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, 2019

Or

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

Commission File Number 001-33672

SENECA BIOPHARMA, 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)

(301) 366-4841

(Registrant's telephone number, including area code**)**

Neuralstem, Inc.

(Former Name**)**

Securities registered pursuant to Section 12(b) of the Act:

Title of Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, $0.01 par value	SNCA	Nasdaq Capital Market

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 every Interactive Data File required to be submitted 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 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 ☒ Smaller reporting company ☒

Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.□

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 November 5, 2019, there were 3,866,457 shares of common stock, $.01 par value, issued and outstanding.

Seneca Biopharma, Inc.

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PART I
FINANCIAL INFORMATION

ITEM 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Seneca Biopharma, Inc.

Unaudited Condensed Consolidated Balance Sheets

	September 30, 2019	December 31, 2018
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 7,299,836	$ 5,787,110
Trade and other receivables	61,154	294,057
Current portion of related party receivable, net of discount	-	63,938
Prepaid expenses	605,312	363,288
Total current assets	7,966,302	6,508,393
Property and equipment, net	51,943	90,311
Patents, net	688,127	763,543
Related party receivable, net of discount and current portion	-	298,238
ROU and other assets	237,141	23,965
Total assets	$ 8,943,513	$ 7,684,450
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 1,181,364	$ 832,564
Short term note and other current liabilities	400,016	218,602
Total current liabilities	1,581,380	1,051,166
Warrant liabilities, at fair value	166,938	583,734
Lease liability, net of current portion	152,632	-
Total liabilities	1,900,950	1,634,900
Commitments and contingencies (Note 5)		
STOCKHOLDERS' EQUITY		
Preferred stock, 7,000,000 shares authorized, $0.01 par value; 200,000 and 1,000,000 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	2,000	10,000
Common stock, $0.01 par value; 300,000,000 shares authorized, 2,818,291 and 910,253 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	28,183	9,103
Additional paid-in capital	226,957,990	219,654,753
Accumulated other comprehensive loss	(7,670)	(413)
Accumulated deficit	(219,937,940)	(213,623,893)
Total stockholders' equity	7,042,563	6,049,550
Total liabilities and stockholders' equity	$ 8,943,513	$ 7,684,450

See accompanying notes to unaudited condensed consolidated financial statements.

Seneca Biopharma, Inc.

Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues	$ 2,500	$ 2,500	$ 12,894	$ 257,500
Operating expenses:				
Research and development expenses	825,486	897,098	3,294,402	3,081,319
General and administrative expenses	1,301,189	1,188,076	3,217,613	3,630,822
Total operating expenses	2,126,675	2,085,174	6,512,015	6,712,141
Operating loss	(2,124,175)	(2,082,674)	(6,499,121)	(6,454,641)
Other income (expense):				
Interest income	15,234	17,619	55,086	54,882
Interest expense	(1,913)	(1,498)	(4,437)	(4,190)
Change in fair value of derivative instruments	320,785	236,270	416,796	1,805,319
Other income (expense)	26,935	-	(282,371)	(5,667)
Total other income	361,041	252,391	185,074	1,850,344
Net loss	$ (1,763,134)	$ (1,830,283)	$ (6,314,047)	$ (4,604,297)
Net loss per share - basic and diluted	$ (0.59)	$ (2.41)	$ (4.80)	$ (6.08)
Weighted average common shares outstanding - basic and diluted	2,975,779	758,575	1,316,597	757,221
Comprehensive loss:				
Net loss	$ (1,763,134)	$ (1,830,283)	$ (6,314,047)	$ (4,604,297)
Foreign currency translation adjustment	(4,501)	(512)	(7,257)	(2,001)
Comprehensive loss	$ (1,767,635)	$ (1,830,795)	$ (6,321,304)	$ (4,606,298)

See accompanying notes to unaudited condensed consolidated financial statements.

Seneca Biopharma, Inc.

Unaudited Consolidated Statements of Changes In Stockholders' Equity

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares (see Note 1)	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at January 1, 2018	**1,000,000**	**$ 10,000**	**758,001**	**$ 7,580**	**$217,194,194**	**$ 2,631**	**$(208,699,276)**	**$ 8,515,129**
Share based payments	-	-	-	-	238,835	-	-	238,835
Foreign currency translation adjustments	-	-	-	-	-	115	-	115
Net loss	-	-	-	-	-	-	(2,146,968)	(2,146,968)
Balance at March 31, 2018	**1,000,000**	**10,000**	**758,001**	**7,580**	**217,433,029**	**2,746**	**(210,846,244)**	**6,607,111**
Share based payments	-	-	-	-	196,742	-	-	196,742
Foreign currency translation adjustments	-	-	-	-	-	(1,604)	-	(1,604)
Net loss	-	-	-	-	-	-	(627,046)	(627,046)
Balance at June 30, 2018	**1,000,000**	**10,000**	**758,001**	**7,580**	**217,629,771**	**1,142**	**(211,473,290)**	**6,175,203**
Share based payments	-	-	-	-	134,696	-	-	134,696
Foreign currency translation adjustments	-	-	-	-	-	(512)	-	(512)
Net loss	-	-	-	-	-	-	(1,830,283)	(1,830,283)
Balance at September 30, 2018	**1,000,000**	**10,000**	**758,001**	**7,580**	**217,764,467**	**630**	**(213,303,573)**	**4,479,104**

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares (see Note 1)	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at January 1, 2019	**1,000,000**	**$ 10,000**	**910,253**	**$ 9,103**	**$219,654,753**	**$ (413)**	**$(213,623,893)**	**$ 6,049,550**
Share based payments	-	-	-	-	337,966	-	-	337,966
Foreign currency translation adjustments	-	-	-	-	-	(1,743)	-	(1,743)
Net loss	-	-	-	-	-	-	(3,113,992)	(3,113,992)
Balance at March 31, 2019	**1,000,000**	**10,000**	**910,253**	**9,103**	**219,992,719**	**(2,156)**	**(216,737,885)**	**3,271,781**
Share based payments	-	-	-	-	128,778	-	-	128,778
Issuance of common stock for conversion of Series A Preferred Stock	(465,191)	(4,652)	90,419	904	3,748	-	-	-
Issuance of common stock for RSU exercises	-	-	1,126	11	(11)	-	-	-
Foreign currency translation adjustments	-	-	-	-	-	(1,013)	-	(1,013)

Net loss	-	-	-	-	-	-	(1,436,921)	(1,436,921)
Balance at June 30, 2019	**534,809**	**5,348**	**1,001,798**	**10,018**	**220,125,234**	**(3,169)**	**(218,174,806)**	**1,962,625**
Share rounding adjustment related to 1:20 reverse stock split	-	-	6,117	61	(61)	-	-	-
Share based payments	-	-	-	-	294,600	-	-	294,600
Issuance of common stock and warrants from capital raises, net	-	-	416,315	4,163	6,548,679	-	-	6,552,842
Issuance of common stock for conversion of Series A Preferred Stock	(334,809)	(3,348)	65,077	651	2,697	-	-	-
Issuance of restricted stock awards	-	-	15,688	157	(157)	-	-	
Issuance of common stock for warrant exercises	-	-	1,313,296	13,133	(13,002)	-	-	131
Foreign currency translation adjustments	-	-	-	-	-	(4,501)	-	(4,501)
Net loss	-	-	-	-	-	-	(1,763,134)	(1,763,134)
Balance at September 30, 2019	**200,000**	**$ 2,000**	**2,818,291**	**$ 28,183**	**$226,957,990**	**$ (7,670)**	**$(219,937,940)**	**$ 7,042,563**

See accompanying notes to unaudited condensed consolidated financial statements.

Seneca Biopharma, Inc.

Unaudited Condensed Consolidated Statements of Cash Flows

	Nine Months Ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (6,314,047)	$ (4,604,297)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	113,735	160,464
Share-based compensation expense	761,344	570,273
Allowance for bad debt	362,176	-
Change in fair value of liability classified warrants	(416,796)	(1,805,319)
Changes in operating assets and liabilities:		
Trade and other receivables	232,903	150,823
Related party receivable	-	71,638
Prepaid expenses	(235,946)	(154,271)
ROU and other assets	24,938	(4,000)
Accounts payable and accrued expenses	340,673	(25,487)
Accrued bonuses	-	(418,625)
Other current liabilities	(48,110)	26,288
Lease and other long term liabilities	(27,618)	(1,876)
Net cash used in operating activities	(5,206,748)	(6,034,389)
Cash flows from investing activities:		
Maturity of short-term investments	-	5,000,000
Net cash provided by investing activities	-	5,000,000
Cash flows from financing activities:		
Net proceeds from the sale of our common stock and warrants	6,552,842	-
Proceeds from warrant exercises	131	-
Proceeds from short-term note payable	414,320	349,578
Payments of short-term note payable	(241,061)	(247,817)
Net cash provided by financing activities	6,726,232	101,761
Effects of exchange rates on cash	(6,758)	(5,383)
Net increase (decrease) in cash and cash equivalents	1,512,726	(938,011)
Cash and cash equivalents, beginning of period	5,787,110	6,674,940
Cash and cash equivalents, end of period	$ 7,299,836	$ 5,736,929
Supplemental disclosure of cash flows information:		
Cash paid for interest	$ 4,437	$ 4,190

See accompanying notes to unaudited condensed consolidated financial statements.

SENECA BIOPHARMA, INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2019 AND 2018

Note 1. Organization, Business and Financial Condition

Nature of business

In October 2019, Neuralstem, Inc. changed the name of the company to Seneca Biopharma, Inc. Seneca Biopharma, Inc. and its subsidiary are referred to as "Seneca," the "Company," "us," or "we" throughout this report. The operations of our wholly owned subsidiary located in the People's Republic of China are consolidated in our unaudited condensed consolidated financial statements and all intercompany activity has been eliminated. The Company operates in one business segment.

Seneca Biopharma, Inc., is a clinical-stage biopharmaceutical company developing novel treatments for various diseases of high unmet medical need. The Company is in the process of transforming the organization through the acquisition or in-licensing of new science and technologies, to develop with the goal of providing meaningful therapies for patients.

On October 31, 2019 the Company announced it had entered into a non-binding term sheet with Jiangsu QYuns Therapeutics Co., Ltd., ("QYuns") for an Exclusive License Agreement for certain of QYuns Therapeutics' assets, a pipeline of cytokine-targeted monoclonal antibodies for the treatment of a range of auto-immune disease. Subject to entering into definitive agreements and receiving necessary approvals, Seneca and QYuns will enter into a royalty- and milestone-free, perpetual, non-cancelable, exclusive worldwide, other than in Greater China (which includes Hong Kong, Macau and Taiwan and certain other Asian territories) license to develop and commercialize the licensed assets. The transaction is subject to several conditions including the parties entering into definitive agreements as well as approval by Seneca's shareholders. As consideration for the license, Seneca will issue QYuns an as yet to be determined number of equity securities. Seneca can give no assurance that the parties will enter into such definitive agreements, that Seneca's shareholders will approve the transaction, or that if approved, the transaction will ultimately be consummated or that Seneca will be able to successfully develop the in-licensed assets.

In addition to the anticipated development of in-licensed or acquired technologies, the Company plans to continue to maintain NSI-566 (stem cell) and NSI-189 (small molecule) and related clinical programs and will seek to partner these assets for further development.

The Company was founded in 1997 and currently has laboratory and office space in Germantown, Maryland and laboratory facilities in the People's Republic of China. Our operations to date have primarily focused on developing business strategies, raising capital, research and development activities, and conducting pre-clinical testing and human clinical trials of our product candidates. The Companies operations will continue to be focused on development activities, including conducting pre-clinical testing and human clinical trials of novel product candidates licensed from QYuns for the treatment of various diseases.

On July 17, 2019 the Company effected a 1-for-20 reverse stock split of its common stock. Stockholders' equity and all references to share and per share amounts in the accompanying consolidated financial statements have been retroactively adjusted to reflect the 1-for-20 reverse stock split for all periods presented.

Liquidity and Going Concern

The Company has incurred losses since its inception and has not demonstrated an ability to generate significant revenues from the sales of its therapies or services and have 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 within one year after the date that the consolidated financial statements are issued. The consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

In making this assessment we performed a comprehensive analysis of our current circumstances including: our financial position at September 30, 2019, our cash flow and cash usage forecasts for the period covering one-year from the issuance date of this Quarterly Report filed on Form 10-Q and our current capital structure including outstanding warrants and other equity-based instruments and our obligations and debts. In July 2019, we completed an underwritten public offering of our securities which resulted in net proceeds of approximately $6.6 million (See Note 4).

We expect that our existing cash and cash equivalents will be sufficient to enable us to fund our anticipated level of operations based on our current operating plans into the third quarter of 2020. Accordingly, we will require additional capital to further develop our product candidates, conduct our pre-clinical and clinical development programs and to fund our operations. We anticipate raising additional

capital through the private and public sales of our equity or debt securities, collaborative arrangements, licensing agreements or a combination thereof. Although management believes that such capital sources will be available, there can be no assurance that any such collaborative or licensing arrangements will be entered into or that financing will be available to us when needed in order to allow us to continue our operations, or if available, on terms acceptable to us. If we do not raise sufficient capital in a timely manner, among other things, we may be forced 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 on unfavorable terms. We currently do not have any commitments for future funding from any source.

We have spent and will continue to spend substantial funds in the research, development, pre-clinical and clinical testing of our small molecule and stem cell product candidates and we anticipate spending additional funds to maintain these programs as we seek partners to further their clinical development. Additionally, if the QYuns transaction is consummated, we anticipate spending substantial funds on the development of the in-licensed programs with the goal of ultimately obtaining approval from the United States Food and Drug Administration (the "FDA") and its international equivalents regulatory agencies, to market and sell our products. We have also begun spending funds on the evaluation and new assets and technologies with the goal of acquisition and development. No assurance can be given that (i) the FDA or any other regulatory agency will grant approval for us to market and sell our product candidates, (ii) if regulatory approval is granted, that we will ever be able to sell our proposed products or be profitable, or (iii) that we will be able to identify and acquire and/or in-license promising new assets or technologies.

Note 2. Significant Accounting Policies and Basis of Presentation

Basis of Presentation

In management's opinion, the accompanying interim unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations and cash flows. The unaudited condensed consolidated balance sheet at December 31, 2018, 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 unaudited condensed consolidated financial statements are read in conjunction with the Financial Statements and Notes included in our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC, and as may be amended.

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The unaudited condensed consolidated financial statements include significant estimates for the expected economic life and value of our licensed technology and related patents, our net operating loss and related valuation allowance for tax purposes, the fair value of our liability classified warrants and our share-based compensation related to employees and directors, consultants and advisors, 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, 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 was 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 and approximates the carrying value. The fair values of our liability classified warrants were estimated using Level 3 unobservable inputs. See Note 3 for further details.

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 subsidiary 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 and Credit Risk

Cash equivalents consist of investments in low risk, highly liquid money market accounts 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.

Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash equivalents. Our investment policy, approved by our Board of Directors, limits the amount we may invest in any one type of investment issuer, thereby reducing credit risk concentrations. We 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.

Revenue

The Company analyzes contracts to determine the appropriate revenue recognition using the following steps: (i) identification of contracts with customers; (ii) identification of distinct performance obligations in the contract; (iii) determination of contract transaction price; (iv) allocation of contract transaction price to the performance obligations; and (v) determination of revenue recognition based on timing of satisfaction of the performance obligation. The Company recognizes revenues upon the satisfaction of its performance obligation (upon transfer of control of promised goods or services to customers) in an amount that reflects the consideration to which it expects to be entitled to in exchange for those goods or services. Deferred revenue results from cash receipts from or amounts billed to customers in advance of the transfer of control of the promised services to the customer and is recognized as performance obligations are satisfied. When sales commissions or other costs to obtain contracts with customers are considered incremental and recoverable, those costs are deferred and then amortized as selling and marketing expenses on a straight-line basis over an estimated period of benefit.

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. For the nine months ended September 30, 2019 and 2018, we recorded approximately $382,000 and $318,000, respectively of cost reimbursements from our grants as an offset to research and development expenses. The Company evaluated the grants and concluded that, based on the specific terms, they represent a cost reimbursement activity as opposed to a revenue generating activity, and are best reflected as an offset to the underlying research and development expense.

Income (Loss) per Common Share

Basic income (loss) per common share is computed by dividing total net income (loss) available to common stockholders by the weighted average number of common shares outstanding during the period. Weighted average shares outstanding includes outstanding “prefunded” warrants with an exercise price of $0.0001. (see Note 4)

For periods of net income when the effects are dilutive, diluted earnings per share is computed by dividing net income available to common stockholders 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 convertible preferred stock, 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, 2019 and 2018. A total of approximately 7.3 and 0.5 million potential dilutive shares have been excluded in the calculation of diluted net income per share for the three- and nine-month periods ended September 30, 2019 and 2018, 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 stock purchase warrants is generally determined at the grant 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 is recognized as expense on a straight-line basis over the requisite service period or based on probability of vesting for performance-based awards.

Intangible and Long-Lived Assets

We assess impairment of our long-lived assets using a "primary asset" approach to determine the cash flow estimation period for a group of assets and liabilities that represents the unit of accounting for a long-lived asset to be held and used. Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The carrying amount of a long-lived asset is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset. No impairment losses were recognized during the three- or nine-month periods ended September 30, 2019 or 2018.

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.

Leases

We determine if an arrangement is or contains a lease at its inception. We have made accounting policy elections whereby we (i) do not recognize right-of-use ("ROU") assets or lease liabilities for our short-term leases (those with original terms of 12-months or less) and (ii) combine lease and non-lease elements of our operating leases. Operating lease ROU assets are included in other noncurrent assets and operating lease liabilities are included in other current liabilities in our consolidated balance sheets. We do not have any finance leases.

ROU assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. Rent expense is recognized on a straight-line basis over the lease term. See Note 5, Commitments and Contingencies, for additional disclosures.

Significant New Accounting Pronouncements

Recently Adopted Guidance

In February 2016, the FASB issued *ASU, No. 2016-02, Leases*. This ASU consists of a comprehensive lease accounting standard. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. The guidance may be adopted on a modified retrospective basis and provides for certain practical expedients. We adopted this guidance effective January 1, 2019 as of the beginning of the period of adoption using the following practical expedients: we did not evaluate any expired leases, nor did we reassess the classification of any existing leases. The Company made an ongoing policy election whereby it will not recognize a lease liability or right of use asset for our short-term leases and that it will combine lease and non-lease elements of leases. The new guidance changes the way we account for our operating leases including recording the future benefits ("ROU assets") of those leases and the related discounted minimum lease payments on our consolidated balance sheets. Upon adoption we recorded a right of use asset of approximately $53,000 and a lease liability of approximately $75,700 on our consolidated balance sheet.

In June 2018, the FASB issued *ASU 2018-07, Compensation-Stock Compensation, Improvements to Nonemployee Share-Based Payment Accounting*. This ASU expands the scope of *ASC 718, Compensation – Stock Compensation* to include share-based payment transactions for acquiring goods and services from nonemployees. This guidance provides for the following changes: (1) awards to nonemployees will be measured at the grant date fair value of equity instruments that the entity is obligated to issue, (2) performance-based awards to nonemployees will be measured based on the probability of the performance condition being met and (3) eliminating the need to reassess the classification (equity or liability) of awards to nonemployees upon vesting. The guidance is effective for fiscal years beginning after December 15, 2018. We adopted this guidance effective January 1, 2019. The adoption resulted in our generally measuring awards to nonemployees using the grant date fair value. The adoption did not have a material impact to our financial statements.

Unadopted Guidance

In June 2016, the FASB issued *ASU No. 2016-13, Financial Instruments – Credit Losses*. This ASU relates to measuring credit losses on financial instruments, including trade receivables. The guidance eliminates the probable initial recognition threshold that was previously required prior to recognizing a credit loss on financial instruments. The credit loss estimate can now reflect an entity's current estimate of all future expected credit losses. Under the previous guidance, an entity only considered past events and current conditions. The guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years and early adoption is permitted. The adoption of certain amendments of this guidance must be applied on a modified retrospective basis and the adoption of the remaining amendments must be applied on a prospective basis. We currently expect that the adoption of this guidance will likely change the way we assess the collectability of our receivables and recoverability of other financial instruments. We have not yet begun to evaluate the specific impacts of this guidance nor have we determined the manner in which we will adopt this guidance.

In August 2018, the FASB issued *ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*. This ASU addresses the disclosure requirements for fair value measurements. The guidance intends to improve the effectiveness of the disclosures relating to recurring and nonrecurring fair value measurements. The guidance is effective for fiscal years beginning after December 15, 2019 and early adoption is permitted. Portions of the guidance are to be adopted prospectively while other portions are to be adopted retroactively. The Company is currently evaluating the impact, if any, that this guidance will have on the consolidated financial statements.

In August 2018, the FASB issued *ASU 2018-15, Intangibles – Goodwill and Other – Internal-Use Software*. This ASU addresses the accounting for implementation, setup and other upfront costs paid by a customer in a cloud computing or hosting arrangement. The guidance aligns the accounting treatment of these costs incurred in a hosting arrangement treated as a service contract with the requirements for capitalization and amortization costs to develop or obtain internal-use software. The guidance is effective for fiscal years beginning after December 15, 2019 and early adoption is permitted. The guidance can be adopted either retrospectively or prospectively. The Company is currently evaluating the impact, if any, that this guidance will have on the consolidated financial statements.

We have reviewed other recent accounting pronouncements and concluded that they are either not applicable to our 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 on a recurring into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date.

At September 30, 2019 and December 31, 2018, we had certain common stock purchase warrants that were originally issued in connection with our May 2016 and August 2017 offerings (See Note 4) that are accounted for as liabilities whose fair value was determined using Level 3 inputs. The following table identifies the carrying amounts of such liabilities:

	Level 1	Level 2	Level 3	Total
Liabilities				
Liability classified stock purchase warrants	$ -	$ -	$ 583,734	$ 583,734
Balance at December 31, 2018	$ -	$ -	$ 583,734	$ 583,734
Liability classified stock purchase warrants	$ -	$ -	$ 166,938	$ 166,938
Balance at September 30, 2019	$ -	$ -	$ 166,938	$ 166,938

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, 2019:

	Mark-to-market liabilities - stock purchase warrants
Balance at December 31, 2018	$ 583,734
Change in fair value - gain	(416,796)
Balance at September 30, 2019	$ 166,938

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, 2018:

	Mark-to-market liabilities - stock purchase warrants
Balance at December 31, 2017	$ 3,852,882
Change in fair value - gain	(1,805,319)
Balance at September 30, 2018	$ 2,047,563

The (gains) losses resulting from the changes in the fair value of the liability classified warrants are classified as other income or expense in the accompanying unaudited condensed consolidated statements of operations. The fair value of the common stock purchase warrants is determined based on the Black-Scholes option pricing model or 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. 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, common stock purchase warrants, or common stock purchase options. Our common stock purchase options and stock purchase warrants have lives of up to ten years from the grant date. Awards vest either upon the grant date or over varying periods of time. The stock options provide for 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. As of September 30, 2019, we have approximately 8.5 million shares of common stock reserved for issuance upon the granting of awards under our equity incentive plans and the exercise of outstanding equity-linked instruments.

We typically record share-based compensation expense on a straight-line basis over the requisite service period. Share-based compensation expenses included in the statements of operations are as follows:

	Three Months Ended September 30,	
	2019	**2018**
Research and development expenses	$ -	$ 22,917
General and administrative expenses	294,600	111,778
Total	$ 294,600	$ 134,695

	Nine Months Ended September 30,	
	2019	**2018**
Research and development expenses	$ 200,337	$ 110,417
General and administrative expenses	561,007	459,856
Total	$ 761,344	$ 570,273

Stock Options

A summary of stock option activity and related information for the nine months ended September 30, 2019 follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2019	81,674	$ 215.60	5.1	$ -
Granted	228,183	$ 7.78		
Exercised	-	$ -		$ -
Forfeited	(10,127)	$ 86.07		
Outstanding at September 30, 2019	299,730	$ 61.78	7.9	$ -
Exercisable at September 30, 2019	206,347	$ 86.15	7.2	$ -

Range of Exercise Prices			Number of Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
$5.90	-	$6.00	58,010	$ 5.99	9.3	$ -
$7.20	-	$8.80	162,593	$ 8.51	9.2	-
$22.20	-	$99.20	36,138	$ 33.20	5.6	-
$107.40	-	$1,102.41	42,989	$ 362.61	2.9	-
			299,730	$ 61.78	7.9	$ -

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. The Company generally uses the “simplified method” to estimate expected life. Significant assumptions used in these models include:

	Nine Months Ended September 30,	
	2019	2018
Annual dividend	-	-
Expected life (in years)	4.8 - 5.5	2.5 - 5.3
Risk free interest rate	1.8% - 2.5%	2.7% - 2.8%
Expected volatility	97% - 115%	97% - 117%

Options granted in the nine months ended September 30, 2019 and 2018, had a weighted average grant date fair value of $3.45 and $15.40 per share, respectively.

Unrecognized compensation cost for unvested stock option awards outstanding at September 30, 2019 was approximately $384,000 to be recognized over approximately 0.7 years.

In the three months ended March 31, 2019, the Company modified certain awards in conjunction with an employee’s termination. The modification provided for the accelerated vesting of all unvested awards and the extension of the post-employment exercise period. The modifications resulted in approximately $102,000 of additional research and development expenses in the three months ended March 31, 2019.

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 grant date fair value of RSUs is based upon the market price of the underlying common stock on the date of grant.

In the nine months ended September 30, 2019 and 2018, we granted 4,904 and 2,253 RSU's, respectively. RSUs granted in the nine months ended September 30, 2019 and 2018, had a weighted average grant date fair value of $5.90 and $22.20, respectively.

RSUs vesting in the nine months ended September 30, 2019 had a total value of approximately $6,400.

At September 30, 2019, we had 5,467 outstanding RSUs with a weighted average grant date fair value of $29.62 and a total intrinsic value of approximately $10,400. Unrecognized compensation cost for unvested RSUs at September 30, 2019 was approximately $22,000 to be recognized over approximately 0.8 years.

In the nine months ended September 30, 2019, 1,127 RSU's having an intrinsic value of approximately $10,400 were converted. No RSU's were converted in the nine months ended September 30, 2018.

Restricted Stock

We have granted restricted stock to certain board members that vest quarterly over the grant year. The grant date fair value of the restricted stock is based upon the market price of the common stock on the date of grant.

In the nine months ended September 30, 2019 and 2018, we granted 15,689 and 2,253 shares of restricted stock, respectively. Restricted stock granted in the nine months ended September 30, 2019 and 2018, had a weighted average grant date fair value of $5.95 and $22.20, respectively.

Restricted stock vesting in the nine months ending September 30, 2019, had a weighted average grant date fair value of $9.73 and a total intrinsic value of approximately $14,500.

At September 30, 2019, we had 11,972 shares of restricted stock outstanding with an average grant date fair value of $5.95. Unrecognized compensation cost for unvested restricted stock awards at September 30, 2019 was approximately $71,300 to be recognized over approximately 0.8 years.

Stock Purchase Warrants.

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 and August 2017, we issued a total of 87,309 and 112,500 common stock purchase warrants, respectively in conjunction with our offerings. Such warrants are classified as liabilities due to the existence of certain net cash settlement provisions contained in the warrants. At September 30, 2019, after giving effect to exercises, 149,136 of these common stock purchase warrants remain outstanding and are recorded at fair value as mark-to-market liabilities (see Note 3).

In February 2019, we granted 25,000 warrants to an outside third party as partial compensation for services. The warrants have an exercise price of $6.00, expire January 2024 and have a grant date fair value of $3.80 per warrant. The warrants vest 25% on grant and 75% on completion of initial services; the warrants were fully vested as of September 30, 2019. The warrants were valued using the Black-Scholes option pricing model with the following inputs: no annual dividend, expected life of 2.5 years, risk-free rate of 2.5% and expected volatility of 110%.

In July 2019, in connection with our underwritten public offering, we issued the following equity classified common stock purchase warrants: (i) 3,194,443 short-term common stock purchase warrants with an exercise price of $2.70 per share, exercisable immediately and expiring on December 31, 2020; (ii) 3,194,443 long-term common stock purchase warrants with an exercise price of $2.70 per share, exercisable immediately and expiring 5-years from issuance and (iii) 2,361,462 "prefunded" common stock purchase warrants with an exercise price of $0.0001 per share, exercisable immediately with no expiration date. As of September 30, 2019, 1,313,296 of the "prefunded warrants" had been exercised generating approximately $100 in proceeds.

In connection with the July public offering we also granted the underwriters 222,223 equity classified common stock purchase warrants with an exercise price of $3.375 per share, exercisable immediately and expiring 5-years from issuance.

A summary of outstanding warrants at September 30, 2019 follows:

Range of Exercise Prices			Number of Warrants Outstanding	Range of Expiration Dates		
$0.0001			1,048,166	perpetual		
$2.19	-	$2.70	6,538,035	December 2020	-	August 2024
$3.38	-	$17.50	406,223	October 2023	-	July 2024
$22.20	-	$782.60	26,479	October 2019	-	July 2023
			8,018,903			

Preferred and Common Stock

We have outstanding 200,000 shares of Series A 4.5% Convertible Preferred Stock issued in December 2016. Shares of the Series A 4.5% Convertible Preferred Stock are convertible into 38,873 shares of the Company's common stock subject to certain ownership restrictions. In July 2019, 334,809 Series A 4.5% Convertible Preferred Stock shares were converted into 65,077 shares of common stock in accordance with their terms.

In July 2019, we completed an underwritten public offering of 416,315 units ("Units") and 2,361,462 prefunded units ("Prefunded Units") at a price of $2.70 per each unit resulting in gross proceeds of approximately $7.5 million. Each Unit was comprised of one share of common stock, one short-term warrant and one long-term warrant. Each Prefunded Unit was comprised of one prefunded-warrant, one short-term warrant and one long-term warrant. The prefunded warrants have an exercise price of $0.0001 per share and are exercisable at any time from issuance until all prefunded warrants are exercised. The short-term and long-term warrants have an exercise price of $2.70 per share and are exercisable immediately. The short-term warrant expires December 31, 2020 and the long-term warrant expires five-years from issuance. The net proceeds of the offering were approximately $6.6 million, after deducting underwriting discounts and commissions and offering expenses. In addition to the above units, the underwriters exercised their option and purchased an additional short-term 416,666 additional short-term and 416,666 additional long-term warrant combinations at the public offering price per share and per warrant combination, before deducting underwriting discounts and commissions. The securities were sold pursuant to a registration statement on Form S-1 (file no. 333- 232273).

Note 5. Commitments and Contingencies

Leases

We currently operate one facility located in the United States and one facility located in the Peoples Republic of China both of which are classified as operating leases.

Our corporate offices and primary research facilities are located in Germantown, Maryland, where we lease approximately 1,500 square feet. This lease provides for monthly payments of approximately $5,700 per month. This lease has an original term of 12 months and expires on December 31, 2019. We did not establish ROU assets or lease liabilities for this short-term lease.

We also lease approximately 11,300 square feet of research facility in the People's Republic of China. This lease commenced in September 2019, provides for minimum lease payments of approximately $4,400 per month, expires in September 2024 and provides us with a future first right of refusal for extending the lease beyond its expiration. This lease currently represents our lone long-term operating lease.

Our long-term operating lease and related sublease for our San Diego facility both terminated in August 2019. We recognized other income of approximately $86,100 from this sublease for the nine months ended September 30, 2019.

We recognized total rent expense of approximately $164,500 and $134,100 in the nine months ended September 30, 2019 and 2018, respectively. Included in the 2019 expense is approximately $83,900 relating to our short-term leases. Lease costs, net of sublease income, for the nine months ended September 30, 2019 consisted of the following:

Operating lease cost	$	141,300
Variable lease cost		23,200
Sublease income		(86,100)
Total net lease cost	$	78,400

In the nine months ended September 30, 2019, we established approximately $204,300 of ROU assets as the result of entering into new lease arrangements.

At September 30, 2019, we have approximately $204,300 of right of use asset included in ROU and Other Assets and approximately $183,500 of lease liability the current portion of which is included in Other Current Assets and the long term portion of which is included in Lease Liability, Net of Current Portion in our consolidated balance sheets. The lease liability was calculated using a discount rate of 12.75%.

Maturities of our lone long-term operating lease as of September 30, 2019 were as follows:

Future undiscounted cash flows:		
	Remainder 2019	$ 11,845
	2020	52,482
	2021	53,498
	2022	55,118
	2023	56,920
	2024	13,390
Total		243,253
Discount factor		(59,733)
Lease liability		183,520
Less current liability		(30,888)
Non-current lease liability		$ 152,632

Other

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

Note 6. 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.

The $658,000 non-interest-bearing receivable was recorded net of a $199,000 discount to reflect the net present value of the future cash payments.

In March 2019, in conjunction with the employee’s termination, we entered into a consulting agreement and release of claims agreement with the employee. As partial consideration for the release, we modified the reimbursement agreement to change the payment terms, extend the maturity and forgive approximately 50% or $229,000 of the outstanding receivable. At September 30, 2019, $229,000 remains outstanding and is due in installments through July 2025. The Company has concluded that this outstanding balance is not recoverable and recorded an allowance against the entire remaining balance.

Note 7. Subsequent Events

Effective October 28, 2019, the Company filed an amendment to it amended and restated certificate of incorporation changing the Company’s name from Neuralstem, Inc. to Seneca Biopharma, Inc.

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 pre-clinical and 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 operations. 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, 2018, filed with the SEC, in our subsequent filings 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" and "Seneca" refers to Seneca Biopharma, Inc. and its subsidiaries. Also, any reference to "common shares" or "common stock," refers to our $.01 par value common stock. Any reference to "Series A Preferred Stock" or "Preferred Stock" refers to our Series A 4.5% Convertible Preferred Stock. The information contained herein is current as of the date of this Quarterly Report (September 30, 2019), unless another date is specified. On July 17, 2019, we completed a 1-for-20 reverse stock split of our common stock. All share and per shares information in this report have been adjusted to reflect the reverse stock split. 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, 2019 are not necessarily indicative of our prospective financial condition and results of operations for the pending full fiscal year ending December 31, 2019. 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 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 you 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 items affecting the Company in order to provide context for the remainder of MD&A.

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

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

- *Results of Operations*— Analysis of our financial results comparing the three-and nine-month periods ended September 30, 2019 to the comparable period of 2018.

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

Executive Overview

We are primarily focused on the research and development of nervous system therapies based on our proprietary human neural stem cells and our small molecule compounds with the ultimate goal of gaining approval from the United States Food and Drug Administration ("FDA"), and its international counterparts, to market and commercialize such therapies. Recently, we have also began an in-licensing and acquisition strategy in which we are evaluating novel therapeutics with the potential to be complimentary to our current technologies or that could benefit from our development experience with the goal of developing such technologies for commercialization.

Our patented technology platform has three core components:

- Over 300 lines of human, regionally specific neural stem cells, some of which have the potential to be used to treat serious or

life-threatening diseases through direct transplantation into the central nervous system;

- Proprietary screening capability – our ability to generate human neural stem cell lines provides a platform for chemical screening and discovery of novel compounds against nervous system disorders; and

- Small molecules that resulted from Seneca's neurogenesis screening platform that may have the potential to treat wide variety of nervous system conditions.

To date. our technology platform has produced two lead assets in clinical development: our NSI-566 stem cell therapy program and our NSI-189 small molecule program.

We believe this technology, in partnership with appropriate development expertise, could facilitate the development and commercialization of products for use in the treatment of a wide array of nervous system disorders including neurodegenerative conditions and regenerative repair of acute and chronic disease. We intend to maintain these programs with the goal of finding suitable development partners.

On October 31, 2019 the Company announced it had entered into a non-binding term sheet with Jiangsu QYuns Therapeutics Co., Ltd., ("QYuns") to exclusively license certain of QYuns Therapeutics' assets, a pipeline of cytokine-targeted monoclonal antibodies for the treatment of a range of auto-immune disease. Subject to entering into a definitive agreements and receiving necessary approvals, Seneca and QYuns will enter into a royalty- and milestone-free, perpetual, non-cancelable, exclusive worldwide, other than in Greater China (which includes Hong Kong, Macau and Taiwan and certain other Asian territories) license to develop and commercialize the licensed assets. Subject to completing the transaction contemplated by the term sheet, which is subject to several conditions including the parties entering into definitive agreements as well as approval by Seneca's shareholders, we intend to focus our development activities on the licensed pipeline of cytokine-targeted monoclonal antibodies for the treatment of a range of auto-immune and other diseases.

In-licensing or Acquisition Strategy

We have initiated an in-licensing and/or acquisition strategy to further expand our product pipeline. This strategy has resulted in the Seneca entering into a non-binding term sheet with QYuns. We believe that this element of our corporate strategy could diversify the risks inherent in focusing on limited therapeutic areas and could increase our probability of commercial success.

Proposed In-licensed Assets
Provided we are able to complete the in-licensing of assets from QYuns, we intend to focus our development activities on the licensed cytokine-targeted monoclonal antibodies.

The in-licensing of the proposed assets is subject to several conditions including the parties entering into definitive agreements as well as approval by Seneca's shareholders. As consideration for the license, Seneca will issue QYuns an as yet to be determined number of equity securities. Seneca can give no assurance that the parties will enter into such definitive agreements, that Seneca's shareholders will approve the transaction, or that if approved, the transaction will ultimately be consummated or that Seneca will be able to successfully develop the in-licensed assets.

Existing Clinical Programs

Historically, we have devoted our efforts and financial resources primarily to the pre-clinical and clinical development of our small molecule compounds and our stem cell therapeutics. Below is a description of our existing clinical programs.

Based on our cash position, we have refocused our development efforts on our exploratory Phase 2 study of NSI-566 for the treatment of Ischemic Stroke (the results of which we do not believe will be able to be used in connection with any regulatory submission in any territory), development of a regulatory plan for NSI-566 in ALS and studies that are being funded by grants. At this time, we anticipate that additional funds for these programs will be focused on maintaining the cell lines, patents, clinical material and data, and relevant licenses associated with these clinical programs as we seek partners for further development.

NSI - 566 (Stem Cells)

The human central nervous system (CNS) has limited capacity for regeneration following injury or the onset of disease. Traditional therapies have mainly focused on minimizing the progression or symptoms of CNS disease or injury but have not been effective at repairing the underlying cause of such disease. The goal of our cell therapy initiatives is the regeneration of neural function which has been lost to disease or injury. We believe that neuroprotection, neuroregeneration, and/or bridging of damaged neural circuitry may be accomplished by implantation of NSI-566 at the injury site.

Our proprietary technology enables the isolation and large-scale expansion of regionally specific neural stem cells from all areas of the developing human brain and spinal cord and enables the generation of commercially useful quantities of highly characterized allogeneic human neural stem cells that can be transplanted into patients to mitigate the consequences of CNS diseases or injury. We have developed and optimized processes that allow us to manufacture these cells under Good Manufacturing Practices or cGMP compliant conditions as required by the FDA for use in clinical trials and have generated cell banks which we believe are sufficient to provide material to meet all our requirements through to completion of Phase 3 studies. We have exclusive licenses for the manufacturing and use of the surgical platform and cannula that enable administration of the cells to the spinal cord for treatment. Based on our preclinical data we believe that our human neural stem cells will differentiate into neurons and glia after grafting into the patient and will provide neuroprotection and stimulate neuroregeneration.

Our lead stem cell program is the spinal cord-derived neural stem cell line, NSI-566, which is being tested for treatment of paralysis due to Amyotrophic Lateral Sclerosis (ALS, or Lou Gehrig's disease), stroke, and spinal cord injury ("SCI"). To date we have completed Phase 1 and Phase 2 safety and dose escalation studies in subjects with ALS and a Phase1 safety and dose escalation study in subjects with motor deficits due to ischemic stroke. Each of these studies are currently in their long-term follow-up stage. In August 2018, we initiated an exploratory Phase 2 study of NSI-566 for the treatment of Ischemic Stroke (the results of which we do not believe will be able to be used in connection with any regulatory submission in any territory). The study is a randomized, double-blind, sham-surgery controlled Phase 2 trial which has enrolled its final subject. We have also conducted a Phase 1 open label study to evaluate the safety of implanting NSI-566 in subjects with chronic SCI.

Amyotrophic Lateral Sclerosis

Amyotrophic lateral sclerosis is a disease of the nerve cells in the brain and spinal cord that control voluntary muscle movement. In 2018 the Centers for Disease Control and Prevention reported that there were between 16,000 and 17,000 individuals in the US with ALS based on information from the National ALS Registry in calendar year 2015. In ALS, nerve cells (motor 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. As the condition progresses, muscles in the chest area stop working, making it difficult or impossible to breathe. NSI-566 is under development as a potential treatment for ALS by providing cells designed to nurture and protect the patient's remaining motor neurons; and possibly repair some motor neurons which have not yet died but which are diseased. We received orphan designation by the FDA for NSI-566 in ALS.

Motor Deficits Due to Ischemic Stroke

Ischemic stroke, the most common type of stroke, occurs as a result of an obstruction within a vessel supplying blood to the brain. In the US, approximately 1.8 million people live with paralysis due to stroke. Post-stroke motor deficits include paralysis in arms and legs and speech impairment 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.

Chronic Spinal Cord Injury

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 17,000 new cases of SCI per year and that at any given time, there are estimated to be approximately 291,000 people in the United States that are living with SCI. Chronic spinal cord injury (cSCI) refers to the time weeks or months after the initial hospitalization. SCIs may be caused by trauma to the spinal cord resulting from motor vehicle accidents, falls, and penetrating injuries such as stab or gunshot wounds. We believe that NSI-566 may provide an effective treatment for cSCI by "bridging the gap" in the spinal cord circuitry created following 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.

Clinical Experience with NSI-566

Ischemic Stroke

In 2013 we commenced an open label, exploratory, Phase 1 safety and dose escalation study to test transplantation of NSI-566 in human subjects for the treatment of motor deficits due to ischemic stroke (the results of which we do not believe will be able to be used in connection with any regulatory submission in any territory). The trial was conducted at BaYi Brain Hospital in Beijing, China and sponsored by Suzhou Neuralstem, a wholly owned subsidiary of Seneca in China. This study was intended to evaluate the safety of direct injections of NSI-566 into the brain and to determine the maximum safe tolerated dose. We completed dosing the final cohort in March 2016, for a total of nine subjects. Subjects were monitored through a 24-month observational follow-up period. Delivery of NSI-566 cells in this population appeared to be safe and well tolerated at all doses.

In June 2018, we presented an abstract at the annual International Society of Stem Cell Research (ISSCR). In the study, 3 cohorts (n=3/cohort) were transplanted with ascending doses of NSI-566, which involved a one-time stereotactic, intracerebral injection of 1.2×10^7, 2.4×10^7, or 7.2×10^7 cells. Immunosuppression therapy with tacrolimus was maintained for 28 days At the 12-Month Visit, compared to Baseline, the mean Fugl-Meyer Motor Score (FMMS, total score of 100) showed 15.6 points of improvement (p=0.0078), the mean Modified Ranking Score (MRS) 0.8 points of improvement (p=0.031), and the mean NIH Stroke Scale (NIHSS) 3.2 points of improvement (p=0.016). The stem cell treatment appears well tolerated at all doses. There were no deaths or serious adverse events related to the treatment.

In August 2018, we initiated an exploratory Phase 2 trial which is a randomized, double-blind, sham-surgery controlled study (the results of which we do not believe will be able to be used in connection with any regulatory submission in any territory). Up to 24 eligible patients will be assigned either to receive NSI-566 stem cells (72 million cells) or sham-surgery at 1:1 ratio. All operations are being conducted at BaYi Brain Hospital, the site of the Phase 1 study, and all follow-up assessments are conducted by blinded, independent neurologists at Beijing Rehabilitation Hospital. The trial has completed patient enrollment and we anticipate having clinical results data in the second half of 2020.

Amyotrophic Lateral Sclerosis

In January 2010, we commenced a Phase 1 trial of NSI-566 in ALS at Emory University in Atlanta, Georgia. The purpose of the trial was to evaluate the safety of our proposed treatment and procedure in a total of 15 subjects. The dosing of subjects in the Phase 1 trial, as designed, was completed in August of 2012. We commenced a Phase 2 clinical trial in subjects suffering from ALS in September of 2013 to further test the feasibility and safety of the treatment and procedure, and maximum tolerated dose of cells. The Phase 2 dose escalation trial enrolled 15 ambulatory subjects in five different dosing cohorts. Each patient in the final cohort had two separate surgeries.

We have completed the transplantations and the observation period of 24 months after the last surgery. The Phase 2 ALS clinical trial met the primary safety endpoints and established what we believe to be the maximum safe tolerated dose. In June 2017, 24-month Phase 2 and combined Phase 1 and Phase 2 data from our ALS trials were presented at the International Society for Stem Cell Research (ISSCR) Annual Meeting, Approaches to Treating ALS, Boston, Massachusetts, by principal investigator Eva Feldman, MD, PhD, Russell N. DeJong Professor of Neurology 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.

To date, substantially all the clinical costs of our ALS studies have been funded by grants.

Chronic Spinal Cord Injury

In 2013, we received authorization from the FDA to commence a Phase 1 clinical trial to treat chronic spinal cord injury. The trial, conducted at The University of California, San Diego or UCSD, commenced in 2014 and the first subject was treated in October 2014. The study enrolled four AIS A classification thoracic spinal cord injury subjects (motor and sensory complete), one to two years' post-injury at the time of stem cell treatment. In January of 2016 we reported six-month follow-up data on all four subjects. The stem cell treatment was found to be safe and well-tolerated by the subjects enrolled and there were no serious adverse events.

In June 2018, the study investigators published the results of the first cohort in the journal Cell Stem Cell. The results support the potential of transplanted NSI-566 to benefit patients with cSCI. At 18 months to 27 months after surgery, the analysis of motor and sensory function and electrophysiology showed changes in three of the four patients after NSI-566 transplantation. There was no evidence of serious adverse events, suggesting the procedure is safe and well-tolerated.

Substantially all the clinical costs of this study have been, and will continue to be, funded by grants arranged through UCSD.

NSI-189 (Small Molecule Pharmaceutical Compound).

NSI-189, a new chemical entity with what we believe to work through a novel mechanism of action and stimulates neurogenesis of human hippocampus derived neural stem cells in vitro and neurogenesis in mouse hippocampus in vivo. Because studies have linked depression with impaired hippocampal neurogenesis, we believe that NSI-189 may provide an effective treatment for patients suffering from Major Depressive Disorder or MDD by promoting synaptogenesis or neurogenesis in the hippocampus.

Major Depressive Disorder (MDD)

Major depressive disorder (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. According to the National Survey on Drug Use and Health (NSDUH), an estimated 17.3 million adults in the United States had at least one major depressive episode in 2017, which represents 7.1% of adults in the US. Treatment of MDD is characterized by a high level of patient turnover due to low efficacy and high side effects. It is estimated that 67% of patients will fail their first line therapy, 75% will then fail their second line prescription and 80% will then fail their third line prescription. These factors combine to create a significant opportunity for a differentiated therapeutic agent, particularly one that may act through a novel mechanism of action.

Clinical Experience with NSI-189

Major Depressive Disorder
We have completed a Phase 2 randomized, placebo-controlled, double-blind clinical trial for the treatment of MDD in an outpatient setting. The study randomized 220 subjects into three cohorts: NSI-189 40 mg twice daily (BID), NSI-189 40 mg once daily (QD), or placebo. After the initial screening period, the dosing portion of the trial was 12 weeks in duration. There was a two week wash out period for those subjects enrolled who were taking an anti-depressant at the time of screening.

The study was 80% powered to show an improvement in the primary endpoint, compared to placebo, with an assumed effect size of Cohen's d=0.5 ($p \leq 0.05$). Subjects eligible for the study had to be diagnosed with major depressive disorder, recurrent, as per Diagnostic and Statistical Manual of Mental Disorders V^3, scoring 20 or greater on the MADRS, at screening and baseline and experiencing at least one eight-week MDD episode. The MADRS score was confirmed to be 20 or greater via remote SAFER interview by an independent rater prior to the baseline visit. After the 12-week trial period, eligible subjects were given the opportunity to enroll in a separate six-month observational study to assess the durability of effect defined as the time until the start of a new antidepressant treatment (ADT). Both the interventional and the observational studies were conducted 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.

On July 25, 2017, we announced top-line results from the trial. The study did not meet its primary efficacy endpoint of a statistically significant reduction in depression symptoms on the Montgomery-Asberg Depression Rating Scale (MADRS), compared to placebo. Both doses appear safe and well-tolerated with no serious adverse events reported.

On December 5, 2017, we presented an updated analysis – including reports on all secondary scales – from the Phase 2 study of NSI-189 in MDD at the 56th American College of Neuropsychopharmacology (ACNP) Annual Meeting. Three additional patient reported outcomes showed statistically significant improvements in depressive and cognitive symptoms: Symptoms of Depression Questionnaire (SDQ): 40mg, p=0.044, Cognitive and Physical Functioning Questionnaire (CPFQ): 40 mg; p = 0.035, and Quick Inventory of Depressive Symptomatology Scale (QIDS-SR): 40 mg; p = 0.040 (Stage 2). Thus, with all three patient reported outcome scales (SDQ, CPFQ, and QIDS-SR) NSI-189 reached statistical significance over placebo.

In addition, we presented data on NSI-189's effect on cognition as measured by computer-administered objective tests of cognition in the MDD patients. Two different test methods were used: Cogstate® and CogScreen®. Cogstate did not yield statistically significant results. In CogScreen® test, NSI-189 40 mg showed statistically significant improvement ($p<0.05$) on objective measures of executive functioning, attention, working memory, and memory.

NSI-189 appeared to be safe and well tolerated with no serious adverse events. There were no clinically meaningful changes in body weight or BMI, or in sexual function inventory. The study results have been published (Papakostas GI, et al. (2019). Mol Psychiatry. 2019 Jan 9. doi: 10.1038/s41380-018-0334-8. [Epub ahead of print] PubMed PMID: 30626911).

Our Technologies

Stem Cells

From a therapeutic perspective, our stem cell-based 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 different types. We believe that our stem cell technology will enable the replacement or supplementation of malfunctioning or dead cells thereby creating a neurotrophic environment that offers protection to neural tissue as a way to treat disease and injury. Many significant and currently untreatable human diseases arise from the loss or malfunction of specific cell types in the body. Our focus is the development of effective methods to generate replacement cells from neural stem cells. We believe that creating a neurotrophic environment by 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.

Our Proprietary and Novel Screening Platform

Our human neural stem cell lines form the foundation for functional cell-based assays used to screen for small molecule compounds that can impact biologically relevant outcomes such as neurogenesis, synapse formation, and protection against toxic insults. We have developed over 300 unique stem cell lines representing multiple different regions of the developing brain and spinal cord at multiple different time points in development, enabling the generation of physiologically relevant human neural cells for screening, target validation, and mechanism-of-action studies. This platform provides us with a unique and powerful tool to identify new chemical entities to treat a broad range of nervous system conditions. NSI-189 was discovered using our stem cell-based screening platform.

Small Molecule Pharmaceutical Compounds.

Utilizing our proprietary stem cell-based screening capability, we have discovered and patented a series of small molecule compounds. We believe our low molecular weight organic compounds can efficiently cross the blood/brain barrier. In mice, research indicated that the small molecule compounds both stimulate neurogenesis of the hippocampus and increase its volume. We believe the small molecule compounds may promote synaptogenesis and neurogenesis in the human hippocampus thereby providing therapeutic benefits in indications such as MDD and may also provide clinical benefit in indications such as Angelman Syndrome, Diabetic Neuropathy, Cognition, Stroke and Radiation Induced Cognitive Deficit.

Intellectual Property

We have developed and maintain a portfolio of patents and patent applications that form the proprietary base for our research and development efforts. We own or exclusively license 20 United States issued and pending patents and over 60 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 2023 through 2035.

Employees

As of October 31, 2019, we had five (5) full-time employees. We also use the services of several outside consultants in business and scientific matters.

Our Corporate Information

We were incorporated in Delaware in 2001. On October 28, 2019 we changed our name from Neuralstem, Inc. to Seneca Biopharma, Inc. 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.senecabio.com.

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

Trends & Outlook

Revenue

We generated no revenues from the sale of our proposed therapies for any of the periods presented.

We have historically generated minimal revenue from the licensing of our intellectual property to third parties as well as payments under a settlement agreement.

On a long-term basis, we anticipate that our revenue will be derived primarily from licensing/royalty fees and the sales of our products currently under development, acquired and/or in-licensed in the future, small molecule compounds and licensing fees and royalties from our cell-based therapies. Based on the development stage of our business, 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 therapies 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 as we proceed into later stage clinical trials or commence development of new product candidates.

We have 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.

In August 2017, we were awarded a Small Business Innovation Research ("SBIR") grant by the National Institutes of Health ("NIH") to evaluate in preclinical studies the potential of NSI-189, a novel small molecule compound, for the prevention and treatment of diabetic neuropathy. The award of approximately $1 million will be paid over a two-year period, if certain conditions are met as mid-term. In June 2018, we were awarded a Department of Defense grant related to our efforts involving stem cell therapy for severe traumatic brain injury. The award totals approximately $150,000. The proceeds from such awards are recorded as a reduction of our gross research and development expenses, based on the terms and conditions of the grant.

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.

Going Concern

Our auditors' report issued in connection with our December 31, 2018 financial statements expressed an opinion that due to recurring losses from operations and accumulated deficit, there is substantial doubt about our ability to continue as a going concern. Our current cash level raises substantial doubt about our ability to continue as a going concern past the third quarter of 2020. If we do not obtain additional capital by such time, we may no longer be able to continue as a going concern and may cease operation or seek bankruptcy protection.

Critical Accounting Policies

Our unaudited condensed 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 Unaudited 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.

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 - The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The unaudited condensed consolidated financial statements include significant estimates for the expected economic life and value of our licensed technology and related patents, our net operating loss and related valuation allowance for tax purposes, the fair value of our liability classified warrants and our share-based compensation related to employees and directors, consultants and advisors, among other things. Because of the use of estimates inherent in the financial reporting process, actual results could differ significantly 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-month periods ended September 30, 2019 and 2018, no significant impairment losses were recognized.

Fair Value Measurements - The fair value of our short-term financial instruments, which primarily include cash and cash equivalents, other short-term investments, accounts payable and accrued expenses, approximate their carrying values due to their short maturities. The fair value of our long-term indebtedness was 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 which approximates the carrying value. The fair values of our liability classified warrants 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, share-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, 2019 and 2018

Revenue

During each of the three months ended September 30, 2019 and 2018 we recognized revenue of $2,500 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 were as follows:

	Three Months Ended September 30,		Increase (Decrease)	
	2019	2018	$	%
Operating Expenses				
Research and development expenses	$ 825,486	$ 897,098	$ (71,612)	(8%)
General and administrative expenses	1,301,189	1,188,076	113,113	10%
Total operating expenses	$ 2,126,675	$ 2,085,174	$ 41,501	2%

Research and Development Expenses

The decrease of approximately $72,000 or 8% in research and development expenses for the three months ended September 30, 2019 compared to the comparable period of 2018 was primarily attributable to a $225,000 decrease in our clinical trial activities, a $59,000 decrease in our personnel and related costs and a $50,000 loss in prior year related to our lease abandonment partially offset by $207,000 increase in our R&D consulting relating to evaluating strategic alternatives and $49,000 decrease in reimbursements (net increase in expense) under our grants. Going forward our R&D spending will be dedicated to completing various clinical activities and the continued evaluation of strategic program options and opportunities.

General and Administrative Expenses

The increase of approximately $113,000 or 10% in general and administrative expenses for the three months ended September 30, 2019 compared to the comparable period of 2018 was primarily attributable to a $183,000 increase in our non-cash share-based compensation expense partially offset by a decreases due to our continued cost cutting efforts and a $67,000 decrease in tax expense.

Other income (expense)

Other income, net totaled approximately $361,000 and $252,000 for the three months ended September 30, 2019 and 2018, respectively.

Other income, net in 2019 consisted primarily of approximately $321,000 of non-cash gains related to the fair value adjustment of our liability classified stock purchase warrants, $27,000 of sublease income and $15,000 of interest income.

Other income, net in 2018 consisted primarily of approximately $236,000 of non-cash gains related to the fair value adjustment of our liability classified stock purchase warrants and $18,000 of interest income.

Comparison of Nine Months Ended September 30, 2019 and 2018

Revenue

During each of the nine months ended September 30, 2019 and 2018 we recognized revenue of $7,500 related to ongoing fees pursuant to certain licenses of our intellectual property to third parties. In addition, during the nine months ended September 30, 2018, we recognized $250,000 of revenues related to milestone-based royalties related to a settlement of a prior patent infringement case.

Operating Expenses

Operating expenses for the nine months ended September 30 were as follows:

	Nine Months Ended September 30,		Increase (Decrease)	
	2019	2018	$	%
Operating Expenses				
Research and development expenses	$ 3,294,402	$ 3,081,319	$ 213,083	7%
General and administrative expenses	3,217,613	3,630,822	(413,209)	(11%)
Total operating expenses	$ 6,512,015	$ 6,712,141	$ (200,126)	(3%)

Research and Development Expenses

The increase of approximately $213,000 or 7% in research and development expenses for the nine months ended September 30, 2019 compared to the comparable period of 2018 was primarily attributable to a $528,000 increase in consulting fees, primarily related to evaluating strategic alternatives and a $90,000 increase in non-cash shared-based compensation expense partially offset by a $225,000 decrease in our clinical trial activities as well as a $122,000 decrease in various expenses resulting from our cost saving activities.

General and Administrative Expenses

The decrease of approximately $413,000 or 11% in general and administrative expenses for the nine months ended September 30, 2019 compared to the comparable period of 2018 was primarily attributable to our continued cost cutting efforts including a $378,000 decrease in consulting and professional fees, along with along with a $146,000 decrease in tax and insurance expenses partially offset by a $101,000 increase in non-cash share-based compensation expense.

Other expense

Other income, net totaled approximately $185,000 and $1,850,000 for the nine months ended September 30, 2019 and 2018, respectively.

Other income, net in 2019 consisted primarily of approximately a $368,000 loss related to the write-off of a related party receivable partially offset by a $417,000 of non-cash gain related to the fair value adjustment of our liability classified stock purchase warrants, $86,000 of sublease income and $55,000 of interest income.

Other income, net in 2018 consisted primarily of approximately $1,805,000 of non-cash gains related to the fair value adjustment of our liability classified stock purchase warrants and $55,000 of interest income.

Liquidity and Capital Resources

Financial Condition

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 as well as the licensing of our intellectual property to third parties.

We had cash and cash equivalents of approximately $7.3 million at September 30, 2019. On July 30, 2019, we completed a firm commitment underwritten public offering of our securities which resulted in approximately $6.6 million of net proceeds.

Based on our expected operating cash requirements, we anticipate our current cash and investments on hand, after taking into account our July offering, will be sufficient to fund our operations, into the third quarter of 2020. As explained in Note 1 to our financial statements, management has determined that there is substantial doubt about our ability to continue as a going concern.

We will require additional capital to pursue our acquisition and in-licensing strategy and continue our pre-clinical and clinical development plans. To continue to fund our operations and the development of our product candidates we anticipate raising additional cash through the private and public sales of equity or debt securities, collaborative arrangements, licensing agreements or a combination thereof. Although management believes that such funding sources will be available, there can be no assurance that any such collaborative arrangement will be entered into or that financing will be available to us when needed in order to allow us to continue our operations, or if available, on terms acceptable to us. If we do not raise sufficient funds in a timely manner, we may be forced to curtail operations, delay or stop our ongoing clinical trials, cease operations altogether, or file for bankruptcy. We currently do not have commitments for future funding from any source. We cannot assure you that we will be able to secure additional capital 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.

Cash Flows – 2019 compared to 2018

	Nine Months ended September 30,		Favorable (Unfavorable)	
	2019	2018	$	%
Net cash used in operating activities	$ (5,206,748)	$ (6,034,389)	$ 827,641	14%
Net cash provided by investing activities	$ -	$ 5,000,000	$ (5,000,000)	100%
Net cash provided by financing activities	$ 6,726,232	$ 101,761	$ 6,624,471	(6510%)

Net Cash Used in Operating Activities

Cash used in operating activities for the nine months ended September 30, 2019, of approximately $5,207,000 reflects our $6,314,000 loss for the period adjusted for certain non-cash items including: (i) $761,000 of share-based compensation, (ii) a $417,000,000 gain related to the change in fair value of our liability classified warrants, (iii) $362,000 of bad debt expense and (iv) $287,000 of net cash inflows related to changes in operating assets and liabilities.

Net Cash (Used in) Provided by Investing Activities

There were no investing activities in the nine months ended September 30, 2019

For the nine months ended September 30, 2018 cash provided by investing activities was comprised solely of proceeds from the maturity of our short-term investments.

Net Cash Used in by Financing Activities

For the nine months ended September 30, 2019, cash used in financing activities consisted of $6.6 million of net proceeds generated from the sale of our common stock and warrants coupled with borrowings and payments under our short-term debt used to finance insurance premiums.

For the nine months ended September 30, 2018, cash provided by financing activities consisted of our borrowings and payments under our short-term debt used to finance insurance premiums.

Future Liquidity and Needs

We have incurred significant operating losses and negative cash flows since inception. We have not been able to generate significant revenues nor achieved profitability and may not be able to do so 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 have relied 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 funds through the out license or sale of our existing clinical programs in addition to financing in the future through the sale of our securities and additional research grants. On June 23, 2017, our shelf registration statement (Registration No. 333-218608), which replaced our prior expiring shelf registration statement, was declared effective by the SEC. Under such replacement shelf registration statement, we can offer and sell up to $100 million of our securities. Through October 31, 2019 we have sold approximately $12.6 million of securities under our shelf registration statement. Based on our current market capitalization, we are limited to the use of our shelf registration statement by Item I.B.6 of Form S-3.

On July 30, 2019, we completed a firm commitment underwritten public offering of our securities. The offering resulted in net proceeds of approximately $6.6 million, after deducting underwriting discounts and commissions and offering expenses. The securities in this offering were sold pursuant to a registration statement on Form S-1(file no. 333- 232273).

As explained in the notes to our financial statements, if we are not able to raise additional funds when needed, there would continue to be substantial doubt as to our ability to continue as a going concern. The source, timing and availability of any future financing will depend principally upon market conditions, interest rates and, more specifically, current and future progress in our exploratory, preclinical and clinical development programs. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate some or all of our research and product development programs, planned clinical trials, and/or our capital expenditures or to license our potential products or technologies to third parties.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Based on an evaluation under the supervision and with the participation of the Company’s management, the Company’s principal executive officer, who is also our principal financial officer, has 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, 2019, 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, who is also our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the quarter ended September 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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, who is also our 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

None.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. We have described below a number of uncertainties and risks which, in addition to uncertainties and risks presented elsewhere in this Quarterly Report, may adversely affect our business, operating results and financial condition. The uncertainties and risks enumerated below as well as those presented elsewhere in this Quarterly Report should be considered carefully when evaluating our company, business and the value of our securities.

Risks Relating to Our Stage of Development, Capital Structure and Listing of Our Securities

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

We have incurred losses since our inception and have not demonstrated an ability to generate revenues from the sales of our proposed products. Our ability to continue as a going concern is dependent on raising capital from the sale of our common stock and/or obtaining debt financing. Our cash, cash equivalents and short-term investment balance at September 30, 2019 was approximately $7.3 million. Based on our current expected level of operating expenditures, we expect to be able to fund our operations into the third quarter of 2020. Our ability to remain a going concern is wholly dependent upon our ability to continue to obtain sufficient capital to fund our operations.

Accordingly, despite our ability to secure capital in the past, there can be no assurance that additional equity or debt financing will be available to us when needed or that we may be able to secure funding from any other sources. In the event that we are not able to secure funding, 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 issued in connection with our December 31, 2018 financial statements expressed an opinion that due to recurring losses from operations and accumulated deficit, there is substantial doubt about our ability to continue as a going concern. Our current cash level raises substantial doubt about our ability to continue as a going concern past the third quarter of 2020. If we do not obtain additional capital by such time, we may no longer be able to continue as a going concern and may cease operation or seek bankruptcy protection.

If we are unable to successfully retain and integrate a new management team, our business could be harmed.

Effective January 1, 2019, we appointed Dr. Kenneth Carter as our Executive Chairman. In such role, Dr. Carter is our Principal Executive and Accounting Officer. Our success depends largely on the development and execution of our business strategy by our senior management team. We currently have a limited full-time executive team which may adversely affect our business. Additionally,

the loss of any members or key personnel would likely harm our ability to implement our business strategy and respond to the rapidly changing market conditions in which we operate. There can be no assurance that we will be able to retain the current members of our management team. Moreover, there may be a limited number of persons with the requisite skills to serve in these positions, and we cannot assure you that we would be able to identify, employ or retain such qualified personnel on acceptable terms, if at all. We cannot assure you that management will succeed in working together as a team. In the event we are unsuccessful, our business and prospects could be harmed.

If we are unable to execute on our in-licensing and acquisition strategy, our business could be materially impacted.

During 2019 we initiated an in-licensing and acquisition strategy to further expand our product pipeline. Our in-licensing strategy consists of evaluating pre-clinical and clinical stage opportunities in therapeutic areas that can benefit from our current product candidates or core expertise in drug development. Although we believe this strategy could diversify some of the risks inherent in focusing on limited therapeutic areas and could increase our probability of commercial success, it is extremely costly and expensive. At present, we are focusing a majority of our efforts and capital resources on such strategy and have greatly reduced our other development activities. If we are not ability to successfully execute this strategy, our business will be materially impacted.

The liquidity of our common stock and shareholder's ability to sell their shares has been affected by our recent reverse stock split.

On July 17, 2019 we effected a 1-for-20 reverse stock split. As a result of the reverse stock split the liquidity of our common stock has decreased as a result of the corresponding reduction in the number of shares that are outstanding following such split. In addition, the reverse stock split increased the number of stockholders who own odd lots (less than 100 shares) of our common stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty effecting such sales.

If we are unable to satisfy NASDAQ maintenance requirements, our common stock may be delisted from NASDAQ, which could impair the liquidity and the value of our common stock.

Our continued listing on NASDAQ generally requires that we meet certain listing maintenance requirements. If we are unable to satisfy NASDAQ'S continued listing requirements, our common stock may be delisted from NASDAQ. In such event, trading in our common stock would likely take place on the over-the-counter market on the "OTC Markets" or the "OTC Bulletin Board." Consequently, the liquidity of our common stock could be impaired, not only in the number of shares of common stock which could be bought and sold, but also through delays in the timing of transactions, a reduction in security analysts and new media coverage and lower prices for our common stock than might otherwise be obtained. While the shares of our common stock currently meet NASDAQ listing requirements and are currently listed on The Nasdaq Capital Market, there can be no assurance that we will continue to meet the criteria for continued listing.

While we continue to monitor our compliance with the requirements for continued listing on The Nasdaq Capital Market, we cannot assure you that we will not fail to satisfy one of the criteria in the future. If that were to occur, NASDAQ may take steps to delist our common stock. A delisting would likely have a negative effect on the price of our common stock and would likely impair your ability to sell or purchase our common stock if and when you wish to do so. In the event of a delisting, we cannot assure you that any action we take to restore listing would be successful. Even if successful, we cannot assure you that any such action would stabilize the market price of our common stock, improve the liquidity of our common stock, or prevent our future non-compliance with NASDAQ listing requirements. Further, if we were to be delisted from The Nasdaq Capital Market, our common stock would no longer be recognized as a "covered security" and we would be subject to regulation in each state in which we offer our securities. Thus, delisting from NASDAQ could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly impact the ability of investors to trade our securities and would negatively impact the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

If our common stock were delisted from NASDAQ, the Company would be subject to the risks relating to penny stocks.

If our common stock were to be delisted from trading on the Nasdaq Capital Market and the trading price of our common stock were below $5.00 per share on the date our common stock is delisted, trading in our common stock would also be subject to the requirements of certain rules promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These rules require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a "penny stock" and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors, generally institutions. These additional requirements may discourage broker-dealers from effecting transactions in securities that are classified as penny stocks, which could severely limit the market price and liquidity of such securities and the ability of purchasers to sell such securities in the secondary market. A penny stock is defined generally as any non-exchange listed equity security that has a market price of less than $5.00 per share, subject to certain exceptions.

We could become the subject to securities litigation.

Commencing in 2017, we have seen a dramatic decrease in the price of our common stock. More recently, in July of 2019 we effected a 1-for-20 reverse stock split and completed an underwritten public offering of our securities. Commencing from the time our reverse stock split became effective, we have seen an even more drastic decrease in the price of our common stock. Plaintiffs have often initiated securities class action litigation against a company following periods of significant decreases in the market price of the company's securities. As a result, we may become the target of litigation. Securities litigation could result in substantial costs and liabilities and could divert management's attention and resources from our operations and business.

We have a history of losses.

Since inception in 1996 through September 30, 2019, we have accumulated losses totaling approximately $219.9 million. As of September 30, 2019, we had a working capital surplus of approximately $6.4 million and stockholders' equity of approximately $7.0 million. Our net losses for the two most recent fiscal years have been approximately $4.9 million and $15.7 million for 2018 and 2017, respectively.

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, 2019, we had cash, cash equivalents and short-term investments on hand of approximately $7.3 million. 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 additional financing, we may be unable to meet our obligations which could result in us initiating bankruptcy proceedings or delaying or eliminating some or all of our research and product development programs.

Risks Relating to Our Business

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

Our business is significantly dependent on our product candidates which are currently at different phases of pre-clinical and clinical development or that we may acquire or in-license in the future. 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 current or future product candidates, we will have invested substantial amounts of time and money without developing revenue-producing products.

Our current and future product candidates are not likely to be commercially available for at least several years, if at all. Our development schedules for our current and future product candidates may be affected by a variety of factors, including difficulties in identifying and in-licensing or acquiring such future products candidates, 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.

We have allocated most 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 current or future technologies or that if developed, our technologies will result in commercially viable products or have any commercial utility or value. We anticipate that the commercial sale of our proposed products and/or royalty/licensing fees related to our technologies, will be our primary sources of revenue. If we are unable to develop our technologies, we may never realize any significant revenue. Additionally, given the uncertainty of our technologies, product candidates and the need for government regulatory approval, we cannot predict when, or if ever, we will be able to realize revenues related to our products. As a result, we will be primarily dependent on our ability to raise capital through the sale of our securities for the foreseeable future.

Our stem cell therapy programs rely on experimental surgical devices and highly invasive experimental 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 stem cell therapies are 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 these devices or the surgical procedures. 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 significant 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 reliance on third parties to manufacture and store our stem cells and small molecule compounds could adversely impact our business.

We currently outsource most of the manufacturing related to our current product candidates to third party contractors and as such have limited ability to adequately control the manufacturing process and the safe storage thereof. Additionally, we may also outsource manufacturing related to any future product candidates that are in-licensed or acquired. 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.

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

Prior to being able to commercialize any of our current or future product candidates, we will need to complete clinical trials. If we are unable to satisfactorily complete our other trials, or if such trials also yield unsatisfactory results, we may be unable to obtain regulatory approval for and commercialize our proposed products. No assurances can be given that our clinical trials will be completed or result in successful outcomes. A number of events, including any of the following, could delay the completion of our planned clinical trials and negatively impact our ability to obtain regulatory approval for, and to market and sell, a particular product candidate:

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

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, clinical trial site IRB's, 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.

Seemingly positive results from pre-clinical studies or clinical studies should not be relied upon as evidence that our clinical trials will succeed. Even if our product candidates achieve positive results in pre-clinical studies 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.

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.

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

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

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

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

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

Our current and future product candidates may be significantly more expensive to manufacture than other drugs or therapies currently on the market today. Even if we can receive approval for the reimbursement of our proposed products the amount of reimbursement may be significantly less than the manufacturing costs of our products. Additionally, other market factors may limit the price which we can charge for our proposed products while still being competitive. Accordingly, even if we are successful in developing our proposed products, we may not be able to charge a high enough price for us to earn a profit.

We depend on a limited number of employees and consultants for our continued operations and future success.

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

The employment contract of Dr. Carter contains significant anti-termination provisions which could make changes in management difficult or expensive.

We have entered into an employment agreement with Dr. Carter, our Executive Chairman and Principal Financial Officer. This agreement may require the payment of severance in the event he ceases to be employed. The provision makes the replacement of Dr. Carter very costly and could cause difficulty in effecting any required changes in management or a change in control.

Our competition has significantly greater experience and financial resources.

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

As a result, our proposed products could become obsolete before we recoup any portion of our related research and development and commercialization expenses. Competition in the biopharmaceutical industry is based significantly on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval for testing, manufacturing and marketing. We compete with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions and governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to us.

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

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

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

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

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

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

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

We currently do not have the in-house capability to conduct clinical trials for our current or future product candidates. We rely, and will rely in the near future, on medical institutions, clinical investigators, contract research organizations, contract laboratories, and

collaborators to perform data collection and analysis and other aspects of our clinical trials. Our reliance on these third parties for clinical development activities results in reduced control over these activities. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. Our preclinical activities or clinical trials conducted in reliance on third parties may be delayed, suspended, or terminated if:

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

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

Risks Relating to Intellectual Property

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

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

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

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

We may infringe the intellectual property rights of others and may not be able to obtain necessary licenses to third-party patents and other rights.

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

Risks Relating to Our Common Stock

The market price for our common shares is particularly volatile.

The market for our common shares is characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will continue to be more volatile than those of a seasoned issuer. The volatility in our share price is attributable to a number of factors. Mainly however, we are a speculative or "risky" investment due to our limited operating history, lack of significant revenues to date and the uncertainty of FDA approval. By way of example, in July of 2019, we completed a firm commitment underwritten public offering of our securities. During the marketing of the offering and post-closing, the market price or our common stock decreased substantially. As a consequence of this enhanced risk, more risk-adverse investors may, under the fear of losing all or most of their investment in the event of negative news or lack of progress, be more inclined to sell their shares on the market more quickly and at greater discounts than would be the case with the stock of a seasoned issuer. Additionally, in the past, plaintiffs have often initiated securities class action litigation against a company following periods of volatility in the market price of its securities. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs and liabilities and could divert management's attention and resources.

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

Future sales of our common stock could cause our stock price to fall.

In July 2019, we completed a firm commitment underwritten public offering of our securities. The offering resulted in, assuming the exercise of all warrants included in the offering, the issuance of approximately 8.3 million shares of our common stock, or approximately 89% of our issued and outstanding common stock. Transactions, such as the July offering, that result in a large amount of newly issued shares that are readily tradable, or other events that cause current stockholders to sell shares, could place downward pressure on the trading price of our common stock. In addition, the lack of a robust trading market may require a stockholder who desires to sell a large number of shares of common stock to sell the shares in increments over time to mitigate any adverse impact of the sales on the market price of our stock. If our stockholders sell, or the market perceives that our stockholders intend to sell for various reasons, substantial amounts of our common stock in the public market, including shares issued upon the exercise of outstanding options or warrants, the market price of our common stock could fall. Sales of a substantial number of shares of our common stock may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate. We may become involved in securities class action litigation that could divert management's attention and harm our business.

Certain of our outstanding common stock purchase warrants contain price protection provisions (anti-dilution protection) in the event that we sell our securities at prices lower than the current exercise price of such warrants, which may have a negative impact on the trading price of our common stock or impair our ability to raise capital.

As of September 30, 2019, we had 149,136 common stock purchase warrants outstanding that were issued in our May 2016 registered offering, May 2016 private placement and August 2017 registered offering that all contain price protection provisions in the event that we sell securities at a price per share below their respective exercise prices (collectively "Price Protection Warrants"). Pursuant to our July 2019 offering, the Price Protection Warrants all had their exercise prices adjusted to $2.19 per share. On July 31, 2019, the closing price of our common stock was $2.20. In the event that we sell securities at a price per share lower than the current exercise price of the Price Protection Warrants, their exercise prices will be further reduced. Any future adjustments to the exercise prices of the Price Protection Warrants may have a negative impact on the trading price of our common stock. Additionally, raising additional capital with new investors may be difficult as a result of the adjustment feature.

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

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

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

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

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

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

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

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

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

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

We are entitled under our certificate of incorporation to issue up to 300,000,000 shares of common stock and 7,000,000 "blank check" shares of preferred stock. Shares of our blank check preferred stock provide our board of directors with broad authority to determine voting, dividend, conversion, and other rights. As of September 30, 2019, we have issued and outstanding 2,818,291 shares of common stock and we have 8,530,401 shares of common stock reserved for future grants under our equity compensation plans and for issuances upon the exercise or conversion of currently outstanding options, warrants and convertible securities. Included in this amount is 1,048,166 shares issuable upon exercise of our $0.0001 strike price, prefunded warrants initially issued in connection with our July public offering. As of September 30, 2019, we had 200,000 shares of preferred stock issued and outstanding which are convertible into 38,873 shares of our common stock. Accordingly, as of September 30, 2019, we are entitled to issue up to 288,651,308 additional shares of common stock and 6,000,000 additional shares of "blank check" preferred stock. Our board may generally issue those common and preferred shares, or convertible securities to purchase those shares, without further approval by our shareholders. Any preferred shares we may issue will have such rights, preferences, privileges and restrictions as may be designated from time-to-time by our board, including preferential dividend rights, voting rights, conversion rights, redemption rights and liquidation provisions. It is likely that we will be required to issue a large amount of additional securities to raise capital in order to further our development and marketing plans. It is also likely that we will be required to issue a large amount of additional securities to directors, officers, employees and consultants as compensatory grants in connection with their services, both in the form of stand-alone grants or under our various stock plans. The issuance of additional securities may cause substantial dilution to our shareholders.

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

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

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

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product

candidate is safe and effective for its proposed indication;

- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA, NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval would impair our ability to develop foreign markets for our drug candidates.

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

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

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

We are subject to healthcare laws, regulation and enforcement and our failure to comply with those laws could adversely affect our business, operations and financial condition.

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal

government and the states in which we conduct our business. The regulations that may affect our ability to operate include, without limitation:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities that provide coding and billing advice to customers;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal physician sunshine requirements under the ACA, which require manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members; and
- HIPAA, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information.

In addition, recent healthcare reform legislation has strengthened these laws. For example, the ACA, among other things, amended the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

These laws and regulations are broad in scope and they are subject to change and evolving interpretations, which could require us to incur substantial costs associated with compliance or to alter one or more of our sales or marketing practices. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the exclusion from participation in federal and state healthcare programs, imprisonment, or the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

Failure to comply with domestic and international privacy and security laws can result in the imposition of significant civil and criminal penalties. The costs of compliance with these laws, including protecting electronically stored information from cyberattacks, and potential liability associated with failure to do so could adversely affect our business, financial condition and results of operations. We are subject to various domestic and international privacy and security regulations, including but not limited to HIPAA. HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA.

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

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

- In December 2018, as an inducement to Dr. Carter's employment, we granted an Inducement Option to purchase 40,000 shares of common stock at an exercise price of $8.50 per share. The Inducement Option has a term of ten years, and vests as follows: 10,000 on the January 1, 2019 employment start date, 10,000 over the two-year period from the employment start date and 20,000 based on the achievement of certain performance-based milestones. The Inducement Option also provides that if within 12 months following the employment start date, the Company enters into a transaction to sell securities in a capital raising effort Mr. Carter will be awarded additional options based on his percentage ownership prior to such transaction. As a result of the July 2019 underwritten offering of securities, the number of shares into which Dr. Carter's inducement grant is exercisable into was increased by 116,213 to 156,213. All other terms of the inducement grant remain the same.

- During February 2019, as compensation for service on the board, we made a conditional grant to Binxian Wei of options to purchase 5,925 shares of our common stock. The grant was conditional upon the Company receiving shareholder approval of such grant. The Company obtained such approval on June 12, 2019. The options have a term of 10 years, vest quarterly over the grant year and have an exercise price of $8.80.

- During February 2019, as partial compensation for consulting services, we issued to one of our consultants, stock purchase warrants to purchase 25,000 shares of common stock at an exercise price of $6.00 per share. 25% of the warrants are exercisable on the grant date and 75% are exercisable upon completion of initial services. The warrants have a five-year term commencing on January 2019.

- During June 2019, as compensation for service on the board, we issued to a new director stock options to purchase 455 shares of common stock at an exercise price of $7.20 per share. The options were issued pursuant to our 2019 Equity Incentive Plan, have a term of 10 years and vested on June 30, 2019.

- During July 2019, as compensation for service on the board, we issued certain equity awards to members of our board pursuant to our 2019 Equity Incentive Plan. Specifically, we issued stock options to purchase 65,590 shares of common stock at exercise prices ranging from $5.90 to $6.00; 4,904 restricted stock units and 15,689 shares of restricted stock. The awards all vest quarterly over the board year and the options and restricted stock units have a term of 10 years.

ITEM 3. DEFAULT UPON SENIOR SECURITIES

None

ITEM 4. MINE SAFETY DISCLOSURE

Not Applicable

ITEM 5. OTHER INFORMATION

Not Applicable

ITEM 6. EXHIBITS

Exhibit No.	Description	Filed/ Furnished Herewith	Incorporated by Reference			
			Form	Exhibit No.	File No.	Filing Date
3.01(i)	Amended and Restated Certificate of Incorporation of Neuralstem, Inc. filed on 1/5/2017		S-1/A	3.01(i)	001-33672	1/6/17
3.01(ii)	Amended and Restated Certificate of Incorporation of Neuralstem, Inc. effective on 7/17/2019		8-K	3.01(i)	001-33672	7/18/19
3.01(ii)	Amendment to Amended and Restated Certificate of Incorporation of Neuralstem, Inc. effective 10/28/19		8-K	3.01	001-33672	10/30/19

3.02(i)	Certificate of Designation of Series A 4.5% Convertible Preferred Stock	8-K	3.01	001-33672	12/12/16
3.03(ii)	Amended and Restated Bylaws of Neuralstem, Inc. adopted on 11/10/2015	8-K	3.01	001-33672	11/16/15
4.01**	Amended and Restated 2005 Stock Plan adopted on 6/28/07	10-QSB	4.2(i)	333-132923	8/14/07
4.02**	Non-qualified Stock Option Agreement between Neuralstem, Inc. and Richard Garr dated 7/28/05	SB-2/A	4.4	333-132923	6/21/06
4.03**	Non-qualified Stock Option Agreement between Neuralstem, Inc. and Karl Johe dated 7/28/05	SB-2/A	4.5	333-132923	6/21/06
4.04**	Neuralstem, Inc. 2007 Stock Plan	10-QSB	4.21	333-132923	8/14/07
4.05	Form of Common Stock Purchase Warrant Issued to Karl Johe on 6/5/07	10-KSB	4.22	333-132923	3/27/08
4.06	Form of Placement Agent Warrant Issued to Midtown Partners & Company on 12/18/08	8-K	4.1	001-33672	12/18/08
4.07	Form of Consultant Common Stock Purchase Warrant issued on 1/5/09	S-3/A	10.1	333-157079	02/3/09
4.08	Form of Series D, E and F Warrants	8-K	4.01	001-33672	7/1/09
4.09	Form of Placement Agent Warrant	8-K	4.02	001-33672	7/1/09
4.10	Form of Consultant Warrant Issued 1/8/10	10-K	4.20	001-33672	3/31/10

4.11	Form of Replacement Warrant Issued 1/29/10	10-K	4.21	001-33672	3/31/10
4.12	Form of Series C Replacement Warrant Issued March of 2010 and May, June and July of 2013 (Original Ex. Price $2.13 and $1.25)	10-K	4.22	001-33672	3/31/10
4.13	Form of employee and consultant option grant pursuant to our 2007 Stock Plan and 2010 Equity Compensation Plan	10-K	4.23	001-33672	3/31/10
4.14	Form of Warrants dated 6/29/10	8-K	4.01	001-33672	6/29/10
4.15**	Amended Neuralstem 2010 Equity Compensation Plan adopted on June 22, 2017	DEF 14A	Appendix I	001-33672	5/1/17
4.16	Form of Consultant Warrant issued 10/1/09 and 10/1/10	S-3	4.07	333-169847	10/8/10
4.17**	Form of Restricted Stock Award Agreement pursuant to our 2007 Stock Plan and 2010 Equity Compensation Plan	S-8	4.06	333-172563	3/1/11
4.18**	Form of Restricted Stock Unit Agreement	S-8	4.08	333-172563	3/1/11
4.19	Form of Common Stock Purchase Warrant issued pursuant to February 2012 registered offering	8-K	4.01	001-33672	2/8/12
4.20	Form of Common Stock Purchase Warrant issued to Consultants in June of 2012 and March 19, 2013	10-Q	4.20	001-33672	8/9/12
4.21	Form of Underwriter Warrant issued to Aegis Capital Corp. on 8/20/12	8-K	4.1	001-33672	8/17/12
4.22	Form of Placement Agent Warrant issued to Aegis Capital Corp. on 9/13/12	8-K	4.1	001-33672	9/19/12
4.23	Form of Consulting Warrant issued January 2011 and March 2012	S-3	4.01	333-188859	5/24/13
	Form of Replacement Warrant issued January, February and May of 2013 (Original Ex. Prices $3.17 and $2.14)				

4.24	Form of Lender Warrant issued March 22, 2013		8-K	4.01	001-33672	3/27/13
4.25	Form of Advisor Warrant issued March 22, 2013		8-K	4.02	001-33672	3/27/13
4.26	Form of Warrant issued June of 2013 and July of 2014 to Legal Counsel		10-Q	4.26	001-33672	8/8/13
4.27	Form of Warrant issued in September 2013 in connection with Issuer's registered direct offering		8-K	4.01	011-33672	9/10/13
4.28	Form of Warrant issued to strategic advisor in August 2013		10-Q	4.28	001-33672	11/12/13
4.29	Form of Investor Warrant issued January 2014		8-K	4.01	001-33672	1/6/14
4.30	Form of Lender Warrant Issued October 28, 2014		8-K	4.01	001-33672	10/29/14
4.31**	Inducement Stock Option Plan adopted 2/15/2016 and as amended on 12/12/2018 and on 9/1/13/2019	*				
4.32**	Form of Inducement Award Non-Qualified Stock Option Grant pursuant to Inducement Stock Option Plan		8-K	4.02	001-33672	2/19/16
4.33	Form of Common Stock Purchase Warrant from May 2016 Public Offering dated May 6, 2016		8-K	4.01	001-33672	5/4/16
4.34	Form of Common Stock Purchase Warrant from May 2016 Private Offering Dated May 12, 2016		8-K	4.01	001-33672	5/13/16
4.35	Form of Series A Preferred Stock Certificate		8-K	4.01	001-33672	9/12/16
4.36	Form of Inducement Warrant issued March 20, 2017 and March 31, 2017		8-K	4.01	001-33672	3/20/17

4.37	Form of Common Stock Purchase Warrant from August 2017 Public Offering Dated August 1, 2017	8-K	4.01	001-33672	7/28/17
4.38	Form of Common Stock Purchase Warrant from October 2018 Offering	8-K	4.01	001-33672	10/29/18
4.39	Form of Placement Agent Common Stock Purchase Warrant from October 2018 Offering	8-K	4.02	001-33672	10/29/18
4.40	Consultant Warrant for Hibiscus BioVentures, LLC issued January 2019	10-Q	4.40	001-33672	5/14/19
4.41**	Neuralstem 2019 Equity Incentive Plan	DEF 14A	Appendix I	001-33672	4/29/19
4.42**	Form of Restricted Stock Unit from 2019 Equity Incentive Plan	S-1	4.42	333-232273	6/21/19
4.43**	Form of Restricted Option Grant from 2019 Equity Incentive Plan	S-1	4.43	333-232273	6/21/19
4.44**	Form of Restricted Stock Grant from 2019 Equity Incentive Plan	S-1	4.44	333-232273	6/21/19
4.45	Form of Series M and Series N warrant from July 2019 Offering	S-1/A	4.45	333-232273	7/24/19
4.46	Form of Series O Pre-Funded Warrant from July 2019 Offering	S-1/A	4.46	333-232273	7/24/19
10.01**	Employment Agreement with Thomas Hazel, Ph.D dated August 11, 2008	10-K/A	10.05	001-33672	10/5/10
10.02**	Employment Agreement with Richard Daly dated February 15, 2016	8-K	10.01	001-33672	2/19/16
10.03**	Employment Agreement with Kenneth Carter dated December 12, 2018	8-K	10.01	001-33672	12/18/18

10.04	Consulting Agreement dated January 2010 between Market Development Consulting Group and the Company and amendments No. 1 and 2.	10-K	10.07	001-33672	3/16/11
10.05**	Renewal of Dr. Tom Hazel Employment Agreement dated 7/25/12	8-K	10.03	001-33672	7/27/12
10.06	Loan and Security Agreement dated March 2013	8-K	10.01	001-33672	3/27/13
10.07	Intellectual Property and Security Agreement dated March 2013	8-K	10.02	001-33672	3/27/13
10.08	At the Market Offering Agreement entered into on October 25, 2013	8-K	10.01	001-33672	10/25/13
10.09	Form of Second Amendment to Loan and Security Agreement dated March of 2013 that was entered into on October 28, 2014	8-K	10.01	001-33672	10/29/14
10.10**	Offer Letter Between Neuralstem, Inc. and Jonathan Lloyd Jones	8-K	10.01	001-33672	5/11/15
10.11**	General Release and Waiver of Claims with I. Richard Garr dated 3/2/2016	8-K	10.01	001-33672	3/4/16
10.12	Form of Securities Purchase Agreement from May 2016 Private Offering	8-K	10.01	001-33672	5/13/16
10.13**	Amendment to General Release and Waiver of claims with I. Richard Garr dated 6/6/16	8-K	10.01	001-33672	6/16/16
10.14	Form of Securities Purchase Agreement between Issuer and Tianjin Pharmaceuticals Holdings, Ltd.	8-K	10.01	001-33672	9/12/16
10.15**	Form of Securities Purchase Agreement between Issuer and Jonathan Lloyd Jones	10-Q	10.22	001-33672	11/8/16
10.16	Form of Securities Purchase Agreement between Issuer and Richard Daly	10-Q	10.23	001-33672	11/8/16
10.17	Form of Letter Agreement for Warrant Exercises on March 20, 2017 and March 30, 2017	8-K	10.01	001-33672	3/20/17
10.18**	Form of Separation Agreement and Release with Jonathan Lloyd Jones dated April 30, 2017	8-K	10.01	001-33672	5/4/17

10.19	Form of Securities Purchase Agreement with Investors from October 2018 Offering		8-K	10.01	001-33672	10/29/18
10.20	Form of Engagement Agreement with H.C. Wainwright & Co. Dated October 25, 2018		8-K	10.02	001-33672	10/29/18
10.21**	Sample Confidential Information and Invention Assignment Agreement		8-K	10.02	001-33672	12/12/18
10.22**	Form of Indemnification Agreement for Directors and Officers		8-K	10.03	001-33672	12/12/18
31.1	Certification of the Principal Executive Officer and Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	*				
32.1	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. § 1350	*				
101.INS	XBRL Instance Document	*				
101.SCH	XBRL Taxonomy Extension Schema	*				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase	*				
101.DEF	XBRL Taxonomy Extension Definition Linkbase	*				
101.LAB	XBRL Taxonomy Extension Label Linkbase	*				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase	*				

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

SIGNATURES

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

SENECA BIOPHARMA, INC.

Date: November 14, 2019

/s/ Kenneth Carter
Kenneth Carter, PhD, Executive Chairman

Exhibit 4.31

NEURALSTEM, INC.

AMENDED AND RESTATED
INDUCEMENT AWARD
STOCK OPTION PLAN

SECTION 1. GENERAL PURPOSE OF THE PLAN; DEFINITIONS

The name of the plan is the Neuralstem, Inc. Inducement Award Stock Option Plan (the "Plan"). The purpose of the Plan is to provide non-qualified stock options to individuals not previously employees or non-employee directors of Neuralstem, Inc. (the "Company") (or following such individuals' bona fide period of non-employment with the Company), as an inducement material to the individuals' entry into employment with the Company within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules. It is anticipated that providing such persons with a direct stake in the Company's welfare will assure a closer identification of their interests with those of the Company and its stockholders, thereby stimulating their efforts on the Company's behalf and strengthening their desire to remain with the Company.

The following terms shall be defined as set forth below:

"Act" means the Securities Act of 1933, as amended, and the rules and regulations thereunder.

"Administrator" means either the Board or the compensation committee of the Board or a similar committee performing the functions of the compensation committee and which is comprised of not less than two Non-Employee Directors who are independent.

"*Board"* means the Board of Directors of the Company.

"Code" means the Internal Revenue Code of 1986, as amended, and any successor Code, and related rules, regulations and interpretations.

"Covered Employee" means an employee who is a "Covered Employee" within the meaning of Section 162(m) of the Code.

"Effective Date" means February 15, 2016.

"*Eligible Individual*" means any individual who was not previously an employee or a non-employee director of the Company or any of its Subsidiaries (or who has had a bona fide period of non-employment with the Company and its Subsidiaries) who is hired by the Company or one of its Subsidiaries.

"*Exchange Act"* means the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder.

"Fair Market Value" of the Stock on any given date means the fair market value of the Stock determined in good faith by the Administrator; provided, however, that if the Stock is admitted to quotation on the National Association of Securities Dealers

Automated Quotation System ("NASDAQ"), NASDAQ Capital Market or another national securities exchange, the determination shall be made by reference to market quotations. If there are no market quotations for such date, the determination shall be made by reference to the last date preceding such date for which there are market quotations; provided further, however, that if the date for which Fair Market Value is determined is the first day when trading prices for the Stock are reported on a national securities exchange, the Fair Market Value shall be the "Price to the Public" (or equivalent) set forth on the cover page for the final prospectus relating to the Company's Initial Public Offering.

"*Non-Employee Director"* means a member of the Board who is not also an employee of the Company or any Subsidiary.

"Non-Qualified Stock Option" means a stock option that is not intended to be an "incentive stock option" under Section 422 of the Code.

"Option Certificate" means a written or electronic document setting forth the terms and provisions applicable to a Non-Qualified Stock Option granted under the Plan. Each Option Certificate is subject to the terms and conditions of the Plan.

"Sale Event" shall mean (i) the sale of all or substantially all of the assets of the Company on a consolidated basis to an unrelated person or entity, (ii) a merger, reorganization or consolidation pursuant to which the holders of the Company's outstanding voting power immediately prior to such transaction do not own a majority of the outstanding voting power of the resulting or successor entity (or its ultimate parent, if applicable) immediately upon completion of such transaction, or (iii) the sale of all of the Stock of the Company to an unrelated person or entity.

"*Sale Price*" means the value as determined by the Administrator of the consideration payable, or otherwise to be received by stockholders, per share of Stock pursuant to a Sale Event.

"Section 409A" means Section 409A of the Code and the regulations and other guidance promulgated thereunder.

"Stock" means the common stock, par value $0.01 per share, of the Company, subject to adjustments pursuant to Section 3.

"Subsidiary" means any corporation or other entity (other than the Company) in which the Company has at least a fifty (50) percent interest, either directly or indirectly.

SECTION 2. ADMINISTRATION OF PLAN; ADMINISTRATOR AUTHORITY TO SELECT GRANTEES AND DETERMINE NON-QUALIFIED STOCK OPTIONS

(a) Administration of Plan. The Plan shall be administered by the Administrator.

(b) Powers of Administrator. The Administrator shall have the power and authority to grant Non-Qualified Stock Options consistent with the terms of the Plan, including the power and authority:

(i) to select the individuals to whom Non-Qualified Stock Options may from time to time be granted;

(ii) to determine the time or times of grant;

(iii) to determine the number of shares of Stock to be covered by Non-Qualified Stock Options;

(iv) to determine and modify from time to time the terms and conditions, including restrictions, not inconsistent with the terms of the Plan, of Non-Qualified Stock Options, which terms and conditions may differ among individual Non-Qualified Stock Options and grantees, and to approve the form of Option Certificates;

(v) to accelerate at any time the exercisability or vesting of all or any portion of Non-Qualified Stock Options;

(vi) subject to the provisions of Section 5(b), to extend at any time the period in which a Non-Qualified Stock Option may be exercised; and

(vii) at any time to adopt, alter and repeal such rules, guidelines and practices for administration of the Plan and for its own acts and proceedings as it shall deem advisable; to interpret the terms and provisions of the Plan and any Non-Qualified Stock Option (including related written instruments); to make all determinations it deems advisable for the administration of the Plan; to decide all disputes arising in connection with the Plan; and to otherwise supervise the administration of the Plan.

All decisions and interpretations of the Administrator shall be binding on all persons, including the Company and Plan grantees.

(c) Delegation of Authority to Grant Options. Subject to applicable law, the Administrator, in its discretion, may delegate to the Chief Executive Officer of the Company all or part of the Administrator's authority and duties with respect to the granting of Non-Qualified Stock Options. Any such delegation by the Administrator shall include specific limitations as to the number of Non-Qualified Stock Options that may be granted during the period of the delegation and shall contain specific guidelines as to the number of Non-Qualified Stock Options that can be made to an Eligible Individual, determination of the exercise price and the vesting criteria. The Administrator may revoke or amend the terms of a delegation at any time but such action shall not invalidate any prior actions of the Administrator's delegate or delegates that were consistent with the terms of the Plan.

(d) Option Certificate. Non-Qualified Stock Options under the Plan shall be evidenced by Option Certificates that set forth the terms, conditions and limitations for each Option which may include, without limitation, the term of a Non-Qualified Stock Option and the provisions applicable in the event employment or service terminates.

(e) Indemnification. Neither the Board nor the Administrator, nor any member of either or any delegate thereof, shall be liable for any act, omission, interpretation, construction or determination made in good faith in connection with the Plan, and the members of the Board and the Administrator (and any delegate thereof) shall be entitled in all cases to indemnification and reimbursement by the Company in respect of any claim, loss, damage or expense (including, without limitation, reasonable attorneys' fees) arising or resulting therefrom to the fullest extent permitted by law and/or under the Company's articles or bylaws or any directors' and officers' liability insurance coverage which may be in effect from time to time and/or any indemnification agreement between such individual and the Company.

(f) Foreign Non-Qualified Stock Option Recipients. Notwithstanding any provision of the Plan to the contrary, in order to comply with the laws in other countries in which the Company and its Subsidiaries operate or have employees or other individuals eligible for Non-Qualified Stock Options, the Administrator, in its sole discretion, shall have the power and authority to: (i) determine which Subsidiaries shall be covered by the Plan; (ii) determine which individuals outside the United States are eligible to participate in the Plan; (iii) modify the terms and conditions of any Non-Qualified Stock Option granted to individuals outside the United States to comply with applicable foreign laws; (iv) establish subplans and modify exercise procedures and other terms and procedures, to the extent the Administrator determines such actions to be necessary or advisable (and such subplans and/or modifications shall be attached to this Plan as appendices); provided, however, that no such subplans and/or modifications shall increase the share limitations contained in Section 3(a) hereof; and (v) take any action, before or after an Non-Qualified Stock Option is made, that the Administrator determines to be necessary or advisable to obtain approval or comply with any local governmental regulatory exemptions or approvals. Notwithstanding the foregoing, the Administrator may not take any actions hereunder, and no Non-Qualified Stock Options shall be granted, that would violate the Exchange Act or any other applicable United States securities law, the Code, or any other applicable United States governing statute or law.

SECTION 3. STOCK ISSUABLE UNDER THE PLAN; MERGERS; SUBSTITUTION

(a) Stock Issuable. The maximum number of shares of Stock reserved and available for issuance under the Plan shall be One Hundred Seventy-Five Thousand (175,000) shares (the "Initial Limit"), subject to adjustment as provided in Section 3(c). For purposes of this limitation, the shares of Stock underlying any Non-Qualified Stock Options that are forfeited, canceled, held back upon exercise of a Non-Qualified Stock Option or settlement of a Non-Qualified Stock Option to cover the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of Stock or otherwise terminated (other than by exercise) shall be added back to the shares of Stock available for issuance under the Plan. In the event the Company repurchases shares of Stock on the open market, such shares shall not be added to the shares of Stock available for issuance under the Plan. The shares available for issuance under the Plan may be authorized but unissued shares of Stock or shares of Stock reacquired by the Company.

(b) Changes in Stock. Subject to Section 3(c) hereof, if, as a result of any reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split or other similar change in the Company's capital stock, the outstanding shares of Stock are increased or decreased or are exchanged for a different number or kind of shares or other securities of the Company, or additional shares or new or different shares or other securities of the Company or other non-cash assets are distributed with respect to such shares of Stock or other securities, or, if, as a result of any merger or consolidation, sale of all or substantially all of the assets of the Company, the outstanding shares of Stock are converted into or exchanged for securities of the Company or any successor entity (or a parent or subsidiary thereof), the Administrator shall make an appropriate or proportionate adjustment in (i) the maximum number of shares reserved for issuance under the Plan, (ii) the number and kind of shares or other securities subject to any then outstanding Non-Qualified Stock Options under the Plan, and (iii) the exercise price for each share subject to any then outstanding Non-Qualified Stock Options, without changing the aggregate exercise price (i.e., the exercise price multiplied by the number of Non-Qualified Stock Options) as to which such Non-Qualified Stock Options remain exercisable. The Administrator shall also make equitable or proportionate adjustments in the number of shares subject to outstanding Non-Qualified Stock Options and the exercise price and the terms of outstanding Non-Qualified Stock Options to take into consideration cash dividends paid other than in the ordinary course or any other extraordinary corporate event. The adjustment by the Administrator shall be final, binding and conclusive. No fractional shares of Stock shall be issued under the Plan resulting from any such adjustment, but the Administrator in its discretion may make a cash payment in lieu of fractional shares.

(c) Mergers and Other Transactions. Except as the Administrator may otherwise specify with respect to particular Non-Qualified Stock Options in the relevant Option Certificate, in the case of and subject to the consummation of a Sale Event, all Non-Qualified Stock Options that are not exercisable immediately prior to the effective time of the Sale Event shall become fully exercisable as of the effective time of the Sale Event unless the parties to the Sale Event agree that Non-Qualified Stock Options will be assumed or continued by the successor entity. Upon the effective time of the Sale Event, the Plan and all outstanding Non-Qualified Stock Options granted hereunder shall terminate, unless provision is made in connection with the Sale Event in the sole discretion of the parties thereto for the assumption or continuation of Non-Qualified Stock Options theretofore granted by the successor entity, or the substitution of such Non-Qualified Stock Options with new Non-Qualified Stock Options of the successor entity or parent thereof, with appropriate adjustment as to the number and kind of shares and, if appropriate, the per share exercise prices, as such parties shall agree (after taking into account any acceleration hereunder). In the event of such termination, (i) the Company shall have the option (in its sole discretion) to make or provide for a cash payment to the grantees holding Non-Qualified Stock Options, in exchange for the cancellation thereof, in an amount equal to the difference between (A) the Sale Price multiplied by the number of shares of Stock subject to outstanding Non-Qualified Stock Options (to the extent then exercisable (after taking into account any acceleration hereunder) at prices not in excess of the Sale Price) and (B) the aggregate exercise price of all such outstanding Non-Qualified Stock Options; or (ii) each grantee shall be permitted, within a specified period of time prior to the consummation of the Sale Event as determined by the Administrator, to exercise all outstanding Non-Qualified Stock Options held by such grantee, including those that will become exercisable upon the consummation of the Sale Event; provided, however, that the exercise of the Non-Qualified Stock Options not exercisable prior to the Sale Event shall be subject to the consummation of the Sale Event.

(d) Substitute Non-Qualified Stock Options. The Administrator may grant Non-Qualified Stock Options under the Plan in substitution for stock and stock based awards held by employees, directors or other key persons of another corporation in connection with the merger or consolidation of the employing corporation with the Company or a Subsidiary or the acquisition by the Company or a Subsidiary of property or stock of the employing corporation. The Administrator may direct that the substitute awards be granted on such terms and conditions as the Administrator considers appropriate in the circumstances. Any substitute Non-Qualified Stock Options granted under the Plan shall not count against the share limitation set forth in Section 3(a).

SECTION 4. ELIGIBILITY

Grantees under the Plan will be such Eligible Individuals as are selected from time to time by the Administrator in its sole discretion.

SECTION 5. NON-QUALIFIED STOCK OPTIONS

Any Non-Qualified Stock Option granted under the Plan shall be in such form as the Administrator may from time to time approve. Non-Qualified Stock Options granted pursuant to this Plan shall be subject to the following terms and conditions and shall contain such additional terms and conditions, not inconsistent with the terms of the Plan, as the Administrator shall deem desirable.

(a) Exercise Price. The exercise price per share for the Stock covered by a Non-Qualified Stock Option shall be determined by the Administrator at the time of grant but shall not be less than one hundred (100) percent of the Fair Market Value on the date of grant.

(b) Option Term. The term of each Non-Qualified Stock Options shall be fixed by the Administrator, but no Stock Option shall be exercisable more than ten years after the date the Stock Option is granted.

(c) Exercisability; Rights of a Stockholder. Non-Qualified Stock Options shall become exercisable at such time or times, whether or not in installments, as shall be determined by the Administrator at or after the grant date. The Administrator may at any time accelerate the exercisability of all or any portion of any Non-Qualified Stock Option. A grantee shall have the rights of a stockholder only as to shares acquired upon the exercise of a Non-Qualified Stock Option and not as to unexercised Non-Qualified Stock Options.

(d) Method of Exercise. Non-Qualified Stock Options may be exercised in whole or in part, by giving written or electronic notice of exercise to the Company, specifying the number of shares to be purchased. Payment of the purchase price may be made by one or more of the following methods to the extent provided in the Option Certificate:

(i) In cash, by certified or bank check or other instrument acceptable to the Administrator;

(ii) Through the delivery (or attestation to the ownership) of shares of Stock that have been purchased by the grantee on the open market or that have been beneficially owned by the grantee for at least six months and that are not then subject to restrictions under any Company plan. Such surrendered shares shall be valued at Fair Market Value on the exercise date;

(iii) By the grantee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company for the purchase price; provided that in the event the grantee chooses to pay the purchase price as so provided, the grantee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Administrator shall prescribe as a condition of such payment procedure; or

(iv) By a “net exercise” arrangement pursuant to which the Company will reduce the number of shares of Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price.

Payment instruments will be received subject to collection. The transfer to the grantee on the records of the Company or of the transfer agent of the shares of Stock to be purchased pursuant to the exercise of a Non-Qualified Stock Option will be contingent upon receipt from the grantee (or a purchaser acting in his stead in accordance with the provisions of the Non-Qualified Stock Option) by the Company of the full purchase price for such shares and the fulfillment of any other requirements contained in the Option Certificate or applicable provisions of laws (including the satisfaction of any withholding taxes that the Company is obligated to withhold with respect to the grantee). In the event a grantee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the grantee upon the exercise of the Non-Qualified Stock Option shall be net of the number of attested shares. In the event that the Company establishes, for itself or using the services of a third party, an automated system for the exercise of Non-Qualified Stock Options, such as a system using an internet website or interactive voice response, then the paperless exercise of Non-Qualified Stock Options may be permitted through the use of such an automated system.

SECTION 6. TRANSFERABILITY

(a) Transferability. Except as provided in Section 6(b) below, during a grantee’s lifetime, his or her Non-Qualified Stock Options shall be exercisable only by the grantee, or by the grantee’s legal representative or guardian in the event of the grantee’s incapacity. No Non-Qualified Stock Options shall be sold, assigned, transferred or otherwise encumbered or disposed of by a grantee other than by will or by the laws of descent and distribution or pursuant to a domestic relations order. No Non-Qualified Stock Options shall be subject, in whole or in part, to attachment, execution, or levy of any kind, and any purported transfer in violation hereof shall be null and void.

(b) Administrator Action. Notwithstanding Section 6(a), the Administrator, in its discretion, may provide either in the Option Certificate regarding a given Non-Qualified Stock Option or by subsequent written approval that the grantee may transfer his or her Non-Qualified Stock Options to his or her immediate family members, to trusts for the benefit of such family members, or to partnerships in which such family members are the only partners, provided that the transferee agrees in writing with the Company to be bound by all of the terms and conditions of this Plan and the applicable Non-Qualified Stock Option. In no event may a Non-Qualified Stock Option be transferred by a grantee for value.

(c) Family Member. For purposes of Section 6(b), "family member" shall mean a grantee's child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including adoptive relationships, any person sharing the grantee's household (other than a tenant of the grantee), a trust in which these persons (or the grantee) have more than 50 percent of the beneficial interest, a foundation in which these persons (or the grantee) control the management of assets, and any other entity in which these persons (or the grantee) own more than 50 percent of the voting interests.

(d) Designation of Beneficiary. Each grantee to whom a Non-Qualified Stock Option has been made under the Plan may designate a beneficiary or beneficiaries to exercise any Non-Qualified Stock Option or receive any payment under any Non-Qualified Stock Option payable on or after the grantee's death. Any such designation shall be on a form provided for that purpose by the Administrator and shall not be effective until received by the Administrator. If no beneficiary has been designated by a deceased grantee, or if the designated beneficiaries have predeceased the grantee, the beneficiary shall be the grantee's estate.

SECTION 7. TAX WITHHOLDING

(a) Payment by Grantee. Each grantee shall, no later than the date as of which the value of a Non-Qualified Stock Option or of any Stock or other amounts received thereunder first becomes includable in the gross income of the grantee for Federal income tax purposes, pay to the Company, or make arrangements satisfactory to the Administrator regarding payment of, any Federal, state, or local taxes of any kind required by law to be withheld by the Company with respect to such income. The Company and its Subsidiaries shall, to the extent permitted by law, have the right to deduct any such taxes from any payment of any kind otherwise due to the grantee. The Company's obligation to deliver evidence of book entry (or stock certificates) to any grantee is subject to and conditioned on tax withholding obligations being satisfied by the grantee.

(b) Payment in Stock. Subject to approval by the Administrator, a grantee may elect to have the Company's minimum required tax withholding obligation satisfied, in whole or in part, by authorizing the Company to withhold from shares of Stock to be issued pursuant to any Non-Qualified Stock Option a number of shares with an aggregate Fair Market Value (as of the date the withholding is effected) that would satisfy the withholding amount due.

SECTION 8. SECTION 409A AWARDS

To the extent that any Non-Qualified Stock Option is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A (a "409A Award "), the Non-Qualified Stock Option shall be subject to such additional rules and requirements as specified by the Administrator from time to time in order to comply with Section 409A. In this regard, if any amount under a 409A Award is payable upon a "separation from service" (within the meaning of Section 409A) to a grantee who is then considered a "specified employee" (within the meaning of Section 409A), then no such payment shall be made prior to the date that is the earlier of (i) six months and one day after the grantee's separation from service, or (ii) the grantee's death, but only to the extent such delay is necessary to prevent such payment from being subject to interest, penalties and/or additional tax imposed pursuant to Section 409A. Further, the settlement of any such Non-Qualified Stock Option may not be accelerated except to the extent permitted by Section 409A.

SECTION 9. TRANSFER, LEAVE OF ABSENCE, ETC.

For purposes of the Plan, the following events shall not be deemed a termination of employment:

(a) a transfer to the employment of the Company from a Subsidiary or from the Company to a Subsidiary, or from one Subsidiary to another; or

(b) an approved leave of absence for military service or sickness, or for any other purpose approved by the Company, if the employee's right to re-employment is guaranteed either by a statute or by contract or under the policy pursuant to which the leave of absence was granted or if the Administrator otherwise so provides in writing.

SECTION 10. AMENDMENTS AND TERMINATION

The Board may, at any time, amend or discontinue the Plan and the Administrator may, at any time, amend or cancel any outstanding Non-Qualified Stock Option for the purpose of satisfying changes in law or for any other lawful purpose, but no such action shall adversely affect rights under any outstanding Non-Qualified Stock Option without the holder's consent. Except as provided in Section 3(c) or 3(d), without prior stockholder approval, in no event may the Administrator exercise its discretion to reduce the exercise price of outstanding Non-Qualified Stock Options or effect repricing through cancellation and re-grants or cancellation of Non-Qualified Stock Options in exchange for cash. To the extent required under the rules of any securities exchange or market system on which the Stock is listed, Plan amendments shall be subject to approval by the Company stockholders entitled to vote at a meeting of stockholders. Nothing in this Section 10 shall limit the Administrator's authority to take any action permitted pursuant to Section 3(c) or 3(d).

SECTION 11. STATUS OF PLAN

With respect to the portion of any Non-Qualified Stock Option that has not been exercised and any payments in cash, Stock or other consideration not received by a grantee, a grantee shall have no rights greater than those of a general creditor of the Company unless the Administrator shall otherwise expressly determine in connection with any Non-Qualified Stock Option or Non-Qualified Stock Options. In its sole discretion, the Administrator may authorize the creation of trusts or other arrangements to meet the Company's obligations to deliver Stock or make payments with respect to Non-Qualified Stock Options hereunder, provided that the existence of such trusts or other arrangements is consistent with the foregoing sentence.

SECTION 12. GENERAL PROVISIONS

(a) No Distribution. The Administrator may require each person acquiring Stock pursuant to a Non-Qualified Stock Option to represent to and agree with the Company in writing that such person is acquiring the shares without a view to distribution thereof.

(b) Delivery of Stock Certificates. Stock certificates to grantees under this Plan shall be deemed delivered for all purposes when the Company or a stock transfer agent of the Company shall have mailed such certificates in the United States mail, addressed to the grantee, at the grantee's last known address on file with the Company. Uncertificated Stock shall be deemed delivered for all purposes when the Company or a Stock transfer agent of the Company shall have given to the grantee by electronic mail (with proof of receipt) or by United States mail, addressed to the grantee, at the grantee's last known address on file with the Company, notice of issuance and recorded the issuance in its records (which may include electronic "book entry" records). Notwithstanding anything herein to the contrary, the Company shall not be required to issue or deliver any certificates evidencing shares of Stock pursuant to the exercise of any Non-Qualified Stock Option, unless and until the Administrator has determined, with advice of counsel (to the extent the Administrator deems such advice necessary or advisable), that the issuance and delivery of such certificates is in compliance with all applicable laws, regulations of governmental authorities and, if applicable, the requirements of any exchange on which the shares of Stock are listed, quoted or traded. All Stock certificates delivered pursuant to the Plan shall be subject to any stop-transfer orders and other restrictions as the Administrator deems necessary or advisable to comply with federal, state or foreign jurisdiction, securities or other laws, rules and quotation system on which the Stock is listed, quoted or traded. The Administrator may place legends on any Stock certificate to reference restrictions applicable to the Stock. In addition to the terms and conditions provided herein, the Administrator may require that an individual make such reasonable covenants, agreements, and representations as the Administrator, in its discretion, deems necessary or advisable in order to comply with any such laws, regulations, or requirements. The Administrator shall have the right to require any individual to comply with any timing or other restrictions with respect to the settlement or exercise of any Non-Qualified Stock Option, including a window-period limitation, as may be imposed in the discretion of the Administrator.

(c) Stockholder Rights. Until Stock is deemed delivered in accordance with Section 12(b), no right to vote or receive dividends or any other rights of a stockholder will exist with respect to shares of Stock to be issued in connection with a Non-Qualified Stock Option, notwithstanding the exercise of a Non-Qualified Stock Option or any other action by the grantee with respect to a Non-Qualified Stock Option.

(d) Other Compensation Arrangements; No Employment Rights. Nothing contained in this Plan shall prevent the Board from adopting other or additional compensation arrangements, including trusts, and such arrangements may be either generally applicable or applicable only in specific cases. The adoption of this Plan and the grant of Non-Qualified Stock Options do not confer upon any employee any right to continued employment with the Company or any Subsidiary.

(e) Trading Policy Restrictions. Option exercises and other Non-Qualified Stock Options under the Plan shall be subject to the Company's insider trading policies and procedures, as in effect from time to time.

(f) Company Documents and Policies. This Plan and all Non-Qualified Stock Options granted hereunder are subject to the corporate articles and by-laws of the Company, as they may be amended from time to time, and all other Company policies duly adopted by the Board or the Administrator and as in effect from time to time regarding the acquisition, ownership or sale of Stock by employees, including without limitation policies intended to limit the potential for insider trading and to avoid or recover compensation payable or paid on the basis of inaccurate financial results or statements, employee conduct, and other similar events.

SECTION 13. EFFECTIVE DATE OF PLAN

This Plan shall become effective upon the Effective Date.

SECTION 14. GOVERNING LAW

This Plan and all Non-Qualified Stock Options and actions taken thereunder shall be governed by, and construed in accordance with, the laws of the State of Delaware, applied without regard to conflict of law principles.

DATE APPROVED BY BOARD OF DIRECTORS: February 15, 2016

DATE AMENDED BY BOARD OF DIRECTORS: December 12, 2018

EXHIBIT 31.1

SECTION 302
CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER

I, Kenneth Carter, certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Seneca Biopharma, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer(s) and I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its unconsolidated investments, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2019

By: /s/ Kenneth Carter
Kenneth Carter, PhD, Executive Chairman (Principal Executive and Financial Officer)

EXHIBIT 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350 AND EXCHANGE ACT RULES 13a-14(b) AND 15d-14(b)
(Section 906 of the Sarbanes-Oxley Act of 2002)

In connection with the Quarterly Report of Seneca Biopharma, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kenneth Carter certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge and belief:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of the operation of the Company.

/s/ Kenneth Carter
Kenneth Carter, PhD, Executive Chairman (Principal Executive and Financial Officer)

November 14, 2019

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.