Neuralstem, Inc.
Form 10-Q
November 08, 2016

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark one)

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

For the Quarterly Period Ended September 30, 2016

Or

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

Commission File Number 001-33672

NEURALSTEM, INC.

(Exact name of registrant as specified in its charter)

Delaware	**52-2007292**
State or other jurisdiction of incorporation or organization	(I.R.S. Employer Identification No.)
20271 Goldenrod Lane	
Germantown, Maryland	**20876**
(Address of principal executive offices)	(Zip Code)

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

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

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

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

Large accelerated filer Accelerated filer

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

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

As of October 31, 2016, there were 114,859,175shares of common stock, $.01 par value, issued and outstanding.

Neuralstem, Inc.

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PART I

FINANCIAL INFORMATION

ITEM 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Neuralstem, Inc.

Unaudited Condensed Consolidated Balance Sheets

	September 30, 2016	December 31, 2015
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$5,676,129	$4,716,533
Short-term investments	-	7,517,453
Trade and other receivables	12,685	37,316
Current portion of related party receivable, net of discount	51,733	-
Prepaid expenses	946,943	1,159,782
Total current assets	6,687,490	13,431,084
Property and equipment, net	315,543	343,200
Patents, net	984,125	1,103,467
Related party receivable, net of discount and current portion	413,466	-
Other assets	49,984	71,797
Total assets	$8,450,608	$14,949,548
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$2,484,335	$1,455,826
Accrued bonuses	-	161,362
Current portion of long-term debt, net of fees and discount	4,829,428	4,545,180
Other current liabilities	538,350	263,104
Total current liabilities	7,852,113	6,425,472
Long-term debt, net of fees, discount and current portion	-	3,382,654
Derivative instruments	4,363,156	-
Other long-term liabilities	20,290	174,144
Total liabilities	12,235,559	9,982,270
Commitments and contingencies (Note 6)		

STOCKHOLDERS' (DEFICIT) EQUITY		
Preferred stock, 7,000,000 shares authorized, zero shares issued and outstanding	-	-
Common stock, $0.01 par value; 300 million shares authorized, 114,823,460 and 92,005,705 shares outstanding in 2016 and 2015, respectively	1,148,235	920,057
Additional paid-in capital	182,699,484	176,002,832
Accumulated other comprehensive income	4,587	3,071
Accumulated deficit	(187,637,257)	(171,958,682)
Total stockholders' (deficit) equity	(3,784,951)	4,967,278
Total liabilities and stockholders' (deficit) equity	$8,450,608	$14,949,548

See accompanying notes to unaudited condensed consolidated financial statements.

Neuralstem, Inc.

Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues	$2,500	$2,500	$7,500	$7,917
Operating expenses:				
Research and development expenses	3,589,793	3,392,086	9,130,012	9,887,750
General and administrative expenses	1,329,712	1,807,934	5,862,374	4,925,389
Total operating expenses	4,919,505	5,200,020	14,992,386	14,813,139
Operating loss	(4,917,005)	(5,197,520)	(14,984,886)	(14,805,222)
Other income (expense):				
Interest income	17,293	24,149	41,862	53,802
Interest expense	(240,462)	(464,197)	(949,375)	(1,377,004)
Change in fair value of derivative instruments	(538,261)	-	219,014	-
Gain on related party settlement	458,608	-	458,608	-
Fees related to issuance of derivative instrument and other expenses	(456)	-	(463,798)	(10,326)
Total other income (expense)	(303,278)	(440,048)	(693,689)	(1,333,528)
Net loss	$(5,220,283)	$(5,637,568)	$(15,678,575)	$(16,138,750)
Net loss per share - basic and diluted	$(0.05)	$(0.06)	$(0.15)	$(0.18)
Weighted average common shares outstanding - basic and diluted	114,855,581	91,569,826	104,248,993	90,532,073
Comprehensive loss:				
Net loss	$(5,220,283)	$(5,637,568)	$(15,678,575)	$(16,138,750)
Foreign currency translation adjustment	21	(2,275)	1,516	(2,280)
Comprehensive loss	$(5,220,262)	$(5,639,843)	$(15,677,059)	$(16,141,030)

See accompanying notes to unaudited condensed consolidated financial statements.

Neuralstem, Inc.

Unaudited Condensed Consolidated Statements of Cash Flows

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	$(15,678,575)	$(16,138,750)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	275,074	255,398
Share based compensation expense	2,866,773	2,121,049
Amortization of deferred financing fees and debt discount	283,493	655,090
Change in fair value of derivative instruments	(219,014)	-
Expenses related to issuance of derivative instrument	466,541	-
Changes in operating assets and liabilities:		
Trade and other receivables	24,631	206,365
Related party receivable	(465,199)	-
Prepaid expenses	212,572	(972,371)
Other assets	21,542	(14,102)
Accounts payable and accrued expenses	1,029,864	(1,269,384)
Accrued bonuses	(161,362)	121,029
Other current liabilities	(38,236)	197,615
Other long term liabilities	(153,854)	(194,343)
Net cash used in operating activities	(11,535,750)	(15,032,404)
Cash flows from investing activities:		
Purchases of short-term investments	-	(5,017,453)
Maturity of short-term investments	7,517,453	15,007,478
Patent costs	(30,183)	(61,417)
Purchase of property and equipment	(98,088)	(128,213)
Net cash provided by investing activities	7,389,182	9,800,395
Cash flows from financing activities:		
Proceeds from issuance of common stock from warrants exercised, net	-	3,073,537
Proceeds from sale of common stock and warrants, net of issuance costs	8,173,686	2,931,925
Payment of fees for future financing	-	(42,758)
Payments of long-term debt	(3,381,898)	-
Proceeds from short-term notes payable	313,483	-
Payments of short-term notes payable	-	(117,068)
Net cash provided by financing activities	5,105,271	5,845,636
Effects of exchange rates on cash	893	(1,812)
Net increase (decrease) in cash and cash equivalents	959,596	611,815

Cash and cash equivalents, beginning of period	4,716,533	12,518,980
Cash and cash equivalents, end of period	$5,676,129	$13,130,795
Supplemental disclosure of cash flows information:		
Cash paid for interest	$869,038	$724,350
Supplemental schedule of non cash investing and financing activities:		
Issuance of common stock for cashless exercise of options, warrants and RSUs	$8,936	$2,736,120

See accompanying notes to unaudited condensed consolidated financial statements.

NEURALSTEM, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2016 AND 2015

Note 1. Basis of Presentation and Liquidity

In management's opinion, the accompanying condensed financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations and cash flows. The condensed consolidated balance sheet at December 31, 2015, has been derived from audited financial statements as of that date. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in the financial statements prepared in accordance with generally accepted accounting principles in the United States of America (U.S. GAAP) have been condensed or omitted pursuant to instructions, rules and regulations prescribed by the U.S. Securities and Exchange Commission (SEC). We believe that the disclosures provided herein are adequate to make the information presented not misleading when these condensed financial statements are read in conjunction with the Financial Statements and Notes included in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC, and as may be amended. Certain prior period amounts have been reclassified to conform to current year classifications.

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

Our operations currently do not generate significant cash. Our management does not know when or if this will change. We have spent and will continue to spend substantial funds in the research, development, clinical and pre-clinical testing of our small molecule product candidates and to a lesser extent on our stem cell product candidates with the goal of ultimately obtaining approval from the United States Food and Drug Administration (the "FDA") and its international equivalents, to market and sell our products.

No assurance can be given that (i) approval will ever be granted for us to market and sell our product candidates, or (ii) that if approval is granted, that we will ever be able to sell our products or be profitable.

Liquidity

The Company has incurred losses since its inception and has not demonstrated an ability to generate revenues from sales or services and has not yet achieved profitable operations. There can be no assurance that profitable operations

will ever be achieved, or if achieved, could be sustained on a continuing basis. In addition, development activities, clinical and pre-clinical testing, and commercialization of our products will require significant additional financing. These factors create substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustment that might be necessary if the Company is unable to continue as a going concern.

Our cash and cash equivalents balance at September 30, 2016 was approximately $5.7 million. Our ability to continue as a going concern is wholly dependent upon obtaining sufficient financing to fund our operations. Although we have entered into a definitive agreement relating to the sale of $20 million of our securities, our current cash level raises substantial doubt about our ability to continue as a going concern past December 31, 2016. Should we fail to complete the closing of the $20 million equity sale or if we do not obtain other additional funds by such time, we may no longer be able to continue as a going concern and will cease operation which means that our shareholders may lose their entire investment.

Despite our ability to secure capital in the past, there is no assurance that additional equity or debt financing will be available to us when needed. If we are not able to secure financing, we may be forced to further curtail operations beyond our May 2016 reduction in force (see note 7), delay or stop ongoing pre-clinical research, clinical trials, cease operations altogether or file for bankruptcy.

On October 18, 2016, we received notice from the Listing Qualifications Staff (the "Staff") of The NASDAQ Stock Market LLC ("Nasdaq") indicating that the Staff had determined to delist the Company's securities from The Nasdaq Capital Market due to the Company's continued non-compliance with the $1.00 bid price requirement unless the Company timely requested a hearing before the Nasdaq Hearings Panel (the "Panel"). The Company has requested a hearing before the Panel, which request will stay any delisting action by the Staff until such hearing is held. At the hearing, the Company will present its plan to regain compliance with all applicable requirements for continued listing on the Nasdaq.

The Company is diligently working on the plan it will present at the hearing; however, there can be no assurance that the Panel will determine to continue listing the Company's common stock on Nasdaq or that the Company will be able to evidence compliance with the applicable listing criteria within the period of time that may be granted by the Panel.

Should Nasdaq reject the Company's plan, the Company faces delisting of its shares on the Nasdaq Capital Market. If delisted, our shares would likely trade on the OTCQB market ("Pink Sheets"). Being delisted from the Nasdaq will likely result in difficulties in future-fund raising efforts and is likely to affect the Company's operations and research efforts going forward.

Note 2. Significant Accounting Policies and Recent Accounting Pronouncements

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The condensed consolidated financial statements include significant estimates for the expected economic life and value of our licensed technology, our net operating loss and related valuation allowance for tax purposes and our stock-based compensation related to employees and directors, consultants and investment banks, among other things. Because of the use of estimates inherent in the financial reporting process, actual results could differ significantly from those estimates.

Fair Value Measurements

The carrying amounts of our short-term financial instruments, which primarily include cash and cash equivalents, other short-term investments, accounts payable and accrued expenses, approximate their fair values due to their short maturities.

Foreign Currency Translation

The functional currency of our wholly owned foreign subsidiary is its local currency. Assets and liabilities of our foreign subsidiary are translated into United States dollars based on exchange rates at the end of the reporting period; income and expense items are translated at the weighted average exchange rates prevailing during the reporting period. Translation adjustments for subsidiaries that have not been sold, substantially liquidated or otherwise disposed of are accumulated in other comprehensive income or loss, a component of stockholders' equity. Transaction gains or losses are included in the determination of net loss.

Cash, Cash Equivalents, Short-Term Investments and Credit Risk

Cash equivalents consist of investments in low risk, highly liquid money market funds and certificates of deposit with original maturities of 90 days or less. Cash deposited with banks and other financial institutions may exceed the amount of insurance provided on such deposits. If the amount of a deposit at any time exceeds the federally insured amount at a bank, the uninsured portion of the deposit could be lost, in whole or in part, if the bank were to fail.

Short-term investments consist entirely of fixed income certificates of deposit (“CDs”) with original maturities of greater than 90 days and not more than one year.

Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash equivalents and short-term investments. Our investment policy, approved by our Board of Directors, limits the amount we may invest in any one type of investment issuer, thereby reducing credit risk concentrations. In addition, our certificates of deposit are typically invested through the Certificate of Deposit Account Registry Service ("CDARS") program which reduces or eliminates our risk related to concentrations of investments above FDIC insurance levels. We attempt to limit our credit and liquidity risks through our investment policy and through regular reviews of our portfolio against our policy. To date, we have not experienced any loss or lack of access to cash in our operating accounts or to our cash equivalents and short-term investments.

Research and Development

Research and development costs are expensed as they are incurred. Research and development expenses consist primarily of costs associated with the pre-clinical development and clinical trials of our product candidates.

Income (Loss) per Common Share

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

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

For all periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive due to the net losses; accordingly, diluted loss per share is the same as basic loss per share for the three-and nine-month periods ended September 30, 2016 and 2015. A total of approximately 63.1 million and 37.3 million potential dilutive shares have been excluded in the calculation of diluted net income per share for the three- and nine-month periods ended September 30, 2016 and 2015, respectively, as their inclusion would be anti-dilutive.

Share-Based Compensation

We account for share-based compensation at fair value. Share-based compensation cost for stock options and warrants granted to employees and board members is generally determined at the grant date while awards granted to non-employee consultants are generally valued at the vesting date using an option pricing model that uses Level 3 unobservable inputs; share-based compensation cost for restricted stock and restricted stock units is determined at the grant date based on the closing price of our common stock on that date. The value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period.

Intangible and Long-Lived Assets

We evaluate our long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. We assess this recoverability by comparing the carrying amount of the asset to the estimated undiscounted future cash flows to be generated by the asset. If an asset is deemed to be impaired, we estimate the impairment loss by determining the excess of the asset's carrying amount over the estimated fair value. During the nine months ended September 30, 2016 and 2015, no significant impairment losses were recognized.

Income Taxes

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

Significant New Accounting Pronouncements

In April 2015, the FASB issued *ASU 2015-03 – Interest-Imputation of Interest, Simplifying the Presentation of Debt Issuance Costs*. This Change in Accounting Principle requires that deferred debt issuance costs related to a recognized debt liability be presented in the balance sheet as a deduction of the carrying amount of the debt liability (similar to debt discounts). This change is effective for fiscal years beginning after December 15, 2015 and early adoption is permitted. This change has been applied retrospectively. This new pronouncement results in our reclassifying amounts previously reflected as current and long-term assets to a contra-liability, which reduces the carrying value of the associated debt instruments. To conform to this standard, approximately $90,000 was reclassified on our December 31, 2015 balance sheet from current assets to current portion of long term debt and approximately $9,000 was reclassified from non-current assets to long term debt.

In August 2014, the FASB issued *ASU No. 2014-15, Presentation of Financial Statements – Going Concern*. This ASU requires entities to evaluate for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). The ASU will become effective for annual reporting periods after December 15, 2016. The Company is currently evaluating the impact of the adoption of this ASU on its consolidated financial statements.

In February 2016, the FASB issued *ASU 2016-02, Leases*. This ASU requires the recognition of lease assets and lease liabilities on the balance sheet and disclosure of key information about leasing arrangements. This ASU will become effective for annual periods beginning after December 15, 2018. The Company is currently evaluating the impact of the adoption of this ASU on its consolidated financial statements.

In March 2016, the FASB issued *ASU 2016-09, Improvements to Employee Share Based Payment Accounting*. This ASU address areas for simplification in several aspects of accounting for share-based payment including income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The ASU will become effective for annual reporting periods after December 15, 2016. The Company is currently evaluating the impact of the adoption of this ASU on its consolidated financial *statements.*

The Company has reviewed other recent accounting pronouncements released during the year and concluded that they are either not applicable to the business, or that no material effect is expected on the consolidated financial statements as a result of future adoption.

Note 3. Fair Value Measurements

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

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

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

- *Level 3* – inputs are generally unobservable and typically reflect management's estimates of assumptions that market participants would use in pricing the asset or liability. The fair values are therefore determined using model-based techniques, including option pricing models and discounted cash flow models.

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

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

The inputs used in measuring the fair value of cash and cash equivalents are considered to be Level 1 in accordance with the three-tier fair value hierarchy. The fair values are based on period-end statements supplied by the various banks and brokers that held the majority of our funds. The fair value of all other financial instruments (prepaid expenses, accounts payable, accrued expenses and long-term debt) approximate their carrying values because of their short-term nature.

At September 30, 2016, we had certain common stock purchase warrants issued in connection with our May 2016 capital raises (See Note 5) that are accounted for as derivative instruments whose fair value was determined using Level 3 inputs. The following table identifies the carrying amounts of such assets and liabilities at September 30, 2016:

	Level 1	Level 2	Level 3	Total

Liabilities				
Derivative instruments - stock purchase warrants	$ -	$ -	$4,363,156	$4,363,156
Balance at September 30, 2016	$ -	$ -	$4,363,156	$4,363,156

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

The following table presents the activity for those items measured at fair value on a recurring basis using Level 3 inputs for the nine months ended September 30, 2016:

	Derivative instruments - stock purchase warrants
Balance at December 31, 2015	$-
Issuance of warrants	4,582,170
Change in fair value	(219,014)
Balance at September 30, 2016	$4,363,156

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

Note 4. Debt

In October 2014, we entered into an agreement to refinance and amend the terms of our March 2013 loan and security agreement. The amended loan provided for refinancing of approximately $5.6 million of outstanding balance of the initial loan along with approximately $4.4 million of new principal for a total of $10 million in principal. The amended loan provides for a variable interest rate based on prime with a floor of 10% and matures in April 2017. The loan provides for interest only payments through September 2015; payments of principal and interest of approximately $461,000 from October 2015 through December 2016, and principal and interest of approximately $435,000 from January, 2016 through March 2017 and a final balloon payment of approximately $2.8 million in April 2017. The loan amendment generated approximately $4.3 million in net proceeds after fees and expenses. The loan amendment is accounted for as a debt extinguishment in accordance with guidance provided for in ASC 470, Debt resulting in a loss on extinguishment of approximately $446,000. In conjunction with the loan amendment we recorded a debt discount relating to the beneficial conversion feature. Such discount is being amortized as interest expense over the term of the debt using the effective interest method.

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

We also incurred expenses with various third parties in connection with the loan amendment, consisting of approximately $86,000 in cash, 28,119 shares of common stock valued at approximately $80,000, and a three-year common stock purchase warrant to purchase 58,141 shares at an exercise price of $2.66 per share. The warrant is classified as equity and has terms substantially similar to the lender warrant. These fees related to the loan amendment are recorded as a deferred financing fees netted against the carrying amount of the loan and are being amortized as interest expense over the term of the debt using the effective interest method.

At September 30, 2016, remaining principal payments due under this loan are approximately $1,187,000 and $3,766,000 payable in the remainder of 2016 and 2017, respectively.

Note 5. Stockholders' Equity

We have granted share-based compensation awards to employees, board members and service providers. Awards may consist of common stock, restricted common stock, restricted common stock units, warrants, or stock options. Our stock options and warrants have lives of up to ten years from the grant date. The stock options and warrants vest either upon the grant date or over varying periods of time. The stock options we grant provide for option exercise prices equal to or greater than the fair value of the common stock at the date of the grant. Restricted stock units grant the holder the right to receive fully paid common shares with various restrictions on the holder's ability to transfer the shares. Vesting of the restricted stock units is similar to that of stock options. As of September 30, 2016, we have approximately 66.8 million shares of common stock reserved for issuance upon the exercise of such awards.

Share-based compensation expense included in the statements of operations is as follows:

	Three Months Ended September 30,	
	2016	2015
Research and development expenses	$397,825	$385,153
General and administrative expenses	180,995	420,079
Total	$578,820	$805,232

	Nine Months Ended September 30,	
	2016	2015
Research and development costs	$1,371,378	$957,907
General and administrative expenses	1,495,395	1,163,142
Total	$2,866,773	$2,121,049

Included in the general and administrative expense for the nine months ended September 30, 2016 is approximately $407,000 related to the acceleration of the vesting of options for the previous CEO who left during the first quarter. In addition, approximately $42,000 and $15,000 is included in research and development and general and administrative expenses, respectively for the nine-month period ended September 30, 2016 related to the modification of certain awards in conjunction with our corporate reorganization. See Note 7.

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

Stock Options

We have granted stock options to our employees, board members and service providers.

A summary of stock option activity during the nine months ended September 30, 2016 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, 2016	17,102,947	$ 2.08	5.0	$550,000
Granted	5,672,232	$ 0.61		
Exercised	-			$-
Forfeited	(774,083)	$ 1.08		
Outstanding at September 30, 2016	22,001,096	$ 1.74	5.3	$71,253
Exercisable at September 30, 2016	16,849,228	$ 2.03	4.3	$-
Vested and expected to vest	20,480,622	$ 1.87	5.7	$67,691

Range of Exercise Prices	Number of Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
$0.25 - $1.00	9,334,844	$ 0.75	7.5	$ 71,253
$1.01 - $2.00	4,942,807	$ 1.18	5.3	-
$2.01 - $3.00	2,119,151	$ 2.50	2.8	-
$3.01 - $5.00	5,604,294	$ 3.60	2.6	-
	22,001,096	$ 1.74	5.3	$ 71,253

The Company uses the Black-Scholes option pricing model for “plain vanilla” options and other pricing models as appropriate to calculate the fair value of options. Significant assumptions used in these models include:

	Nine Months Ended September 30,	
	2016	2015
Annual dividend	-	-
Expected life (in years)	5.8 - 7.3	4.0 - 6.0
Risk free interest rate	1.34% - 1.75%	1.39% - 1.78%
Expected volatility	69.0% - 80.2%	68.6% - 71.8%

The options granted in the nine months ended September 30, 2016 and 2015 had a weighted average grant date fair value of $0.40 and $1.89, respectively.

Unrecognized compensation cost for unvested stock option awards outstanding at September 30, 2016 was approximately $3,391,000 to be recognized over approximately 1.6 years.

RSUs

We have granted restricted stock units (RSUs) to certain employees and board members that entitle the holders to receive shares of our common stock upon vesting and subject to certain restrictions regarding the exercise of the RSUs. The fair value of RSUs granted is based upon the market price of the underlying common stock as if they were vested and issued on the date of grant.

A summary of our restricted stock unit activity for the nine months ended September 30, 2016 is as follows:

	Number of RSU's	Weighted-Average Grant Date Fair Value
Outstanding at January 1, 2016	150,906	$ 2.13
Granted	-	
Exercised and converted to common shares	(55,255)	$ 1.77
Forfeited	(6,465)	$ 2.02
Outstanding at September 30, 2016	89,186	$ 2.36
Exercisable at September 30, 2016	89,186	$ 2.36

The total intrinsic value of the outstanding restricted stock units at September 30, 2016 was approximately $28,500. The total value of all restricted stock units that were converted in the nine months ended September 30, 2016 was approximately $35,000.

Restricted Stock

We have granted restricted stock to certain board members.

A summary of our restricted stock activity for the nine months ended September 30, 2016 is as follows:

	Shares of Restricted Stock	Weighted-Average Grant Date Fair Value
Outstanding at January 1, 2016	213,904	$ 1.87
Granted	-	
Vested	(213,904)	$ 1.87
Forfeited	-	
Outstanding at September 30, 2016	-	

All restricted stock was vested as of September 30, 2016. The total intrinsic value of all restricted stock vested in the nine months ended September 30, 2016 was approximately $111,000.

Stock Purchase Warrants. In the past, we have issued Warrants to purchase common stock to certain officers, directors, stockholders and service providers as well as in conjunction with debt and equity offerings and at various times replacement warrants were issued as an inducement for warrant exercises.

In May 2016, we issued 22,700,000 stock purchase warrants in conjunction with our equity raise transactions. Such warrants are classified as derivative liabilities and are recorded at fair value each period due to the existence of non-standard anti-dilution conditions contained in the warrants. See Note 3.

A summary of warrant activity for the nine months ended September 30, 2016 is as follows:

	Number of Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2016	19,652,096	$ 2.34	3.1	$309,724
Granted	22,850,000	$ 0.40	4.6	
Exercised	-			$-
Forfeited	(1,440,000)	$ 3.85		
Outstanding at September 30, 2016	41,062,096	$ 1.20	3.7	$3,000
Exercisable at September 30, 2016	40,949,596	$ 1.21	3.7	$750

Common Stock

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

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

During the nine months ended September 30, 2015, we issued 1,059,980 shares of our common stock upon the cashless exercise of 2,209,000 outstanding common stock purchase warrants and stock options. The warrants and options were exercised at an average price of $0.62. We received no proceeds from the exercises.

During the nine months ended September 30, 2016, we issued 55,255 shares of our common stock upon the conversion of 61,720 outstanding restricted stock units.

On May 03, 2016, we completed a public offering of 20,000,000 shares of common stock and 20,000,000 common stock purchase warrants at a public offering price of $0.40 per each share and common stock purchase warrant. We received aggregate gross proceeds of $8.0 million and net proceeds of approximately $7,229,000 from the offering. The warrants allow the holder to purchase one share of common stock, have an exercise price of $0.40 per share and a

term of 5 years. The warrants contain certain non-standard anti-dilution protection and consequently, are being accounted for as derivative instruments recorded at fair value each period (See Note 3). The costs directly related to this offering were allocated between the common stock and the derivative instruments with those being allocated to the derivative instruments being expensed as incurred and those allocated to the common stock being charged directly to additional paid-in capital. This offering was made pursuant to our shelf registration statement declared effective by the SEC on June 19, 2014 (Registration No. 333-196567).

On May 12, 2016, we entered into private placement securities purchase agreements with certain accredited investors to purchase 2,700,000 of common stock and 2,700,000 common stock purchase warrants at a price of $0.40 per each share and common stock purchase warrant. We received aggregate gross proceeds of approximately $1,080,000 and net proceeds of approximately $925,000. The warrants allow the holder to purchase one share of common stock, have an exercise price of $0.40 per share and a term of 5 years. The warrants contain certain non-standard anti-dilution protection and consequently, are being accounted for as derivative instruments recorded at fair value each period (See Note 3). The costs directly related to this offering were allocated between the common stock and the derivative instruments with those being allocated to the derivative instruments being expensed as incurred and those allocated to the common stock being charged directly to additional paid-in capital. This private placement transaction was not made pursuant to any registration statement.

During the nine months ended September 30, 2016 we issued 62,500 shares of common stock as a result of stock sales to certain employees at an average price of $0.32. We received $20,000 of net proceeds from these sales.

Note 6. Commitments and Contingencies

We currently operate three facilities located in the United States and one facility located in People’s Republic of China. Our corporate offices and primary research facilities are located in Germantown, Maryland, where we license approximately 1,500 square feet. This license provides for monthly payments of approximately $5,300 per month, expires on December 31, 2016 and can be terminated by us upon 60 days written notice.

In 2015, we entered into a lease consisting of approximately 3,100 square feet of research space in San Diego, California. This lease provides for current monthly payments of approximately $11,000 and expires on August 31, 2018. In conjunction with our recent cost-reduction exercise, we are currently exploring opportunities to sub-lease this facility.

In 2016, we entered into a license for an Incubator Laboratory Facility in Urbana, Illinois. The license provides for monthly payments of $1,800, expires on December 31, 2019 and can be terminated by us upon 90 days written notice.

We also lease a research facility in People's Republic of China. This lease expires on September 30, 2018 with lease payments of approximately $3,200 per month.

From time to time, we are parties to legal proceedings that we believe to be ordinary, routine litigation incidental to the business of present or former operations. We are currently not a party to any litigation or legal proceeding.

The Company is currently obligated under three written employment agreements and a general release agreement. The employment agreements are with our: (i) Chief Executive Officer, (ii) Chief Scientific Officer ("CSO") and (iii) Chief Financial Officer ("CFO"): Pursuant to the terms of the agreements, our CEO, CSO and CFO receive annual salaries of $410,000, $490,000 and $315,000, respectively. The agreements also provide for the payment of severance in the event one of the executives is terminated and in certain circumstances, the agreements also provide for the acceleration of vesting with regard to options.

On March 1, 2016, Neuralstem, Inc. (the "Company") entered into a General Release and Waiver of Claims ("General Release") with I. Richard Garr in connection with his resignation as the Company's chief executive officer. Pursuant to the General Release, Mr. Garr will: (i) continue to receive his monthly salary of $36,667 until March 1, 2017, (ii) receive lump sum payments of $177,000 to be paid on June 1, 2016, January 1, 2017 and March 1, 2017, (iii) receive healthcare benefits until January 1, 2017, and (iv) be entitled to the immediate vesting of any previously outstanding but unvested equity awards (collectively, the "Severance"). This General Release and Waiver of Claims was amended on June 16, 2016, whereupon Mr. Garr voluntarily agreed to forego the lump sum payments due to him on January 1, 2017 and March 1, 2017.

Note 7. Cost-Reduction Plan

On May 20, 2016 we announced that we had committed to a cost-reduction plan in order to better utilize our resources on the implementation of our refocused clinical and corporate strategy. This cost-reduction plan includes a reduction in force across all of the Company's departments. With the exception of an on-going lease obligations on our facility in San Diego, California we completed this cost-reduction plan in the quarter ended June 30, 2016. As a result of this cost-reduction plan we incurred total costs of approximately $470,000 comprised of $413,000 for severance and other

employee payments, and $57,000 of non-cash costs for the modification of employee stock options. Of the total expense, $312,000 is included in research and development expense and $158,000 is included in general and administrative expense in our statement of operations for the nine months ended September 30, 2016. At September 30, 2016, a balance of approximately $17,000 remained to be paid and such balance is reflected as an accrued expense in our unaudited condensed consolidated balance sheet.

Our facility in San Diego, California consists of 3,100 square feet of research space. This lease provides for current monthly payments of approximately $11,000 and expires on August 31, 2018. We are currently exploring opportunities to sub-lease this facility.

Note 8. Related Party Receivable

On August 10, 2016, we entered into a reimbursement agreement with a former executive officer. Pursuant to the reimbursement agreement, the former officer agreed to repay the Company, over a six-year period, approximately $658,000 in expenses that the Company determined to have been improperly paid under the Company's prior expense reimbursement policies. In addition to this reimbursement agreement, the Company has implemented and is continuing to implement enhanced policies and procedures for travel expense reimbursements and disbursements.

The $658,000 non-interest bearing receivable is recorded net of a $199,000 discount to reflect the net present value of the future cash payments. The Company recorded a non-operating gain of $459,000 for the three- and nine- month periods ended September 30, 2016. The discount will be amortized through interest income using the effective interest method. The entire amount of $658,000 remains outstanding at September 30, 2016 and is payable in $100,000 annual installments with a final balloon payment due six years from issuance.

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

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

We urge you to read this entire Quarterly Report on Form 10-Q, including the "Risk Factors" section, the financial statements, and related notes. As used in this Quarterly Report, unless the context otherwise requires, the words "we," "us," "our," "the Company," "Neuralstem" and "Registrant" refers to Neuralstem, Inc. and its subsidiaries. Also, any reference "common shares," "common stock," or "shares" refers to our $.01 par value common stock. The information contained herein is current as of the date of this Quarterly Report (September 30, 2016), unless another date is specified. We prepare our interim financial statements in accordance with U.S. GAAP. Our financials and results of operations for the three- and nine-month periods ended September 30, 2016 are not necessarily indicative of our prospective financial condition and results of operations for the pending full fiscal year ending December 31, 2016. The interim financial statements presented in this Quarterly Report as well as other information relating to our Company contained in this Quarterly Report should be read in conjunction and together with the reports, statements and information filed by us with the United States Securities and Exchange Commission or SEC.

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

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

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

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

- *Results of Operations*— Analysis of our financial results comparing the three-month and nine-month periods ended September 30, 2016 to the comparable period of 2015.

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

Executive Overview

We are focused on the research, development and commercialization of central nervous system therapies based on our proprietary human neural stem cells and small molecule compounds discovered from our stem cell-based screening platform. We are headquartered in Germantown, Maryland and have a wholly-owned subsidiary in China, Suzhou Neuralstem Biopharmaceutical Co. Ltd ("Neuralstem China").

Our technology base has produced three primary assets: Our NSI-189 small molecule program, our NSI-566 stem cell therapy program and our novel and proprietary new chemical entity screening platform. We have two product candidates in clinical development in a total of four indications.

In the cell therapy program, our patented technology enables the commercial-scale production of multiple types of central nervous system stem cells, which are under development for the potential treatment of various central nervous system diseases and conditions. Our lead product is the spinal cord-derived neural stem cell line, NSI-566, which is being tested for treatment of paralysis due to ALS, spinal cord injury and stroke. In addition, our ability to generate human neural stem cell lines provides a platform for screening and discovery of novel CNS-targeted compounds. This proprietary screening platform led to the discovery of our lead molecule, NSI-189, which is being tested for treatment of major depressive disorder.

We have developed and maintain what we believe is a strong portfolio of patents and patent applications that form the proprietary base for our research and development efforts. We own or exclusively license over 20 U.S. issued and pending patents and over 120 foreign issued and pending patents in the field of regenerative medicine, related to our stem cell technologies as well as our small molecule compounds.

We believe our technology base, in combination with our expertise, and collaborative projects with major research institutions, could facilitate the development and commercialization of products for use in the treatment of a wide array of central nervous system disorders including neurodegenerative and psychiatric conditions.

There can be no assurances that we will ultimately produce any viable products or processes or that our screening platform will lead to the discovery of any additional product candidates. Even if we are able to produce a commercially viable product, there are strong competitors in this field and our products may not be able to successfully compete against them.

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

Recent Clinical & Business Highlights

- In May 2016, we enrolled the first subject in our NSI-189 Phase 2 clinical trial for the treatment of major depressive disorder (MDD).

- In June 2016, we announced new NSI-189 preclinical data showing enhancement of mouse long term potentiation (LTP), an in vitro biomarker of memory by NSI-189 in a concentration-dependent and time-dependent manner. We believe that this study not only suggests the cognition enhancing potential of NSI-189, but also contributes toward the understanding of its mechanism of action.

- In September 2016, we entered into a definitive agreement with Tianjin Pharmaceutical Holdings Co., Ltd. for a private placement of common stock and convertible preferred stock for gross proceeds of $20 million. This agreement is expected to close in the fourth quarter of 2016.

- In September 2016, we achieved 50% enrollment in our Phase 2 clinical trial evaluating NSI-189 for the treatment of major depressive disorder (MDD).

- In September 2016, we presented preclinical data which showed that NSI-189 was effective in the prevention and reversal of diabetic neuropathies in Type 1 and Type 2 diabetic mouse models.

- In October 2016, we presented preclinical data which showed NSI-189's ability to ameliorate radiation-induced cognitive impairment and to protect hippocampal neurogenesis in a mouse model of brain injury due to radiation therapy of brain cancers.

Clinical Development Program Review

We have devoted substantially all of our efforts to the pre-clinical and clinical development of our small molecule compounds and our stem cell therapeutics. Below is a description of our most advanced clinical programs, their intended indications, current stages of development and our expected future development plans:

Clinical Pipeline:

Pipeline Summary

NSI-189 Phase 2 randomized, placebo-controlled, double-blind clinical trial for the treatment of MDD

- In May 2016, we enrolled the first subject in our NSI-189 Phase 2 clinical trial for the treatment of MDD. The Phase 2 trial will randomize 220 patients, in three cohorts (two active doses plus placebo), at 12 select trial sites, under the direction of study principal investigator (PI) Maurizio Fava, MD, Executive Vice Chair, Department of Psychiatry and Executive Director, Clinical Trials Network and Institute, Massachusetts General Hospital. In September 2016, we announced that we had achieved 50% enrollment in the study. We expect to release the results of this study in the second half of 2017.

NSI-566 Phase 1 and 2 safety trials for the treatment of Amyotrophic Lateral Sclerosis (ALS)

- In September 2015, the Phase 2 interim data and the Phase 1 and Phase 2 combined interim data were presented at the American Neurological Association Annual Meeting by the principal investigator, Eva Feldman, MD, PhD, Director of the A. Alfred Taubman Medical Research Institute and Director of Research of the ALS Clinic at the University of Michigan Health. The data showed that the intraspinal transplantation of the cells was safe and well tolerated. Subjects from both the Phase 1 and Phase 2 continue to be monitored for long-term follow-up evaluations.

NSI-566 Phase 1 safety trial for the treatment of chronic Spinal Cord Injury (cSCI)

- In January 2016, we reported on the interim status of the Phase 1 safety data on all four subjects with thoracic spinal cord injuries; the stem cell treatment demonstrated feasibility and safety. A self-reported ability to contract some muscles below the level of injury was confirmed via clinical and electrophysiological follow-up examinations in one of the four subjects treated. All subjects will be followed for five years. This study is being conducted with support from the University of California, San Diego (UCSD) School of Medicine.

NSI-566 Phase 1 safety trial for the treatment of motor deficits in stroke

- In March, 2016, we completed dosing the third planned cohort, for a total of nine subjects, in a Phase 1 clinical trial evaluating safety at BaYi Brain Hospital in Beijing. Subjects are currently being monitored through their 24 month observational follow-up period. The trial is being conducted by Suzhou Neuralstem, a wholly owned subsidiary of Neuralstem in China.

Pre-Clinical Development Pipeline

We conduct investigational and discovery research on our proprietary neural stem cell lines, neurogenic small molecule screening platform, and neurogenic small molecule portfolio. We believe each of our three proprietary technologies are best in class. Our technologies enable us to identify unique neural stem cell lines for potential transplantation therapies and to utilize these stem cell lines to screen for novel new small molecule drugs. NSI-189 is a result of this screening technology, which we believe will be a significant treatment option for patients with depression or cognitive impairment.

Our preclinical research on NSI-189 is focused on elucidating its mechanism of action and investigating its potential utility as a broad neuroregenerative drug that promotes self-repair of various types of central and peripheral nerve degeneration. Recent preclinical data support this perspective on NSI-189 beyond the current indication of MDD. Supportive data include the finding that treatment of mouse brain slices with NSI-189 can cause within a few hours a dose-dependent enhancement of the magnitude of long term potentiation, a measure of synaptic plasticity and an in vitro biomarker of memory. Additionally, NSI-189 treatment of brain slices from mice with Angelman Syndrome-like genetic defect (which in humans leads to inherited mental retardation) restored LTP to normal levels. NSI-189 treatment of rats irradiated to induce brain injury that leads to cognitive impairment protected the brain to normal levels. These results suggest that the potential application of NSI-189 to treat diseases with cognitive impairment could be successful. Furthermore, NSI-189 was effective in the prevention and reversal of peripheral neuropathies due to diabetes in Type 1 or Type 2 diabetic mouse models, which suggest NSI-189's broad applicability toward treating both central and peripheral neuropathies arising from diverse etiologies. We believe that these data support our future outlook for NSI-189 beyond the ongoing Phase 2 clinical trial for the treatment of MDD and beyond even the potential treatment benefit of residual cognitive impairment in depressed patients.

Our Technologies

Stem Cells

Our technology enables the isolation and large-scale expansion of regionally specific, human neural stem cells from all areas of the developing human brain and spinal cord, thus enabling the generation of physiologically relevant human neurons of all types. We believe that our stem cell technology will assist the body in producing new cells to replace malfunctioning or dead cells as a way to treat disease and injury. Many significant and currently untreatable human diseases arise from the loss or malfunction of specific cell types in the body. Our focus is the development of effective methods to protect such cell types and in certain cases to generate replacement cells from neural stem cells. We believe that protecting the healthy cells or replacing damaged, malfunctioning or dead neural cells with fully functional ones may be a useful therapeutic strategy in treating many diseases and conditions of the central nervous system. We own or exclusively license over 10 U.S. issued and pending patents and over 70 foreign issued and pending patents related to our stem cell and related medical device technologies.

Small Molecule Compounds

The inhibition of adult hippocampal neurogenesis has been implicated in a number of diseases that affect cognition and/or emotion such as major depressive disorder. Utilizing our proprietary stem cell-based screening capability, we have developed and patented a series of small molecule compounds that stimulated neurogenesis in vitro. As part of our research, we focused on small molecule compounds that could enhance the baseline level of neurogenesis in normal healthy young mice in vivo.

Subsequent research indicated that some of the small molecule compounds could stimulate the neurogenesis of hippocampus as well as increase its volume. We believed that a compound that stimulates in vitro neurogenesis, enhances in vivo neurogenesis, increases hippocampal volume, and exerts anti-depressive effects on animals could be well-suited for treating major depressive disorder. During our preclinical research, we identified NSI-189 as the lead candidate that could stimulate all four activities. Pre-clinical testing of this compound at multiple doses showed antidepressant activity at 10, 30, and 100mg/kg doses with rapid bioavailability in the brain. Histology analysis of the mouse brains suggested a bell-shaped dose-response curve, 10mg/kg and 30mg/kg being optimal for pharmacologically active concentrations and with higher doses not necessarily yielding larger biological effects. Our collaborators at Massachusetts General Hospital have presented the human data from the Phase 1b MDD safety study which showed large effect size of clinical improvement in depressive and cognitive scales. This result was unexpected given the small size of the trial and may be indicative of the drug's promise as a therapeutic agent. We believe that NSI-189 stimulates neurogenesis and synaptogenesis in the human hippocampus.

Our portfolio of small molecule compounds which includes NSI-189 are covered by 10 U.S. exclusively owned issued and pending patents and over 60 exclusively owned foreign issued and pending patents related to our small molecule compounds.

Targeted Indications

Major Depressive Disorder (MDD)

NSI-189 is being developed for the treatment of major depressive disorder and other psychiatric and/or cognitive impairment indications associated with hippocampal atrophy. NSI-189 is the lead compound in our neurogenic small molecule drug platform. We believe that NSI-189 may provide an effective treatment for patients suffering from MDD by promoting neurogenesis and an underlying molecular pathway.

Major depressive disorder, or MDD (also known as recurrent depressive disorder, clinical depression, major depression, unipolar depression, or unipolar disorder), is a mental disorder characterized by episodes of all-encompassing low mood accompanied by low self-esteem and loss of interest or pleasure in normally enjoyable activities. MDD affects approximately 14.8 million American adults, or about 6.7 percent of the U.S. population age 18 and older in a given year. Additionally, there is a high failure rate with existing therapies. According to the STAR*D* study, 51% of subjects fail to respond to first-line therapy, 72% fail second-line therapy and 83% fail third line therapy. This creates a large unmet medical need and a significant market opportunity for alternative branded molecules such as NSI-189 for use as mono- or adjunct therapies that may replace or enhance current marketed therapies.

* Sequenced Treatment Alternatives to Relieve Depression (STAR*D) trial (Am J Psychiatry 2006; 163:1905–1917)

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Amyotrophic Lateral Sclerosis (ALS)

Amyotrophic lateral sclerosis, or ALS, is a disease of the nerve cells in the brain and spinal cord that control voluntary muscle movement. ALS is an orphan condition in the U.S. and EU and approximately 6,400 people in the U.S. are diagnosed with the condition each year. The incidence of ALS is two per 100,000 people, and it is estimated that more than 20,000 Americans may be living with ALS at any given time. In ALS, nerve cells (neurons) waste away or die, and can no longer send messages to muscles. This eventually leads to muscle weakening, twitching, and an inability to move the arms, legs, and body. The condition slowly gets worse. When the muscles in the chest area stop working, it becomes hard or impossible to breathe. NSI-566 is under development as a potential treatment for ALS by providing cells designed to nurture and protect the patients' remaining motor neurons; and possibly repair some motor neurons which have not yet died but which are diseased. Neuralstem received orphan designation by the FDA for NSI-566 in ALS.

Chronic Spinal Cord Injury

A spinal cord injury, or SCI, generally refers to any injury to the spinal cord that is caused by trauma instead of disease although in some cases, it can be the result of diseases. It is estimated that there are 12,500 new cases of SCI per year and that at any given time, there are between 240,000 and 337,000 people in the United States that are living with SCI. Chronic spinal cord injury generally refers to the phase beginning 6 months after the initial injury. SCIs are most often traumatic, caused by lateral bending, dislocation, rotation, axial loading, and hyperflexion or hyperextension of the cord or cauda equina. Motor vehicle accidents are the most common cause of SCIs, while other causes include falls, work-related accidents, sports injuries, and penetrations such as stab or gunshot wounds. In certain instances, SCIs can also be of a non-traumatic origin, as in the case of cancer, infection, intervertebral disc disease, vertebral injury and spinal cord vascular disease. We believe that NSI-566 may provide an effective treatment for chronic spinal cord injury by "bridging the gap" in the spinal cord circuitry created in traumatic spinal cord injury and providing new cells to help transmit the signal from the brain to points at or below the point of injury.

Ischemic Stroke

Ischemic strokes, the most common type of stroke, occur as a result of an obstruction within a blood vessel supplying blood to the brain. Approximately 15 million people worldwide suffer stroke of which it is estimated that 87% of all strokes are ischemic strokes. Post-stroke motor deficits include paralysis in arms and legs and can be permanent. We believe that NSI-566 may provide an effective treatment for restoring motor deficits resulting from ischemic stroke by both creating new circuitry in the area of injury and through repairing and or nurturing diseased cells to improve function in patients.

Intellectual Property

Our research and development is supported by our intellectual property. We own or exclusively license over 20 U.S. issued and pending patents and over 120 foreign issued and pending patents in the field of regenerative medicine, related to our stem cell technologies as well as our small molecule compounds. Our issued patents have expiration dates ranging from 2016 through 2034, based on appropriate Patent Expansions. In our opinion the patents expiring in 2016 and in the near term are not critical to our business.

Operating Strategy

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

Employees

As of September 30, 2016, we had 11 full-time employees. Of these full-time employees, 7 work on research and development and clinical operations and 4 work in administration. We also use the services of numerous outside consultants in business and scientific matters.

Our Corporate Information

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

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

Trends & Outlook

Revenue

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

During the nine months ended September 30, 2016 and 2015, we recognized approximately $8,000 of revenue in each period related to ongoing fees pursuant to certain licenses of our intellectual property to third parties.

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

Research and Development Expenses

Our research and development expenses consist primarily of clinical trial expenses, including payments to clinical trial sites that perform our clinical trials and clinical research organizations (CROs) that help us manage our clinical trials; manufacturing of small molecule drugs and stem cells for both human clinical trials and for pre-clinical studies and research; personnel costs for research and clinical personnel; and other costs including research supplies and facilities.

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, which include expenses related to our ongoing clinical trials, will increase in the future, as funding allows and we proceed with our Phase 2 trial in major depressive disorder.

We have formed a wholly owned subsidiary in the People's Republic of China. We anticipate that this subsidiary will primarily: (i) conduct pre-clinical research with regard to proposed stem cells therapies, and (ii) oversee our approved future clinical trials in China, including the current trial to treat motor deficits due to ischemic stroke.

General and Administrative Expenses

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

Critical Accounting Policies

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

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

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

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

Long Lived Intangible Assets - Our long lived intangible assets consist of our intellectual property patents including primarily legal fees associated with the filings and in defense of our patents. The assets are amortized on a straight-line basis over the expected useful life which we define as ending on the expiration of the patent group. These assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. We assess this recoverability by comparing the carrying amount of the asset to the estimated undiscounted future cash flows to be generated by the asset. If an asset is deemed to be impaired, we estimate the impairment loss by determining the excess of the asset’s carrying amount over the estimated fair value. These determinations use assumptions that are highly subjective and include a high degree of uncertainty. During the nine months ended September 30, 2016 and 2015, no significant impairment losses were recognized.

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

Share-Based Compensation - We account for share-based compensation at fair value; accordingly we expense the estimated fair value of share-based awards over the requisite service period. Share-based compensation cost for stock options and warrants issued to employees and board members is determined at the grant date while awards granted to non-employee consultants are generally valued at the vesting date using an option pricing model. Option pricing models require us to make assumptions, including expected volatility and expected term of the options. If any of the assumptions we use in the model were to significantly change, stock based compensation expense may be materially different. Share-based compensation cost for restricted stock and restricted stock units issued to employees and board members is determined at the grant date based on the closing price of our common stock on that date. The value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period.

RESULTS OF OPERATIONS

Comparison of Three Months Ended September 30, 2016 and 2015

Revenue

During each of the three months ended September 30, 2016 and 2015, we recognized approximately $2,500 of revenue related to ongoing fees pursuant to certain licenses of our intellectual property to third parties.

Operating Expenses

Operating expenses for the three months ended September 30, 2016 and 2015 were as follows:

	Three Months Ended September 30,		Increase (Decrease)	
	2016	2015	$	%
Operating Expenses				
Research and development expenses	$3,589,793	$3,392,086	$197,707	6 %
General and administrative expenses	1,329,712	1,807,934	(478,222)	(26%)
Total operating expenses	$4,919,505	$5,200,020	$(280,515)	(5 %)

Research and Development Expenses

The increase of approximately $198,000 or 6% in research and development expenses for the period ended September 30, 2016 compared to the comparable period of 2015 was primarily attributable to increased spending on clinical trials associated with our on-going Phase 2 MDD study, partially offset by salary and benefits saving associated with our reduction-in-force in May and reduced manufacturing expenses

General and Administrative Expenses

The decrease of approximately $478,000 or 26% in general and administrative expenses for the period ended September 30, 2016 compared to the comparable period of 2015 was primarily due to a reduction in salaries, benefits and consulting expenses as a result of our May 2016 reduction-in-force.

Other expense

Other expense, net totaled approximately $303,000 and $440,000 for the three months ended September 30, 2016 and 2015, respectively. Other expense, net in 2016 consisted of approximately $538,000 of losses related to the fair value adjustment of our derivative instruments and $240,000 of interest expense primarily related to our long-term debt, partially offset by a gain of approximately $459,000 related to our entering into a reimbursement agreement with a former executive officer.

Other expenses, net in 2015 consisted primarily of approximately $464,000 of interest expense principally related to our long-term debt partially offset by approximately $24,000 in interest income.

Comparison of Nine months ended September 30, 2016 and 2015

Revenue

During the nine months ended September 30, 2016 and 2015, we recognized approximately $7,500 and $7,900 of revenue, respectively, related to ongoing fees pursuant to certain licenses of our intellectual property to third parties.

Operating Expenses

Operating expenses for the nine months ended September 30, 2016 and 2015 were as follows:

	Nine Months Ended September 30,		Increase (Decrease)	
	2016	2015	$	%
Operating Expenses				
Research and development expenses	$9,130,012	$9,887,750	$(757,738)	(8 %)
General and administrative expenses	5,862,374	4,925,389	936,985	19%
Total operating expenses	$14,992,386	$14,813,139	$179,247	1 %

Research and Development Expenses

The decrease of approximately $758,000 or 8% in research and development expenses for the period ended September 30, 2016 compared to the comparable period of 2015 was primarily attributable to a decrease in manufacturing costs associated with producing clinical supplies of NSI-189 partially offset by an increase pre-clinical and clinical trial expenses related to the initiation of our Phase 2 MDD study.

General and Administrative Expenses

The increase of approximately $937,000 or 19% in general and administrative expenses for the period ended September 30, 2016 compared to the comparable period of 2015 was primarily due to a severance accrual and increased non-cash stock based compensation resulting from the accelerated vesting of options, both related to the resignation of our former Chief Executive Officer coupled with non-cash stock based compensation expense resulting from grants to our new Chief Executive Officer which were partially offset by a decrease in our employee bonus expense.

Research and development and general and administrative expenses for the nine months ended September 30, 2016 include approximately $312,000 and $158,000, respectively related to our May 2016 cost-reduction effort. The total $470,000 of expense is comprised of approximately $413,000 for severance and other employee payments, and $57,000 of non-cash costs for modification of employee stock options.

Other expense

Other expenses, net totaled approximately $694,000 and $1,334,000 for the nine months ended September 30, 2016 and 2015, respectively. Other expense, net in 2016 consisted of approximately $949,000 of interest expense primarily related to our long-term debt and $464,000 of fees related to the issuance of our derivative instruments, partially offset by a gain of approximately $459,000 related to our entering into a reimbursement agreement with a former executive officer of the Company and $219,000 of gain related to the change in the fair value adjustment of our derivative instruments.

Other expenses, net in 2015 consisted primarily of approximately $1,377,000 of interest expense principally related to our long-term debt partially offset by approximately $54,000 in interest income.

Liquidity and Capital Resources

Financial Condition

Our Cash and Cash Equivalent balances were approximately $5.7 million as of September 30, 2016. We believe these funds are only sufficient to fund operations through December 2016.

We will require additional capital to continue to develop our pre-clinical and clinical development operations. We cannot assure you that we will be able to secure additional financing or that the expected income will materialize. Several factors will affect our ability to raise additional funding, including, but not limited to market conditions, interest rates and, more specifically, our progress in our exploratory, preclinical and future clinical development programs.

Since our inception, we have financed our operations through the sales of our securities, issuance of long term debt, the exercise of investor warrants, and to a lesser degree from grants and research contracts.

	Nine Months Ended September 30,	Increase (Decrease)

	2016	2015	$	%
Net cash used in operating activities	$(11,535,750)	$(15,032,404)	$3,496,654	23 %
Net cash provided by investing activities	$7,389,182	$9,800,395	$(2,411,213)	25 %
Net cash provided by financing activities	$5,105,271	$5,845,636	$(740,365)	(13%)

Net Cash Used in Operating Activities

We used approximately $11,536,000 and $15,032,000 of cash in our operating activities for the nine months ended September 30, 2016 and 2015, respectively. The decrease in our use of cash in operating activities of approximately $3,497,000 was primarily due to reduction in cash used in our daily operations and a reduction in cash invested in working capital.

Net Cash Provided by Investing Activities

For the nine months ended September 30, 2016 and 2015 respectively, we received approximately $7,389,000 and $9,800,000 of cash primarily in connection with the liquidation of our CDAR investments as they matured in order to fund operations.

Net Cash Provided by Financing Activities

We received approximately $5,105,000 and $5,846,000 from financing activities in the nine months ended September 30, 2016 and 2015, respectively. Net proceeds from our two financings in May 2016 of approximately $8,154,000 were partially offset by loan principal repayments of approximately $3,382,000. For the corresponding period in 2015, net cash provided in financing activities related substantially to proceeds from equity transactions.

Future Liquidity and Needs

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

We intend to pursue opportunities to obtain additional financing in the future through the sale of our securities and additional research grants. We currently have two shelf registration statements that are effective. On September 13, 2013, our shelf registration statement (Registration No. 333-190936) registering the sale of up to $50 million of our securities was declared effective by the SEC. To date, through September 30, 2016 we have sold or reserved for sale upon the exercise of outstanding warrants approximately $48.2 million of securities under this shelf registration statement. On June 19, 2014, our shelf registration statement (Registration No. 333-196567) registering the sale of up to $100 million of our securities was declared effective by the SEC. To date, through September 30, 2016 we have sold or reserved for sale upon exercise of outstanding warrants approximately $16.0 million of securities under this shelf registration statement.

On September 7, 2016, we entered into a definitive securities purchase agreement with Tianjin Pharmaceutical Holdings Co., Ltd. for the private placement of $20,000,000 of our securities. The offering is expected to close during the fourth quarter of 2016 in accordance with the regulations of money transfers of the People’s Republic of China. Notwithstanding the foregoing, there can be no assurance that the transaction will close during such period.

We anticipate conducting financing in the future based on our shelf registration statement when and if financing opportunities arise.

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

We are subject to interest rate risk for our long-term debt which contains a floating interest rate based on Wall Street Journal published prime rate. For the full year ended December 31, 2016 a one percentage point increase in the prime rate would increase our interest expense by approximately $61,000.

Our foreign operations in China subject us to changes in foreign exchange rates. Changes in exchange rates for the year ended December 31, 2016 are not expected to have a material effect as the operations are expected to be limited. Future changes to foreign exchange rates could have a material effect on us as our clinical trial activity increases.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Based on an evaluation under the supervision and with the participation of the Company's management, the Company's principal executive officer and principal financial officer have concluded that the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act were effective as of September 30, 2016, to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms and (ii) accumulated and communicated to the Company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

Management has identified the following changes in our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) that occurred during the second quarter of 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

In conjunction with the cost-reduction plan discussed in Footnote 7, we have outsourced the majority of our accounting and finance functions to external third party consultants. These outside consultants work under the supervision of and will be supported by our Chief Financial Officer.

Inherent Limitations Over Internal Controls

The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles ("GAAP"). The Company's internal control over financial reporting includes those policies and procedures that:

(i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the Company's assets;

(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that the Company's receipts and expenditures are being made only in accordance with authorizations of the Company's management and directors; and

(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Management, including the Company's principal executive officer and principal financial officer, does not expect that the Company's internal controls will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of internal controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Also, any evaluation of the effectiveness of controls in future periods are subject to

the risk that those internal controls may become inadequate because of changes in business conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PART II

OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. We have described below a number of uncertainties and risks which, in addition to uncertainties and risks presented elsewhere in this Quarterly Report, may adversely affect our business, operating results and financial condition. The uncertainties and risks enumerated below as well as those presented elsewhere in this Quarterly Report, and those included in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC should be considered carefully in evaluating our company and our business and the value of our securities.

Risks Relating to Our Stage of Development and Capital Structure

We may not be able to continue as a going concern if we do not obtain additional financing by December, 2016.

The Company has incurred losses since its inception and has not demonstrated an ability to generate revenues from sales or services. These factors create substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustment that might be necessary if the Company is unable to continue as a going concern.

Our cash and cash equivalents balance at September 30, 2016 was approximately $5.7 million. Based on our current expected level of operating expenditures, we expect these funds to be only sufficient to fund our operations through December 31, 2016. On September 7, 2016, we entered into a definitive securities purchase agreement with Tianjin Pharmaceutical Holdings Co., Ltd. for the private placement of $20,000,000 of our securities. The offering is expected to close during the fourth quarter of 2016 in accordance with the regulations of money transfers of the People's Republic of China. Notwithstanding the foregoing, there can be no assurance that the transaction will close during

such period or at all. Our ability to continue as a going concern is wholly dependent upon obtaining sufficient financing to fund our operations.

Despite our ability to secure capital in the past, there is no assurance that additional equity or debt financing will be available to us when needed. In the event that we are not able to secure financing, we may be forced to curtail operations, delay or stop ongoing clinical trials, cease operations altogether or file for bankruptcy.

Our auditors have expressed substantial doubt about our ability to continue as a going concern.

Our auditors' report on our December 31, 2015 financial statements expressed an opinion that our capital resources as of the date of their Audit Report were not sufficient to sustain operations or complete our planned activities for the upcoming year unless we raised additional funds. Accordingly, our current cash level raises substantial doubt about our ability to continue as a going concern. If we do not obtain additional funds by such time, we may no longer be able to continue as a going concern and will cease operation which means that our shareholders may lose their entire investment.

We have a history of losses.

Since inception in 1996 and through September 30, 2016, we have accumulated losses totaling approximately $187,637,000. On September 30, 2016, we had a working capital deficit of approximately $1,165,000 and stockholders' deficit of approximately $3,785,000. Our net losses for the two most recent fiscal years have been approximately $20,904,000 and $22,629,000, for 2015 and 2014, respectively, while our loss for the nine months ended September 30, 2016 was approximately $15,679,000. We have generated no significant revenue from the sales of our proposed products.

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

We will need to raise additional capital to continue operations.

Since our inception, we have funded our operations through the sale of our securities, credit facilities, the exercise of options and warrants, and to a lesser degree, from grants and research contracts and other revenue generating activities such as licensing. As of September 30, 2016, we had cash, cash equivalents and short-term investments on hand of approximately $5.7 million. On September 7, 2016, we entered into a definitive securities purchase agreement with Tianjin Pharmaceutical Holdings Co., Ltd. for the private placement of $20,000,000 of our securities. The offering is expected to close during the fourth quarter of 2016 in accordance with the regulations of money transfers of the People's Republic of China. Notwithstanding the foregoing, there can be no assurance that the transaction will close during such period or at all. We cannot assure you that we will be able to secure additional capital through financing transactions, including issuance of debt, licensing agreements or grants. Our inability to license our intellectual property, obtain grants or secure additional financing will materially impact our ability to fund our current and planned operations.

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

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

We have a substantial level of debt. As of September 30, 2016, we had approximately $4,953,000 in aggregate principal amount long-term indebtedness outstanding. Under our amended loan and security agreement, we were required to make monthly interest only payments through September 2015; and are required to make monthly interest and principal payments of approximately $435,000 per month from January 2016 through March 2017 and make a balloon payment for the remaining principal in April 2017. As security for such indebtedness, we have pledged substantially all of our assets, including our intellectual property. If we are unable to make the required payments, or if we fail to comply with the various requirements and covenants of our indebtedness, we would be in default, which would permit the holders of our indebtedness to accelerate the maturity and require immediate repayment and lead to potential foreclosure on the assets securing the debt. Any default under our indebtedness would have a material adverse effect on our business, operating results and financial condition. Additionally, our amended loan and security agreement governing this loan also contains a number of affirmative and restrictive covenants, including reporting requirements and other collateral limitations, certain limitations on liens and indebtedness, dispositions, mergers and acquisitions, restricted payments and investments, corporate changes and limitations on waivers and amendments to certain agreements, our organizational documents, and documents relating to debt that is subordinate to our

obligations under the credit facility. Our failure to comply with the covenants in the amended loan and security agreement could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our debt and potential foreclosure on the assets securing the debt. If we are unable to refinance or repay our indebtedness as it becomes due, including upon an event of default, we may become insolvent and be unable to continue operations.

If we are unable to submit and gain approval for a compliance plan with the Nasdaq Capital Market, our securities will be delisting.

On October 18, 2016, we received notice from the Listing Qualifications Staff (the "Staff") of The NASDAQ Stock Market LLC ("Nasdaq") indicating that the Staff had determined to delist the Company's securities from The Nasdaq Capital Market due to the Company's continued non-compliance with the $1.00 bid price requirement unless the Company timely requested a hearing before the Nasdaq Hearings Panel (the "Panel"). The Company has requested a hearing before the Panel, which request will stay any delisting action by the Staff until such hearing is held. At the hearing, the Company will present its plan to regain compliance with all applicable requirements for continued listing on Nasdaq.

The Company is diligently working on the plan it will present at the hearing; however, there can be no assurance that the Panel will determine to continue listing the Company's common stock on Nasdaq or that the Company will be able to evidence compliance with the applicable listing criteria within the period of time that may be granted by the Panel.

Should Nasdaq reject the Company's plan, the Company faces delisting of its shares on the Nasdaq Capital Market. If delisted, our shares would likely trade on the OTCQB market ("Pink Sheets"). Being delisted from the Nasdaq will likely result in difficulties in future-fund raising efforts and is likely to affect the Company's operations and research efforts going forward. If our common stock is delisted, this would, among other things, substantially impair our ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for us.

Additionally, even if our plan is approved, we cannot be sure we will meet the requirements for continued listing of our shares on the Nasdaq Capital Market in the future or that we will comply with the other continued listing requirements.

Risks Relating to Our Business

Our business is dependent on the successful development of our product candidates and our ability to raise additional capital.

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

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

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

We have allocated the majority of our resources to the development of our stem cell and small molecule technologies. Our ability to generate revenue and operate profitably will depend on being able to develop these technologies for human applications. These are emerging technologies that may have limited human application. We cannot guarantee that we will be able to develop our technologies or that if developed, our technologies will result in commercially viable products or have any commercial utility or value. We anticipate that the commercial sale of our proposed products and/or royalty/licensing fees related to our technologies, will be our primary sources of revenue. We recognized revenue of approximately $10,000 and $19,000 for the years ended December 31, 2015 and 2014, respectively, and $7,500 for the nine months ended September 30, 2016, related to the licensing of certain intellectual property to third parties and certain subcontractor services that we provided. If we are unable to develop our technologies, we may never realize any significant revenue. Additionally, given the uncertainty of our technologies,

product candidates and the need for government regulatory approval, we cannot predict when, or if ever, we will be able to realize revenues related to our products. As a result, we will be primarily dependent on our ability to raise capital through the sale of our securities for the foreseeable future.

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

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

Our stem cell therapy programs rely on experimental surgical devices and experimental and highly invasive surgical procedures.

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

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

Given the uncertainty of our technologies and the need for government regulatory approval, we cannot predict when, or if ever, we will be able to realize revenues related to our products.

Our proposed products are not likely to be commercially available for at least several or more years, if ever. Accordingly, we do not foresee generating any significant revenue during such time. As a result, we will be primarily dependent on our ability to raise capital through the sale of our securities to fund our operations for the foreseeable future.

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

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

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

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

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

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

The results of pre-clinical studies and clinical trials may not be predictive of the results of our later-stage clinical trials and our proposed products may not have favorable results in later-stage clinical trials or receive regulatory approval.

Positive results from pre-clinical studies or our Phase 1 and Phase 2 trials should not be relied upon as evidence that our clinical trials will succeed. Even if our product candidates achieve positive results in pre-clinical studies or during our Phase 1 and Phase 2 studies, we will be required to demonstrate through further clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale. There is typically an extremely high rate of attrition from the failure of product candidates as they proceed through clinical trials. If any product candidate fails to demonstrate sufficient safety and efficacy in any clinical trial, then we may experience potentially significant delays in, or be required to abandon, development of that product candidate. Additionally, failure to demonstrate safety and efficacy results acceptable to the FDA in later stage trials could impair our development prospects and even prevent regulatory approval of our current and future product candidates. Any such delays or abandonment in our development efforts of any of our product candidates would materially impair our ability to generate revenues.

Our research and development expenses are subject to uncertainty.

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

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

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

We are subject to numerous risks inherent in conducting clinical trials.

We outsource the management of our clinical trials to third parties. Agreements with clinical investigators and medical institutions for clinical testing and with other third parties for data management services, place substantial responsibilities on these parties that, if unmet, could result in delays in, or termination of, our clinical trials. For

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

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

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

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

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

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

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