UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2019.

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____.

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**)**

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

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. ☐Yes ☒ No

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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 Act). ☐ Yes ☒ No

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the Company’s common equity was last sold as of the last business day of the registrant’s most recently completed second fiscal quarter based upon the closing price of the common stock as reported by NASDAQ on such date, was $4,578,167.

The number of shares outstanding of Registrant’s common stock, $0.01 par value at February 29, 2020 was 9,428,011.

DOCUMENTS INCORPORATED BY REFERENCE

None.

SENECA BIOPHARMA, INC

ANNUAL REPORT ON FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2019

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PART I

We urge you to read this entire Annual Report on Form 10-K, including the "Risk Factors" section, the financial statements and the related notes included therein. As used in this Annual Report, unless context otherwise requires, the words "we," "us," "our," "the Company," "Neuralstem," "Seneca" and "Registrant" refer to Seneca Biopharma, Inc. and its subsidiary. Also, any reference to "common share" or "common stock," refers to our $.01 par value common stock. Additionally, any reference to our "Series A Preferred Stock" refers to our Series A 4.5% Convertible Preferred Stock.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements in this annual report that are not strictly historical are forward-looking statements made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and include statements about products in development, results and analyses of pre-clinical studies, clinical trials and studies, future research and development expenses, anticipated cash expenditures, regulatory applications and approvals, and third-party relationships, 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 and may often be identified by words such as "expect," "anticipate," "intend," "plan," "believe," "seek" or "will." These forward-looking statements are not guarantees of future performance and are subject to substantial risks and uncertainties that may cause actual results to differ materially from those described in the forward-looking statements These Forward-looking statements by their nature address matters that are uncertain. Specific risks and uncertainties that could cause our actual results to differ materially from those expressed in our forward-looking statements include risks inherent in our ability to identify and in-license compounds and/or assets, conduct and obtain successful results from our clinical trials, retain management and operate our business, commercialize our technology, obtain regulatory approval for our product candidates, contract with third parties to adequately test and manufacture our proposed products, protect our intellectual property rights and obtain additional financing to continue our development efforts and execute on our business plans. These forward-looking statements are based on current expectations and assumptions that are subject to risks and uncertainties, which could cause our actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to those discussed in this Annual Report, and in particular, the risks discussed under the caption "Risk Factors" in Item 1A and those discussed in other documents we file with the Securities and Exchange Commission (SEC). We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

The information contained herein is current as of the date of this Annual Report (December 31, 2019), unless another date is specified.

ITEM 1. BUSINESS

Overview

In October 2019, we changed our name from Neuralstem, Inc. to Seneca Biopharma, Inc. Historically, we have been 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. In early 2019 we commenced an in-licensing and acquisition strategy in which we are evaluating novel therapeutics that could benefit from our development experience with the goal of developing such technologies for commercialization.

Our patented technology platform has three core components:

1. 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;

2. 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

3. Small molecules that resulted from Seneca's neurogenesis screening platform that may have the potential to treat a 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. A component of our strategy is seeking an asset sale, out-license, or global development partnerships to further development of NSI-566 and NSI-189. We have recently initiated a formal initiative aimed at securing partners to advance the clinical development of these two programs.

We believe this technology, in partnership with an established biopharmaceutical company with the appropriate development expertise and financial resources, 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.

Recent Highlights

- 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 diseases. Subsequently, on January 10, 2020, we filed a Current Report on Form 8-K disclosing that we were not able to reach a definitive licensing agreement with QYuns and accordingly, no longer expected to complete this transaction.

- On January 17, 2020 we entered into an agreement with certain accredited investors from our July 30, 2019 underwritten offering. Pursuant to the agreement the investors exercised certain warrants to purchase an aggregate of 5,555,554 shares of common stock having an initial exercise price of $2.70, at a reduced exercise price of $1.36 per share. In consideration for the immediate exercise of the warrants for cash, the exercising holders received new unregistered warrants exercisable into an aggregate of up to 5,555,554 shares of common stock, at an exercise price of $1.23 per share, 2,777,777 of which have a term of two years and 2,777,777 of which have a term of five years. The Company received approximately $7.55 million in gross proceeds.

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.

Based on our cash position, we have refocused our development efforts primarily 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.

Below is a description of our clinical programs, their intended indication and current stage of development:

Asset	Indication	Phase I	Phase II	Phase III	Objective
NSI-566	Amyotrophic Lateral Sclerosis (ALS)				Reversal of Paralysis
	Chronic Ischemic Stroke				
	Chronic Spinal Cord Injury (cSCI)				
NSI-189	Major Depressive Disorder (MDD)				Depression and Cognition

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 current Good Manufacturing Practices (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 our requirements through 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), ischemic 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 Phase 1 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 a non-GCP (Good Clinical Practice) compliant randomized, double-blind, placebo-controlled Phase 2 trial in subjects with chronic ischemic stroke. We are also conducting a Phase 1 open label study to evaluate the safety of implanting NSI-566 in subjects with chronic SCI.

Motor Deficits Due to Ischemic Stroke

Over 700,000 individuals suffer stroke each year in the US, the majority of whom experience long-term functional deficits. Ischemic stroke, which accounts for about 75% of all strokes, occurs as a result of an obstruction within a vessel supplying blood to the brain. Post-stroke motor deficits include paralysis or weakness in arms and legs and speech impairment and can be permanent. In the US, approximately 1.8 million people live with paralysis due to stroke. We believe that NSI-566 may provide an effective treatment for restoring motor deficits resulting from ischemic stroke by creating new circuitry in the area of injury and promoting regeneration of neural tissue damaged by the ischemic event.

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 United States Centers for Disease Control and Prevention reported that over 16,000 Americans have ALS, a prevalence of 5.2 cases per 100,000 people. 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. We received orphan designation by the FDA for NSI-566 in ALS.

Chronic Spinal Cord Injury

SCI may result from trauma or disease affecting the spinal cord, and is in many cases a long term, chronic and disabling neurological condition. In the US it is estimated that there are 17,000 new cases of SCI per year, with a prevalence of 249,000-363,000 people. Chronic spinal cord injury (cSCI) refers to the window after recovery has plateaued, beginning approximately 6-12 months after injury. 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, non-GCP compliant, Phase I 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 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, for a total of nine subjects, in March 2016. 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. There were no deaths or serious adverse events related to the treatment (Zhang et al., Stem Cells Transl Med 2019, 8(10):999-1007).

In August 2018, we initiated a non-GCP compliant Phase 2 trial which is designed as a randomized, double-blind, placebo-controlled study. A total of 22 subjects were randomized to receive NSI-566 stem cells (72 million cells) or sham-surgery at a 1:1 ratio. All operations were conducted at BaYi Brain Hospital, the site of the Phase 1 study, and all follow-up assessments are being conducted by blinded, independent neurologists at Beijing Rehabilitation Hospital. The final subject was enrolled in this study in August 2019, and the final visit for this subject is scheduled to occur in August 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 multisite 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.

In June 2017, 24-month Phase 2 results 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.

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, which is taking place 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 April of 2018 we enrolled the first subject in the second cohort of the trial, which included patients with AIS-A complete, quadriplegic, cervical injuries involving C5-C7 of their spinal cord. The final patient of this cohort was enrolled in March of 2019.

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 well-tolerated.

Pre-Clinical Experience with NSI-566 and other candidates in our stem cell pipeline

Our preclinical studies with NSI-566 have served to provide the foundation for our ongoing clinical trials by demonstrating performance and efficacy of this cell line in animal models for ALS (Hefferan et al., *PLoS One* 2012, 7(8):e42614; Xu et al., *Transplantation* 2006, 82(7):865-875; Xu et al., *J Comp Neurol* 2009, 514(4):297-309; Xu et al., *Neurosci Lett* 2011, 494(3):222-226; Yan et al., *Stem Cells* 2006, 24(8):1976-1985), spinal cord injury (Cizkova et al., *Neuroscience* 2007, 147(2):546-560; Lu et al., *Cell* 2012, 150(6):1264-1273; van Gorp et al., *Stem Cell Res Ther* 2013, 4(3):57), and ischemic stroke (Tajiri et al., *PLoS One* 2014, 9(3):e91408), and demonstrated safety in large animals (Raore et al., *Spine* 2011, 36(3):E164-E171; Usvald et al., *Cell Transplant* 2010, 19(9):1103-1122). Additional studies involving NSI-566 or other proprietary cell lines are directed at identifying new therapeutic candidates. These include: 1) an ongoing collaboration with investigators at the Miami Project to Cure Paralysis to evaluate the application of NSI-566 in preclinical animal models for traumatic brain injury (Spurlock et al., *J Neurotrauma* 2017, 34(11):1981-1995), and 2) evaluation of the ability of NSI-532.IGF1, a human neural stem cell line engineered to express the trophic factor IGF1, to reverse the cognitive impact of neurodegeneration in a mouse model of Alzheimer's Disease (McGinley et al., *Sci Rep* 2018, 8(1):14776).

NSI-189 (Small Molecule Pharmaceutical Compound)

NSI-189 represents a new chemical entity that works through what appears to be a novel mechanism of action to stimulate neurogenesis of stem cells in the hippocampus, as well as generation of new synapses. Because impaired hippocampal neurogenesis has been linked with depression, we conducted clinical trials to evaluate the safety and effectiveness of NSI-189 in patients suffering from Major Depressive Disorder or MDD.

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 World Health Organization, MDD is the leading cause of disability in the U.S. for persons age 15 to 44. In 2017, an estimated 17.3 million adults in the United States had at least one major depressive episode in the prior year. This number represented 7.1% of all adults in the US. (https://www.nimh.nih.gov/health/statistics/prevalence/major-depression-among-adults.shtml). 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 (Rush et al., *Control Clin Trials* 2004, 25(1):119-142).

Clinical Experience with NSI-189

In 2011 we commenced a Phase 1A clinical trial to evaluate the safety and pharmacokinetics of NSI-189 in healthy volunteers. The study enrolled 41 healthy male and female subjects into a single ascending dose phase. No dose-limiting toxicity was observed, and no serious adverse events (AE) were noted. This study was followed in 2012 with a Phase 1B randomized, double-blind, placebo-controlled, multiple-dose escalation study to evaluate safety, tolerability, pharmacokinetic (PK), and pharmacodynamic (PD) effects of NSI-189 phosphate in subjects with MDD. Trial data were presented in June 2014 at the American Society of Clinical Psychopharmacology Annual Meeting (ASCP) and published in the journal Molecular Psychiatry (Fava et al., *Mol Psychiatry* 2016, 21(10):1372-1380). NSI-189 was well tolerated and there were no serious adverse events.

In May of 2016 we initiated an exploratory 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, and was 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. 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 were 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; 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 et al., *Mol Psychiatry* 2019, doi: 10.1038/s41380-018-0334-8).

Preclinical Experience with NSI-189

NSI-189 has shown promise in preclinical studies evaluating its impact in animal models for number of different disease indications, including:

1. Ischemic stroke—in 2017 Tajiri and colleagues published a manuscript reporting that NSI-189 ameliorated motor and neurological deficits in a rodent model of ischemic stroke (Tajiri et al., *J Cell Physiol* 2017, 232(10):2731-2740)
2. Radiation-induced cognitive dysfunction—in 2018 Allen and colleagues published a manuscript reporting that NSI-189 treatment could reverse cognitive deficits in rats caused by cranial irradiation, a model of cranial radiotherapy in the treatment of brain tumors (Allen et al., *Radiat Res* 2018, 189(4):345-353).
3. Angelman syndrome—in 2019 Liu and colleagues published a manuscript reporting that NSI-189 reversed impairments in cognitive and motor deficits in a rodent model of Angelman syndrome and increased synaptic strength in sections of brains taken from these animals (Liu et al., *Neuropharmacology* 2019, 144:337-344). Angelman syndrome (AS) is a rare congenital genetic disorder caused by a lack of function in the UBE3A gene on the maternal 15th chromosome. It affects approximately one in 15,000 people - about 500,000 individuals globally. Symptoms of AS include developmental delay, lack of speech, seizures, and walking and balance disorders.
4. Diabetes-associated peripheral neuropathy—in 2019 Jolivalt and colleagues published a manuscript reporting that NSI-189 mitigated or reversed disease-associated central and peripheral neuropathy in two rodent models of diabetes (Jolivalt et al., *Diabetes* 2019, (11):2143-2154). Improvements resulting from NSI-189 treatment were seen on multiple sensory and cognitive indices.

A common theme emerging from these and other preclinical studies has been the ability of NSI-189 to promote synaptogenesis as well as hippocampal neurogenesis, along with its neuroprotective properties. Due to the favorable safety profile seen in the Phase I and II clinical studies of NSI-189 and the impact on cognitive measures observed in the Phase II trial in MDD patients, we feel that this asset may have potential in treatment of one or more diseases including those described above. On August 9, 2018, NSI-189 received orphan designation for the treatment of Angelman syndrome.

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.

Small Molecule Pharmaceutical Compounds.

Utilizing our proprietary stem cell-based screening capability, we have discovered and patented a series of small molecule compounds that includes NSI-189. 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 potentially 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.

Research and Development

Substantial resources have been and will be devoted to our research and development programs. Our efforts are directed at developing therapies utilizing our stem cells and small molecule regenerative drug candidates. This research is conducted internally, through the use of third party laboratories, consulting companies under our direct supervision, and through collaboration with academic institutions.

Manufacturing

We currently manufacture our cells both in-house and on an outsourced basis. We outsource the manufacturing of our pharmaceutical compounds and our clinical supply of stem cells to cGMP compliant third-party manufacturers. We manufacture neural stem cells in-house for use in our research and collaborative programs.

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 17 United States issued and pending patents and over 77 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 2038.

When appropriate, we seek patent protection for inventions in our core technologies and in ancillary technologies that support our core technologies or which we otherwise believe will provide us with a competitive advantage. We accomplish this by filing patent applications for discoveries we make, either alone or in collaboration with scientific collaborators and strategic partners. Typically, although not always, we file patent applications both in the United States and in select international markets. In addition, we plan to obtain licenses or options to acquire licenses to patent filings from other individuals and organizations that we anticipate could be useful in advancing our research, development and commercialization initiatives and our strategic business interests.

In addition to patenting our technologies, we also rely on confidential and proprietary information and take active measures to control access to that information, including the use of confidentiality agreements with our employees, consultants and certain of our contractors.

Our policy is to require our employees, consultants and significant scientific collaborators and sponsored researchers to execute confidentiality and assignment of invention agreements upon the commencement of an employment or consulting relationship with us. These agreements generally provide that all confidential information developed or made known to the individual by us during the course of the individual's or entity’s relationship with us, is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees and consultants, the agreements generally provide that all inventions conceived by the individual or entity in the course of rendering services to us shall be our exclusive property.

In-licensing or Acquisition Strategy

In addition to the development of our current product candidates, we have initiated an in-licensing and/or acquisition strategy to further expand our product pipeline. Our in-licensing strategy consists of 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 candidates for commercialization. We believe that this element of our corporate strategy could provide new opportunities for product development and diversify risks inherent in focusing on a limited product portfolio and therapeutic areas, thus potentially increasing our probability of commercial success.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly evolving technology and intense competition. Our competitors include major multinational pharmaceutical companies, specialty biotechnology companies and chemical and medical products companies. Many of these companies are well-established and possess greater resources for technical, research, development, financial, sales and marketing initiatives than we do. Other, less well-established companies have formed or may form strategic collaborations, partnerships and other types of joint ventures with larger, well established industry competitors that may provide research and development and commercialization advantages to these competitors. Academic institutions, governmental agencies and other public and private research organizations are also conducting and financing research activities which may produce products directly competitive to those we are developing. Moreover, many of these competitors may be able obtain patent protection, or FDA and other regulatory approvals that may impede our freedom to develop and commercialize our programs.

The diseases and medical conditions we are targeting have a demographic in which there are large numbers of patients who do not respond to current therapies or have limited therapies available. Nevertheless, we expect that our technologies and product candidates, if or when approved, will compete with a variety of therapeutic products and procedures offered by other pharmaceutical and biotechnology companies. Many pharmaceutical and biotechnology companies are investigating new drugs and therapeutic approaches for the same or similar indications. These companies' efforts may achieve new efficacy profiles, extend the therapeutic window for such products, alter the prognosis of these diseases, or prevent their onset. We believe that our products, if or when approved, will attempt to compete with these products principally on the basis of improved and extended efficacy and safety and their overall economic benefit to the health care system. Competition for our products may be in the form of existing and new drugs, other forms of cell transplantation, surgical procedures, gene therapy or other proprietary technology and expertise. We expect that all of these products will compete with our product candidates, if or when approved, based on efficacy, safety, cost and intellectual property positions. We cannot be certain that that other entities have not filed patents that block our freedom to commercialize our programs and we may be required to seek licenses from these entities in order to commercialize certain of our proposed products, and such licenses may not be granted or be extremely expensive to obtain.

If we develop products that receive regulatory approval, they would then have to compete for market acceptance and market share. For our potential products, an important success factor will be the timing of market introduction of competitive products. This timing will be a function of the relative speed with which we and our competitors can develop products, complete the clinical testing and approval processes, and supply commercial quantities of a product to the market. These competitive products may also impact the timing of clinical testing and approval processes by limiting the number of clinical investigators and subjects available to test our potential products.

Government Regulation

Regulation by governmental authorities in the United States and other countries is a significant factor in our research and development and will be a significant factor in the manufacture and marketing of our proposed products. The nature and extent to which such regulation applies to us will vary depending on the nature of any products we may develop. Governmental authorities, including the FDA and comparable regulatory authorities in other countries, regulate the design, development, testing, manufacturing, safety, efficacy, labeling, storage, record-keeping, advertising, promotion and marketing of pharmaceutical products, including drugs and biologics, under the Federal Food, Drug, and Cosmetic Act, or FFDCA, and its implementing regulations, and, for biologics, under the Public Health Service Act, or PHSA, and its implementing regulations. Non-compliance with applicable requirements can result in fines and other judicially imposed sanctions, including product seizures, import restrictions, injunctive actions and criminal prosecutions of both companies and individuals. In addition, administrative remedies can involve requests to recall violative products; the refusal of the government to enter into supply contracts; or the refusal to approve pending product approval applications until manufacturing or other alleged deficiencies are brought into compliance. The FDA also has the authority to cause the withdrawal of approval of a marketed product or to impose labeling restrictions. The process of obtaining approvals and the subsequent compliance with appropriate statutes and regulations require the expenditure of substantial time and money, and there can be no guarantee that approvals will be granted.

United States Product Development Process

We believe that, in the United States, our human neural stem cell candidates are regulated as biologic pharmaceuticals, or biologics, and our small-molecule compounds are regulated as drugs.

The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- Completion of preclinical testing of new pharmaceutical or biological products, generally conducted in the laboratory and in animal studies in accordance with Good Laboratory Practice or GLP standard, and applicable requirements for the humane use of laboratory animals or other applicable regulations to evaluate the potential efficacy and safety of the product candidate;
- Submission of the results of these studies to the FDA as part of an Investigational New Drug application or IND, which must become effective before clinical testing in humans can begin;
- Manufacturing of investigational medicine under current Good Manufacturing Practice or cGMP standard;
- Performance of adequate and well-controlled human clinical trials according to Good Clinical Practice or GCP and any additional requirements for the protection of human research patients and their health information, to establish the safety and efficacy of the product candidate for its intended use;
- Submission to the FDA of a biological license application, or BLA, for any biologic or a new drug application, or NDA, for any new chemical entity drug we seek to market that includes substantive evidence of safety, purity, and potency, or safety and effectiveness from results of nonclinical testing and clinical trials;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product is produced, packaged and distributed, to assess compliance with cGMPs, to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity, and, if applicable, the FDA's current good tissue practices, or GTPs, for the use of human cellular and tissue products;
- Potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA or NDA; and
- FDA review and approval of the NDA, or licensure, of the BLA.

Typically, human clinical evaluation involves a time-consuming and costly three-phase process.

- Phase 1. The product is initially introduced into healthy human volunteers and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2. The product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be required and conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated similar trials. Similarly, an institutional review board, or IRB, can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product has been associated with unexpected serious harm to patients.

Human cell-based therapies in the field of regenerative medicine are relatively novel. Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the trial period, the number of patients the FDA will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of such products, or that the data generated in these trials will be acceptable to the FDA to support marketing approval.

United States Review and Approval Process

After the completion of clinical trials of a product candidate, FDA approval of a BLA or NDA must be obtained before commercial marketing of the product. The BLA or NDA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information as well as a significant user fee. The FDA may grant deferrals for submission of data, or full or partial waivers. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA or NDA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

The FDA may refuse to file any BLA or NDA that it deems incomplete or not properly reviewable at the time of submission, and may request additional information. Once the submission is accepted for filing, the FDA reviews the BLA or NDA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is safe and effective for its intended use, and in each case, whether the product is being manufactured in accordance with cGMP or GTP, if applicable. During the product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA or NDA must submit a proposed REMS. The FDA will not approve a BLA or NDA without a REMS, if required.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA or NDA does not satisfy its regulatory criteria for approval and deny approval via a letter detailing such deficiencies. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the FDA denies an application, the applicant may either resubmit the BLA or NDA, addressing all of the deficiencies identified by the FDA, or withdraw the application.

United States Post-Approval Requirements

Any products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses, known as off-label use, limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. We rely, and expect to continue to rely, on third parties for the production of some, or all, clinical and commercial quantities of our products in accordance with cGMP and GTP regulations, as applicable. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, GTP and other laws.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our product candidates under development.

European, China and Other Regulatory Review and Approval

Whether or not FDA approval has been obtained, approval of a product by comparable regulatory authorities in Europe, China and other countries will be necessary prior to commencement of marketing the product in such countries. The regulatory authorities in each country may impose their own requirements and may refuse to grant an approval, or may require additional data before granting it, even though the relevant product has been approved by the FDA or another authority. As with the FDA, the regulatory authorities in the European Union, China and other developed countries have lengthy approval processes for biological and pharmaceutical products. The process for gaining approval in particular countries varies, but generally follows a similar sequence to that described for FDA approval.

Other Health Care Laws

In the event any of proposed products are ever approved for marketing, we may also be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments where we may market our product candidates, if approved. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, physician sunshine and privacy and security laws and regulations.

Other Regulations

We are also subject to various U.S. federal, state, local and international laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our business. We cannot accurately predict the extent of government regulation which might result from future legislation or administrative action.

For additional information about governmental regulations as well as risk related to our business that could affect our planned and intended business operations, see the *"Risk Factors"* Section of this Annual Report.

Employees

As of February 29, 2020, we had five full-time employees. We also use the services of numerous 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.

Where to Find More Information

We make our public filings with the SEC, including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all exhibits and amendments to these reports. Also, our executive officers, directors and holders of more than 10% of our common stock, file reports with the SEC on Forms 3, 4 and 5 regarding their ownership of our securities. These materials are available on the SEC's web site, http://www.sec.gov. You may also read or copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Alternatively, you may obtain copies of these filings, including exhibits, by writing or telephoning us at:

SENECA BIOPHARMA, INC
20271 Goldenrod Lane
Germantown, Maryland 20876
Attn: Investor Relations
Tel: (301) 366-4841

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

Risks Relating to Our Stage of Development, Capital Structure, Acquisition and In-Licensing Strategy 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 December 31, 2019 was approximately $5.1 million. On January 17, 2020 we entered into an agreement with certain accredited investors from our July 30, 2019 underwritten offering. Pursuant to the agreement, we agreed to reduce the exercise price of 5,555,554 common stock purchase warrants from $2.70 to $1.36 in consideration for the immediate exercise of the warrants for cash and issued the investors an aggregate of 5,555,554 replacement warrants having an exercise price of $1.23 per share. Of the replacement warrants, 2,777,777 have a term of two years and 2,777,777 have a term of five years. We received approximately $6.8 million in net proceeds. Based on our current expected level of operating expenditures, we expect to be able to fund our operations for more than 12 months from this filing. Our ability to remain a going concern is wholly dependent upon our ability to continue to obtain sufficient capital to fund our operations.

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 on our December 31, 2019 consolidated financial statements expressed an opinion that our capital resources as of the date of their audit report were not sufficient to sustain operations or complete our planned activities for the upcoming year unless we raised additional funds. Our current cash level raises substantial doubt about our ability to continue as a going concern past the third quarter of 2021. 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.

We may experience intense competition related to the acquisition and/or in-licensing of assets.

We expect to encounter intense competition from other entities undertaking similar acquisition and/or in-licensing strategies. Many of these entities, including venture capital firms, partnerships and corporations, blind pool companies, large industrial and financial institutions, small business investment companies and wealthy individuals, are well-established and have extensive experience in connection with identifying, licensing and/or acquiring therapeutic assets. Many of these competitors possess greater financial, technical, human and other resources than us and there can be no assurance that we will have the ability to compete successfully. Our financial resources will be limited in comparison to those of many of our competitors. This inherent competitive limitation may compel us to select certain less attractive prospects. There can be no assurance that such prospects will permit us to achieve our stated business objectives.

We may be subject to uncertainty in the competitive environment of a target.

In the event that we succeed in completing an acquisition and/or the in-licensing of a therapeutic assets, we will, in all likelihood, become subject to intense competition from competitors developing similar assets and therapies that target the same indication. In particular, certain indications or therapeutic areas with greater market potential frequently attract a large number of competitors, including competitors with greater financial, marketing, technical, human and other resources than the initial competitors in the industry. The degree of competition characterizing the industry of any prospective target asset cannot presently be ascertained. There can be no assurance that, subsequent to a consummation of a transaction, we will have the resources to compete effectively.

We may pursue a target asset outside the United States which would subject us to additional risks relating to doing business in a foreign country

We may effectuate an acquisition and/or in license a target asset from outside the United States. In such event, we may face the significant additional risks associated with doing business in that country. In addition to the language barriers, different presentations of information, different business practices, different regulatory practices and other cultural differences and barriers, may make it difficult to evaluate such a target assets, ongoing business risks may result from the internal political situation, uncertain legal systems and applications of law, prejudice against foreigners, corrupt practices, uncertain economic policies and potential political and economic instability that may be exacerbated in various foreign countries.

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. Presently, the price of our common stock has been below $1.00 per share and accordingly, below the NASDAQ maintenance requirement for minimum bid. 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 December 31, 2019, we have accumulated losses totaling approximately $222 million. As of December 31, 2019, we had a working capital surplus of approximately $4.4 million and stockholders' equity of approximately $5.1 million. Our net losses for the two most recent fiscal years have been approximately $8.4 million and $4.9 million for 2019 and 2018, 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 December 31, 2019, we had cash, cash equivalents and short-term investments on hand of approximately $5.1 million. In January 2020, as a result of certain investors exercising outstanding common stock purchase warrants, we were able to raise an additional $6.8 million, net. We anticipate that based upon our cash position on December 31, 2019, and taking into account the $6.8 million in cash that we received in January, we will be able to fund our operations for more than 12 months after this filing. 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 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 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.

We entered into employment contracts with members of our senior management team that contain significant anti-termination provisions which could make future changes in management difficult or expensive.

We have entered into employment agreements with members of our senior management team. These agreements may require the payment of severance in the event one of these employees ceases to be employed. These provision makes the replacement of these employees 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.

Business or economic disruptions or global health concerns could seriously harm our development efforts and increase our costs and expenses.

Broad-based business or economic disruptions could adversely affect our ongoing or planned research and development activities as well as the execution of our acquisition and/or in-licensing strategy. For example, in December 2019 an outbreak of a novel strain of coronavirus originated in Wuhan, China, and has since spread around the world, including to the United States. To date, this outbreak has already resulted in extended shutdowns of many businesses around the world, including in the United States. Global health concerns, such as coronavirus, could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate. We cannot presently predict the scope, severity and longevity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage or plan to engage, including the suppliers, clinical trial sites, regulators and other third parties with whom we conduct business or plan to conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. It is also possible that global health concerns such as this one could disproportionately impact the hospitals and clinical sites in which we conduct or plan to conduct any of our clinical trials, which could have a material adverse effect on our business and our results of operation and financial condition.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate information about our products and the diseases that our therapies are designed to treat. Social media practices in our industry continue to evolve and regulations related to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients and others may use social media channels to comment on the effectiveness of a product or to report an alleged adverse event. When such disclosures occur, we may fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend against political and market pressures generated by social media due to restrictions on what we may say about our products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face overly restrictive regulatory actions or incur other harm to our business.

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 January 2020, we completed an inducement offering pursuant to which we reduced the exercise price of outstanding warrants in exchange for the holder exercising such warrants for cash. As a result, we issued 5,555,554 shares of common stock, or approximately 61% of our issued and outstanding common stock. Transactions, such as the inducement 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 December 31, 2019, we had 149,149 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 January 2020 inducement offering, the Price Protection Warrants all had their exercise prices adjusted to $1.14 per share. 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 December 31, 2019, we have issued and outstanding 3,866,457 shares of common stock and we have 7,479,777 shares of common stock reserved for future grants under our equity compensation plans and for issuances upon the exercise or conversion of currently outstanding options, warrants and convertible securities. As of December 31, 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 December 31, 2019, we are entitled to issue up to 288,653,766 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 and countries. 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 foreign 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, both in the U.S. and in foreign countries could substantially change. 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 1B. UNRESOLVED STAFF COMMENTS

None

ITEM 2. PROPERTIES

We currently operate one facility located in the United States and one facility located in China. 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. Our prior lease expired on December 31, 2019. We are currently operating on a month-to-month lease as we negotiate an extension.

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.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURE

Not Applicable

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is traded on The Nasdaq Capital Market under the symbol "SNCA."

Holders

As of February 29, 2020, our common stock was held by approximately 218 record holders. Because many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these holders.

Dividends

We have not paid any cash dividends to date and have no plans to do so in the immediate future. Additionally, we are prohibited from paying any cash dividends under the terms of certain agreements to which we are a party.

Equity Compensation Plan Information

See information contained in Part III, Item 12 of this Annual Report filed on Form 10-K.

Equity Compensation Plans Not Approved by Security Holders

See information contained in Part III, Item 12 of this this Annual Report filed on Form 10-K.

Recent Sales or Issuances of Unregistered Securities

The following information is given with regard to unregistered securities sold during the period covered by this report. The following securities were issued in private offerings pursuant to the exemption from registration contained in the Securities Act and the rules promulgated thereunder in reliance on Section 4(2) thereof, relating to offers of securities by an issuer not involving any public offering:

- 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 adjusted by 116,213 to 156,213. All other terms of the inducement grant remain the same.

- In 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.

- In 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.

- In 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.

- In 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.

- In January 2020, as an inducement to certain existing holders of 5,555,554 outstanding stock purchase warrants we issued replacement warrants. The warrants will be exercisable into an aggregate of up to 5,555,554 shares of common stock, at an exercise price of $1.23 per share, 2,777,777 of which have a term of exercise equal to two years and 2,777,777 of which have a term of exercise equal to five years.

ITEM 6. SELECTED FINANCIAL DATA

Not Applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

- *Executive Overview* — Overview discussion of our business in order to provide context for the remainder of MD&A.
- *Trends & Outlook* — Discussion of what we view as the overall trends affecting our business and the strategy for 2020.
- *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: (i) year ended December 31, 2019 to the year ended December 31, 2018.
- *Liquidity and Capital Resources*—Analysis of cash flows and discussion of our financial condition and future liquidity needs.

Executive Overview

Historically, we have been 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. In early 2019, we also began an in-licensing and acquisition strategy by 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:

1. 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;

2. 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

3. 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. A component of our current strategy is out-licensing and we have recently initiated a formal out- licensing initiative aimed at securing partners to advance the clinical development of these two programs.

We believe this technology, in partnership with an established biopharmaceutical company with the appropriate development expertise and financial resources, 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.

We are also seeking to in-license and acquire other novel therapeutics. 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. Subsequently, on January 10, 2020, the Company filed a form 8-K disclosing that it was not able to reach an agreement on the exclusive license agreement and no longer expected to complete this transaction. However, we continue to seek other products to in-license or acquire.

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 fees and sales of our products. Because we are at such an early stage in the clinical trials process, we are not yet able to accurately predict when we will have a product ready for commercialization, if ever.

Research and Development Expenses

Our research and development expenses consist primarily of clinical trial expenses, including payments to clinical trial sites that perform our clinical trials and clinical research organizations (CROs) that help us manage our clinical trials, manufacturing of small molecule drugs and stem cells for both human clinical trials and for pre-clinical studies and research, personnel costs for research and clinical personnel, and other costs including research supplies and facilities. Our 2019 research and development expenses reflect the costs of the technical evaluation of our internal programs as well as the evaluation of certain potential assets we considered for acquisition.

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 ischemic stroke clinical trial, will decrease in the future as we seek partners to further the clinical development of our therapeutic programs. This could change if we are successful in our in-licensing and acquisition strategy in which we are evaluating novel therapeutics, our research and development expenditures will be primarily devoted to advancing the acquired programs towards or through later stage clinical trials.

We have a wholly owned subsidiary in the People’s Republic of China that primarily oversees our current clinical 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. The award performance period was extended through 7/31/2020 to complete the data collection and report writing. The grant balance was approximately $109,000 at 12/31/19, we anticipate receiving this amount over the extended performance period. 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 of approximately $150,000 was received in 2019. The proceeds from the awards are recorded as a reduction of our gross research and development expenses, based on the terms and conditions of the grants.

General and Administrative Expenses

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

Critical Accounting Policies

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“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 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 - Our financial statements prepared in accordance with U.S. GAAP require us to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Specifically, we have estimated the expected economic life and value of our patent technology, our net operating loss carryforward and related valuation allowance for tax purposes the fair value of our liability classified warrants and our share-based compensation expenses related to employees, directors, consultants and investment banks. Actual results could differ from those estimates.

Long Lived Intangible Assets - Our long-lived intangible assets consist of our intellectual property patents including primarily legal fees associated with the filings and in defense of our patents. The assets are amortized on a straight-line basis over the expected useful life which we define as ending on the expiration of the patent group. These assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. We assess this recoverability by comparing the carrying amount of the asset to the estimated undiscounted future cash flows to be generated by the asset. If an asset is deemed to be impaired, we estimate the impairment loss by determining the excess of the asset's carrying amount over the estimated fair value. These determinations use assumptions that are highly subjective and include a high degree of uncertainty. During the years ended December 31, 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.

Comparison of Our Results of Operations for the Years Ended December 31, 2019 and 2018

Revenue

During each of the years ended December 31, 2019 and 2018, we recognized revenue of $10,000 related to ongoing fees pursuant to certain licenses of our intellectual property to third parties. In addition, during the year ended December 31, 2018, we recognized $250,000 of milestone-based royalties related to a settlement of a prior patent infringement case.

Operating Expenses

Operating expenses for 2019 and 2018 were as follows:

	Year Ended December 31,		Increase (Decrease)	
	2019	2018	$	%
Operating Expenses				
Research & development costs	$ 4,061,450	$ 3,960,191	$ 101,259	3%
General & administrative expenses	4,585,638	4,559,265	26,373	1%
Total operating expense	$ 8,647,088	$ 8,519,456	$ 127,632	1%

Research and Development Expenses

The increase of approximately $101,000 or 3% in research and development expenses was primarily attributable to an increase in external consulting services engaged in the technical evaluation of our internal programs as well as the evaluation of certain potential assets we considered for acquisition. These costs were partially offset by lower clinical trial expenditures as we wind down clinical activities related to the stem cell assets. We expect that research and development expenses, which include expenses related to our ongoing stroke clinical trial, will decrease in the future as we seek partners to further the clinical development. This could change if we are successful in our in-licensing and acquisition strategy in which we are evaluating novel therapeutics, our research and development expenditures will be primarily devoted to advancing the acquired programs towards or through later stage clinical trials.

General and Administrative Expenses

G&A expenses increased approximately $26,000 or 1%. As noted above we have shifted the Company strategy and focus from the development of the stem cell assets and initiated an out-licensing effort to partner these programs while seeking to in license or acquire 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. Associated with this shift in strategic focus our G&A expenses in 2019 reflect an enhanced internal management structure including individual consultants in key roles.

Other income (expense)

Other income, net totaled approximately $280,000 and $3,335,000 for the years ended December 31, 2019 and 2018, respectively. Other income, net in 2019 consisted of approximately $499,000 of non-cash gains related to the change in the fair value of our liability classified stock purchase warrants, $86,000 of sublease income and $68,000 of interest income partially offset by a $368,000 loss related to the write-off of a related party receivable.

Other income, net in 2018 consisted of approximately $3,269,000 of non-cash gains related to the change in the fair value of our liability classified stock purchase warrants and $79,000 of interest income.

Liquidity and Capital Resources

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 $5.1 million at December 31, 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. In addition, in January 2020, we raised approximately $6.8 million of net proceeds from the exercise of certain common stock purchase warrants pursuant to an inducement offer.

Based on our expected operating cash requirements, we anticipate our current cash and investments on hand will be sufficient to fund our operations, for more than 12 months after this filing. 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, asset sales 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

	Year Ended December 31,		Increase (Decrease)	
	2019	2018	$	%
Net cash used in operating activities	$ (7,255,680)	$ (7,692,419)	$ 436,739	(6)%
Net cash provided by investing	$ -	$ 4,998,286	$ (4,998,286)	(100)%
Net cash provided by financing activities	$ 6,589,505	$ 1,814,233	$ 4,775,272	263%

Net Cash Used in Operating Activities

Cash used in operating activities for the year ended December 31, 2019, of approximately $7,256,000 reflects our $8,352,000 loss for the period adjusted for certain non-cash items including: (i) $881,000 of share-based compensation, (ii) a ($499,000) gain related to the change in fair value of our liability classified warrants, (iii) $362,000 of write-off of related party receivable, (iv) $208,000 of net cash inflows related to changes in operating assets and liabilities and (v) $144,000 adjustment for amortization and depreciation.

Cash used in operating activities for the year ended December 31, 2018, of approximately $7,692,000 reflects our $4,925,000 loss for the period adjusted for certain non-cash items including: (i) $634,000 of share-based compensation (ii) ($3,269,000) related to the change in fair value of our liability classified warrants, (iii) ($337,000) of net cash outflows related to changes in our operating assets and liabilities and (iv) $186,000 adjustment for amortization and depreciation.

Net Cash Used in Investing Activities
There were no investing activities in the year ended December 31, 2019.

For the year ended December 31, 2018 cash provided by investing activities was comprised primarily of proceeds from the maturity of our short-term investments.

Net Cash Provided by Financing Activities

For the year ended December 31, 2019, cash provided by financing activities consisted primarily 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 year ended December 31, 2018, cash provided by financing activities consisted primarily of approximately $1.8 million of net proceeds from our October financing transaction.

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 December 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).

In January 2020, pursuant to the terms of an inducement offer, certain holders of 5,555,554 of our common stock purchase warrants exercised their warrants at an exercise price of $1.36 per share generating approximately $7.6 million of gross proceeds.

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.

Off-balance Sheet Arrangements

None.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Not Applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders of Seneca Biopharma, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Seneca Biopharma, Inc. (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has accumulated deficit that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Dixon Hughes Goodman LLP

We have served as the Company's auditor since 2016.

Baltimore, Maryland
March 27, 2020

Seneca Biopharma, Inc.

Consolidated Balance Sheets

	December 31, 2019	December 31, 2018
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 5,114,917	$ 5,787,110
Trade and other receivables	21,064	294,057
Current portion of related party receivable, net of discount	-	63,938
Prepaid expenses	510,900	363,288
Total current assets	5,646,881	6,508,393
Property and equipment, net	41,036	90,311
Patents, net	668,936	763,543
Related party receivable, net of discount and current portion	-	298,238
ROU and other assets	227,036	23,965
Total assets	$ 6,583,889	$ 7,684,450
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 824,406	$ 832,564
Accrued bonuses	135,686	-
Short term notes and other current liabilities	264,665	218,602
Total current liabilities	1,224,757	1,051,166
Warrant liabilities, at fair value	84,596	583,734
Lease liability, net of current portion	148,543	-
Total liabilities	1,457,896	1,634,900
Commitments and contingencies (Note 8)		
STOCKHOLDERS' EQUITY		
Preferred stock, 7,000,000 shares authorized, $0.01 par value; 200,000 and 1,000,000 shares issued and outstanding in 2019 and 2018, respectively	2,000	10,000
Common stock, $0.01 par value; 300 million shares authorized, 3,866,457 and 910,253 shares issued and outstanding in 2019 and 2018, respectively	38,665	9,103
Additional paid-in capital	227,067,058	219,654,753
Accumulated other comprehensive loss	(6,186)	(413)
Accumulated deficit	(221,975,544)	(213,623,893)
Total stockholders' equity	5,125,993	6,049,550
Total liabilities and stockholders' equity	$ 6,583,889	$ 7,684,450

See accompanying notes to consolidated financial statements.

Seneca Biopharma, Inc.

Consolidated Statements of Operations and Comprehensive Loss

	Year Ended December 31,	
	2019	**2018**
Revenues	$ 15,394	$ 260,000
Operating expenses:		
Research and development costs	4,061,450	3,960,191
General and administrative expenses	4,585,638	4,559,265
Total operating expenses	8,647,088	8,519,456
Operating loss	(8,631,694)	(8,259,456)
Other income (expense):		
Interest income	67,731	78,780
Interest expense	(8,920)	(7,698)
Gain from change in fair value of liability classified warrants	499,138	3,269,148
Write-off of related party receivable and other income (expense)	(277,906)	(5,391)
Total other income (expense)	280,043	3,334,839
Net loss	$ (8,351,651)	$ (4,924,617)
Net loss per common share - basic and diluted	$ (3.80)	$ (7.54)
Weighted average common shares outstanding - basic and diluted	2,197,434	653,221
Comprehensive loss:		
Net loss	$ (8,351,651)	$ (4,924,617)
Foreign currency translation adjustment	(5,773)	(3,044)
Comprehensive loss	$ (8,357,424)	$ (4,927,661)

See accompanying notes to consolidated financial statements.

Seneca Biopharma, Inc.

Consolidated Statements of Changes In Stockholders' Equity

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	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	-	-	-	-	634,082	-	-	634,082
Issuance of common stock and warrants from capital raises, net	-	-	150,000	1,500	1,826,500	-	-	1,828,000
Issuance of restricted stock awards	-	-	2,252	23	(23)	-	-	-
Foreign currency translation adjustments	-	-	-	-	-	(3,044)	-	(3,044)
Net loss	-	-	-	-	-	-	(4,924,617)	(4,924,617)
Balance at December 31, 2018	**1,000,000**	**10,000**	**910,253**	**9,103**	**219,654,753**	**(413)**	**(213,623,893)**	**6,049,550**
Share rounding adjustment related to 1:20 reverse stock split	-	-	6,117	61	(61)	-	-	-
Share based payments	-	-	-	-	880,789	-	-	880,789
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	(800,000)	(8,000)	155,496	1,555	6,445	-	-	-
Issuance of restricted stock awards	-	-	15,688	157	(157)	-	-	-
Issuance of common stock for warrant exercises	-	-	2,361,462	23,615	(23,379)	-	-	236
Issuance of common stock for RSU exercises	-	-	1,126	11	(11)	-	-	-
Foreign currency translation adjustments	-	-	-	-	-	(5,773)	-	(5,773)
Net loss	-	-	-	-	-	-	(8,351,651)	(8,351,651)
Balance at December 31, 2019	**200,000**	**$ 2,000**	**3,866,457**	**$ 38,665**	**$ 227,067,058**	**$ (6,186)**	**$ (221,975,544)**	**$ 5,125,993**

See accompanying notes to consolidated financial statements.

Seneca Biopharma, Inc.

Consolidated Statements of Cash Flows

	Year Ended December 31, 2019	2018
Cash flows from operating activities:		
Net loss	$ (8,351,651)	$ (4,924,617)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	143,859	185,803
Share based compensation expenses	880,789	634,082
Change in fair value of liability classified warrants	(499,138)	(3,269,148)
Provision for bad debt	362,176	-
Loss on disposal of fixed assets and patent abandonment	-	18,342
Changes in operating assets and liabilities:		
Trade and other receivables	272,993	18,745
Related party receivable	-	62,064
Prepaid expenses	(142,310)	32,303
ROU and other assets	39,643	(3,991)
Accounts payable and accrued expenses	(15,741)	(36,991)
Accrued bonuses	135,686	(418,625)
Other current liabilities	(47,414)	11,490
Lease and other long term liabilities	(34,572)	(1,876)
Net cash used in operating activities	(7,255,680)	(7,692,419)
Cash flows from investing activities:		
Maturity of short-term investments	-	5,000,000
Purchase of property and equipment	-	(1,714)
Net cash provided by investing activities	-	4,998,286
Cash flows from financing activities:		
Net proceeds from the sale of common stock and warrants	6,552,842	1,828,000
Proceeds from warrant exercises	236	-
Proceeds from short term notes payable	414,320	349,578
Payments of short term notes payable	(377,893)	(363,345)
Net cash provided by financing activities	6,589,505	1,814,233
Effects of exchange rates on cash	(6,018)	(7,930)
Net decrease in cash and cash equivalents	(672,193)	(887,830)
Cash and cash equivalents, beginning of year	5,787,110	6,674,940
Cash and cash equivalents, end of year	$ 5,114,917	$ 5,787,110

See accompanying notes to consolidated financial statements.

Seneca Biopharma, Inc.

Consolidated Statements of Cash Flows (continued)

	Year Ended December 31,	
	2019	**2018**
Supplemental cash flow information:		
Cash paid for interest	$ 8,920	$ 7,698

See accompanying notes to consolidated financial statements.

Note 1. Organization and Business and Financial Condition

Nature of Business

In October 2019, we changed our name from Neuralstem, Inc. 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 and controlled subsidiary located in the People's Republic of China are consolidated in our 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, in furtherance of our in-licensing strategy, we announced that we had entered into a non-binding term sheet with Jiangsu QYuns Therapeutics Co., Ltd., ("QYuns") for an exclusive license to certain of QYuns Therapeutics' assets, including a pipeline of cytokine-targeted monoclonal antibodies for the treatment of a range of auto-immune disease. Subsequently, on January 10, 2020, we disclosed that we were not able to reach a definitive licensing agreement with QYuns and accordingly, no longer expected to complete this transaction.

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 Company's operations will continue to be focused on development activities, including conducting pre-clinical testing and human clinical trials of novel product candidates that we may in-license or acquire in the future.

On July 17, 2019, we effected a 1-for-20 reverse stock split of our 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 December 31, 2019, our cash flow and cash usage forecasts for the period covering one-year from the issuance date of this Annual Report filed on Form 10-K and our current capital structure including outstanding warrants and other equity-based instruments and our obligations and debts.

We expect that our existing cash and cash equivalents as of December 31, 2019, along with the proceeds from our January inducement offer will be sufficient to enable us to fund our anticipated level of operations based on our current operating plans for more than 12 months after this filing. 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. 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

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The financial statements include the accounts of the Company and our wholly owned subsidiary. All significant intercompany transactions and balances have been eliminated.

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 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 years ended December 31, 2019 and 2018, we recorded approximately $459,000 and $538,000, 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.

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 years ended December 31, 2019 and 2018. A total of approximately 7.3 million and 0.6 million potential dilutive shares have been excluded in the calculation of diluted net income per share for the years ended December 31, 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 granted to employees and board members is generally determined at the grant date while awards granted to non-employee consultants are generally valued at the vesting date using an option pricing model that uses Level 3 unobservable inputs; share-based compensation cost for restricted stock and restricted stock units is determined at the grant date based on the closing price of our common stock on that date. The value of the award is recognized as expense on a straight-line basis over the requisite service period.

Intangible and Long-Lived Assets

We assess impairment of our long-lived assets using a "primary asset" approach to determine the cash flow estimation period for a group of assets and liabilities that represents the unit of accounting for a long-lived asset to be held and used. Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The carrying amount of a long-lived asset is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset. No impairment losses were recognized during the years ended December 31, 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.

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 smaller reporting companies for fiscal years beginning after December 15, 2022, 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. We are currently evaluating the impact, if any, that this guidance will have on our consolidated financial statements but do not expect it to have a significant effect.

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. We are currently evaluating the impact, if any, that this guidance will have on our consolidated financial statements but do not expect it to have a significant effect.

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 December 31, 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 capital raises (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	$ -	$ -	$ 84,596	$ 84,596
Balance at December 31, 2019	$ -	$ -	$ 84,596	$ 84,596

The following table presents the activity for those items measured at fair value on a recurring basis using Level 3 inputs for the year ended December 31, 2019:

	Mark-to-market liabilities - stock purchase warrants
Balance at December 31, 2018	$ 583,734
Change in fair value - gain	(499,138)
Balance at December 31, 2019	$ 84,596

The following table presents the activity for those items measured at fair value on a recurring basis using Level 3 inputs for the year ended December 31, 2018:

	Mark-to-market liabilities - stock purchase warrants
Balance at December 31, 2017	$ 3,852,882
Change in fair value - gain	(3,269,148)
Balance at December 31, 2018	$ 583,734

The gains resulting from the changes in the fair value of the liability classified warrants are classified as other income or expense in the accompanying 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. In addition, we have issued warrants to purchase common stock in conjunction with debt and equity offerings. 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 December 31, 2019, we have approximately 7,441,532 million shares of common stock reserved for issuance upon the exercise of share-based awards.

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

	Year Ended December 31,	
	2019	2018
Research and development costs	$ 200,337	$ 133,334
General and administrative expenses	680,452	500,748
Total	$ 880,789	$ 634,082

Stock Options

A summary of stock option activity and related information for the year ended December 31, 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/Expired	(38,197)	$ 67.90		
Outstanding at December 31, 2019	271,660	$ 61.83	7.8	$ -
Exercisable at December 31, 2019	207,813	$ 78.30	7.4	$ -

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	55,484	$ 5.99	9.5	$ -
$7.20	-	$8.80	146,972	$ 8.51	9.0	-
$22.20	-	$99.20	28,501	$ 31.63	5.7	-
$107.40	-	$1,102.41	40,703	$ 351.63	2.8	-
			271,660	$ 61.83	7.8	$ -

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

	Year Ended December 31,					
	2019			2018		
Annual dividend		-			-	
Expected life (in years)	4.8	-	5.5	2.5	-	5.3
Risk free interest rate	1.8%	-	2.5%	2.5%	-	2.8%
Expected volatility	97%	-	115%	97%	-	113%

Options granted in the years ended December 31, 2019 and 2018 had weighted average grant date fair values of $3.45 and $9.40, respectively. The total fair value of the options vested during the years ended December 31, 2019 and 2018 was approximately $671,100 and $205,000, respectively.

Unrecognized compensation cost for unvested stock option awards outstanding at December 31, 2019 was approximately $155,000 to be recognized over approximately 0.6 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 (RSU’s) that entitle the holders to receive shares of our common stock upon vesting and subject to certain restrictions regarding the exercise of the RSU’s and the holders’ ability to transfer the shares received upon exercise. The fair value of RSU’s granted is based upon the market price of the underlying common stock as if they were vested and issued on the date of grant.

A summary of our RSU activity for the year ended December 31, 2019 follows:

	Number of RSU's		Weighted-Average Grant Date Fair Value
Outstanding at January 1, 2019	2,816	$	64.80
Granted	4,904	$	5.90
Exercised and converted to common shares	(1,127)	$	22.20
Forfeited	(1,126)	$	22.20
Outstanding at December 31, 2019	5,467	$	29.62
Exercisable at December 31, 2019	2,925	$	50.23

The total intrinsic value of the outstanding RSU’s at December 31, 2019 was approximately $5,400. The total fair value of RSU’s vested during the years ended December 31, 2019 and 2018, was approximately $13,900 and $50,000, respectively. The total value of all RSU’s that were converted in the year ended December 31, 2019 was approximately $10,400. No RSU’s were converted in the year ended December 31, 2018.

Unrecognized compensation cost for unvested RSU’s outstanding at December 31, 2019 was approximately $15,000 to be recognized over approximately 0.5 years.

Restricted Stock

We have granted restricted stock to certain board members.

A summary of our restricted stock activity for the year ended December 31, 2019 is as follows:

	Shares of Restricted Stock	Weighted-Average Grant Date Fair Value
Outstanding at January 1, 2019	1,127	$ 22.20
Granted	15,689	$ 5.95
Vested	(8,835)	$ 8.03
Forfeited	-	$ -
Outstanding at December 31, 2019	7,981	$ 5.95

The total intrinsic value of the outstanding restricted stock at December 31, 2019 was approximately $7,900. The total intrinsic value of all restricted stock vested in the year ended December 31, 2019 was approximately $18,500.

Unrecognized compensation cost for unvested restricted stock outstanding at December 31, 2019 was approximately $47,500 to be recognized over approximately 0.5 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 the offering of our securities. Such warrants are classified as liabilities due to the existence of certain net cash settlement provisions contained in the warrants. At December 31, 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 December 31, 2019, all of the “prefunded warrants” had been exercised generating approximately $200 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 December 31, 2019 follows:

Range of Exercise Prices			Number of Warrants Outstanding	Range of Expiration Dates		
$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	24,650	March 2020	-	July 2023
			6,968,908			

In January 2020, pursuant to the terms of an inducement offer, certain holders of 5,555,554 of our common stock purchase warrants exercised such warrants at an exercise price of $1.36 per share generating approximately $7.6 million of gross proceeds. As an inducement to exercise we reduced the exercise price on the existing warrants from $2.70 to $1.36 and issued 5,555,554 replacement warrants with an exercise price of $1.23 per share. Of the replacement warrants, 2,777,777 have a two-year term and 2,777,777 have a five-year term. In conjunction with the transaction we issued to the placement agent 444,445 common stock purchase warrants with an exercise price of $1.70 and a five-year term.

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 April and July 2019, 800,000 Series A 4.5% Convertible Preferred Stock shares were converted into 155,496 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. Property and Equipment

The major classes of property and equipment consist of the following at December 31:

	2019	2018
Furniture and fixtures	$ 35,407	$ 35,407
Computers and office equipment	138,897	138,897
Lab equipment	817,149	818,267
	991,453	992,571
Less accumulated depreciation	(950,417)	(902,260)
Property and equipment, net	$ 41,036	$ 90,311

The above includes approximately $70,000 of equipment located at our research facility in China. Property and equipment are recorded at cost and are depreciated using the straight-line method over the estimated useful lives of the respective assets. Depreciation expense for the years ended December 31, 2019 and 2018, was approximately $49,000 and $84,000, respectively

Note 6. Patents

The Company holds patents related to its stem cell and small molecule technologies. Patent costs are capitalized and are being amortized over the life of the patents. The weighted average remaining unamortized life of issued patents was approximately 8.6 years at December 31, 2019. Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The carrying amount of a long-lived asset is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset. Long-lived assets to be disposed of are reported at the lower of carrying amount or fair value less cost to sell. During the years ended December 31, 2019 and 2018, no impairment losses were recognized. The Company's intangible assets and accumulated amortization consisted of the following at December 31:

	2019	2018
Patent asset	$ 2,006,443	$ 2,006,443
Accumulated amortization	(1,337,507)	(1,242,900)
Net intangibles	$ 668,936	$ 763,543

Amortization expense for the years ended December 31, 2019 and 2018 was approximately $95,000 and $102,000, respectively. The expected average future annual amortization expense over the next five years is approximately $75,000 based on current balances of our intangible assets.

Note 7. Income Taxes

Our provision for income taxes for the years ended December 31, 2019 and 2018 consists of the following:

		2019	2018
Current provision:			
	Federal	$ -	$ -
	State	-	-
	Foreign	-	-
Total current provision		-	-
Deferred provision (benefit):			
	Federal	(545,792)	7,726
	State	1,001,786	(2,749,386)
	Foreign	-	-
Total deferred provision (benefit)		455,994	(2,741,660)
Valuation allowance		(455,994)	2,741,660
Consolidated income tax provision		$ -	$ -

We provide a full valuation allowance on our net deferred tax assets because management has determined that it is more likely than not that we will not earn income sufficient to realize the deferred tax assets during the asset reversal periods.

The difference between income taxes computed by applying the statutory federal income tax rate to consolidated losses before income taxes and the consolidated provision for income taxes is attributable to the following:

	2019	2018
Federal statutory rate	(21.0%)	(21.0%)
State income taxes, net of Federal benefits	(5.3%)	(5.0%)
Rate changes	(6.4%)	(66.3%)
Change in fair value of liability classified warrants	(1.6%)	(17.3%)
Other, including non-deductible expenses	28.8%	53.9%
Valuation allowance	5.5%	55.7%
Total	0.0%	0.0%

The tax effects of significant temporary differences representing deferred tax assets as of December 31 are:

	2019	2018
Net operating loss carryforwards	$ 43,190,604	$ 42,580,533
Stock based compensation expense	2,605,277	2,643,471
Tax credit carryforwards and other	889,372	1,005,255
Gross deferred tax assets	46,685,253	46,229,259
Valuation allowance	(46,685,253)	(46,229,259)
Net deferred tax assets	$ -	$ -

The Company had Federal net operating loss (“NOL”) carryforwards of approximately $160 million at December 31, 2019 of which $146 million was created prior to 2018 and began expiring in 2019. The Company also has certain Federal tax credit carryforwards that will begin expiring in 2020. The timing and manner in which these net operating loss carryforwards and credits may be used in any year will be limited to the Company’s ability to generate future earnings and also may be limited by certain provisions in the U.S. tax code. The Company has not identified any uncertain tax positions and did not recognize any adjustments for unrecognized tax benefits. The Company remains subject to examination for income tax returns dating back to 2016.

Note 8. Commitments and Contingencies

Leases

We currently operate one facility located in the United States and one facility located in China under leases which are both 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 had an initial term of 12 months and expired on December 31, 2019. We are currently operating on a month-to-month lease as we negotiate an extension. We did not establish a right of use ("ROU") asset or lease liability 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. This new lease obligation resulted in us obtaining an ROU asset of approximately $205,000.

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 year ended December 31, 2019.

We recognized total rent expense of approximately $194,200 and $164,000 in the years ended December 31, 2019 and 2018, respectively. Included in the 2019 expense is approximately $67,700 relating to our short-term leases. Lease costs, net of sublease income, for the year ended December 31, 2019 consisted of the following:

Operating lease cost	$171,000
Variable lease cost	23,200
Sublease income	(86,100)
Total net lease cost	$108,100

In the year ended December 31, 2019, we established approximately $204,300 of ROU assets as the result of entering into new lease arrangements.

At December 31, 2019, we have approximately $201,700 of ROU assets included in ROU and Other Assets and approximately $180,900 of lease liability the current portion of which is included in Short-term Notes and Other Current Liabilities 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 December 31, 2019 were as follows:

Future undiscounted cash flows:		
	2020	$ 53,503
	2021	54,539
	2022	56,190
	2023	58,027
	2024	13,650
Total		235,909
Discount factor		(54,997)
Lease liability		180,912
Less current liability		(32,369)
Non-current lease liability		$ 148,543

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 9. 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 former executive officer's termination, we entered into a consulting agreement and release of claims agreement with the former executive officer. 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 December 31, 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 10. Subsequent Events
In January 2020, pursuant to the terms of an inducement offer, certain holders of 5,555,554 of our common stock purchase warrants exercised their warrants at an exercise price of $1.36 per share generating approximately $7.6 million of gross proceeds. See Note 4 for additional details over this transaction.

On March 23, 2020, in order to provide the Company with flexibility in inducing new employees, the Board of Directors approved an amendment to the Company's Inducement Award Stock Option Plan, increasing the number of shares authorized under the plan by 500,000 for an aggregate total of 715,000 shares.

In December 2019 an outbreak of a novel strain of coronavirus originated in Wuhan, China, and has since spread around the world, including to the United States. This outbreak has already resulted in extended shutdowns of many businesses around the world, including in the United States. We cannot presently predict the scope, severity and longevity of any potential business shutdowns or disruptions, but business or economic disruptions as are now being experienced, could adversely affect our ongoing or planned research and development activities as well as the execution of our acquisition and/or in-licensing strategy.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None

ITEM 9A. 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 the principal financial officer, concluded that the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") were effective as of December 31, 2018 to provide reasonable assurance 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 Securities and Exchange Commission rules and forms and (ii) accumulated and communicated to the Company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

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 accounting principles generally accepted in the United States ("U.S. 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 U.S. 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 the 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.

Management's Annual Report on Internal Control Over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Management conducted an assessment of the effectiveness of the Company's internal control over financial reporting based on the criteria set forth in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the Company's assessment, management has concluded that its internal control over financial reporting was effective as of December 31, 2019 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. GAAP.

Changes in Internal Control Over Financial Reporting

There were no changes in the Company's internal control over financial reporting during the fourth quarter of 2019, which were identified in connection with management's evaluation required by paragraph (d) of rules 13a-15 and 15d-15 under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Effective January 1, 2019, we appointed Dr. Kenneth Carter as our Executive Chairman. In such role, Dr. Carter will be our Principal Executive and Financial Officer.

ITEM 9B. OTHER INFORMATION

- On March 26, 2020, Messrs. Ogilvie and Smith informed the Company that they are resigning effective immediately from the Company's Board of Directors. Both of Messrs. Ogilvie's and Smith's resignation from the Board did not result from any disagreement with the Company on any matter relating to the Company's operations, policies or practices.

- On March 26, 2020, the Company and Dr. Kenneth Carter, our Executive Chairman, entered into an amendment (the "Amendment") to Dr. Carter's employment agreement with an effective date of April 1, 2020. The material terms of the Amendment that control and supersede the prior employment agreement are described herein.

  Dr. Carter is to be employed as Chief Executive Officer and Executive Chairman of the Company and will spend substantially all of his duties, attention, skill, and efforts working for Seneca Biopharma. He will not receive any signing / retention bonus. Dr. Carter will be reimbursed up to $5,000 in legal, accounting and other expenses related to the negotiation and drafting of the amendment.

  Pursuant to the terms of the Amendment, Dr. Carter will continue to serve as the Executive Chairman of the Company and will receive an annual base salary of $525,000. Additionally, on the effective date, Dr. Carter will receive a conditional option to purchase 471,400 shares of common stock ("Option Grant") of the Company, subject to the receipt of shareholder approval as well as the forfeiture of all of his previously issued vested and unvested grants. The Option Grant will have a term of ten (10) years from issuance, and an exercise price equal to the closing trading price of the Company's common stock on the effective date. The Option Grant vests (i) one quarter (1/4) on the effective date and (ii) three quarters (3/4) on a monthly basis over the thirty-six (36) month period following the effective date, provided Dr. Carter remains a service provider to the Company over such period. For a period of nine (9) months from the effective date (or until the closing of a transaction related to issuing securities that was approved during such nine (9) month period) (the "Measurement Period"), the Option Grant will be subject to adjustment to maintain the percentage ownership the Option Grant reflects on the date of grant in the event that (i) the Company issues any common stock (including, without limitation, by virtue of exercise, conversion or exchange of any common stock equivalents that are issued and outstanding prior to the end of the Measurement Period) during the Measurement Period, or (ii) there is any exercise, conversion, or exchange of common stock equivalents that are issued and outstanding prior to the end of the Measurement Period.

Upon termination by reason of death or disability (as such terms are defined in the Amendment), Dr. Carter will be entitled to receive any unpaid salary, awarded but unpaid bonuses, unpaid expenses, unpaid benefits, accrued but unpaid indemnification rights, and accrued but unused vacation (collectively, the "Accrued Obligations").

Upon termination by the Company for "Cause" or by Dr. Carter without "Good Reason," as such terms are described in the Amendment, Dr. Carter will only be entitled to receive the Accrued Obligations.

Upon termination by the Company without "Cause" or by Dr. Carter with "Good Reason," Dr. Carter will be entitled to (i) the Accrued Obligations, (ii) the continued payment of his base salary for (a) twelve (12) months if termination occurs after the nine (9) month anniversary of the effective date or (b) seven (7) months if termination occurs prior to the nine (9) month anniversary of the effective date (each as applicable, the "Severance Term") (iii) payment of his bonus pro-rata for the time employed during the year of termination, (iv) COBRA payments for the applicable Severance Term, and (v) the continued vesting of all outstanding equity grants for the earlier of (y) the term of the equity awards or (z) the applicable Severance Term. Dr. Carter will be considered a service provider under the applicable plan in which such grants were issued until the last day of the Severance Term.

Upon a termination by the Company without "Cause" or by Dr. Carter with "Good Reason" three (3) months prior to or twelve (12) months subsequent to a Change of Control (as such term is defined in the Amendment), Dr. Carter will be entitled to (i) the Accrued Obligations, (ii) the continued payment of his base salary for (a) eighteen (18) months if termination occurs after the nine (9) month anniversary of the effective date, or (b) nine (9) months if termination occurs prior to the nine (9) month anniversary of the effective date (each as applicable, "Change of Control Severance Term"), (iii) payment of 100% of target cash bonus for year of termination, (iv) COBRA payments for the applicable Change of Control Severance Term, and (v) the full vesting of all outstanding equity grants on the date of termination. Dr. Carter will be considered a service provider under the applicable plan in which such grants were issued until the last day of the applicable Change of Control Severance Term.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The names of our directors and executive officers and their ages, positions, and biographies as of March 15, 2020 are set forth below. Our executive officers are appointed by and serve at the discretion of the Board. There are no family relationships among any of our directors or executive officers.

Name	Position	Age	Position Since
Named Executive Officers			
Kenneth Carter	Executive Chairman	60	2019
Independent Directors			
Scott V. Ogilvie [(1)]	Director	68	2007
Sanford D. Smith [(1)]	Director	73	2014
Cristina Csimma, PharmD., MHP	Director	61	2017
David J. Mazzo, PhD	Director	63	2019
Binxian Wei	Director (Series A Preferred)	50	2019
Mary Ann Gray, PhD	Director	67	2019

(1) Effective March 26, 2020, Messrs. Ogilvie and Smith resigned from the Company's Board of Directors.

Kenneth Carter PhD, has served as our executive chairman since January 2019. Dr. Carter has over 20 years of experience working in positions of substantial responsibility in the development and operations of early-stage biotechnology companies. Since 2010 when he co-founded the company, Dr. Carter has served as chairman of the board of directors of Noble Life Sciences, a private biotechnology company in Maryland. From 2011 through 2017, Dr. Carter served as president and chief executive officer of Neximmune, Inc., a private biopharmaceutical company in Maryland. He continues to serve as senior advisor of NexImmune. Prior to that, from 1999 through 2009, Dr. Carter served as president and chief executive officer of Avalon Pharmaceuticals, Inc. (NASDAQ: AVRX) until the company merged with Clinical Data, Inc. Dr. Carter also currently serves on the following boards of directors (i) since 2016, Antidote Therapeutics, Inc., a private biopharmaceutical company in Maryland, (ii) since 2011, BetaCat Pharmaceuticals, a private pharmaceutical company in Texas, and Maryland BioHealth Innovation, a biotechnology intermediary company in Maryland, and (iii) since 2007, Maryland Health Care Product Development Corporation, a biotechnology investment firm in Maryland. Dr. Carter additionally serves as a lecturer and Adjunct Faculty member of Johns Hopkins University in Maryland. Dr. Carter holds a BS in Biology and Chemistry from Abilene Christian University, a Ph.D. in Human Genetics and Cell Biology from the University of Texas Medical Branch, and a Postdoctoral degree in Cell and Molecular Biology from University of Massachusetts Medical School. In evaluating Dr. Carter's specific experience, qualifications, attributes and skills in connection with his appointment to our board, we took into account his prior work with both public and private organizations, including his experience in building biopharmaceutical organizations, his strong business development background and his past experience and relationships in the biopharma and biotech fields.

Scott V. Ogilvie, served as a director on our board from February 2008 until March 26, 2020, the date that he resigned from our board. Mr. Ogilvie is currently the Executive Chairman of Formula Four Beverages, Inc., a functional beverage company that manufactures and sell OXiGEN water. Additionally, Mr. Ogilvie is currently the President of AFIN International, Inc., an international private equity and strategic advisory firm, which he founded in 2006. Prior to December 31, 2009, he was CEO of Gulf Enterprises International, Ltd, an investment and strategic advisory company with primary activities in the Middle East and North Africa. He held this position since August 2006. Mr. Ogilvie previously served as Chief Operating Officer of CIC Group, Inc., an investment manager, a position he held from 2001 to 2007. He began his career as a corporate and securities lawyer with Hill, Farrer & Burrill, and has extensive public and private corporate management and board experience in finance, real estate, and life science and technology companies. During the past 5 years, Mr. Ogilvie has served on the board of directors of Inpsyr Therapeutics, Inc. (OTCQB: NSPX) and Oxigenesis, Inc. and the Advisory Board of Profusa, Inc.. In evaluating Mr. Ogilvie's specific experience, qualifications, attributes and skills in connection with his appointment to our board, we took into account his prior work in both public and private organizations regarding corporate finance, securities and compliance and international business development.

Sandford D. Smith, served on our board of directors from March 2014 until March 26, 2020, the date that he resigned from our board. Since December 2011, Mr. Smith has served as Founder and Chairman of Global Biolink Partners. From 1996 until 2011, Mr. Smith served in various senior and executive management positions at Genzyme Corporation (Formerly NASDAQ: GENZ), including Executive Vice President and President, International Group with responsibility for the commercial activities for Genzyme's products outside of the U.S. Prior to joining Genzyme, Mr. Smith served from 1986 to 1996 as President and Chief Executive Officer and a Director of Repligen Corporation, a formerly publicly traded biotechnology company. Mr. Smith previously held a number of positions with Bristol-Myers Squibb Company (NYSE: BMY) from 1977 to 1986, including Vice President of Business Development and Strategic Planning for the Pharmaceutical Group. Mr. Smith currently serves as a director of Cytokynetics, Inc. (NASDAQ: CYTK), Apricus Biosciences, Inc. (NASDAQ: APRI) and as chairman of Aegerion Pharmaceuticals, Inc. (NASDAQ: AEGR) and. Mr. Smith serves as a member of the President's Advisory Board of Brigham and Women's Hospital in Boston, member of the Advisory Board of Tullis Health Investors in Greenwich, and an advisor to BioNEST Partners in New York and Paris. Mr. Smith also is the founder of Smith Scholars, a medical residency program for physicians from resource-poor nations. In selecting Mr. Smith as a board member, the board took into account his history of marketing and developing of therapies targeted at rare disease or those with orphan designations as well as his general experience in the biotech industry.

Cristina Csimma PharmD, MHP,, has served on our board of directors since September 2017. She also serves on the Board of Directors of Idera Pharmaceuticals (NASDAQ: IDRA), a clinical stage biopharmaceutical company, Caraway Therapeutics, a preclinical stage biopharmaceutical company, and T1D Exchange, a nonprofit research organization for type 1 diabetes. She also serves on various advisory boards, including: the Muscular Dystrophy Association Venture Philanthropy Scientific Advisory Committee; the Executive Oversight Board to the National Institutes of Health (NIH) NeuroNext Network; the Harvard and Brigham and Women's Hospital MRCT Center External Advisory Board, and the TREAT-NMD Advisory Committee for Therapeutics (TACT) She was previously the Executive Chair of the Board of Directors of Exonics Therapeutics, a Director of Juniper Pharmaceuticals (acquired in August 2018 by Catalent), Vtesse (acquired in March 2017 by Sucampo Pharmaceuticals) and Cydan, where she was also President and founding CEO, the Vice President of Drug Development at Virdante Pharmaceuticals Inc (acquired by Momenta), Principal at Clarus Ventures LLC, and held roles in Clinical Development and Translational Research at Wyeth (now Pfizer), Genetics Institute and Dana Farber Cancer Institute. Dr. Csimma holds both a Doctor of Pharmacy and a Bachelor of Science in Pharmacy from the Massachusetts College of Pharmacy and Allied Health Sciences, as well as a Master of Health Professions from Northeastern University. In selecting Dr. Csimma, the board took into account her vast experience in the pharmaceutical industry, including her successes in developing drugs for various diseases throughout her career.

Binxian Wei, has served on our board of directors since February 2019. He has been the V.P. of Darsheng Trade & Tech. Development Co, Ltd. (a subsidiary to Tianjin Tiayo Pharmaceutical Co., Ltd.) since 2015. He is responsible for API and finished dosage marketing for Chinese pharmaceutical companies. From 2008 through 2010, he worked as a business development manager for Sakai Trading. He holds a Master's degree in Mathematical & Computer Sciences from Colorado School of Mines, a Master's Degree and Bachelor's Degree in Chemical Engineering from Tianjin University in China. Bin-Xian Wei was appointed as the director representative of the Series A 4.5% Convertible Preferred Stock by Tianjin Pharmaceuticals Group International Holdings Co., LTD, the sole holder of the outstanding Series A 4.5% Convertible Preferred Stock.

David J. Mazzo, PhD, has served on our board of directors since June 2019. Dr. Mazzo brings over 35 years of experience in the pharmaceutical industry. Dr. Mazzo currently serves as President and Chief Executive Officer and a Director of Caladrius Biosciences (NASDAQ: CLBS), a late-stage therapeutics development biopharmaceutical company developing autologous cell therapies for select cardiovascular and autoimmune diseases. Dr. Mazzo also serves on the Board of Directors of EyePoint Pharmaceuticals (formerly known as pSivida Corp) (NASDAQ: EYPT), a biopharmaceutical company with a focus on products for the diseases of the eye. Previously, Dr. Mazzo served from August 2008 to October 2014 as Chief Executive Officer and as a member of the Board of Directors of Regado Biosciences, Inc., (NASDAQ: RGDO) a pharmaceutical company focused on the development of novel antithrombotic drug systems for acute and sub-acute cardiovascular indications. Prior to his leading Regado, from March 2007 to April 2008, Dr. Mazzo was President, Chief Executive Officer and a Director of Æterna Zentaris, Inc., (NASDAQ: AEZS), an international biopharmaceutical company. From 2003 until 2007, Dr. Mazzo served as President, Chief Executive Officer and a director of Chugai Pharma USA, LLC, a biopharmaceutical company which was the U.S. subsidiary of Chugai Pharmaceutical Co., Ltd. of Japan and a member of the Roche Group (Switzerland). Prior to joining Chugai, Dr. Mazzo held executive positions at several large international pharmaceutical companies, including: Schering-Plough Corporation, a publicly held pharmaceutical company that was subsequently acquired by Merck & Co., Inc. where he was also a Director of the Essex Chimie European subsidiary; Hoechst Marion Roussel, Inc., the US subsidiary of Hoechst AG, which was subsequently acquired by Sanofi, a multinational pharmaceuticals company; and Rhone-Poulenc Rorer, Inc., a subsidiary of Rhone-Poulenc SA, a French pharmaceuticals company, which was subsequently acquired by Hoechst AG. From October 2005 through January 2015, he also served on the board of directors of Avanir Pharmaceuticals, a biopharmaceutical company which was sold to Otsuka Holdings in 2015. Dr. Mazzo earned a B.A. in the Honors Program (Interdisciplinary Humanities) and a B.S. in Chemistry from Villanova University. In addition, Dr. Mazzo received his M.S. in chemistry and his Ph.D. degree in analytical chemistry from the University of Massachusetts, Amherst. He was also a research fellow at the Ecole Polytechnique Federale de Lausanne, Switzerland. In selecting Dr. Mazzo, the board took into account his vast experience in the pharmaceutical industry, as well as his service on other boards of directors in the biopharmaceutical industry.

Mary Ann Gray, Ph.D. has served on our board of directors since July 2019. From 2018 to current, Dr. Gray has served on the board of directors of Sarepta Therapeutics, Inc. From 2010 to 2018, Dr. Gray served as a member of the Board of Senomyx Inc., a biotechnology company working toward developing additives to amplify certain flavors and smells in foods. She served as a member of the compensation committee of Senomyx from May 2011 to November 2018, as the Chair of the Board and a member of the audit committee from May 2016 to November 2018, and as Lead Director from May 2017 to November 2018. Dr. Gray also served as a member of the Board and audit committee Chair of Juniper Pharmaceuticals, a women's health company, from April 2016 to August 2018. From November 2014 to December 2016, she served as a Board member of TetraLogic, a publicly-held clinical-stage biopharmaceutical company focused on oncology and infectious diseases. She served as the Chair of the audit committee of Tetralogic from March 2015 to December 2016. Dr. Gray also served as a Board member of Acadia Pharmaceuticals, focused on commercialization of CNS therapies, from 2005 to 2016, and served as a member of the audit committee from 2005 to 2016 and as a member of the compensation committee from 2010 to 2016. She served as a Board member of Dyax Corp., a rare disease company acquired by Shire in 2016, from 2001 to 2016, serving as a Lead Director from 2008 to 2016, a member of the audit committee from 2004 to 2012, a member of the nominating and corporate governance committee from 2001 to 2016, and Chair of the compensation committee from 2012 to 2016. Dr. Gray is the President of Gray Strategic Advisors, LLC, a biotechnology strategic planning and advisory firm. Dr. Gray has a distinguished scientific background, completing pharmacology research in tumor biology, including the impact of therapeutics on cardiac membranes and beginning her career in biotechnology as a scientist focused on new drug development. She subsequently worked in equities research before becoming a senior analyst and portfolio manager. Dr. Gray earned a B.S. from University of South Carolina, a Ph.D. in pharmacology from the University of Vermont, and completed her post-doctoral work at Northwestern University Medical School and at the Yale University School of Medicine. Our nominating and corporate governance committee believes that Dr. Gray's extensive experience in the biotechnology and biopharmaceutical industry qualifies her for service as a member of our Board.

SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Exchange Act requires our officers, directors, and stockholders owning more than ten percent of our common stock, to file reports of ownership and changes in ownership with the SEC and to furnish us with copies of such reports. Based solely on our review of Form 3, 4 and 5's, the following table provides information regarding any of the reports which were filed late during the fiscal year ended December 31, 2019:

Name of Reporting Person	Type of Report and Number Filed Late	No. of Transactions Reported Late
Kenneth Carter	Form 3	1
Binxian Wei	Form 3	1
Mary Ann Gray	Form 3	1

Corporate Governance Guidelines and Code of Ethics

We have adopted Corporate Governance Guidelines that are intended to ensure that our Board has the necessary authority and practices in place to review and evaluate our business operations and to make decisions that are independent of management. The Corporate Governance Guidelines are intended to align the interests of directors and management with those of our shareholders and establish practices for the Board with regard to its oversight of the Company. Under our guidelines, the Board conducts a self-evaluation to assess adherence to the Corporate Governance Guidelines and identify opportunities to improve Board performance. A copy of our codes can be viewed on our website at www.senecabio.com under "Governance Documents" in the "Corporate Governance" section under the "Investors" tab.

In addition to our Corporate Governance Guidelines, we have adopted several guidelines intended to promote the honest and ethical conduct of our officers, directors, employees and consultants. They include, our "Code of Ethics" that applies to our officer, directors and employees and our "Finance Code of Professional Conduct" that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and any persons who participate in our financial reporting process. A copy of our codes can be viewed on our website at www.senecabio.com under "Governance Documents" in the "Corporate Governance" section under the "Investors" tab.

The codes incorporate our guidelines designed to deter wrongdoing and to promote honest and ethical conduct and compliance with applicable laws and regulations. The codes also incorporate our expectations of our officers, directors and employees that enable us to provide accurate and timely disclosure in our filings with the SEC and other public communications. In addition, the codes incorporate guidelines pertaining to topics such as complying with applicable laws, rules, and regulations; reporting violations; and maintaining accountability for adherence to the codes.

We intend to disclose future amendments to certain provisions of our codes, or waivers of such provisions on our web site within four business days following the date of such amendment or waiver.

Board of Directors

Our Board consists of seven (7) members. Our business, property and affairs are managed under the direction of the Board. Members of the Board are kept informed of our business through discussions with the Executive Chairman and other members of management, by reviewing materials provided to them and by participating in meetings of the Board and its committees.

Our Board is responsible for establishing broad corporate policies and for overseeing our overall management. In addition to considering various matters which require its approval, the Board provides advice and counsel to, and ultimately monitors the performance of, our senior management.

Classification of Board

Pursuant to our bylaws, we have a classified Board which is divided into three classes with staggered three-year terms. Only one class may be elected each year, while the directors in the other classes continue to hold office for the remainder of their three-year terms. The Board may, on its own, determine the size of the exact number of directors on the Board and may fill vacancies on the Board. Notwithstanding, the holder of our Series A 4.5% Convertible Preferred Stock has the right to appoint one board member. Binxian Wei has been appointed and currently serves as such director since February 5, 2019. The procedure for electing and removing directors on a classified board of directors generally makes it more difficult for stockholders to change management control by replacing a majority of the board at any one time, and the classified board structure may discourage a third party tender offer or other attempt to gain control of the Company and may maintain the incumbency of directors. In addition, under our bylaws, directors may only be removed from office by a vote of the majority of the shares then outstanding and eligible to vote.

Independent Directors

Our common stock is listed on the NASDAQ Capital Market. As such, we are subject to the NASDAQ Stock Market LLC ("NASDAQ") director independence standards. In accordance with these standards, in determining independence the Board affirmatively determines whether a director has a "material relationship" with Seneca Biopharma that would compromise his or her independence from management or would cause him or her to fail to meet the NASDAQ's specific independence criteria. When assessing the "materiality" of a director's relationship with Seneca Biopharma the Board considers all relevant facts and circumstances, not merely from the director's standpoint, but from that of the persons or organizations with which the director has an affiliation, and, where applicable, the frequency and regularity of the services, and whether the services are being carried out at arm's length in the ordinary course of business. Material relationships can include commercial, consulting, charitable, familial and other relationships. A relationship is not material if, in the Board's judgment, it is not inconsistent with the NASDAQ'S director independence standards and it does not compromise a director's independence from management.

Applying the NASDAQ's standards, the Board has determined that Mr. Wei and Drs. Mazzo, Gray, and Csimma are each "independent" as that term is defined by the NASDAQ's standards.

Communications with Directors

We have adopted a formal process for shareholder communications with our independent directors. The policy, is available on our website, *www.senecabio.com* in the "Governance Documents" section in the "Corporate Governance" section under the "Investors" tab. The Document is named "Board Contact." Individuals wanting to communicate with our directors are invited to communicate with the non-management members of the Board by sending correspondence to the non-management members of the Board of Directors, c/o Corporate Secretary, Seneca Biopharma, Inc., 20271 Goldenrod Lane, Suite 2024, Germantown, MD 20876.

The Corporate Secretary will review all such correspondence and forward to the non-management members of the Board a summary of all such correspondence received during the prior month and copies of all such correspondence that deals with the functions of the Board or committees thereof or that otherwise is determined to require attention of the non-management directors. Non-management directors may at any time review the log of all correspondence received by us that are addressed to the non-management members of the Board and request copies of any such correspondence. Concerns relating to accounting, internal controls or auditing matters will immediately be brought to the attention of the Chairman of the Audit Committee.

Stock Ownership Guidelines

On November 10, 2016, we adopted stock ownership guidelines for our Chief Executive Officer, Chief Scientific Officer and named executive officers. Under the guidelines, our CEO and CSO are expected to own shares of our common stock that have a value equal to 2x their respective annual salaries. All other named executive officers or Section 16 filing employees are expected to own shares of our common stock that have a value equal to 1x their respective annual salaries. Shares may be owned directly by the individual or owned jointly with or separately by the individual's spouse, or held in trust for the benefit of the individual, the individual's spouse or children. Share ownership requirements must be met within five years after first becoming subject to the guidelines.

Committees

We have established three (3) corporate governance committees comprised of the: (i) Audit Committee; (ii) Compensation Committee; and (iii) Governance and Nominating Committee. The committee membership and the function of each of the committees are described below. Each committee is governed by written committee charters. We periodically review such charters and may amend or update the process and procedures contained therein. In the event of such amendment or update, we will promptly post our revised charter on our website. In addition to our established committee, we may from time to time establish special committees as the Board deems necessary. A copy of each respective committee's charter can be viewed on our website at www.senecabio.com under "Corporate Governance" under the "Investors" tab.

The table below identifies the Board's standing committees and committee membership as of March 15, 2020:

Director	Independent	Audit Committee	Governance and Nominating Committee	Compensation Committee
Scott Ogilvie (1)	Yes	Member	Member	---
David J. Mazzo, PhD	Yes	---	Member	Member
Cristina Csimma, PharmD, MHP	Yes	---	Chair	Member
Sandford D. Smith (1)	Yes	Member	---	Chair
Mary Ann Gray, PhD	Yes	Chair	---	---

(1) Effective March 26, 2020, Messrs. Ogilvie and Smith resigned as members of our Board of Directors and from all committees.

Each member of the Audit Committee, the Compensation Committee and the Governing and Nominating Committee is considered independent under Nasdaq listing criteria.

Audit Committee

We have a designated audit committee in accordance with section 3(a)(58)(A) of the Exchange Act. Subsequent to the resignation of Messrs. Ogilvie and Smith, our only current member of the Audit Committee is Dr. Gray. The Board anticipates appointing new members to the Audit Committee to fill the vacancies created by the resignations of Messrs. Ogilvie and Smith. The main function of our Audit Committee is to oversee our accounting and financial reporting processes. The Audit Committee assists the Board in fulfilling its oversight and monitoring responsibility of reviewing the financial information provided to shareholders and others, appoints Seneca Biopharma's independent registered public accounting firm, reviews the services performed by the independent registered public accounting firm and Seneca Biopharma's finance department, evaluates Seneca Biopharma's accounting policies and the system of internal controls established by management and the Board, reviews significant financial transactions, and oversees enterprise risk management.

The Board has determined that Dr. Gray is an "audit committee financial expert" within the meaning of SEC rules. An audit committee financial expert is a person who can demonstrate the following attributes: (1) an understanding of generally accepted accounting principles and financial statements; (2) the ability to assess the general application of such principles in connection with the accounting for estimates, accruals and reserves; (3) experience preparing, auditing, analyzing or evaluating financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of issues that can reasonably be expected to be raised by the Company's financial statements, or experience actively supervising one or more persons engaged in such activities; (4) an understanding of internal controls and procedures for financial reporting; and (5) an understanding of audit committee functions.

Governance and Nominating Committee

Our Governance and Nominating Committee's purpose is to assist our board of directors in identifying individuals qualified to become members of our board of directors consistent with criteria set by our board of directors, to oversee the evaluation of the board of directors and management, and to develop and update our corporate governance principles. Subsequent to the resignation of Mr. Ogilvie, Drs. Csimma and Mazzo are the members of the Governance and Nominating Committee. The Board anticipates appointing a new member to the Governance and Nominating Committee to fill the vacancy created by Mr. Ogilvie.

The Governance and Nominating Committee evaluates candidates for the Board. Candidates may come to the attention of the Governance and Nominating Committee through current Board members, professional search firms, stockholders or other persons. The Governance and Nominating Committee will consider nominees recommended by our stockholders.

Compensation Committee

The Compensation Committee reviews and approves the compensation arrangements for Seneca Biopharma's executive officers, including the Executive Chairman, administers our equity compensation plans, and reviews the Board's compensation. Subsequent to the resignation of Mr. Smith, Drs. Mazzo and Csimma are members of the Compensation Committee. The Board anticipates appointing a new member to the Compensation Committee to fill the vacancy created by the resignation of Mr. Smith.

Leadership Structure

The Board does not have a policy regarding the separation of the roles of Chief Executive Officer and Chairman of the Board as the Board believes it is in the best interests of the Company to make that determination based on the position and direction of the Company and the membership of the Board. At present, the positions of Chairman and Chief Executive Officer are held by the same individual. Based on our Executive Chairman's knowledge of the Company, its business and its industry, the Board believes this structure is currently in the best interest of the Company and its shareholders.

Risk Oversight

The Company has a risk management program overseen by our Principal Executive Officer. Material risks are identified and prioritized by management, and each prioritized risk is referred to a Board Committee or the full Board for oversight. For example, strategic risks are referred to the full Board while financial risks are referred to the Audit Committees. The Board regularly reviews information regarding the Company's liquidity and operations, as well as the risks associated with each, and annually reviews the Company's risks as a whole. Also, the Compensation Committee periodically reviews the most important risks to the Company to ensure that compensation programs do not encourage excessive risk-taking. The Company currently does not have a lead independent director as it has currently determined one to not be necessary given the Company's size. The Company's lead independent director has the following responsibilities:

- Advising the executive chairman of the Board as to the quality, quantity, and timeliness of the flow of information from management that is necessary for the independent directors to perform their duties effectively and responsibly.
- Confirming the agenda with the Chief Executive Officer for meetings of the Board.
- Coordinating and moderating executive sessions of the Board's independent directors.
- Acting as the principal liaison between the independent directors and the executive chairman of the Board on sensitive issues.
- Performing such other duties as the Board may from time to time delegate in order to assist the Board in the fulfillment of its responsibilities.

ITEM 11. EXECUTIVE COMPENSATION

Our non-executive director and executive compensation programs impact all of our employees by establishing a general framework for compensation and creating a work environment focused on expectations, goals, and rewards. Because the performance of every employee is important to the overall success of the Company, our Board is mindful of the impact that our compensation programs have on all of our employees. In considering our compensation policies and practices, our Board balances the needs to conserve cash and minimize stockholder dilution against the requirements to attract, retain, and motivate our non-executive directors, executives and other employees while fostering an innovative and entrepreneurial corporate culture. Our Board strives to act in the long-term best interests of the Company and its stockholders, as well as ensure that the components of compensation do not, individually or in the aggregate, encourage excessive risk-taking.

Compensation-Setting Process

Role of the Board, Compensation Committee and Management

The Compensation Committee is responsible for overseeing, determining, recommending and approving the compensation of our non-executive directors, CEO and other executives, including the other Named Executive Officers. From time to time during the year, the Compensation Committee will review the compensation of our non-executive directors, CEO and other executives, determine whether to make any adjustments to their respective compensation. With regard to our executive officers, the Compensation Committee reviews base salaries, determine whether an annual incentive award was earned for the last completed fiscal year based on its assessment of the Company and individual performance for that period and, if so, the amount of any such bonuses, and determine whether to make equity awards based on Company and individual performance.

As described below, the Compensation Committee gives considerable weight to our CEO's performance evaluation of the other executives because of his direct knowledge of each executive's performance and contributions. The Compensation Committee conducts an annual review of our executives' compensation and considers adjustments in executive compensation levels to ensure alignment with our compensation strategy and competitive market practices. During this process, the Compensation Committee is also mindful of the results of the shareholder's Advisory Vote on Executive Compensation during the most recent vote and although not binding, is considered in the compensation setting process.

Role of Senior Management

The Compensation Committee typically seeks the input of our CEO when discussing the performance of and compensation for our other executives, including the other Named Executive Officers. In this regard, at the request of the Compensation Committee our CEO reviews the performance of the other executives, including the other Named Executive Officers, annually and presents to the Compensation Committee his conclusions and recommendations as to their compensation, including base salary adjustments, annual incentive awards, and long-term equity incentive awards. The Compensation Committee then uses these recommendations as one factor in its deliberations to determine the compensation of our executives.

Role of Compensation Consultant

The Compensation Committee is authorized to retain the services of one or more executive compensation advisors, as it sees fit, in connection with the oversight of our non-executive director and executive compensation program and related policies and practices. For compensation related to the year ended December 31, 2019, the Compensation Committee consulted with Nancy Arnosti and Associates ("Arnosti"), a compensation consulting firm with regard to our executive compensation program. Arnosti was engaged to provide the Compensation Committee with information, recommendations, and other advice relating to these compensation programs on an ongoing basis. Arnosti was directly engaged and serves at the discretion of the Compensation Committee and provides no other services to the Company.

Competitive Positioning

In making compensation decisions, the Compensation Committee reviews independent survey data, as well as publicly available data from companies with which we compete for executive talent. The companies chosen for comparison may differ from one executive to the next depending on the scope and nature of the business for which the particular executive is responsible.

Although the compensation data from comparable companies is useful comparative information, the Compensation Committee does not require that the compensation components of the non-executive directors or individual executives bear any particular relationship to the compensation of non-executive director or executives of similar positions of those comparable companies. In development-focused companies within the biopharmaceutical industry, many traditional measures of corporate performance, such as earnings-per-share or sales growth, may not readily apply in reviewing the performance of executives. Because of the Company's current stage of development, the Compensation Committee evaluates other indications of performance, including progress towards the Company's research and development programs and corporate development activities, as well as the Company's success in securing capital sufficient to enable the Company to continue research and development activities, in its decision-making process.

Say-on-Pay

At our 2017 Annual Meeting of Stockholders held on June 22, 2017, we submitted two proposals to our stockholders regarding our executive compensation practices.

The first was an advisory vote on the 2016 compensation awarded to our named executive officers (commonly known as a “say-on-pay” vote). At our 2017 annual meeting, excluding broker non-votes, approximately 88,471 shares cast votes with regard to the say-on-pay proposal. Of those, 77,834 or approximately 88%, of the shares approved the compensation of named executive officers. We believe that the outcome of our say-on-pay vote signals our stockholders’ support of our compensation approach, specifically our efforts to retain and motivate our named executive officers. In light of this stockholder support, the Compensation Committee determined not to change its approach to compensation. However, even though stockholders demonstrated overwhelming support for our compensation approach in 2017, the Compensation Committee annually reevaluates our compensation practices to determine how they might be improved. The Compensation Committee will continue to consider the outcome of say-on-pay votes when making future compensation decisions for our named executive officers.

The second proposal was a vote on the frequency of future stockholder advisory votes regarding compensation awarded to named executive officers (commonly known as a “say-when-on-pay” vote). The frequency of every year received the highest number of votes cast. Notwithstanding these results, our Board of Directors determined that we would hold our next say-on-pay votes at the 2020 Annual Meeting.

Summary Compensation Table

The following table sets forth information regarding the compensation paid to, or earned by, our named executive officers for the years ended December 31, 2019 and 2018:

Name and Principal Position (a)	Year (b)	Salary ($) (c)	Bonus ($) (d)	Stock Awards ($) (e)	Option Awards ($) (f) [2]	Nonequity Incentive Plan Compensation ($) (g)	Non-qualified Deferred Compensation Earnings ($) (h)	All Other Compensation ($) (i) [1]	Total ($) (j)
Kenneth Carter,	2019	$ 395,000	20,000	-	425,409(3)	-	-	-	$ 840,409
Executive Chairman	2018	$ -	-	-	-	-	-	-	$ -
Richard J. Daly,	2019	$ -	-	-	-	-	-	-	$ -
Former Chief Executive, President	2018	$ 239,167	146,370	-	-	-	-	-	$ 385,537
James Scully,	2019	$ -	-	-	-	-	-	-	$ -
Former Chief Executive, President	2018	$ 208,725	-	-	191,310(4)	-	-	-	$ 400,035

(1) Includes automobile allowance, relocation allowance, perquisites and other personal benefits.
(2) For additional information regarding the valuation of Option Awards, refer to Note 4 of our financial statements contained in this report.
(3) Includes an Inducement Award of 40,000 options issued initially and an anti-dilution true-up issuance of an additional 116 253 options per Dr. Carter's employment agreement. The options have a strike price of $8.50 and vest over time and based on milestones.
(4) Represents 12,500 options issued pursuant to Mr. Scully’s consulting agreement to serve as interim CEO on August 4, 2018 valued at $191,310. The options have a strike price of $23.00. The options vested fully on grant date.

Amendment to Employment Agreement with Kenneth Carter

On March 26, 2020, Dr. Kenneth Carter’s employment agreement was amended, having an effective date of April 1, 2020. For a description of the terms of the amendment, please see the Item 9B of Section 2 of this Annual Report entitled “Other Information.”

Employment Agreement with Kenneth Carter

On December 18, 2018, Dr. Kenneth Carter was appointed the executive chairman of the Company to be effective January 1, 2019. In connection with Dr. Carter’s employment, we entered into an at-will employment agreement. Pursuant to the terms of his employment agreement, he received a signing bonus of $20,000 and receives a base salary of $395,000 per year and is eligible to receive an annual cash bonus based on achievement of certain performance milestones with a target of 50% of his base salary.

Dr. Carter was also issued an inducement option to purchase 40,000 shares of common stock on December 12, 2018. The inducement option has an exercise price of $8.50 per share, a term of ten (10) years, and vests as follows: (i) 10,000 options on the effective date, (ii) 5,000 options on the six (6) month anniversary of the effective date, (iii) 5,000 options vest on the two (2) year anniversary of the effective date, and (iv) the remaining 20,000 vest upon the achievement of performance-based milestones. As of December 31, 2019, 27,000 shares have vested, 4,000 have been forfeited for failure to meet the milestone vesting requirements, and 9,000 are currently unvested, subject to meeting vesting conditions.

For a twelve (12) month period following the effective date, Dr. Carter's employment agreement further calls for the adjustment in the number of shares underlying the inducement option in the event of a capital raising transaction such that Dr. Carter's ownership percentage would remain the same prior and subsequent to such transaction. Pursuant to the Company's registered direct offering on July 30, 2019, the Company issued Dr. Carter an additional 116,213 options as an adjustment. Of this issuance, 78,444 shares have vested, 11,621 have been forfeited for failure to meet the vesting requirements, and 26,148 remain unvested as of December 31, 2019.

Dr. Carter's employment agreement also provides for severance in the event the Company terminates his employment without "cause" or he resigns with "good reason," or as a result of his death or disability as each term is defined in the employment agreement or upon termination due to death or disability, Dr. carter will be entitled to (i) payment of his accrued base salary, unreimbursed expenses, unpaid but earned bonuses, and accrued and unused vacation time; (ii) the accelerated vesting of 100% of Dr. Carter's then outstanding unvested equity awards, (iii) the continued payment of his base salary for (a) eighteen (18) months following the termination if such termination occurs within six (6) months of the effective date or if termination occurs within the eighteen (18) month period following a "sale event" or "change of control" and (b) twelve (12) months following the termination date if termination occurs after the initial six (6) month period following the effective date and (iv) payment of a pro rata portion of his target annual bonus for the year in which termination occurs. Dr. Carter will not be entitled to any continued payment of salary after the twenty-four (24) month anniversary of the effective date

In the event of a termination for any reason other than "Cause," we will be required to make such payments, approximately as follows:

Officer	Severance	Accelerated Vesting of Awards	Total
Kenneth Carter [(1)]	$ 592,500(2)	$ 0	$ 592,500

(1) Assumes termination at December 31, 2019. The effective date of Dr. Carter's agreement is January 1, 2019.
(2) Includes 12 months continued payment of base salary of $395,000 plus target bonus of 50% of base salary equal to $197,500.

Employment Agreement with James Scully

Effective August 1, 2018, James Scully was appointed as the interim Chief Executive Officer and Principal Accounting Officer of the Company. On December 31, 2018, Mr. Scully was replaced by Kenneth Carter, PhD., our current executive Chairman.

During Mr. Scully's tenure, he was entitled to $25,000 per calendar month and obligated to work three (3) full days per week. In the event that he worked additional days, he received $2,000 per full day of service. Mr. Scully's employment agreement was for a period of six (6) months beginning August 1, 2018 and ending on January 31, 2019, unless terminated earlier upon sixty (60) days' notice. Mr. Scully was also issued an option to purchase 12,500 shares of Common Stock with a grant date of August 4, 2018, a term of five (5) years, and an exercise price of $23.00 per share which vested fully on the grant date.

Employment Agreement with Richard Daly

On February 15, 2016, Richard Daly was appointed Chief Executive Officer, President, and as a member of the Company's board of directors. Mr. Daly resigned effective July 31, 2018 as CEO, president and as a member of the Board. Pursuant to the terms of the employment agreement, Mr. Daly received a base salary of $440,000 per year (reduced to $410,000 per year pursuant to voluntary salary reduction on June 1, 2016) and was eligible to receive an annual cash bonus based on achievement of certain performance goals with a target of 50% of his base salary.

Mr. Daly's employment agreement provided for severance in the event Company terminates Mr. Daly's employment without Cause or Mr. Daly resigned with Good Reason, as each term is defined in the employment agreement, Pursuant to Mr. Daly's resignation, no severance was paid pursuant to the terms of his employment agreement..

Equity Compensation Plans

We currently have the following equity compensation plans outstanding as of the date hereof: (i) 2007 Equity Compensation Plan, (ii) 2010 Equity Compensation Plan, (iii) Inducement Award Stock Option Plan and (iv) 2019 Equity Incentive Plan.

For information related to our equity compensation plans for which our officers and directors are issued securities from, please see ”Equity Compensation Plan Information” contained in the Section entitled “Market for Registrant’s common equity, related stockholder matters” contained in this Form 10-K.

Outstanding Equity Awards Value at Fiscal Year-End

The following table includes information with respect to the value of all outstanding equity awards previously awarded to our named executive officers as of December 31, 2019. All references to common stock, share, and per share amounts have been retroactively restated to reflect the 1:20 reverse stock split that became effective on July 17, 2019

Name (a)	Number of securities underlying unexercised options - exercisable (#) (b)	Number of securities underlying unexercised options - unexercisable (#) (c)	Equity incentive plan awards: Number of securities underlying unexercised unearned options (#) (d)	Option exercise price ($) (e)	Option expiration date (f)	Number of shares or units of stock that have not vested (#) (g)	Market value of shares of units of stock that have not vested ($) (h)	Equity incentive plan award: Number of unearned shares, units or other rights that have not vested (#) (i)	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested (#) (j)
Kenneth Carter, PhD [1] [2]	105,444	35,148	–	$ 8.50	12/12/28	–	–	–	–
James Scully [3]	12,500			$ 23.00	8/4/23	–	–	–	–

[1] On December 12, 2018, in connection with his employment agreement, we granted Dr. Kenneth Carter, our executive chairman, an inducement option to purchase 40,000 shares under our inducement stock option plan. The Options vest as follows: (i) 10,000 on the effective date (January 1, 2019), (ii) 5,000 on the six (6) month anniversary of the effective date, (iii) 5,000 on the two (2) year anniversary of the effective date, and (iv) 20,000 on the achievement of performance-based milestones to be completed within a time domain of six (6) to twelve (12) months following the effective date.

[2] On July 30, 2019, in accordance with the terms of his employment agreement and original grant, we granted Kenneth Carter an additional inducement option to purchase 116,213 shares under our inducement stock plan. The options vest in the same proportions as the initial award on both a time and performance basis.

[3] On August 4, 2018, we granted our interim CEO an option to purchase 12,500 common shares. The options were granted under our 2010 Stock Plan. The award vested on the grant date.

DIRECTOR COMPENSATION

Board Compensation Arrangements

Our non-executive director compensation program is overseen and approved by our Compensation Committee and is designed to enable us to continue to attract and retain highly qualified directors by ensuring that director compensation is in line with peer companies competing for director talent, and is designed to address the time, effort, expertise, and accountability required of active board membership. In general, we believe that annual compensation for non-employee directors should be cash and equity based and designed to compensate members for their service on the Board and its committees, align the interests of directors and stockholders and, by vesting over time, to create an incentive for continued service on the Board. Our Compensation Committee annually reviews and approves compensation programs related to our non-employee members of the Board of Directors.

The following are the terms of our Director Compensation Plans pursuant to which non-employee directors are compensated:

Director Compensation Plan

Each non-employee director receives a $100,000 annual board fee subject to annual review and adjustment. The annual board fee is payable as follows: (i) up to $50,000 in cash and (ii) the balance in equity grants consisting of common stock purchase options, restricted stock units or restricted stock, at the election of each non-employee director. Directors electing to receive a portion of their annual fee in cash will receive four equal quarterly payments during the year. Applicable equity grants will be made as of July 1 of each year and will vest quarterly over the grant year. Fees for new directors appointed or elected during the year will be pro-rated and made on the fifth (5^{th}) day following such approval and acceptance on the Board.

Each non-employee director continuing service will be required to make an election to receive the board fee in either cash, restricted stock, restricted stock units, or common stock options or a combination thereof by June 15th of each year. All grants of restricted stock and restricted stock units will be valued using the adjusted closing bid price of the Company's common stock on the applicable grant date. All option grants will be valued using the Black-Scholes option pricing model and are subject to customary assumptions used in the preparation of the financial statements.

Board Compensation for 2019 Board Year

The following table summarizes compensation paid/to be paid to non-employee directors during the year ended December 31, 2019.

Name (a)	Fees Earned or Paid in Cash ($) (b)	Stock Awards ($) (c)	Option Awards ($) (d)	Nonequity Incentive Plan Compensation ($) (e)	Non-qualified Deferred Compensation Earnings ($) (f)	All Other Compensation ($) (g)	Total ($) (h)
William Oldaker Independent Director [1]	$ 37,500	-	$ 37,500	-	-	-	$ 75,000
Scott Ogilvie Independent Director [2][8]	$ 50,000	-	$ 50,000	-	-	-	$ 100,000
David J. Mazzo, PhD. Independent Director [3]	$ 27,361	-	$ 27,466	-	-	-	$ 54,827
Cristina Csimma, PharmD, MHP Independent Director [2]	$ 50,000	-	$ 50,000	-	-	-	$ 100,000
Binxian Wei Independent Director [4]	-	-	$ 84,114	-	-	-	$ 84,114
Sandford Smith Independent Director [5][8]	$ 50,000	$ 50,000	-	-	-	-	$ 100,000
Mary Ann Gray, PhD Independent Director [6]	-	$ 34,830	$ 11,608	-	-	-	$ 46,438
Stanley Westreich [7] Independent Director	$ 22,639	-	$ 25,000	-	-		$ 47,639

(1) The Director's compensation includes $37,500 from the vesting of 4,017 stock purchase options. Of these options, 1,491 have an exercise price of $22.20 and 2,526 have an exercise price of $6.00. All options have an original contractual term of 10 years. Effective September 30, 2020, Mr. Oldaker resigned from the Board of Directors. All options were forfeited as of December 31, 2019.

(2) The Director's compensation includes $50,000 from the vesting of 6,543 stock purchase options. Of these options, 1,491 have an exercise price of $22.20 and 5,052 have an exercise price of $6.00. All options have an original contractual term of 10 years.

(3) The Director's compensation includes $27,466 from the vesting of 5,507 stock purchase options. Of these options, 455 have an exercise price of $7.20 and 5,052 have an exercise price of $6.00. All options have an original contractual term of 10 years.

(4) The Director's compensation includes $84,114 from the vesting of 16,031 stock purchase options. Of these options, 5,925 have an exercise price of $8.80 and 10,106 have an exercise price of $6.00. All options have an original contractual term of 10 years.

(5) The Director's compensation includes $25,000 from the vesting of 1,127 restricted stock units and $25,000 from the vesting of 4,167 shares of restricted stock.

(6) The Director's compensation includes $11,608 from the vesting of 2,385 stock purchase options $13,936 from the vesting of 2,362 restricted stock units and $20,894 from the vesting of 3,541 shares of restricted stock. The options have exercise price of $4.87 and an original contractual term of 10 years.

(7) The Director's compensation includes $25,000 from the vesting of 1,491 stock purchase options. The options have exercise price of $22.20 and an original contractual term of 10 years. Effective June 30, 2020, Mr. Westreich resigned from the Board of Directors. All options were forfeited as of December 31, 2019.

(8) The Directors resigned from the Board on March 26, 2020.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

Equity Compensation Plan Information

The following table sets forth information with respect to our equity compensation plans as of December 31, 2019.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options and Rights (a)	Weighted-Average Exercise Price for Outstanding Options and Rights (b)	Number of Securities Remaining Available for Future Issuance under Equity compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders			
2007 Stock Plan	1,903	$ 187.40	*
2010 Equity Compensation Plan	67,864	$ 218.93	10,497
2019 Equity Incentive Plan (1)	74,749	$ 5.19	109,964
Equity compensation plans not approved by security holders			
Inducement Plan	140,592	$ 8.50	74,408
Total	285,108	$ 58.91	194,869

* Our 2007 Stock Plan terminated. Accordingly, although certain outstanding awards under the plan can still be exercised, no additional grants may be made pursuant to such plan.

(1) On January 1 of each calendar year, the number of shares of common stock authorized under the 2019 Equity Incentive Plan increases by 4% of the total shares of common stock issued and outstanding on such date.

2019 Equity Incentive Plan

Our 2019 Equity Incentive Plan ("2019 Plan") was approved by our stockholders on June 12, 2019 and is administered by our board or our compensation committee. The 2019 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock, performance units, performance shares, restricted tock units, and other stock-based awards to our employees, directors, and consultants. The purpose of the 2019 Plan is to attract and retain the best available personnel for positions of substantial responsibility, to provide additional incentive to our employees, directors and consultants, and to promote the success of our business. Under the terms of the 2019 Plan, we initially reserved 200,000 shares of common stock, subject to an automatic increase on the first day of each calendar year by 4% of the total shares of common stock issued and outstanding on such date. The 2019 Plan further authorized the administrator to amend the exercise price and terms of certain awards thereunder.

Equity Compensation Plans Not Approved by Security Holders

Our Inducement Award Stock Option Plan ("Inducement Plan") is administered by our board or our compensation committee. The Inducement Plan is intended to be used in connection with the recruiting and inducement of senior management and employees. The issuance of awards under the Inducement Plan is at the discretion of the administrator which has the authority to determine the persons to whom any awards shall be granted and the terms, conditions and restrictions applicable to any award. Pursuant to the Inducement Plan, as amended and currently in effect, the Company may grant stock options for up to a total of 175,000 shares of common stock to new employees of the Company. As of December 31, 2019, 140,592 grants have been made pursuant to the Inducement Plan. The Inducement Plan is intended to qualify as an inducement plan under NASDAQ Listing Rule 5635(c)(4) and accordingly, the Company did not seek stockholders' approval.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth, as of March 15, 2020, information regarding beneficial ownership of our capital stock by:

- each person, or group of affiliated persons, known by us to be the beneficial owner of 5% or more of any class of our voting securities;
- each of our current directors and nominees;
- each of our current named executive officers; and
- all current directors and named executive officers as a group.

Beneficial ownership is determined according to the rules of the SEC. Beneficial ownership means that a person has or shares voting or investment power of a security and includes any securities that person or group has the right to acquire within 60 days after the measurement date. This table is based on information supplied by officers, directors and principal stockholders. Except as otherwise indicated, we believe that each of the beneficial owners of the common stock listed below, based on the information such beneficial owner has given to us, has sole investment and voting power with respect to such beneficial owner's shares, except where community property laws may apply.

	Common Stock			
Name and Address of Beneficial Owner [1]	**Shares**	**Shares Underlying Convertible Securities**	**Total**	**Percent of Class [2]**
Directors and named executive officers				
Kenneth Carter	-	105,444	105,444	1.11%
Stanley Westreich [3]	6,370	-	6,370	*
William Oldaker [4]	1,276	-	1,276	*
Scott Ogilvie	331	12,175	12,506	*
Sandford Smith	7,395	287	7,682	*
Cristina Csimma, Pharm.D, MHP	1,430	10,561	11,991	*
Binxian Wei [5]	-	21,084	21,084	*
David Mazzo	-	8,033	8,033	*
Mary Ann Gray, Ph.D	9,081	3,670	12,751	*
All directors and named executive officers as a group (9 individuals)			187,137	*
5% owners as reported on form SC 13G				
None				
All directors, named executive officers, and 5% owners as a group (9 entities)			187,137	1.97%

(1) Except as otherwise indicated, the persons named in this table have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them, subject to community property laws where applicable and to the information contained in the footnotes to this table. Unless otherwise indicated, the address of the beneficial owner is c/o Seneca Biopharma, Inc. 20271 Goldenrod Lane, Germantown, MD 20876.

(2) Pursuant to Rules 13d-3 and 13d-5 of the Exchange Act, beneficial ownership includes any shares as to which a shareholder has sole or shared voting power or investment power, and also any shares which the shareholder has the right to acquire within 60 days, including upon exercise of common shares purchase options or warrants. There are 9,428,011 shares of common stock issued and outstanding as of March 10, 2020.

(3) Mr. Westreich's tenure as a Board member ended on June 12, 2019.

(4) Mr. Oldaker resigned from the Board effective September 30, 2019.

(5) Mr. Wei is appointed by the Series A 4.5% Convertible Preferred Stock owners.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

RELATED PARTY TRANSACTIONS

Related Party Transactions Procedures

We review all known relationships and transactions in which Seneca Biopharma and our directors, executive officers, and significant stockholders or their immediate family members are participants to determine whether such persons have a direct or indirect interest. Our management, in consultation with our outside legal consultants, determines based on specific fact and circumstances whether Seneca Biopharma or a related party has a direct or indirect interest in these transactions. In addition, our directors and executive officers are required to notify us of any potential related party transactions and provide us with the information regarding such transactions.

If it is determined that a transaction is a related party transaction, the Audit Committee must review the transaction and either approve or disapprove it. In determining whether to approve or ratify a transaction with a related party, the Audit Committee will take into account all of the relevant facts and circumstances available to it, including, among any other factors it deems appropriate:

- the benefits to us of the transaction;
- the nature of the related party's interest in the transaction;
- whether the transaction would impair the judgment of a director or executive officer to act in the best interests of Seneca Biopharma and our stockholders;
- the potential impact of the transaction on a director's independence; and
- whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances.

Any member of the Audit Committee who is a related party with respect to a transaction under review may not participate in the deliberations or vote on the approval of the transaction.

Related Party Transactions

Summarized below are certain transactions and business relationships between Seneca Biopharma and persons who are or were an executive officer, director or holder of more than five percent of any class of our securities since January 1, 2018.

Information regarding disclosure of an employment relationship or transaction involving an executive officer and any related compensation solely resulting from that employment relationship or transaction is included in the Section of this Annual Report entitled "*Director Compensation*" and "*Executive Compensation*."

Information regarding disclosure of compensation to a director is included in the Section of this Annual Report entitled "*Director Compensation.*"

Information regarding the identification of each independent director is included in the Section of this Annual Report entitled "*Directors, Executive Officers and Corporate Governance*."

All of our officers and directors enter into our standard indemnification agreement.

During the Board fiscal year of January 1, 2018 through December 31, 2018, we paid the following compensation to our non-employee board members:

1. An aggregate of $250,000 in cash;
2. An aggregate of 3,624 restricted stock awards valued at $164,178;
3. An aggregate of 6,307 common stock purchase options valued at $125,000; and
4. An aggregate of 1,359 restricted stock units valued at $50,000.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table summarizes the approximate aggregate fees billed to us or expected to be billed to us by our independent auditors, Dixon Hughes Goodman LLP for our 2019 and 2018 fiscal years, respectively:

Type of Fees	**2019**	**2018**
Audit Fees	$ 119,350	$ 121,823
Audit Related Fees	30,000	-
Tax Fees	12,000	8,622
All other Fees [(1)]	-	-
Total Fees	**$ 161,350**	**$ 130,445**

(1) Fees associated with registration statements and issuance of comfort letters

Pre-Approval of Independent Auditor Services and Fees

Our audit committee reviewed and pre-approved all audit and non-audit fees for services provided by Dixon Hughes Goodman LLP and has determined that the provision of such services to us during fiscal 2019 and in connection with the audit of our 2019 consolidated financial statements is compatible with and did not impair independence. It is the practice of the audit committee to consider and approve in advance all auditing and non-auditing services provided to us by our independent auditors in accordance with the applicable requirements of the SEC. Dixon Hughes Goodman LLP did not provide us with any services, other than those listed above.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

1. Financial Statements:

2. 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, 9/13/2019, and 3/23/20	*				
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
4.47	Form of Series P Replacement Warrant issued in January 2020 Offering	8-K	4.01	001-33672	1/22/20
4.48	Form of Series Q Replacement Warrant issued in January 2020 Offering	8-K	4.02	001-33672	1/22/20
4.49	Form of Placement Agent Warrant issued in January 2020 Offering	8-K	4.03	001-33672	1/22/20
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
10.23	Letter Agreement from January 2020 Offering	8-K	10.01	001-33672	1/22/20

10.24	Form of Placement Agent Agreement from January 2020 Offering		8-K	10.02	001-33672	1/22/20
10.25	Amendment to Employment Agreement with Kenneth Carter effective April 1,2020	*				
14.01	Code of Ethics and Conduct		10-K	14.01	001-33672	4/2/18
14.02	Financial Code of Professional Conduct	*				
21.01	Subsidiaries of Registration		10-K	21.01	001-33672	3/10/14
23.01	Consent of Dixon Hughes Goodman LLP	*				
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.*

ITEM 16. FORM 10-K SUMMARY

None

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NEURALSTEM, INC

Dated: March 27, 2020

By: /S/Kenneth Carter

Kenneth Carter, PhD
Executive Chairman

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the following capacities and on the dates indicated.

Name	Title	Date
/s/Kenneth Carter Kenneth Carter	Executive Chairman (Principal Executive Officer and Financial Officer)	March 27, 2020
/s/ Cristina Csimma Cristina Csimma	Director	March 27, 2020
/s/ Mary Ann Gray Mary Ann Gray	Director	March 27, 2020
/s/ David Mazzo David Mazzo	Director	March 27, 2020
/s/ Binxian Wei Binxian Wei	Director	March 27, 2020

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 Seven Hundred Fifteen Thousand (715,000) 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 10.25

Amendment to Employment Agreement

This amendment (the "Amendment") dated as of March 26, 2020 is entered into by and between Seneca Biopharma, Inc., a Delaware Corporation (the "Company") and Kenneth C. Carter ("Employee"). Any term not defined herein shall have the definition ascribed to them in the Employment Agreement (as defined below). The Company and Employee may both be referred to hereinafter each as a "party," and collectively as the "parties."

WHEREAS, the Company and Employee previously entered into an employment agreement on December 12, 2018, which was subsequently amended on the same day (the "Employment Agreement") whereby Employee was hired to serve as Executive Chairman of the Company;

WHEREAS, the parties now desire to amend and restate certain terms and conditions of the Employment Agreement and accordingly, are entering into this Amendment; and

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth herein, the parties hereby agree as follows:

SECTION 1

Agreement

1.1 Amendment**.** The Agreement is hereby amended, modified and restated as follows:

Section 1. entitled "*Definitions*" is hereby amended and restated in its entirety as follows:

(a) "Accelerated Equity Benefit" shall mean, as applicable: (i) the continued vesting of any outstanding stock options or other equity awards with time-based vesting during the period ending on the earlier of (x) the expiration of the term of the respective stock option or other equity award (without giving effect to any provision of any equity incentive or stock option plan or award agreement applicable to any such stock option or other equity award that provides for any early termination or forfeiture of any such stock options or other equity awards by virtue of any termination of employment or other service of Employee with the Company) or (y) the end of the applicable Severance Term, provided, however, that for avoidance of doubt, any stock option or other equity award that includes both a performance-based vesting condition (which would include the achievement of a certain stock price or milestone) and a time-based vesting provision, no acceleration shall be provided unless such performance-based vesting condition has been satisfied as of the Date of Termination; or (ii) in the event of a Change of Control, the full vesting of all of Employee's outstanding stock options or other equity awards as of the Date of Termination. Additionally, for purpose of determining the ability of Employee to exercise any vested outstanding stock options or other equity awards, Employee will be deemed to have ceased being a Service Provider on the last day of the applicable Severance Term.

(b) "Accrued Obligations" shall mean (i) all accrued but unpaid Base Salary through the Date of Termination, (ii) all bonuses that have been awarded but remain unpaid as of the Date of Termination, (iii) any unpaid or unreimbursed expenses incurred in accordance with Section 6 hereof, (iv) any accrued but unpaid benefits provided under the Company's employee benefit plans, subject to and in accordance with the terms of those plans, (v) any accrued but unpaid rights to indemnification by virtue of the Employee's position as an officer or director of the Company or its subsidiaries and the benefits under any directors' and officers' liability insurance policy maintained by the Company, in accordance with its terms thereof, and (vi) any accrued but unused vacation time through the Date of Termination.

(c) "Annual Equity Grant" shall have the meaning ascribed to in Section 4(c) hereof.

(d) "Base Salary" shall mean the salary provided for in Section 4(a) hereof.

(e) "Beneficial Ownership" shall have the meaning set forth in in Rule 13d-3 of the Exchange Act; provided, however, that, notwithstanding anything in Rule 13d-3 of the Exchange Act to the contrary, for purposes of Section 1(k)(1) below, a Person shall not be deemed to have Beneficial Ownership of any shares of Common Stock underlying any Common Stock Equivalents unless and until such Person actually acquires such shares of Common Stock upon exercise, exchange or conversion of such Common Stock Equivalents.

(f) "Board" shall mean the Board of Directors of the Company or any committee thereof.

(g) "Common Stock" shall mean the Company's common stock, $0.01 par value per share.

(h) "Common Stock Equivalents" shall mean any securities of the kind which would entitle the holder thereof to acquire at any time, Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

(i) "Confidentiality Agreement" shall mean the Company's Confidential Information and Invention Assignment Agreement previously entered into by Company and Employee.

(j) "Cause" shall mean (i) Employee's willful failure (except where due to a physical or mental infirmity or incapacity) or refusal to perform in any material respect Employee's duties and responsibilities if and to the extent that such duties and responsibilities are reasonable and lawful, (ii) any willful or grossly negligent act of Employee that has, or could reasonably be expected to have, the effect of injuring the business of the Company or its subsidiaries in any material respect; (iii) Employee's conviction of, or plea of guilty or no contest to: (x) a felony (other than a felony related to the operation of a motor vehicle), (y) any material violation of federal or state securities laws or (z) any other criminal charge that has, or could be reasonably expected to have, a material adverse effect on the performance of Employee's duties to the Company or otherwise result in material injury to the business of the Company or its subsidiaries; (iv) the willful commission by Employee of an act of fraud or embezzlement against the Company or its subsidiaries; (v) any material violation by Employee of the written policies of the Company or its subsidiaries to the extent provided or made available to Employee, including but not limited to those relating to sexual harassment or business conduct and those otherwise set forth in the manuals or statements of policy of the Company or its subsidiaries, which material violation has, or could reasonably be expected to have, the effect of injuring the business of the Company or its subsidiaries in any material respect, or (vi) Employee's willful and material breach of this Agreement or the Confidentiality Agreement. For clarity, the inability of Employee to perform any or all of his duties, responsibilities or obligations as an employee of the Company or under this Agreement or the Confidentiality Agreement, in each case on account of Employee's death or Employee's physical or mental disability or infirmity, shall not be deemed or treated as a breach of this Agreement or the Confidentiality Agreement by the Employee and shall not constitute Cause for any purpose of this Agreement.

(k) "Change of Control" shall mean the occurrence of any of the following events:

(1) The acquisition by a Person or its affiliates of ownership of stock of the Company if, immediately after such acquisition, such Person and its affiliates collectively have Beneficial Ownership of issued and outstanding stock of the Company representing more than twenty percent (20%) of the total voting power of the issued and outstanding stock of the Company; provided, however, that for purposes of this subsection (1), the acquisition of stock by a Person from the Company in a transaction or issuance (including pursuant to equity awards) approved by the Board will not be considered a Change of Control (even if, immediately after such acquisition, such Person and its affiliates collectively have Beneficial Ownership of issued and outstanding stock of the Company representing more than twenty percent (20%) of the total voting power of the issued and outstanding stock of the Company, unless at the time of such acquisition or at any time within one year following such acquisition, the Company's Executive Chairman is no longer deemed a Service Provider to the Company and the change in the Executive Chairman's status was involuntary and not the result of a termination due to death or disability, in which case such acquisition shall be treated as a Change of Control for purposes of this subsection (1) notwithstanding that such acquisition or the transaction that resulted in such acquisition was approved by the Board; or

(2) If, during any period of twelve (12) months in which the Company has a class of securities registered pursuant to Section 12 of the Exchange Act, a change in the composition of the Board occurs as a result of which fewer than a majority of the members of the Board are Incumbent Directors; or

(3) The consummation of a merger or consolidation of the Company with any other entity, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or its parent) at least a majority of the total voting power represented by the voting securities of the Company or such surviving entity or its parent outstanding immediately after such merger or consolidation; or

(4) The acquisition by a Person or its affiliates (or a series of acquisitions by a Person or its affiliates during the twelve (12) month period ending on the date of the most recent acquisition by such Person or any of its affiliates) of assets from the Company that have a total gross fair market value equal to or more than fifty percent (50%) of the total gross fair market value of all of the assets of the Company immediately prior to such acquisition or such series of acquisitions; provided, however, that the foregoing provisions of this subsection (4) shall not be applicable to a transfer of assets by the Company to an entity, fifty percent (50%) or more of the total value or voting power of which is owned, directly or indirectly, by the Company. For purposes of this subsection (4), gross fair market value means the value of the assets of the Company, or the value of the assets being disposed of, determined without regard to any liabilities associated with such assets.

For the avoidance of doubt, a transaction will not constitute a Change of Control for purposes of this Section 1(k) if: (i) its primary purpose is to change the jurisdiction of the Company's incorporation, or (ii) its primary purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction.

For purposes of this Section, "affiliate" will mean, with respect to any specified Person, any other Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such specified Person ("control," "controlled by" and "under common control with" will mean the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a person, whether through ownership of voting securities, by contact or credit arrangement, as trustee or executor, or otherwise).

(l) "Code" shall mean the Internal Revenue Code of 1986, as amended, and the rules and regulations promulgated thereunder.

(m) "Date of Termination" shall mean the date on which Employee ceases to be a Service Provider to the Company.

(n) "Dilutive Event" shall mean, except in the case and to the extent of Common Stock issued upon exercise of Excluded Securities, the issuance by the Company of Common Stock (i) at any time during the Measurement Period (including, without limitation, by virtue of the exercise, conversion or exchange of any Qualifying Securities at any time on or prior to the end of the applicable Measurement Period) or (ii) in connection with the exercise, conversion or exchange of any Qualifying Securities at any time after the Measurement Period.

(o) "Disability" shall mean any physical or mental disability or infirmity of Employee that prevents the performance of Employee's duties for a period of (i) ninety (90) consecutive days or (ii) one hundred twenty (120) non-consecutive days during any twelve (12) month period. Any question as to the existence, extent, or potentiality of Employee's Disability upon which Employee and the Company cannot agree shall be determined in writing by a qualified, independent physician mutually acceptable to the Company and Employee or, if applicable, his guardian (which approval shall not be unreasonably withheld). The determination of Disability made by such physician in writing to the Company and Employee shall be final and conclusive for all purposes of this Agreement.

(p) "Effective Date" shall mean the date on which this Amendment is signed by the parties but in no event earlier than April 1, 2020.

(q) "Exchange Act" means the Securities Exchange Act of 1934, as amended.

(r) "Excluded Securities" shall mean stock options exercisable for shares of Common Stock that are granted to officers or employees (provided that such stock options do not exceed 10% of the Company's issued and outstanding shares of Common Stock at the end of the Measurement Period).

(s) "Good Reason" shall mean, without Employee's consent, (i) except as a result of Employee voluntarily accepting or requesting a reduction in his status as a full time employee: (A) a material diminution in Employee's duties, or responsibilities (other than temporarily while Employee is physically or mentally incapacitated or as required by applicable law), (B) adverse change in Employee's title, position, or person or entity to whom Employee reports or (C) assignment to Employee of duties not commensurate with his position, (ii) a reduction in Base Salary as set forth in Section 4(a) hereof expect as a result of Employee voluntarily accepting or requesting a reduction in his status as a full time employee, or (iii) any other material breach of a provision of this Agreement by the Company (other than a provision that is covered by clause (i) or (ii) above). Notwithstanding the foregoing, during the Term, in the event that the Company reasonably believes that Employee may have engaged in conduct that could constitute Cause hereunder, the Company may, in its sole and absolute discretion, suspend Employee from performing Employee's duties hereunder for a period not to exceed 90 days, and in no event shall any such suspension constitute an event pursuant to which Employee may terminate employment with Good Reason or otherwise constitute a breach hereunder; provided , that no such suspension shall alter the Company's obligations under this Agreement during such period of suspension (including, but not limited to, payment of Base Salary as set forth in Section 4(a) hereof).

(t) "Incumbent Directors" means members of the Board who either (A) are members of the Board as of the date of this Agreement or (B) are elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the Incumbent Directors at the time of such election or nomination (but will not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company).

(u) "Measurement Period" shall mean: (i) the nine (9) month period following the Effective Date, or (ii) in the event that during such nine (9) month period, the Board authorizes or approves a Dilutive Event or the Company enters into a written agreement that contemplates effecting a Dilutive Event, then the period of time commencing on the Effective Date and ending upon the occurrence of such Dilutive Event, whichever is later. Provided however that in the event the Board decides to not consummate the transaction(s) contemplated in subsection (ii) contained herein, the Measurement Period will be as provided for in subsection (i) contained in this definition.

(v) "Option Award" shall have the meaning ascribed to it in Section 4(d) hereof.

(w) "Option Award Adjustment" shall mean, in the event that the Option Award remains outstanding at the time of a Change of Control transaction (after giving effect to the provisions under the definition of Accelerated Equity Benefit that pertain to the ability of Employee to exercise any vested outstanding stock options or other equity awards following the last day of the applicable Severance Term) and that, in connection with such Change of Control transaction, any then outstanding Qualifying Securities are entitled to receive consideration in connection with such Change of Control transaction or are assumed in connection with such Change of Control transaction, then, any such Qualifying Securities shall be deemed to be exercised, converted or exchanged in full immediately prior to the closing of such Change of Control transaction, all of the shares of Common Stock underlying such Qualifying Securities shall be deemed to be issued immediately prior to the closing of such Change of Control Transaction and such deemed issuance of such shares of Common Stock shall be deemed to be a Dilutive Transaction that will result in an increase in the number of Option Shares in accordance with the provisions contemplated in Section 4(d).

(x) "Option Shares" shall mean the shares of Common Stock underlying the Option Award.

(y) "Payment Date" shall have the meaning ascribed to it in Section 7(h) hereof.

(z) "Person" shall mean an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind or more than such person or entity acting as a group.

(aa) "Post-Dilutive Event Common Shares" shall mean, with respect to a Dilutive Event, the number of shares of Common Stock issued in connection with such Dilutive Event plus the number of shares of Qualifying Common Stock outstanding immediately before such Dilutive Event.

(bb) "Pre-Dilutive Event Common Shares" shall mean, with respect to a Dilutive Event, the number of shares of Qualifying Common Stock outstanding immediately prior to such Dilutive Event.

(cc) "Prior Inducement Grant" means the non-qualified stock option grant, granted to employee on December 12, 2018.

(dd) "Qualifying Common Stock" shall mean (i) shares of Common Stock that are issued and outstanding at any time on or prior to the end of the applicable Measurement Period (including, without limitation, by virtue of the exercise, conversion or exchange of any Qualifying Securities at any time on or prior to the end of the applicable Measurement Period), plus (ii) any shares of Common Stock that are issued at any time after the end of the applicable Measurement Period upon the exercise, conversion or exchange of any Qualifying Securities.

(ee) "Qualifying Securities" shall mean any Common Stock Equivalents that are issued and outstanding at any time on or prior to the end of the applicable Measurement Period.

(ff) "Release of Claims" shall mean a release of claims made by the Employee in favor of the Company and its subsidiaries in the form attached hereto as Exhibit A (with any updates reasonably determined by the Company to be necessary to comply with applicable law) and the execution of which is a condition precedent to Employee's eligibility for Severance Benefits and the Accelerated Equity Benefit in the event his employment is terminated by the Company without Cause or by Employee for Good Reason, as described in Sections 7(d) and 7(e), or in connection with a Change of Control, as described in Section 7(g).

(gg) "Severance Benefits" shall mean (i) continued payment of the Base Salary (as in effect immediately prior to the Date of Termination and without giving effect to any proration or any reduction to the Base Salary that gives rise to Good Reason) during the Severance Term, payable in accordance with the Company's regular payroll practices, (ii) either (x) a lump sum payment equal to the product of: (A) Employee's Target Cash Bonus for the year in which the Termination Date occurs, paid at a rate equivalent to 100% achievement of objectives for such year and (B) a fraction, the numerator of which is the number of days the Employee was employed by the Company during the year in which the Date of Termination occurs and the denominator of which is the number of days in such year, which lump sum payment shall be paid on the Payment Date (as defined in Section 7(h), or (y) in the event of termination of Employee's employment with the Company in connection with a Change of Control as described in Section 7(g), Employee's Target Cash Bonus for the year in which the Date of Termination occurs, paid at a rate equivalent to 100% achievement of objectives for such year, and (iii) if Employee qualifies for and timely elects continued coverage under the Company's group medical plan and/or group dental plan pursuant to Section 4980B of the Code ("COBRA"), monthly payment during the Severance Term of the amount the Company pays on behalf of comparable employees who have elected the same level of coverage as Employee.

(hh) "Service Provider" shall means an employee, director or consultant.

(ii) "Severance Term" shall mean: (i) in the event the Date of Termination occurs after the 9 month anniversary of the Effective Date, (y) the twelve (12) month period, which commences on the first day following the Date of Termination by the Company without Cause or by Employee for Good Reason, or (z) in the event of a Change of Control as described in Section 7(g), the eighteen (18) month period commencing on the first day following the Date of Termination by the Company without Cause or by Employee for Good Reason, or (ii) in the event the Date of Termination occurs within 9 months of the Effective Date, (a) the seven (7) month period, which commences on the first day following the Date of Termination by the Company without Cause or by Employee for Good Reason, or (b) in the event of a Change of Control as described in Section 7(g), the nine (9) month period commencing on the first day following the Date of Termination by the Company without Cause or by Employee for Good Reason.

(jj) "Target Cash Bonus" shall have the meaning ascribed to it in Section 4(b) hereof.

(kk) "Term" shall have the meaning ascribed to it in Section 2 hereof.

Sub-Section 3(a) entitled "*Position, Duties and Responsibilities*" is hereby amended and restated in its entirety as follows:

(a) Position, Duties, and Responsibilities. During the Term, Employee shall be employed and serve as Chief Executive Officer and Executive Chairman of the Company (together with such other position or positions consistent with Employee's title or as the Company shall specify from time to time) and shall have such duties and responsibilities commensurate therewith, and such other duties as may be assigned and/or prescribed from time to time by the Board or a committee thereof. During the Term, the Board will nominate Employee for election to the Board by the Company's stockholders; provided that Employee hereby agrees to submit written notice of resignation of his directorship to the Board, if requested by a majority of the Board, at any time following the Date of Termination.

Sub-Section 3(b) entitled "*Performance*" is hereby amended and restated in its entirety as follows:

(b) Performance. Employee will be employed by the Company on a full-time basis and devote substantially all of his business time, attention, skill, and best efforts to the performance of his duties under this Agreement and shall not engage in any other business, occupation or activity that (x) conflicts with the interests of the Company, (y) materially interferes with the proper and efficient performance of Employee's duties for the Company, or (z) materially interferes with Employee's exercise of judgment in the Company's best interests, with such determination to be made by the Board in its reasonable good faith discretion. Notwithstanding the foregoing, nothing herein shall preclude Employee from: (i) continuing to serve on existing boards of directors as of the Effective Date, (ii) performing his Professional Activities (as defined below) or (iii) undertaking other professional or charitable activities (subject to the restrictions contained in clauses (x), (y) and (z) of this Section 3(b)), with the prior consent and approval of the Compensation Committee, (which shall not be unreasonably withheld or delayed) of non-competing businesses and charitable organizations; (iv) engaging in charitable activities and community affairs; and (v) managing Employee's personal investments and affairs; provided, however, that the activities set out in clauses (i), (ii), (iii), (iv) and (v) herein shall be limited by Employee so as not to interfere in any material respect, individually or in the aggregate, with the performance of Employee's duties and responsibilities hereunder, or pose a conflict of interest or violate any provision of this Agreement such determinations to be made at the reasonable good faith discretion of the Board. Employee represents that he has provided the Compensation Committee with a comprehensive list of all outside professional activities with which he is currently involved or reasonably expects to become involved at the current time (such activities, the "Professional Activities"). In the event that, during his employment by the Company, the Employee desires to engage in other outside professional activities, not included on such list, Employee will, prior to engaging in any such activities, first seek written approval from the Compensation Committee and such approval shall not be unreasonably withheld.

Sub-Section 4(a) entitled "Base Salary" is hereby amended and restated in entirety as follows:

(a) Base Salary. In exchange for Employee's performance of his duties and responsibilities, Employee initially shall be paid an annual base salary of $525,000 ("Base Salary"), payable in accordance with the regular payroll practices of the Company. All payments referenced in this Agreement, including the Signing Bonus, are on a gross, pre-tax basis and shall be subject to all applicable federal, state and local withholding, payroll and other taxes. Notwithstanding the foregoing, the Base Salary will be pro-rated in the event Employee voluntarily accepts or requests a reduction in his status as a full time employee, with the amount of time Employee actually devotes to the performance of his duties under this Agreement.

Sub-Section 4(c) entitled "Annual Stock Option Award" is hereby amended and restated in its entirety as follows:

(c) Annual Equity Award. In addition to the Base Salary and Target Cash Bonus, Employee will be eligible to receive an annual market-based equity grant (the "Annual Equity Grant") issued pursuant to the terms of one of the Company's equity compensation plans. The actual amount of such Annual Equity Grant, if any, will be determined by the Board based upon Company performance, its financial condition (including market value and capitalization), Employee's achievement of pre-agreed performance milestones and any other factors that the Board, in its reasonable good faith discretion, deems appropriate. Achievement of such milestones or any such other factors shall be determined by the Board in its reasonable good faith discretion. In connection with such grants, the Employee shall enter into one of the Company's standard equity grant agreements which will incorporate the vesting schedule and other terms as determined by the Board.

Sub-Section 4(d) entitled "Inducement Grant" is hereby amended and restated in its entirety as follows:

(d) Retention Grant. On the Effective Date, as an inducement for Employee's continued employment, the Company will grant Employee an option to purchase 471,400 shares of Common Stock, which option shall be issued pursuant to a conditional grant, subject to receiving required shareholder approval and shall be subject to the terms and conditions set forth in this Agreement, the applicable equity compensation plan from which it was issued, if any, and a stock option agreement to be entered by the Company and the Employee to evidence such grant, the form of which has been made available to Employee prior to the Effective Date (the "Option Agreement" and such grant the "Option Award"). Upon receiving shareholder approval, as a condition to the Option Award, Employee will forfeit the Prior Inducement Grant, in its entirety, without giving effect to whether the Prior Inducement Grant is vested or unvested. In the event of a conflict between the Option Agreement or the applicable equity compensation plan from which it was issued, on the one hand, and this Agreement, on the other hand, with respect to the Option Award or any of the terms and conditions thereof, this Agreement shall control. The option subject to the Option Award shall have a term of ten (10) years from the date of grant and an exercise price equal to the closing trading price of the Common Stock on the Effective Date (or the prior closing price if the Effective Date is on a day that the trading markets are not open). The Option Award will be subject to vesting as follows: (i) 1/4 of the Option Award will vest on the Effective Date, and (ii) the balance of the Option Award will vest monthly over the following thirty six (36) months; provided, however, that Employee must be a Service Provider through the applicable vesting dates, and the Option Award shall be subject to accelerated vesting under certain circumstances in accordance with the provisions of Section 7 hereof. The Option Award shall be subject to the terms set forth in the Option Agreement, the terms of the plan under which it is issued, this Section 4(d), Section 7 hereof, and any other restrictions and limitations generally applicable to Common Stock of the Company or equity awards held by similarly situated Company executives that are imposed by law. Upon the occurrence of a Dilutive Event, the Option Shares will be increased by such number as required to make the percentage that the Option Shares (after giving effect to such increase) represent of the Post-Dilutive Event Common Shares equal to the percentage that the number of Option Shares immediately prior to the Dilutive Event represent of the Pre-Dilutive Event Common Shares. In addition, the Option Shares may be increased by the Option Award Adjustment, if applicable, in connection with a Change of Control transaction. Any increase in the number of Option Shares, as contemplated above in this Section 4(d), in connection with the occurrence of a Dilutive Event or a Change of Control transaction shall occur automatically pursuant to the terms and conditions of the Option Award as set forth in this Section 4(d) and the Option Agreement without any act or action required to be taken by either the Company or Employee.

Sub-Section 4(e) entitled "*Signing Bonus*" is hereby removed in its entirety.

Section 4 is hereby amended to contain the following new Sub-Sections 4(e), 4(f) and 4(g):

(e) Amendment Expense Reimbursement. The Company agrees to reimburse Employee's reasonable legal, accounting and other expenses incurred in connection with the negotiation, drafting and execution of this Amendment and any agreements ancillary to this Amendment, in an amount not to exceed $5,000.

(f) Directors' and Officers' Liability Insurance. Employee shall be designated as a "covered person" under the Company's Director's and Officer's insurance coverage, if any, and shall be covered to the same extent as other directors and executive officers, including following the termination of Employee's employment for any reason for the maximum statute of limitations period which could apply to any claim against Employee which otherwise would be covered by such insurance.

(g) Clawback Provisions. Notwithstanding any other provisions in this Agreement to the contrary, any incentive-based or other compensation paid to the Employee under this Agreement or any other agreement or arrangement with the Company which is subject to recovery under any law, government regulation, or stock exchange listing requirement will be subject to such deductions and clawback as may be required to be made pursuant to such law, government regulation, or stock exchange listing requirement (or any policy adopted by the Company pursuant to any such law, government regulation or stock exchange listing requirement).

Section 7 is hereby amended and restated in its entirety as follows:

Section 7. Termination of Employment.

(a) General. Employee's employment with the Company shall terminate upon the earliest to occur of: (i) Employee's death, (ii) a termination by reason of Employee's Disability, (iii) a termination by the Company with or without Cause, or (iv) a termination by Employee with or without Good Reason.

(b) Termination Due to Death or Disability. Employee's employment under this Agreement will terminate automatically upon Employee's death. The Company also may terminate Employee's employment immediately upon the occurrence of a Disability, such termination to be effective upon Employee's receipt of written notice of such termination. In the event of Employee's termination as a result of Employee's death or Disability, Employee's or Employee's estates or beneficiaries, as the case may be, will be entitled to receive the Accrued Obligations. Employee shall have no further rights to any compensation or any other benefits under this Agreement.

(c) Termination by the Company with Cause.

(i) The Company may terminate Employee's employment at any time with Cause, effective upon Employee's receipt of written notice of such termination; provided, however, that with respect to any Cause termination relying on clause (i), (ii), (v), or (vi) of the definition of Cause set forth in this Agreement, to the extent that such act or acts or failure or failures to act are curable, Employee shall be given thirty (30) days' written notice by the Company of its intention to terminate his employment with Cause, such notice to state the act or acts or failure or failures that constitute the grounds on which the proposed termination with Cause is based, and such termination shall be effective at the expiration of such thirty (30) day notice period unless Employee has fully cured such act or acts or failure or failures to act, to the Board's complete satisfaction, that give rise to Cause during such period.

(ii) In the event that the Company terminates Employee's employment with Cause, Employee shall be entitled only to the Accrued Obligations. Following such termination of Employee's employment with Cause, except as set forth in this Section 7(c)(ii), Employee shall have no further rights to any compensation or any other benefits under this Agreement. For the avoidance of doubt, Employee's sole and exclusive compensation upon a termination of employment by the Company with Cause shall be receipt of the Accrued Obligations.

(d) Termination by the Company without Cause. The Company may terminate Employee's employment at any time without Cause, effective upon Employee's receipt of written notice of such termination. In the event that Employee's employment is terminated by the Company without Cause (other than due to death or Disability) and, with respect to the Severance Benefits and the Accelerated Equity Benefits, provided that he fully executes and does not revoke an effective Release of Claims as described in Section 7(h), then, except as otherwise provided in Section 7(g), Employee shall be entitled to:

(i) the Accrued Obligations;

(ii) the Severance Benefits; and

(iii) the Accelerated Equity Benefit.

Notwithstanding the foregoing, the Severance Benefits shall immediately terminate, and the Company shall have no further obligations to Employee with respect thereto, in the event that Employee is found by a court of competent jurisdiction to have breached this Agreement, any provision of the Confidentiality Agreement or the Release of Claims. Any such termination of payment or benefits shall have no effect on the Release of Claims or any of Employee's post-employment obligations to the Company. Following such termination of Employee's employment by the Company without Cause, except as set forth in this Section 7(d) or 7(g), Employee shall have no further rights to any compensation or any other benefits under this Agreement. For the avoidance of doubt, except as otherwise provided in Section 7(g), Employee's sole and exclusive compensation upon a termination of employment by the Company without Cause shall be receipt of (i) the Severance Benefits and Accelerated Equity Benefits subject to his execution of the Release of Claims, and (ii) the Accrued Obligations. If the Company makes overpayments of Severance Benefits, Employee promptly shall return any such overpayments to the Company and/or hereby authorizes deductions from future Severance Benefit amounts so long as such deduction does not violate Section 409A of the Code.

(e) Termination by Employee with Good Reason. Employee may terminate his employment with Good Reason by providing the Company at least thirty (30) days' written notice setting forth in reasonable specificity, the event that constitutes Good Reason, which written notice, to be effective, must be provided to the Company on or prior to the later of: (i) within thirty (30) days of the occurrence of such event or (ii) promptly upon Employee's actual knowledge of such event. During such notice period, the Company shall have a cure right (if curable), and if not cured within such period, Employee's termination will be effective upon the expiration of such cure period, and Employee shall be entitled to the same payments and benefits as provided in Section 7(d) hereof, subject to the same conditions on payment and benefits as described in Section 7(d) hereof. Following such termination of Employee's employment by Employee with Good Reason, except as set forth in this Section 7(e) or as otherwise provided in Section 7(g), Employee shall have no further rights to any compensation or any other benefits under this Agreement. For the avoidance of doubt, except as otherwise provided in Section 7(g), Employee's sole and exclusive compensation upon a termination of employment with Good Reason shall be receipt of the same payments and benefits described in Section 7(d) hereof, subject to the same conditions on payment and benefits as described in Section 7(d).

(f) Termination by Employee without Good Reason. Employee may terminate his employment without Good Reason by providing the Company at least thirty (30) days' written notice of such termination. In the event of a termination of employment by Employee under this Section 7(f), Employee shall be entitled only to the Accrued Obligations. In the event of termination of Employee's employment under this Section 7(f), the Company may, in its sole and absolute discretion, by written notice accelerate such date of termination without changing the characterization of such termination as a termination by Employee without Good Reason. Following such termination of Employee's employment by Employee without Good Reason, except as set forth in this Section 7(f) or as otherwise provided in Section 7(g), Employee shall have no further rights to any compensation or any other benefits under this Agreement. For the avoidance of doubt, Employee's sole and exclusive compensation upon a termination of employment by Employee without Good Reason shall be receipt of the Accrued Obligations.

(g) Termination in connection with a Change of Control. In the event that Employee's employment is terminated in the three (3) month period preceding or the twelve (12) month period following a Change of Control: (a) by the Company for any reason other than as a result of Employee's death or Disability pursuant to Section 7(b) or Cause as provided in Section 7(c), or (b) by Employee with Good Reason pursuant to Section 7(e), then Employee shall be entitled to (in lieu of, and not in addition to, any payments described in Section 7(d) or (e) of this Agreement):

(i) the Accrued Obligations;

(ii) the Severance Benefits; and

(iii) the Accelerated Equity Benefit.

Notwithstanding the foregoing, the Severance Benefits shall immediately terminate, and the Company shall have no further obligations to Employee with respect thereto, in the event that Employee is found by a court of competent jurisdiction to have breached this Agreement, any provision of the Confidentiality Agreement or the Release of Claims. Any such termination of payment or benefits shall have no effect on the Release of Claims or any of Employee's post-employment obligations to the Company. If the Company makes overpayments of Severance Benefits, Employee promptly shall return any such overpayments to the Company and/or hereby authorizes deductions from future Severance Benefit amounts.

(h) Release. Notwithstanding any provision herein to the contrary, the payment of the Severance Benefits and the provision of the Accelerated Equity Benefit, pursuant to subsection (b), (d), (e) or (g) of this Section 7, shall be conditioned upon Employee's execution, delivery to the Company, and non-revocation of the Release of Claims (and the expiration of any revocation period contained in such Release of Claims) in accordance with the time limits set forth therein (and, in all events, within sixty (60) days following the Date of Termination); provided, that, in the case of Employee's death or Disability, such actions shall be taken by a representative with authority to bind Employee or, if applicable, his estate. If Employee or his representative fails to execute the Release of Claims in such a timely manner, or timely revokes Employee's acceptance of such release following its execution, Employee and his estate or beneficiaries shall not be entitled to any of the Severance Benefits or the Accelerated Equity Benefit. Payment of the Severance Benefits will commence (or, at the election of the Company, may be paid in a lump-sum cash payment rather than in installments during the Severance Term) on the first regular Company payday that is at least five (5) business days following the date the Company receives a timely, effective and non-revocable Release of Claims (the "Payment Date"); provided, however, that the first payment will be retroactive to the day immediately following the Date of Termination. Payment of the bonus contained in the Severance Benefits defined in Section 1(gg) will also be made on the Payment Date. Notwithstanding the foregoing, to the extent that any portion of the Severance Benefits or the bonus contained in the Severance Benefits defined in Section 1(gg) constitutes "non-qualified deferred compensation" subject to Section 409A of the Code, any payment of such portion scheduled to occur prior to the sixtieth (60th) day following the date of Employee's termination of employment hereunder, but for the condition on executing the Release of Claims as set forth herein, shall not be made until the first regularly scheduled payroll date following such sixtieth (60th) day unless otherwise permitted by Section 409A of the Code, after which any remaining such benefits shall thereafter be provided to Employee according to the applicable schedule set forth herein. If the sixty (60) day period following Employee's separation from service begins in one calendar year and ends in a second calendar year (a "Crossover 60-Day Period"), and if there are any payments due to Employee that are: (i) conditioned on Employee signing and not revoking a release of claims and (ii) otherwise due to be paid during the portion of, the Crossover 60-Day Period that falls within the first year, then such payments will be delayed and paid in a lump sum during the portion of the Crossover 60-Day Period that falls within the second year.

Section 19 is hereby amended and restated in its entirety as follows:

Section 19. Entire Agreement. This Agreement, together with Release of Claims, Confidentiality Agreement, the Indemnification Agreement, and any stock option agreement entered into between the Company and Employee thereunder, constitute the entire understanding and agreement of the parties hereto regarding the employment of Employee. This Agreement supersedes all prior negotiations, discussions, correspondence, communications, understandings, and agreements between the parties (including without limitation that any term sheet or offer letter that may have been given to Employee) relating to the subject matter of this Agreement.

1.2 **Additional Changes.** Any necessary undertaking or changes to the Employment Agreement in order to effect the intent of the amended and restated terms of the Employment Agreement contained in and contemplated by this Amendment are hereby approved. Notwithstanding the foregoing, except for the purposes contained herein, no other section of the Employment Agreement will be modified as a result of this Amendment.

1.3. **Effectiveness**. This Amendment shall become effective on the Effective Date.

SECTION 2
Miscellaneous

2.1 **Amendment to Employment Agreement.** The Employment Agreement shall be henceforth deemed to be amended, modified and supplemented in accordance with the provisions hereof, and the respective rights, duties, and obligations under the Employment Agreement shall hereafter be determined, exercised and enforced under the Employment Agreement, as amended by this Amendment, subject in all respects to such amendments, modifications, and supplements and all terms and conditions thereof.

2.2 **Entire Agreement.** This Amendment constitutes the full and entire understanding and agreement between the parties with regard to the subjects hereof and thereof.

2.3 **Counterparts.** This Amendment may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument.

2.5 **Governing Law**. This Amendment shall be construed in accordance with and governed by Section 15 of the Employment Agreement.

(signature page follows)

The undersigned have caused this Amendment to be executed as of the date first written above.

SENECA BIOPHARMA, INC.

Signed: _____
By: David J. Mazzo, PhD
Its: Compensation Committee Member

EMPLOYEE

Signed: _____
By: Kenneth C. Carter, PhD

Exhibit 14.02

Seneca Biopharma Finance Code of Professional Conduct

Seneca Bio Finance's mission includes promotion of professional conduct in the practice of financial management. Seneca Bio's Chief Executive Officer (CEO), Chief Financial Officer (CFO), and other employees of the finance organization hold an important and elevated role in corporate governance in that they are uniquely capable and empowered to ensure that all stakeholders' interests are appropriately balanced, protected, and preserved. This Finance Code of Professional Conduct embodies principles which we are expected to adhere to and advocate. These principles of ethical business conduct encompass rules regarding both individual and peer responsibilities, as well as responsibilities to Seneca Bio employees, the public, and other stakeholders. The CEO, CFO, and finance organization employees are expected to abide by this Code as well as all applicable Seneca Bio business conduct standards and policies or guidelines in Seneca Bio's employee handbook relating to areas covered by the Finance Code of Professional Conduct. Any violations of the Seneca Bio Finance Code of Professional Conduct may result in disciplinary action, up to and including termination of employment.

All employees covered by the Finance Code of Professional Conduct will:

- Act with honesty and integrity, avoiding actual or apparent conflicts of interest in their personal and professional relationships.
- Provide stakeholders with information that is accurate, complete, objective, fair, relevant, timely, and understandable, including information in our filings with and other submissions to the U.S. Securities and Exchange Commission and other public bodies.
- Comply with rules and regulations of federal, state, provincial, and local governments, and of other appropriate private and public regulatory agencies.
- Act in good faith, responsibly, with due care, competence, and diligence, without misrepresenting material facts or allowing one's independent judgment to be subordinated.
- Respect the confidentiality of information acquired in the course of one's work except when authorized or otherwise legally obligated to disclose.
- Not use confidential information acquired in the course of one's work for personal advantage.
- Share knowledge and maintain professional skills important and relevant to stakeholders' needs.
- Proactively promote and be an example of ethical behavior as a responsible partner among peers, in the work environment and the community.
- Exercise responsible use, control, and stewardship over all Seneca Bio assets and resources that are employed by or entrusted to us.
- Not coerce, manipulate, mislead, or unduly influence any authorized audit or interfere with any auditor engaged in the performance of an independent audit of Seneca Bio's system of internal controls, financial statements, or accounting books and records.

If you are aware of any suspected or known violations of this Finance Code of Professional Conduct, the Code of Ethics and Conduct, or other Seneca Bio policies or guidelines, you have a duty to promptly report such concerns either to the Chief Financial Officer, the Chairman of the Audit Committee, or, anonymously utilizing the Company's confidential Ethics Hotline.

If you have a concern about a questionable accounting or auditing matter and wish to submit the concern confidentially or anonymously, you may do so by contacting the Ethics Hotline, hosted by a third party provider, on the web at www.SenecaBio.ethicspoint.com or or by calling 1-855- 228-2634.

The Company will handle all inquiries discreetly and make every effort to maintain the confidentiality of and prohibit the intimidation or retaliation against anyone who, in good faith, requests guidance, reports questionable behavior and/or a compliance concern, cooperates in an investigation, conducts a self-evaluation, or takes remediation steps related to upholding our Finance Code of Professional Conduct.

Last reviewed and approved August, 2015

Exhibit 23.01

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the registration statements on Form S-1 (No. 333-232273), Form S-3 (Nos. 333-196567, 333-218608, 333-219195, and 333-236543), and Form S-8 (Nos. 333-172563, 333-194881, and 333-220813) of Seneca Biopharma, Inc. (the "Company") (formally known as Neuralstem, Inc.) of our report dated March 27, 2020, which report includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to the consolidated balance sheets of the Company as of December 31, 2019 and 2018 and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the years then ended, which report appears in the Company's Annual Report on Form 10-K for the year ended December 31, 2019.

/s/ Dixon Hughes Goodman LLP

Baltimore, Maryland
March 27, 2020

EXHIBIT 31.1

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

I, Kenneth Carter, certify that:

(1) I have reviewed this Annual Report on Form 10-K 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: March 27, 2020

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, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Kenneth Carter, certify, as of the dates hereof, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Seneca Biopharma, Inc. on Form 10-K for the fiscal year ended December 31, 2019 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Form 10-K fairly presents in all material respects the financial condition and results of operations of Seneca Biopharma, Inc. at the dates and for the periods indicated.

Date: March 27, 2020

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

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