our balance sheets and cash flows, and discussion of our financial condition including the credit quality of our investment portfolio and potential sources of liquidity.

The various sections of the 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, particularly in the “Risk Factors” in Part II, Item 1A of this Quarterly Report. Our actual results may differ materially.

OVERVIEW

Neuralstem is focused on the development and commercialization of treatments for diseases affecting the central nervous system (the brain and the spinal cord, or the “CNS”). Our primary development focus has been on identifying and developing potential cell-based therapeutics utilizing our proprietary neural stem cell based technologies which treat disease by replacing dead or diseased cells with new healthy cells. In particular, we have concentrated our research and devoted the majority of our efforts on developing a neural stem cell therapy for the treatment of amyotrophic lateral sclerosis (“ALS” or “Lou Gehrig’s Disease”). To date, this research has all been pre-clinical. On September 21, 2009 the U.S. Food and Drug Administration (FDA) approved our Investigational New Drug (IND) application to commence a Phase I human trial for ALS. As a result, we anticipate that for the next 18 months, our primary focus will be on our duties as the sponsor of this Phase I clinical trial.

In addition to ALS, we are also working on the following indications for our stem cells based therapies: Chronic Spinal Cord Injury, Acute/subacute Spinal Cord Injury, Stroke, Epilepsy, Traumatic Brain Injury and Huntington's disease. Even though we believe our stem cell based technologies may be effective in the treatment of such diseases, we are still involved in pre clinical work and testing for all of these indications..

In June of 2009 we received a notice of allowance from the U.S. Patent and Trademark Office (USPTO) for a patent on our small molecule compounds. Patent application 12/049,922, entitled "Use of Fused Nicotinamides to Promote Neurogenesis," claims four chemical entities and any pharmaceutical composition including them. We believe the development of these compounds may lead to a new class of drug with both neurogenic¹ and neuroprotective² properties. Preliminary testing of a lead compound from this group in animal models has lead us to chose the treatment of depression as the first indication to pursue. Provided we are able to secure financing, in excess of that which will be required to complete our current clinical trial for ALS, we anticipate conducting additional preclinical research regarding this compound and the filing of an IND to commence a Phase I trial to treat major depression by the end of 2011. We also believe that our small molecule compounds may be applicable to the treatment of such diseases as Anxiety, Schizophrenia, Dementia, Alzheimer's disease and Diabetic neuropathy. Although we believe our small molecule compound may be effective in the treatment of such diseases, we are still at the stage of creating proof of principal pre clinical data for these other indications.

We continue to deploy 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 be 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 fixed costs than that required by our competitors.

Revenue

We have not derived any revenue or cash flows from the sale or commercialization of any therapeutic products. In prior periods, we derived some revenues from grant reimbursements and licensing fees which we do not foresee continuing. As a result, we have incurred annual operating losses since inception and expect to incur substantial operating losses in the future. Therefore, we are dependent upon external financing.

Our focus is now on initiating and successfully managing the clinical trial for ALS. We are also pursuing, to a lesser extent, pre-clinical studies on other central nervous system indications for our cell based and small molecule therapies in preparation for additional clinical trials. We are not concentrated on generating revenue. We do not anticipate realizing any revenue in the near future.

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

Before we can derive revenue or cash inflows from the commercialization of any of our therapeutic product candidates, we will need to: (i) conduct substantial testing and characterization of our proprietary cell types, (ii) undertake preclinical and clinical testing for specific disease indications; (iii) pursue required regulatory approvals. These steps are risky, expensive and time consuming.

-
- 1 Promotes the generation of new neurons.
 - 2 Protects neurons from apoptosis or degeneration.

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 packages. This approach allows the Company to use the best expertise available for each task and keep its spending inside available cash resources. There are numerous factors associated with the successful commercialization of any of our cell-based and small molecule products, including future regulatory requirements and legal restrictions on the testing and research of cell based products, many of which cannot be determined with accuracy at this time given the stage of our development and the novel nature of primary stem cell based technologies. The regulatory pathways, both in the United States and internationally, are complex and fluid given the novel and, in general, clinically unproven nature of stem cell technologies. At this time, due to such uncertainties and inherent risks, we cannot estimate in a meaningful way the duration of, or the costs to complete, our R&D programs or whether, when or to what extent we will generate revenues or cash inflows from the commercialization and sale of any of our therapeutic product candidates or any non-therapeutic applications of our cell-based technologies. Our future R&D expenses will depend in large part on the availability of funding and on the determinations we make as to the scientific and clinical prospects of each product candidate, as well as our ongoing assessment of the regulatory requirements and each product candidate's commercial potential.

There can be no assurance that we will be able to develop any product successfully, or that we will be able to recover our development costs, whether upon commercialization of a developed product or otherwise. We cannot provide assurance that any of these programs will result in products that can be marketed or marketed profitably. If certain of our development-stage programs do not result in commercially viable products, our results of operations could be materially adversely affected.

Stem Cells

Our development priority is the ALS clinical trial at Emory University in Atlanta. We estimate that the Phase I trial will require 12 to 18 patients at an estimated cost of \$130,000 per patient. The per-patient number includes the costs of the operation to administer our spinal cord cells, and 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 build to \$100,000 per month after a number of patients have been treated. The completion of the trial could be delayed if concerns arise over safety or if we encounter challenges in recruitment. Any delay in the trial for any reason would increase the cost of the trial and delay the process of bringing the treatment to market.

As previously stated, we believe our cell based technology also has therapeutic value for a number of additional indications. We will also work on proof of principle testing, dosing rationale, and the development of clinical protocols for the most promising of these indications. We intend to submit IND applications to the FDA to initiate

clinical trials for the most promising treatment candidates.

Small Molecule Compounds

We believe we have successfully demonstrated proof of principle to support advancement of our lead small molecule compound for treatment of major depression. WE have completed planning for toxicology, tumorigenicity, dosing rationale, and development of the clinical protocol. We will issue work orders to contractors for these efforts when funding is available. If the remaining preclinical testing results are successful we will file an IND with the FDA. We hope to begin clinical trials for this indication in 2011.

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 pre-clinical to a clinical phase.

We anticipate G&A expenses related to our core business will increase at a slower rate than that of similar companies making such transition, due in large part to our outsourcing model.

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—our revenues, to date, has been derived primarily from providing services as a subcontractor under federal grant programs and licensing fees. 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 period ended September 30, 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.

Beginning in 2006, we adopted the new guidance issued by the FASB related to share based payments. The new guidance requires compensation costs related to share-based payment transactions to be recognized in the financial statements.

RESULTS OF OPERATIONS

Summary Income Statement for the Three and Nine Months Ended September 30, 2009 & 2008

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Revenues	-	-	-	-
Operating expenses	\$ 2,522,582	\$ 3,184,058	\$ 8,158,789	\$ 8,448,044
Operating loss	(2,522,582)	(3,184,058)	(8,158,789)	(8,448,044)
Non-operating income (expense)	(2,574,401)	6,101	778,038	37,963
Net income (loss)	\$ (5,096,983)	\$ (3,177,957)	\$ (7,380,751)	\$ (8,410,081)

For the third quarter of 2009, the Company reported a net loss of \$5,096,983, or \$0.15 per share, compared to a net loss of \$3,177,957, or \$0.10 per share, for the comparable 2008 period. The increase was caused by a non cash charge related to a change in the way we account for certain warrants offset in part by reductions in most other expense categories. Net loss attributable to common stockholders for the first nine months of 2009 was \$7,380,751 or \$0.22

per share, compared to \$8,410,081, or \$0.26 per share for the comparable period in 2008. The decrease in net loss from year to year was due to a year to date gain in our warrant accounting, partially offset by increases in non cash stock-based compensation expense, R&D , and legal fees.

Results of Operations for the Three Months ending September 30, 2009 and 2008

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

The company did not have revenues for the three months ended September 30, 2009 and 2008, respectively.

We do not anticipate any revenues for 2009.

Operating expenses totaled \$2,522,582 and \$3,184,058 for the three months ended September 30, 2009 and 2008. The decrease in operating expense of \$661,476 was due to a decrease in R&D spending, and a decrease in non-cash stock based compensation expense.

Research and development expenses totaled \$1,308,565 for the three months ended September 30, 2009 compared to \$1,766,040 for the same period of 2008. The decrease of \$457,475 or 26% for the three months ended September 30, 2009 compared to the comparable period in 2008 was primarily attributable to significant reductions in spending on contracted research in the third quarter as the FDA clinical trial application was completed in the second quarter. In addition, stock option expense dropped by \$113,871 as an option award became fully vested and expensed at the end of the previous quarter.

General and administrative expenses totaled \$1,191,480 for the three months ended September 30, 2009 compared to \$1,400,795 for the same period of 2008. The decrease of \$209,315 or 15% for the three months ended September 30, 2009 compared to the comparable period in 2008 was primarily attributable to reductions in stock option expenses of \$126,087 as several early option grants were fully vested and expensed. The remaining expense decrease was spread over a wide range of categories and reflects management's ongoing efforts to manage cash consumption.

Depreciation and amortization expenses totaled \$22,537 for the three months ended September 30, 2009 compared to \$17,223 for the same period of 2008. The increase of \$5,314 or 31% for the three months ended September 30, 2009 compared to the comparable period in 2008 was attributable to additions to fixed asset and capitalized patent filing fees over the past year.

Nonoperating (expense) income totaled (\$2,574,401) and \$6,101 for the three months ended September 30, 2009 and 2008, respectively. The increase in nonoperating expense was due to expenses associated with the Company's warrant accounting.

Interest income totaled \$6,080 for the three months ended September 30, 2009 compared to \$6,101 for the same period of 2008. The decrease for the three months ended September 30, 2009 compared to the comparable period in 2008 was attributable to lower cash balances.

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 March 30, 2009, the fair value of these common stock purchase warrants decreased because of a decrease in the stock price, resulting in a gain for the quarter. In the three months ended June 30, 2009, the fair value of these common stock purchase warrants increased to \$3.2 million because of an increase in the stock price. We recognized a \$0.5 million non-cash expense from the change in fair value of these warrants for the three months ended June 30, 2009. In the three months ended September 30, 2009 the fair value of the common stock purchase warrants increased again, due to an increase in the stock price. We recognized a \$2.6 million expense for the three months ended September 30, 2009.

Results of Operations for the Nine Months ending September 30, 2009 and 2008

The company did not have revenues for the nine months ended September 30, 2009 and 2008, respectively. We do not anticipate any revenues for 2009.

Operating expenses totaled \$8,158,789 and \$8,448,044 for the nine months ended September 30, 2009 and 2008. About half of the decrease of \$289,255 for the nine months ended September 30, 2009 compared to the comparable period in 2008 was attributable to decreased research and development expenditures and a decrease in non-cash stock compensation expense.

Research and development expenses totaled \$4,195,366 for the nine months ended September 30, 2009 compared to \$4,598,611 for the same period of 2008. The decrease of \$403,245 for the nine months ended September 30, 2009

compared to the comparable period in 2008 was primarily attributable to the costs in 2008 of completing the application to the FDA to move our cell based products into clinical trials and a reduction in non-cash stock-based compensation expense of \$82,144.

General and administrative expenses totaled \$3,898,666 for the nine months ended September 30, 2009 compared to \$3,802,673 for the same period of 2008. The increase of \$95,993 or 3% for the nine months ended September 30, 2009 compared to the same period in 2008 was primarily attributable to increased litigation expenses of \$115,029 and increased non-cash stock-based compensation expense of \$38,737 offset by expense decreases spread over a wide range of categories and reflects management's ongoing efforts to manage cash consumption.

Depreciation and amortization expenses totaled \$64,757 for the nine months ended September 30, 2009 compared to \$46,760 for the same period of 2008. The increase of \$17,997 or 39% for the nine months ended September 30, 2009 compared to the same period in 2008 was attributable to fixed asset and patent filing fee additions over the past year.

Nonoperating (expense) income totaled \$778,038 and \$37,963 for the nine months ended September 30, 2009 and 2008, respectively. The nonoperating income or expense is discussed below.

Interest income totaled \$17,054 for the nine months ended September 30, 2009 compared to \$37,963 for the same period of 2008. The decrease of \$20,909 for the nine months ended September 30, 2009 compared to the comparable period in 2008 was attributable to lower cash balances and much reduced interest rates on short term savings.

Gain (loss) 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 classification 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 first quarter ended March 30, 2009, the fair value of these common stock purchase warrants decreased because of a decrease in the stock price, resulting in a gain for the quarter. In the three months ended June 30, 2009, the fair value of these common stock purchase warrants increased to \$3.2 million because of an increase in the stock price. We recognized a \$473,799 non-cash expense from the change in fair value of these warrants for the three months ended June 30, 2009. In the three months ended September 30, 2009, the fair value of these common stock purchase warrants increased to \$5.6 million due to an increase in the stock price. We recognized a \$2.6 million non-cash expense (or loss) from the change in fair value of these warrants for the three months ended September 30, 2009. The net gain for the nine month period ended September 30, 2009 is \$761,178.

LIQUIDITY AND CAPITAL RESOURCES

Since inception we have financed our operations through the private placement of our securities, the exercise of investor warrants, and to a lesser degree from research grants. Our current monthly cash burn rate is approximately \$425,000. We anticipate that our available cash will be sufficient to finance most of our current activities for at least the next five months from September 30, 2009, although certain activities and related personnel may need to be reduced.

On December 18, 2008, we filed our first IND with the FDA. We estimate that we will have sufficient cash and cash equivalents to finance our current operations, pre-clinical and clinical work for at least five months from September 30, 2009. 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.

	Nine Months Ended Sept. 30,	
	2009	2008
Cash and cash equivalents	\$ 2,420,715	\$ 5,249,805
Net cash used in operating activities	\$ (3,613,084)	\$ (4,731,442)
Net cash used in investing activities	\$ (88,989)	\$ (133,701)
Net cash provided by financing activities	\$ 1,219,509	\$ 2,711,211

Total cash and cash equivalents was \$2,240,715 and \$5,249,805 for the nine months ended September 30, 2009 and 2008, respectively. The decrease in our cash and cash equivalents of \$3,009,090 or 57% for the nine months ended September 30, 2009 compared to the same period in 2008 was primarily attributed to placement of our common equity of \$2,711,211 in the first nine months of 2008 versus \$1,219,510 in the first nine months of 2009.

Net Cash Used in Operating Activities

Operating activities required \$3,613,084 for the nine months ended September 30, 2009 compared to \$4,731,442 for the same period in 2008. The decrease in cash consumption of \$1,118,358 or 24% for the nine months ended September 30, 2009 compared to the same period in 2008 was primarily attributable to an increase of \$1,087,768 in short term financing by vendors, employees and other service providers in the first nine months of 2009 and a reduction in spending particularly in research.

Net Cash Used in Investing Activities

In our investment activities we used \$88,990 for the nine months ended September 30, 2009 compared to \$133,701 for the same period of 2008. The decrease in our cash of \$44,711 or 34% for the nine months ended September 30, 2009 compared to the same period in 2008 was primarily attributable to the fact that we had a decrease in our purchase of property and equipment.

Net Cash Provided by Financing Activities

Cash provided by financing activities was \$1,219,510 for the nine months ended September 30, 2009, compared to \$2,711,211 for the same period of 2008.

Listed below are our key financing transactions. Also, please refer to the section of this Quarterly Report entitled “Recent Sale of Unregistered Securities” for a further description of the following transactions:

- In February of 2008, we sold to a strategic purchaser \$2,500,000 of our common stock.
- On December 18, 2008, we sold \$2,000,000 of common stock pursuant to our shelf registration statement on Form S-3.
- On June 30, 2009, we sold \$1,000,000 of common stock and warrants to purchase an additional 2,440,000 common shares pursuant to our shelf registration statement on Form S-3.
 - In September 2009, we received \$347,418 as a result of warrant exercises.

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 sale of our securities, exercise of outstanding warrants and grants to fund our operations.

We intend to pursue opportunities to obtain additional financing in the future through the sale of our securities and additional research grants. We have a shelf registration statement which was declared effective on September 29, 2008 and covers up to approximately \$25,000,000 of our securities that could be available for financings. On December 18, 2008 and June 30, 2009, we filed Prospectus Supplements under which we sold securities with an aggregate market value pursuant to General Instruction I.B.6. of Form S-3, of \$6,167,520. Accordingly, depending on our market capitalization and other restrictions and conditions contained in General Instruction I.B.6. of Form S-3, we may be able to sell up to an additional \$18,832,420 pursuant to our shelf registration statement.

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 the Quarterly Reports filed or submitted under the Exchange Act is 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 Quarterly Report, there are no material pending legal or governmental proceedings relating to our company or properties to which we are a party, and to our knowledge there are no material proceedings to which any of our directors, executive officers or affiliates are a party adverse to us or which have a material interest adverse to us, other than the following:

On May 7, 2008, Neuralstem filed suit against StemCells, Inc., StemCells California, Inc. (collectively “StemCells”) and Neurospheres Holding Ltd., (collectively StemCells and Neurospheres Holding Ltd. are referred to as “Defendants”) 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. StemCells filed a near “mirror image” lawsuit in California the same day which was subsequently transferred to Maryland. See Civil Action No. 08-2664. On May 13, Neuralstem 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 nor do they constitute unfair competition as alleged by the Plaintiffs. On July 15, 2008, the Defendants 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. Discovery has started in this case, but no trial date has been set. This matter has also been consolidated with Civil Action Nos. 06-1877 and 08-2664. It is not known when nor on what basis these matters will be concluded.

On July 28, 2006, StemCells, Inc. and StemCells California, Inc. (“StemCells”) 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 (Civil Action No. 06-1877). The case was stayed for approximately two years pending reexamination proceedings in the United States Patent & Trademark Office. The stay in this case was recently lifted and this matter was consolidated with Civil Action Nos. 08-1173 and 08-2664. Discovery has started, but no trial date has been set. 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.

The occurrence of any event detailed in the following risk factors could result in a substantial decrease in 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 September 30, 2009, we have raised \$59,659,495 of capital and recorded accumulated losses totaling \$64,583,219. On September 30, 2009, we had a working capital surplus of \$227,662 and stockholders' (deficit) equity of \$(4,923,724). Our net losses for the two most recent fiscal years have been \$11,830,798 and \$7,063,272 for 2008 and 2007 respectively. Our net loss for the nine month period ended September 30, 2009 was \$7,380,751. We had no revenues for the nine months ended September 30, 2009.

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

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 primarily come primarily from the sale of common stock and the exercise of investor warrants. As of September 30, 2009, we had cash and cash equivalents on hand of \$2,420,715. Presently, we have a monthly cash burn rate of approximately \$425,000. We will need to raise additional capital to fund anticipated operating expenses and future expansion. Among other things, external financing will be required to cover the further development of our technologies and products, as well as general operating costs. On September 21, 2009 the FDA approved the IND application to commence Phase I trials for ALS. As a result, we expect the additional cost related to increase our monthly burn rate.

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.

Our long term capital requirements are expected to depend on many factors, including:

- the continued progress and costs of our research and development programs;
- the progress of pre-clinical studies and clinical trials;
- the time and costs involved in obtaining regulatory clearance;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- the costs of developing sales, marketing and distribution channels and our ability to sell our products if developed;
- the costs involved in establishing manufacturing capabilities for commercial quantities of our proposed products;
 - competing technological and market developments;
 - market acceptance of our proposed products;
- the costs of recruiting and retaining employees and consultants; and

- the costs associated with educating and training physicians about our proposed products.

We cannot assure you that financing will be available if needed. If additional financing is not available, we may not be able to fund operations and planned growth, develop or enhance our technologies, take advantage of business opportunities or respond to competitive market pressures. If we exhaust our cash reserves and are unable to realize adequate additional financing, we may be unable to meet operating obligations and be required to initiate bankruptcy proceedings or delay, or eliminate 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 through the sale of our products. Accordingly, we will be required to secure additional financing which 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 and may result in substantial dilution.

Risks Relating to Our Business

At present our ability to progress as a company is significantly dependent on a single product candidate for ALS which is about to enter 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 any of 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 substantial 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 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 the 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 in order to commence clinical trials. Although we have received approval from the FDA to commence 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 successful. The failure of such trials could delay or prevent regulatory approval and could harm our ability to generate revenues, operate profitably or remain a viable business.

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 clinical trials will succeed. Even if our product candidates achieve positive results in 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 reputation in the industry and in the investment community would likely be significantly damaged, each such outcome would cause our stock price to decrease significantly.

The commencement of clinical testing of our potential product candidates may be delayed.

The commencement of clinical trials may be delayed for a variety of reasons, including:

- delays in reaching agreement on acceptable terms with contract research organizations and clinical trial sites;
- delays in obtaining institutional review board approval to conduct a clinical trial at a prospective site; and
- insufficient financial resources.

In addition, the commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease, and the eligibility criteria for the clinical trial. Delays in the commencement of clinical testing of our product candidates could significantly increase our product development costs and delay product commercialization. In addition, many of the factors that may cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to a denial of regulatory approval of a product candidate.

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, 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. For a further description of pending litigation, see Item 1. of Part II to the Quarterly Report entitled "Legal Proceedings."

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. The Company 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 two key employees for our continued operations and future success.

The loss of either of our key executive officers, Richard Garr and Karl Johe, would be detrimental to us.

- We currently do not maintain “key person” life insurance on the life of Mr. Garr. As a result, the Company will not receive any compensation upon the death or incapacity of this key individual;
- We currently do maintain “key person” life insurance on the life of Mr. Johe. As a result, the Company will receive approximately \$1,000,000 in the event of his death or incapacity.

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 of 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 \$1,230,000 per contract and the immediate vesting of all outstanding options and/or warrants held by Messrs. Garr and Johe.

We have no product liability insurance, which may leave us vulnerable to future claims that we will be unable to satisfy.

The testing, manufacturing, marketing and sale of human therapeutic products entails an inherent risk of product liability claims, and we cannot assure you that substantial product liability claims will not be asserted against us. We have no product liability insurance. In the event we are forced to expend significant funds on defending product liability actions, and in the event those funds come from operating capital, we will be required to reduce our business activities, which could lead to significant losses.

We cannot assure you that adequate insurance coverage will be available in the future on acceptable terms.

We have limited commercial insurance policies. Any significant claim would have a material adverse effect on our business, financial condition and results of operations. Insurance availability, coverage terms and pricing continue to vary with market conditions. We will endeavor to obtain appropriate insurance coverage for insurable risks that we identify. In the event a loss occurs that is not covered, depending on the size of such loss, it could materially affect our business plan or ability to operate.

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 enter into collaborations with third parties in order to further

develop the technology and products. In the event we are not able to enter into such relationships in the future, our ability to 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. Also, we currently rely on third parties to assist us with a substantial portion of our research and development. The failure of any of these third parties may hinder our ability to develop products in a timely fashion.

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.

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.

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-averse 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 or non-existent, 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.

As a result of a recent accounting pronouncement, we no longer meet the continued listing requirements of the NYSE AMEX.

Effective January 1, 2009, we adopted new guidance issued by FASB related to determining whether an instrument or embedded feature is indexed to an entity’s own stock. As a result, we reclassified 8,547,762 of our issued and outstanding common stock purchase warrants from equity to liability status. The adjustment also had the effect of reducing stockholder’s equity by \$2.8 million. Due to such adjustment, we may no longer meet the continued listing requirements of the NYSE AMEX with regard to stockholders (deficit) equity. On June 4, 2009, as anticipated, we received notification from the NYSE AMEX that we are not in compliance with continued listing requirements contained in Section 1003(i) of the NYSE AMEX company guide. In order to maintain our listing on the NYSE AMEX, we were required to submit a plan detailing how we intend to regain compliance. On July 6, 2009, we submitted our plan. On August 18, 2009, the NYSE AMEX notified that it would continue listing our common shares subject to the following conditions:

- That we regain compliance with Section 1003(i) of the NYSE AMEX company guide by December, 2010, and
- That we provide the Exchange Staff with updates in conjunction with the initiatives of the Plan as appropriate or upon request, but no later than at each quarter completion concurrent with our appropriate filing with the Securities and Exchange Commission.

The NYSE AMEX will periodically review our progress toward regaining compliance with the company guide regulations. If it concludes that our progress is not satisfactory, it may suspend and delist the Company’s common stock. If our common stock is no longer eligible for listing and is delisted, trading in our common stock may be

conducted on the over-the-counter bulletin board or on the “pink sheets.” In such event, broker-dealers may be less willing or able to sell and/or make a market in our common stock. Moreover, such markets have historically been less liquid than the NYSE AMEX.

The delisting of our common shares from the NYSE Amex may limit the ability of our stockholders to sell their common stock.

We currently do not meet the continued listing requirements of the NYSE AMEX. If we are delisted, our stock will most likely commence trading on the Over-the-Counter Bulletin Board or the Pink Sheets. In such case, a stockholder likely would find it more difficult to trade our common stock or to obtain accurate market quotations for it. If our common stock is delisted, it will become subject to the Securities and Exchange Commission’s “penny stock rules,” which impose sales practice requirements on broker-dealers that sell that common stock to persons other than established customers and “accredited investors.” Application of this rule could make broker-dealers unable or unwilling to sell our common stock and limit the ability of stockholders to sell their common stock in the secondary market.

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, our common shares are sporadically or thinly traded. 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.). On October 2, 2009, the SEC announced it would extend the deadline for non-accelerated filers to comply with Section 404(b) of the Sarbanes-Oxley Act. Unless further extended, we will be required to include attestation reports in our annual report for year ending on December 31, 2010. 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 September 30, 2009, we have issued and outstanding 34,829,234 common shares, 24,408,487 common shares reserved for issuance upon the exercise of current outstanding options and warrants (excluding options and warrants issued under our equity compensation plans), 223,341 common shares reserved for issuance of additional grants under our 2005 incentive stock plan, and 760,000 shares reserved for issuance of grants under our 2007 stock plan. Accordingly, we will be entitled to issue up to 89,778,938 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, 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 U.S. Patent and Trademark Office. 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. For a further description of pending litigation, see Item 1 of Part II to the Quarterly Report entitled "Legal Proceedings."

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

We anticipate conducting research in countries outside of the United States. 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 September 21, 2009 the FDA approved our IND application to commence a Phase I trial for ALS. 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 cGTP, 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 Good Manufacturing Practices, or cGMP. Accordingly, we will need to enter into supply agreements with companies that manufacture these components to cGMP 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 will be materially and negatively impacted.

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

We incorporate by reference the information pertaining to unregistered sales of equity securities as disclosed in our annual report file on Form 10-K for the period ended December 31, 2008. The following information is given with regard to unregistered securities sold during the period covered by this report that were not registered under the Securities Act and were not previously included in a Current Report on Form 8-K.

- In January of 2009, we exchanged previously issued warrants to purchase 50,000 common shares for options under our 2005 Stock Plan. The warrants were originally issued on December 11, 2008 and have an exercise price of \$2.75 per share. The warrants expire on November 13, 2013. We exchanged the warrants for options that have the same terms and duration.
- On January 12, 2009 we granted a consultant an option to purchase 100,000 common shares at a price per share of \$1.64. The option is 100% vested as of the grant date and has a term of 7 years. The option was issued pursuant to our 2005 Stock Plan.
- On March 30, 2009, we granted a consultant an option to purchase 96,000 common shares at a price per share of \$1.25. The option has a five year term and vests 100% on March 31, 2009.

•